PANTEION UNIVERSITY OF SOCIAL AND POLITICAL SCIENCES
DEPARTMENT OF INTERNATIONAL AND EUROPEAN STUDIES
FACULTY OF LAW AND ECONOMICS OF INTERNATIONAL TRAID AND INVESTMENT

THE PARALLEL TRADE BY PHARMACEUTICALS IN THE SINGLE MARKET AND THE RECENT DECISION OF THE CFI IN THE GLAXO CASE (T-168/01)

Supervisor: professor K. Stephanou
Student: Nasypayko K

ATHENS, 2007

CONTENT

INTRODUCTION

Parallel trade, also called grey-market or parallel imports, is the process whereby goods protected by an intellectual property right (such as a patent, trademark or copyright) are placed into circulation on one market, and then (re-)imported into a second market without the authorization of the local owner of the intellectual property right. Some argue that parallel trade is a good thing on the grounds that it leads to lower prices for consumers. Others argue that parallel trade undermines intellectual property protection and thereby undermines the incentives to invest in the research, development and marketing of IP-based products, which may harm the consumer in various ways. Those others are manufacturers, and mainly pharmaceutical manufacturers, because they spend a lot of money for research and development of new drugs.

Present paper is about parallel trade in pharmaceuticals in the single market, particularly in EU, and justification of restriction of parallel trade.

It begins with the history of parallel trade and the analysis of parallel trade generally.

Parallel trade of pharmaceuticals has existed since the inception of the European common market. As my research shows, wherever there are sufficient price differentials to make movement of goods economically viable, and a regulatory framework which permits it, parallel trade will exist. In the case of pharmaceuticals, there are still important price differentials between countries, and goods are relatively inexpensive to transport. The costs of marketing pharmaceuticals by parallel traders are fairly high, because it is a closely regulated industry with rigorous standards and regulatory requirements, but there is still enough margin to make the practice worthwhile, and parallel trade in pharmaceuticals has grown consistently throughout EU. Moreover, in EU parallel trade is supported by the Treaty of Rome. The relevant legal provisions prohibit two types of conduct: anti-competitive agreements between two or more companies and unilateral action by firms which amounts to an abuse of a dominant position. These rules are found in Articles 81 and 82 of the EC Treaty and have as a principal goal the market integration of the European Union, notably the development of trade and strengthening of competition.

However, to reconcile free movement of goods and the need to protect intellectual property rights the principle of exhaustion of rights has been created.

Nevertheless, as I mentioned in the beginning, parallel trade is a thorn in the side of the R&D based brand-owner companies. Such companies lose turnover to foreign affiliates, which makes sales performance difficult to determine, and can have a negative impact on company morale, and they lose profit overall, because a sale is satisfied by a lower-priced equivalent product. Naturally, brand owners would like to see parallel trade disappear, or at least reduce substantially.

Brand owners have often used their intellectual property rights to attack the ability of parallel importers to sell their goods, usually unsuccessfully. They invented a lot of methods for restraining activity of parallel traders, for example dual-pricing, various styles of packaging, supply-restriction etc. If trademark

owners could cut off supplies to parallel traders, the problems caused by parallel sales would go away, and they would not need to worry about asserting their intellectual property rights. But all attempts to implement it had no future. However, the situation may change and very soon. That assumption arose from the recent decisions of European Court of Justice and analyzed in the given research. Following this, my paper concludes with a review of future of pharmaceutical manufacturers and parallel traders, in particular the possibility of elimination of parallel import.

1 INSIGHT OF PARALEL TRADE

1.1 HISTORY OF PARALLEL TRADE

According to the majority of sources, "parallel trade", refers to a genuine (i.e. non-counterfeit) product placed on the market in one country, which is subsequently imported into a second country without the permission of the owner of the intellectual property rights which attach to the product in the second country."

For example, suppose that an Indonesian authorized dealer of compact disks produced under license to Sony sells them locally at a wholesale price below the retail price prevailing in Australia. If allowed to do so, the dealer or an independent parallel trader could then ship the compact disks to Australia and make a profit net of tariffs and shipping and distribution costs. Because the goods are originally produced and sold under authorization, they are legitimate copies rather than pirated copies or knock-off. Accordingly, parallel traded goods are identical to legitimate goods, save for the fact that they may be packaged differently and may not carry the original manufacturer's warranty.

The parallel trade known as "parallel" to the extent that it takes place outside and, in most cases, in parallel with the distribution network that the manufacturers or original suppliers have established for their products, while it concerns products which are in every respect similar to the ones marketed by the distribution networks.[1] Or in other words parallel trade is the cross-border trade in a particular product, through a route that the manufacturer may not have originally intended.

But I prefer definition from the report of Tommaso Valletti and Stefan Szymanskiz.[2] I believe that definition more comprehensive than others.

"Parallel trade (sometimes called 'grey market' trade) involves the shipment of bona fide goods (i.e., not illegal counterfeits) across international borders in order to exploit price differences. In a free-trade environment, parallel trade prevents monopoly suppliers from engaging in international price discrimination. However, where the good is protected by an intellectual property right, such as a patent or trademark, this right may permit the owner to prohibit international arbitrage."

Most of the sources use term "parallel import", some of them use "parallel trade" or "re-importation" or "parallel distribution", all those terms define exactly the same activity.

However, to use the term "parallel import" is not always correct. For this reason, EU has changed its legislation, and since 1 May 2004 bringing goods from another EU/EEA member state is not an "import" by definition. Therefore

[1] COM(2003) 839 final, "Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted" Brussels, 30.12.2003

[2] Tommaso Valletti, Stefan Szymanski (2006) "Parallel trade, international exhaustion and intellectual property rights: a welfare analysis", Journal of Industrial Economics Vol. 54 N. 4, introduction

expressions: “Parallel Trade” and “Parallel Distribution” are used more and more widely[3].

Parallel trade is a worldwide phenomenon and has existed since goods were first traded. It can be seen with a wide range of branded products, from motor cars to computers, from cameras to pianos, and from compact disks to ski equipment. However, it is very difficult to define exact date of appearing of PT, because accurate data on parallel trade are limited, that is why the business is inherently rather secretive.

In the late 1970s and early 1980s, studies of parallel trade in the anglophone world were largely the domain of economists and political scientists. The dominant perspective on parallel trade was that it developed as a result of excessive regulation, price distortions, and the corruption of post-independence African governments and would be eliminated once these distortions were corrected.

During the same period, an alternative interpretation of the origins of parallel trade was put forward by the more historically and empirically oriented studies of economic historians, anthropologists, and francophone geographers. These studies emphasize its pre-colonial origins, which are seen to be rooted in the traditions of ethnic solidarity of pre-colonial Africa and in the extensive long-distance trading networks that operated across vast areas of the continent for centuries before the creation of colonial national boundaries. Parallel trade is seen as a form of indigenous resistance to the imposition of colonial borders and metropolitan economic regulations on traditional African economic and social formations.

Significantly, parallel activities have flourished in areas where pre-colonial, long-distance trade was most highly developed, notably in East and West Africa. This contrasts with the situation in Southern Africa, where indigenous systems of long-distance trade were poorly developed in the pre-colonial period. This helps to explain the subsequent lack of significant levels of parallel activity in the post-independence period. With the exception of countries bordering on East and central Africa, such as Zambia, Mozambique, and Angola, the main smuggling networks in southern Africa have, until recently, involved essentially underworld circuits organized around stolen cars, soft drugs, and gem stones. The high level of conflict and the accompanying movement of refugees in the region have increased the level of parallel activity, but this trade does not compare with that of East and West Africa either in volume or in the extensiveness of traditional trading infrastructure to support the movement of goods.

As regard to US, in 1985, the US Department of Commerce reported rising parallel trade volumes in 37 product categories, especially trademarked goods such as “Mercedes-Benz sedans, Opium perfume and Nikon cameras”[4] and were estimated at $7-10 billion, or 2-3 percent of the U.S. import bill. One study suggested that these imports were due to the rise in the US dollar and that grey imports occurred because parallel importers were able to get a free ride on the authorised distributors’ marketing costs.

---

[3] Parallel trade, source www.handelrownolegly.pl

[4] Jakob Arfwedson (2003)“Parallel trade in pharmaceuticals”, Institute for Policy Innovation and an IPI visiting scholar, p. 9

The collapse of several Asian currencies in the late 1990s also encouraged parallel trade in the USA, Japan and Europe of construction equipment, computers, automobiles and branded consumer goods.

Generally in Europe, the trade traditionally existed only in Germany, the Netherlands, and the United Kingdom (see Table 1.1.1) where the reimbursement of drug prices tended to be significantly higher than in the most other member states. Supplies were sourced from Belgium, France and other southern European countries.

Table 1.1.1 The starting of parallel trade in Europe

Country	Parallel trade starting in
Austria	2002
Belgium	2001
Denmark	1995
Finland	1996
Germany	End of '70s
Ireland	1984
Italy	1997
Netherlands	Early'70s
Norway	1995
Poland	2004
Sweden	1997
United Kingdom	1984

Table 1.1.2 Share of Parallel Trade in selected markets[5]

Country	Market share
UK	15,0
Denmark	10,8
Germany	4,7
Holland	8,9
Norway	5,1
Sweden	9,3

The history of the parallel trade in the pharmaceutical industry, the key subject of my research, originated from Europe. Commonly accepted date for the foundation of Parallel Trade in Europe is 1974 when first ruling of the European Court of Justice (ECJ) in the De Peijper[6] case was taken followed by subsequent ruling in 1996, where a Dutch importer, Adriaan de Peijper, was prosecuted for importing a medicinal product from a wholesaler in the UK without the approval of the Dutch authorities, and without possessing either the product marketing approval documents or the batch records. De Peijper argued that he was unable to provide such evidence because the manufacturer would not give him access to the

[5] Source: EFPIA

[6] ECJ 31.10.74, case C-105/74 (Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc) Europeancourt reports 1976, page 00613

necessary data. The product was authorised in both the Netherlands and the UK, and the Dutch court referred the matter to the ECJ.

The Court found in favour of the plaintiff; asking him to produce the records demanded by the Dutch authorities was held restrictive:

"National rules or practices which make it possible for a manufacturer of the pharmaceutical product in question and his duly appointed representative, simply by refusing to produce the documents relating to the medicinal preparation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of that product, must be regarded as being unnecessarily restrictive."

Further ECJ's decisions confirmed the legality of Parallel Trade as well as interpreted arguments raised by the pharmaceutical industry.

1.2 THE CONCEPT OF PARALLEL TRADE

Parallel trade in general and in particular for pharmaceuticals arises because there are profitable opportunities for arbitrage[7] between national markets with different prices for identical goods. Specifically, parallel trade in patented and branded life sciences products occur because of:

- IPR protection may vary from one country to another, so that a product may remain under patent in one jurisdiction for longer than it is under patent in a neighbouring jurisdiction. In the latter jurisdiction, the product may then be subject to competition from generic suppliers, driving down the price of the branded product.
- Variations in purchasing power, per capita income and preferences affect demand and market size, reflected in price differentials. Also, rebates negotiated by government or donations of medicines can lead to substantial price differences.
- Government's regulation of prices.
- Differing inflation rates, which create exchange rate differentials, which, combined with national price controls, may translate into retail price variations.
- Tax rates, notably sales taxes, may motivate differential international pricing to ensure efficient sales.
- The patent holder may develop various marketing and sales strategies with corresponding price differences for selected markets.

All above-mentioned constitute reasons for substantial differences between the prices of identical goods, which is an important element for existence of parallel trade. However, price differentials need not necessarily be the sole criteria for promoting parallel trade. A number of other conditions and market factors also need to be considered, like

- Cultural, political and economic conditions in the importing country
- Availability of sufficient supplies of drugs in the exporting country

[7] In economics and finance, arbitrage is the practice of taking advantage f a price differential between two or more markets: a combination of matching deals are struck that capitalize upon the imbalance, the profit being the difference between the market prices.

- Reasonable transportation costs between the supply and destination markets so as to make parallel trade commercially feasible. In other words the costs of transport in relation to the cost of goods must be low
- Presence of supporting legal and regulatory framework
- Consumer and market acceptance of the re-imported pharmaceutical product
- Unrestricted free trade between the countries involved
- The distribution of goods must be entirely separate from their manufacture

As I mentioned before, parallel trade occurs when products are purchased in a country where they are cheaper and transported for resale to other countries where they are more expensive. The target product is in most cases a new, innovative medicine offering a high price differential and therefore a high profit margin in the import country. According to one report, a margin below 15 percent is very unlikely to be worthwhile for a parallel trader. Other factors determining the choice of target product are the patient population, formulation, transport, re-labelling and storage requirements.

In practice, the importers and the exporters are entrepreneurs at heart. The importers buy a medicine from the exporters who are well-established, authorized pharmaceutical wholesalers in countries where it is cheaper. With a specific authorisation from the government in the country of destination for the medicine, the importer can sell it to wholesalers or direct to pharmacies.

The importer must meet costs associated with regulatory compliance, purchasing, transport, warehousing, insurance, repackaging, quality assurance, distribution and promotion. But still they will be able to undercut the price offered by the pharma-company directly on certain medicines. The price advantage left must be passed on to the social health insurance system or national health service. Importers do not manufacture any medicines themselves, but they have to change the labelling - and perhaps the packaging - in order to meet local requirements under strict government supervision and always according to national law. The original patient package inserts are replaced with others giving the same information in the local language.

In other words, the parallel importer only has to identify a profitable arbitrage situation, and then deal with repackaging and re-labelling the product before re-importation.

The parallel importer buys chiefly from retail vendors in other EU countries. The retailers in turn make their purchases either directly from the original manufacturers or from licensed resellers. In most European countries, there are several retailers that work mainly on a regional basis.

Other actors, who are not directly involved in parallel trade, may nevertheless influence the conditions under which re-importation takes place. These include physicians who may or may not choose re-imported medicines when they make prescriptions. Similarly, pharmacists may have incentives to promote re-imported products over alternatives. Finally, consumers have their own reasons for discriminating between parallel imported pharmaceuticals and products from licensed providers.

Parallel trade is extremely safe. Exporters and importers both apply internal supply chain controls and must meet stringent external regulatory checks to guarantee patient safety.

However, detractors of the parallel trade (particularly drug manufacturers) would like people to believe that it is only the traders themselves who benefit. Nothing could be further from the truth. According to the report[8] of Panos Kanavos[9], there are five stakeholders who benefit from PT. They are: Health insurance, pharmacy, patients, parallel importers, pharmaceutical industry. Other sources[10] add one more stakeholder – Government, policy makers, economy. The PT provides next benefits for them:

Table 1.2.1 Impact of Parallel trade

Stakeholder	Benefits
Patients	It makes available original, innovative medicines at a lower cost Lower drug prices. Incoming parallel trade creates general price erosion, benefiting all buyers in all markets, by bringing an important, dynamic competitive element to bear, especially in the price uncompetitive patent-protected segment, the part of the market that generics cannot reach. It gives a choice
Pharmacy/Healthcare providers	Lower drug prices It gives a choice
Parallel traders	Reap financial rewards from selling cheaply purchased drugs to higher priced economies
Pharmaceuticals Manufacturers	It gives a choice
Government/policy makers/Economy	It offer a solution to states' healthcare funding deficits It allows regulators to avoid implementing other more interventionist or market-distorting cost-containment measures It accelerates integration of the internal market and increases intra-Community trade Creation of additional jobs

[8] Kanavos Panos, (2004) "The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A stakeholder analysis", Special research paper, London School of Economics and Political Science, p 31-40

[9] Panos Kanavos, PhD, is a lecturer in International Health Policy in the Department of Social Policy, and Research Fellow in Pharmaceutical Economics at LSE Health and social care.

[10] European Association of Euro-Pharmaceutical companies, www.eaepc.org

	Payments of various additional taxes It boosts the infrastructure for production and distribution in the countries of supply, as well as increasing foreign exchange earnings there It generates added-value and added tax revenues and increases the effectiveness of the market
Health insurance	It provides both direct and indirect cost savings for social health insurance systems

Here are some examples how above-mentioned stakeholders benefit from parallel trade: in the UK - the National Health Service recovers via the "clawback" mechanism the average saving it estimates pharmacies have realised from their total parallel trade purchases. In Ireland and Sweden - a parallel traded product must offer savings to the state before it is reimbursed. In the Netherlands and Norway - the cost difference between the domestic product and its parallel-traded equivalent is split between the dispensing pharmacist and the payer. In Germany and Denmark - the sick funds and government respectively oblige pharmacists to dispense cheaper synonyms, including parallel-traded forms, when certain levels of savings are possible.

As do exporting countries: Wholesalers in exporting countries are legally obliged to meet domestic demand first - in fact most countries impose, through national law or a voluntary code of conduct, a so-called "public service obligation". But the distribution chain - wholesalers and community pharmacies - needs a certain level of income to provide the prompt and highly efficient service European patients have come to expect. Additional income from margins with parallel trade sales lessens the burden on the social healthcare system of exporting countries.

The patients have next benefits: In Belgium, Denmark, Finland, France, Greece, Luxembourg, Norway, Portugal, Spain, Sweden the majority of patients pay a share of the cost of prescribed medicines they consume, so use of cheaper parallel-traded products will mean lower out-of-pocket demands. With so-called "lifestyle drugs" - treatments for erectile dysfunction, smoking cessation aids and oral contraceptives - the "patient" makes a direct saving from the cash purchase of a parallel-traded medicine on private prescription. WIdO, the statistical arm of the AOK, the Federal Association of Local Sick funds in Germany, is on the record as saying that women in Germany can save 54 percent on the pharmacy-selling price of Stediril D, an oral contraceptive, by purchasing it in parallel trade form.

The doctors and pharmacies also benefit: It has been estimated that office-based doctors in Germany can save between €2500 and €5000 on their drug budget each year by prescribing parallel-traded versions, all of which are priced on average 10 percent less (some can be even 30 percent less) than their domestic equivalents. It is no coincidence that parallel trade penetration is highest where

pharmacies are either financially rewarded for the use of parallel trade (Netherlands) or penalised for not doing so (UK, Germany).

While parallel trade offers a number of advantages, it has its own disadvantages. Let us look at some of the short-term and long term implications for a few key stake-holders.

Table 1.2.2 Disadvantages of PT

Stakeholder	Short-term	Long-term
Patients	Human errors in repackaging, re-labeling may jeopardize the safety of patients. Many leaflets or packs are printed in the wrong language, with the wrong trademark, carrying inaccurate, missing or confusing information about side-effects, expiry date, manufacturer address, dosage, batch number, etc.	Reduced number of new molecules, new treatment options may adversely impact patient community
Parallel Traders		Repackaging, re-labeling may lead to cases of IPR infringement
Pharmaceutical Manufacturers	Loss of revenue due to erosion of domestic sales. For example, AstraZeneca is the producer most affected by parallel trade in Sweden since it produces half the products re-imported into Sweden Increased competition forcing them to reduce prices	Reduced availability of funds to invest in R&D. Adversely hit the morale of employees who may lose the incentive to market and provide information about the product as the benefits accrue mainly to the parallel trader
Government Policy Makers Economy	Reduced healthcare expenditure Millions of dollars spent on law suits, litigations	May open the door for entry of counterfeit drugs into pharma value chain[11]

As you can see from Table 1.2.2, the most suffering stakeholders are manufacturers and in particular pharmaceutical manufacturers. Because, parallel

[11] However for EU, this argument has never been factually or logically proven. Parallel distribution in medicines is a highly regulated business. The medicines are products of the original manufacturers, often from the very same plant that produces the domestic version. Parallel-distributed products are either exactly identical with these, or with very small differences in color or inert excipients, differences which the regulatory authorities verify have the therapeutic consequences. If a manufacturer criticizes a parallel-distributed product it amounts to criticism of its own product.

trade is one of the most effective ways to slow or even halt the production of new drugs. It is no coincidence that the European Union has lost significant market share to the U.S. in terms of drug research and development during the past decade, with its share of the world market declining to 22 percent from 32 percent in that time.

New drugs cost, on average, $400-$800 million to develop. According to GlaxoSmithKline[12], it takes about 12-15 years and costs J500 million to discover and develop new medicine[13], in 2005 Pfizer[14] spent $7.4 billion for research and development[15]. As a result the prices of new medicines need to reflect that huge investment. Otherwise, there would be little incentive to develop them. According to Novartis[16]:

"Drug prices vary across countries. While the prices that manufacturers charge to the distribution chain (wholesales, pharmacists) are converging within geographic regions (the prices within Europe for new medicines are on average only +/- 10 percent different from the regional mean), the prices that consumers pay at the pharmacy still vary significantly. On top of the manufacturer price, charges to wholesalers and pharmacies as well as Value Added Tax may double the price at the pharmacy in some countries (e.g. Austria), where they increase the price by only 12% in other markets (e.g. UK and Sweden).

National authorities often demand the minimum price or the average price across a basket of reference countries. Further, free trade regions, such as the European Union, allow distributors to purchase goods in the cheapest market, and sell them in higher priced markets. This practice results in 'exporting' price controls, which counters the principle that goods should be priced differently across the world, in line with the wealth and ability to pay of different countries.

Manufacturers face a situation where their revenues could actually be reduced by launching medicines into a lower price market. As a consequence, patients in these markets may be deprived of new medicines."[17]

And only a tiny fraction of new drugs actually make it to the market because of clinical trials and regulatory policies. To improve access to new medicines, policy makers and activists should concentrate on facilitating the approval of new drugs, not the siren song of re-importation.

---

[12] GlaxoSmithKline plc is a British based pharmaceutical, biological, and healthcare company. GSK is a research-based company with a wide portfolio of pharmaceutical products covering anti-infectives, central nervous system (CNS), respiratory, gastro-intestinal/metabolic, oncology and vaccines products. It also has a Consumer Healthcare operation comprising leading oral healthcare products, nutritional drinks and over the counter medicines.

[13] www.gsk.com

[14] Pfizer Incorporated is the world's largest research-based pharmaceutical company. The company is based in New York City. It produces the number-one selling drug Lipitor (atorvastain, used to lower blood cholesterol), the oral antifungal medication Difluctan, the long-acting antibiotic Zithromax, the well-known erectile dysfunction drug Viagra and the anti inflammatory Celebrex.

[15] www.pfizer.com

[16] Novartis International AG is a multinational pharmaceutical company based in Basel, Switzerland that manufactures products such as dietary fiber supplements, Benefiber and the antifungal preparation Lamisil.

[17] Drug pricing. www.corporatecitizenship.novartis.com

2 PARALLEL TRADE IN PHARMACEUTICALS IN THE SINGLE MARKET

2.1 THE EUROPEAN SINGLE MARKET

All necessary preconditions[18] for existing of parallel trade can be achieved in the single market. Single market is perfect environment for appearing and flourishing of parallel trade.

A single market is a customs union with common policies on product regulation, and freedom of movement of all the four factors of production (land, enterprise, capital and labor).

Sometimes a single market is differentiated as a more advanced form of common market. In comparison to common a single market envisions more efforts geared towards removing the physical (borders), technical (standards) and fiscal (taxes) barriers among the member states. These barriers obstruct the freedom of movement of the four factors of production. To remove these barriers the member states need political will and they have to formulate common economic policies. The first and most important example of attempt to create a single market is European Union.

For the EU the single market means the free trade within the EU and single economy. It is one of the most wide-ranging and significant symbols of European integration, encompassing many of the policy areas where the EU is most influential. These include the European Customs Union, the single currency, the Schengen Convention and many other policies and laws designed to unite the diverse national economies of Europe into a single unit. Although it has been developing ever since the European Community was founded in 1957, the single market has only taken off in recent years and continues to develop.

The Treaty of Rome of 1957 set out four economic freedoms that it wanted to create in Europe: free movement of goods, free movement to provide services, free movement of capital and free movement of people. The first of these was established relatively quickly, with the creation of the European Customs Union in 1968. A further step forward was made in 1979 with a European Court of Justice (ECJ) ruling that created the principle of mutual recognition. Progress on the other areas was much slower. It was not until the Single European Act (1986) that a deadline of 1992 was set for the full completion of the single market. This involved the removal of barriers to movement of people, the harmonisation of national standards, rules on how governments buy services and goods, the liberalisation of financial institution, the setting of more standard VAT rates and European business laws. In 1992, the Maastricht Treaty began the final leg – Economic and Monetary Union. This came into being in 1999. Since then, the Commission has focused its efforts on liberalising the market for services and improving competitiveness through the Lisbon strategy.

[18] See page 6

A single market can be described as area where people are free to trade goods, invest their money and move around looking for work without facing legal, technical or physical barriers. For both business within the market and consumers, a single market is a very competitive environment. This means that inefficient companies will suffer a loss of market share and may have to close down. However, efficient firms can benefit from economies of scale, increased competitiveness and lower costs, as well as expect profitability to be a result. Consumers are benefited by the single market in the sense that the competitive environment brings them cheaper products, more efficient providers of products and also increased choice of products. What is more, businesses in competition will innovate to create new products, another benefit for consumers.

The EU single market is designed to create economies of scale, allow the establishment of Europe-wide commerce and faster growth by setting the same rules across the EU. To regulate this, the EU Commission has authority over a range of areas of economic policy under the Single European Act. Its regulations are most often passed down to national governments via directives that are then adopted into national law.

However the EU cannot be described as a true single market, because it doesn't have a unified taxation or welfare system, the single currency is not used by all members of the EU and some countries have opt-outs from rules such as the Schengen Convention. Many member states have also been reluctant to adopt some EU directives.

From all above-mentioned follows next advantages and disadvantages of the single market in the EU.

Table 2.1.1 Pros and Cons of the single market

Pros	Cons
By standardising national regulations, the single market makes it easier to do business in the EU and contributes to faster economic growth	National governments continue to resist single market measures, so the system can't work properly.
Economic ties are good for European stability because they make conflicts like World War II unthinkable today	A single market can never operate across an area with such different cultures and levels of wealth.
A single market helps ensure an open, liberal Europe	The single market hasn't removed regulations – it has just moved them to a European level.

Despite of its disadvantages the EU single market still constitutes "a fertile field" for parallel trade. That can be proved by statistical data. A 1999 study by economic consultancy NERA found the following:

Table 2.1.2 Parallel trade within the EU[19]

Parallel trade within the EU	
Footwear and leather goods	< 5%
Musical recordings	overall 5-10%, some releases up to 20%
Motor cars	estimates up to 5%
Consumer electronics	around 5%
Domestic appliances	< 5%
Cosmetics and perfumes	around 13% for upper end of market
Clothing	5-10%
Soft drinks	0-15%
Confectionery	< 10%
Alcoholic drinks	<5%

As regard to the pharmaceuticals, here is more complicated situation, first of all because of the specific character of the pharmaceutical industry. Pharmaceutical market is not a normal market where all well-known market mechanisms operate:

- This market is specific as far as the product is concerned (the increase of sales of medicines can never be the objective), but also because it concerns patients and insurance companies. In short, the person who orders the medication, the physician, does not pay for the product, and the one that pays for the product, the insurance company (or the state) does not receive it.
- Prices within national markets are controlled by Member State governments. Some Member States choose to pay higher prices by way of recognition of innovation. Others seek the lowest possible price. The industry rhetoric is that they will sell their products in line with the price countries can “afford” (i.e. are willing to pay), so long as at least some contribution is made to sink investment costs. There is therefore a claimed ethical dimension to supply of medicinal products;
- Access to pharmaceuticals is regarded as a public “right” by Member States. The poor demand-side controls in some States mean prices must be kept down to assure cost containment. Higher prices (the consequence of convergence to a European "corridor price" for lower priced countries) threatens inequality of access to medicines if health budgets remain contained;
- In general, the customer is the State or a State insurance scheme, rather than the direct consumer. In a significant sector of the market neither the consumer nor demand is sensitive to price;
- Price differentials between Member States - which exist because of different abilities to pay, and policy on regard of innovation - fuel parallel trade. But the majority of price differentials are taken as profit by the arbitrageurs.

[19] NERA and SJ Berwin&Co: The Economic Consequences of the Choice of Regime of Exhaustion in the Area of Trademarks, Report for DG XV of European Commission, London, 1999

Little is passed on to governments or to consumers. Neither do they have more than marginal effects on price convergence. Parallel trade in pharmaceuticals - against a background of price control - is extremely inefficient;

- price convergence (if it occurs) may mean lower prices in higher priced markets - but the quid pro quo is likely to be higher prices in lower priced markets if expensive innovative products are still expected to be placed on the European market. There is therefore a tension between welfare and profit, which in the present circumstances of the market parallel trade exacerbates.
- It is also true that this industry is different from others in its high "advertising" costs. These are the post-placement costs required to compete in a very tight market, where competition is not so much based on price but on market shares.

Pharmaceutical products, as pointed out above, are not the same as ordinary consumer goods, and therefore need to be treated differently. As a result, in EU arose an important task for creation of the single market for pharmaceuticals.

2.2 THE SINGLE MARKET FOR PHARMACEUTICALS

The creation of a harmonized market for pharmaceuticals has been a long-standing objective for European Community. Since 1985 starting from the "White book" the European Commission took a series of actions to promote harmonization in the pharmaceutical sector and a volume of legislation has been produced.

However, existing divergent national policies combined with inherent specificity of the pharmaceutical market and the structure of the industry made a completion of a single European market for pharmaceuticals a particularly difficult task. European Community has been facing the dilemma of how to deal with the tension that exists between Member States differing national pricing policies for pharmaceutical products and the Community's free movement of goods principle. A European Court of Justice ruling in 1996 itself recognized that "the imposition of price controls is indeed a factor which may, in certain conditions, distort competition between Member States".

In addition, the European Court of Justice (ECJ) has dealt with a number of cases which sought to examine whether price fixing by Member States was compatible with the free movement of goods in the European Union. The Court has noted that price control systems, although not in themselves contrary to the principle of free movement of goods, may nevertheless be so when the prices are fixed at a level such that the sale of imported products becomes either impossible or more difficult than that of domestic products – in particular the judgment in Roussel case.[20] In its most recent statement on these issues, in the judgment on Merck v Primecrown, the court noted that "distortions caused by different price legislation in a Member State must be remedied by measures taken by the

[20] ECJ 29.11.1983, case C-181/82 (Roussel Laboratoria BV v Etat neerlandais), paragraph 17

Community authorities and not by the adoption by another Member State of measures incompatible with the rules on free movement of goods."[21] In this judgment, the Court of Justice also confirmed that a patent holder may not impede the parallel importation of his own products from a Member State where the product could not be protected by a patent, unless he can prove that he is under a genuine, existing legal obligation to market the product in that Member State. However, It is natural that prices might differ between countries given that value judgments in healthcare differ and that there is a varying willingness and ability to pay.

Prices also differ because, as commercial enterprises, pharmaceutical companies will naturally aim to obtain the highest price each national market will bear, and so distinguish between countries to reflect differences in the ability to pay. Price differentiation is known to yield higher profits than uniform pricing (the so called Ramsey pricing theory).

Manufacturers can also control the sequence of launches across Europe so as to limit the opportunities for the authorities to depress these prices in major markets through application of international price referencing.

The only thing that stops prices of innovative medicines spiraling out of control is some degree of government intervention and competition from parallel trade. The role of the EU in pharmaceutical pricing is limited to enforcing the price transparency Directive, which does not attempt to control or harmonise prices but merely ensures that price setting is transparent and does not discriminate by country of origin of the product.

The current American market for medicines provides an example of what can happen when no parallel trade is permitted and where the federal government does not intervene.

Americans already pay the highest prescription drug prices in the world, and these continue to soar. They have risen at three times the rate of inflation over the past four years. Without the legal certainty of having incoming parallel trade enshrined in US law, an estimated one million Americans regularly cross the border in person or use foreign-based internet pharmacies to obtain more affordable medicines.

As well, the essential problem facing the EU was how to settle conflicting policy objectives. On the one hand, the European Commission is concerned to secure the safety of products, to restrain over-consumption and keep health care costs under control. But on the other hand, incentives are needed for the industry to make useful innovations, some of which can save long term health care costs, particularly inpatient costs and reduce and prevent long term disability, and generally increase exports and thus employment and income in Member States.

In its 1994 Communication on the outlines of an industrial policy for the pharmaceutical sector in the European Community (COM(93)718 of 2 March 1994), the Commission expressed concerns that part of the pharmaceutical industry

[21] ECJ 5.12.96, joined cases C-267/95 and C-268/95 (Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd.), paragraph 47.

in the European Union may be losing global competitiveness, with consequent economic and social cost for Europe. These concerns have been shared by both the European Parliament (in its resolution of 16 April 1996) and the Council (in its resolution of 23 April 1996), which also drew attention to the need to establish a stable and predictable environment for pharmaceuticals in order to protect the health of patients, to ensure rapid access to the market and to encourage therapeutic innovation. For this reason, there have been undertaken efforts for the completion of the single market in the European Union, which resulted to the adoption of the Commission Communication on the single market in Pharmaceuticals[22]. The purpose of the completion of the Single Market in pharmaceuticals is not just to provide an environment which is favorable for pharmaceutical innovation and industrial development, it is also to improve consumer choices in pharmaceuticals of the required quality, safety and efficacy, at affordable cost. It must be clear that these policy orientations have to lead up to improvements in the provision of healthcare for all citizens.

However while the idea of creating a genuine single market in pharmaceuticals makes a great deal of sense, the reality is that each Member State still has differing resources and a different system of social protection. There are still considerable differences between EU Member states, with multinationals being obliged to adapt to the specific requirements imposed by each national authority. Pricing and financing systems are far from being similar. Furthermore, patent protection together with trade protection for brand names are essential to the process of product differentiation in a unified market. Different labeling and packaging systems, as well as distribution mechanisms, also obstruct the creation of the single market. The fundamental characteristics of health care markets such as moral hazard, the agency relationship between doctor and patient, as well as fixed profits for wholesalers and pharmacists, "obstruct" the function of a free market mechanism.

For this reason parallel trade fails to operate in a fully dynamic fashion. If pharmaceuticals markets were otherwise open, parallel trade would stimulate greater competition.

But, the parallel trade obtains a lot of advantages from the single market in pharmaceuticals and the most important part of those advantages is price differences.

2.3 SAVINGS FROM PARALLEL TRADE

Some of organizations, such as EFPIA[23], consider that the desire to create a single market for nationally price-controlled pharmaceuticals in Europe, through the encouragement of parallel trade, is unrealistic and damaging, as it creates a significant loss to the research-driven pharmaceutical industry. And that the European Commission is taking an overly formalistic approach in applying the EC

[22] COM(98)588 final "Commission Communication on the Single Market in Pharmaceuticals", Brussels, 25th/11/1998

[23] European Association of Euro-Pharmaceutical Companies

competition rules to protect parallel trade where such a rigid approach is not warranted in the case of price-controlled pharmaceuticals.

However most of the countries of the EU facilitate the parallel trade.

"Within the EU we most certainly intervene to facilitate parallel trade in pharmaceuticals. We think parallel imports are a good thing" - Commission DG Internal Market spokesman Jonathan Todd.[24]

According to various estimates, more than 10 percent of prescription drugs in Europe are re-imported. The recourse to parallel trade is expected to intensify, as governments and public health services increasingly seek ways to curb health expenditures.

Virtually all of the largest EU countries have some type of national healthcare insurance, including prescription drug benefits. Large budget deficits and an aging population have led to a variety of policies designed to control and reduce drug prices. In France, although pharmaceutical firms are permitted to freely set prices not covered by the National Insurance Plan or Securité Sociale, the reality is that for drugs sold through non-hospital channels, the French government carefully controls prices. Indeed, the Securité Sociale's pricing committee, the Comité Économique du Medicament (CEM) negotiates prices directly with pharmaceutical companies, and a major reason high demand and low prices characterizes the French pharma-market.

Other major EU countries also tacitly, or openly, encourage parallel trade. Recent legislation in Germany, for example, requires pharmacists to source at least 5.5 percent of the medicines they dispense from outside markets. IMS data show that this law has already resulted in the doubling of parallel trade in Germany during the past 12 months.

In the United Kingdom, the National Health Service (NHS) pays for the majority of prescriptions dispensed and so the government has an incentive to encourage the use of cheaper products such as imports. Although, all prescription drugs carry a co-payment not all NHS patients are required to pay this prescription charge. Exempt from paying the prescription charge are school-age children, disabled persons, the unemployed and the elderly – and these patients consume 85 percent of prescription medicines. Prescriptions dispensed to the employed adult population (around 12-15 percent by volume but half that in terms of value) carry a fixed co-payment meaning that patients have no incentive to demand cheaper medicines.

Additionally, the Pharmaceutical Price Regulation Scheme (PPRS) and the industry trade group, the Association of the British Pharmaceutical Industry (ABPI) negotiate target rates of return for brand name products and limits promotional expenditures by pharma-companies. Though this policy does permit pharma-companies to enjoy some flexibility with their pricing, particularly for newly launched products, subsequent price increases require prior authorization by the NHS.

[24] www.eaepc.com

With a generally favorable regulatory environment, the European parallel traders are now much more sophisticated than a decade ago. They are capable of identifying future blockbusters before they are launched, and drug licenses are much quicker to obtain – resulting in trading firms that today are better financed. In addition, because they deal with wholesalers as their main clients rather than selling into individual pharmacies, parallel traders are more able to offload stock quickly and receive payment. Their operations are more fluid, they are able to become involved earlier in the product life cycle and, as a consequence, their influence on the available market for a particular drug is growing.

Such a big interest to the parallel trade from European countries is logical, because parallel trade helps to increase the effectiveness of the European medicines market. It is a pro-competitive solution to keep costs of medicines in Europe in check. As a result, the healthcare authorities and, depending on the various systems, the consumer, in the product's country of destination will pay less for the parallel traded medicine than for the domestic version being marketed by the manufacturer. It helps to restrain costs in a high-value market which is not usually price sensitive.

The price charged for a parallel-traded medicine is invariably less than that for the domestic version. If this were not the case, the entire justification for the existence of parallel trade would cease, as would the trade itself.

I believe that the most important advantages of parallel trade for European countries are cost savings.

"Over period of some 25 years, the trade in both generic and parallel imports has greatly expanded, and their availability has resulted in considerable cost savings both to the health services and to patients."[25]

In all EU Member States where parallel trade does exist, national governments and/or their national health providers have introduced measures to guarantee savings through parallel trade. For example, since 1993 the German pharmacies are obliged to dispense parallel trade only, if parallel-traded products are at least 10 percent cheaper than the same products sold by industry itself. In reality parallel-prices are up to 35 percent lower (see below). This effectively means that substantial price-differences are created by Parallel Trade products - and reach the consumers, whether they pay directly or indirectly through their contributions to health-care systems. Such price related savings amount to 60 million ECU per year, in Germany alone.

Table 2.3.1 Example of savings for consumers paying direct

Marvelon[26] Organon (126 tbl), original	DM 85,25
Marvelon Organon (126 tbl), parallel traded	DM 72,59

[25] Drugs and Money, Dukes MNG et al (editors), World Health Organization Regional Office for Europe, IOS Press, 2003

[26] Marvelon tablets are a type of hormonal contraception commonly know as "the pill" or combined oral contraceptive pill

The British, German, Dutch, Danish, Swedish and Norwegian healthcare systems make direct savings of hundreds of million of Euros every year thanks to parallel-traded medicines.

Direct savings accrue to social health insurance and national health services in every country with incoming parallel trade. This is because national governments and/or their national health providers have introduced various measures to guarantee savings through parallel trade.

In a 2003 study of the market for parallel trade in medicines, entitled "Benefits to Payers and Patients from Parallel Trade", York Health Economics Consortium found that parallel trade generated direct savings to patients and social health insurance systems in excess of €630 million in 2002.

Table 2.3.2 Savings for 2002

Country	Savings (€, million)
UK	342
Sweden	47
Germany	194
Netherlands	32
Denmark	16
Total – 5 countries	631

According to report of Panos Kanavos the savings to health insurance and pharmacy constitute:

Table 2.3.3 Savings to health insurance, 2003

Country	Savings (€)	% of market
Norway	€ 500,000	0.7
Germany	€ 17,720,000	0.8
Sweden	€ 3,382,000	2
Denmark	€ 2,980,000	0.6
UK w/o clawback UK w clawback	€ 6,887,000 €55,887,000	0.3 2.4
Netherlands w/o clawback Netherlands w clawback	€ 11,620,000 €18,798,000	2 3.2

Table 2.3.4 Pharmacy benefit, 2003

Country	Direct benefits	% of market
Norway	€ 500,000	0.5
Germany	€ 0	-
Sweden	€ 0	-
Denmark	€ 0	-
UK	€ positive but invisible	-
The Netherlands	€ 5,902,000	1.5

Not only does a parallel trader have to better the price of the medicine directly imported by the domestic trademark owner, it will also need to compete on price and availability with other parallel traders operating in the same national market. In Sweden, for example, it has been shown that the price of a particular parallel traded medicine continues to fall the more parallel trade entrants there are.

With AstraZeneca's Spirocort Inhaler (alternatively known in other countries as Pulmicort) for the prevention of asthmatic attacks it was calculated by EAEPC Danish member association (PFL) that direct savings in Denmark in 2001 from the use of parallel traded versions amounted to DKr 30.05 million (approx €4.04 million) or 29.5 percent of the cost of the brand to social health insurance.

To these direct savings must be added a much higher amount of indirect savings as a result of parallel trade being the only form of price competition to monopolistic patent-protected brands.

A 2003 study by the York Health Economics Consortium, found that "parallel trade generates indirect savings by creating competition, where otherwise there is none, and thus forcing pharmaceutical manufacturers to reduce the prices of domestically sourced products".

- Denmark – in 1997 independent market researcher Medica Consult calculated that the downward spiral of prices through alternating price reductions by manufacturers and parallel traders led to annual savings of more than €50 million.
- Finland – a study by the University of Kuopio in 2001 modelled a hypothetical case in which manufacturers decided to react to lower parallel trade prices. This resulted in potential savings of between €5.2 million and €17.3 million. Ismo Linnosmaa & Taru Karhunen: "Parallel Imported Pharmaceuticals in Finland", 30 November 2001, Center for Pharmaceutical Policy and Economics, University of Kuopio
- Sweden – a study from the Research Institute of Industrial Economics in 2001 found that the prices of Swedish brands subject to competition from parallel trade increased less than other products during the period 1995-1998 Mattias Ganslandt & Keith E Markus: Parallel Imports of Pharmaceutical Products in the European Union, 2001, Working Paper No 546, the Research Institute of Industrial Economics, Stockholm. (Working Paper available on Website)
- UK – in a joint Department of Health/ABPI study into competitiveness of pharmaceutical supply in the UK in 2002 all hospital pharmacists interviewed said that parallel trade "had resulted in some affected manufacturers reducing their prices" Department of Health/ABPI: PPRS – The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS", December 2002, London.
- Italy – a version of Daflon, a treatment from Servier for venous disease – was launched in June 2002 at a 5 percent discount to the domestic product price. The pricing of Daflon is free from government interference.

Faced with competition from parallel trade, for the first time in almost 15 years Servier's Italian subsidiary did not increase the price of Daflon in 2003

Patients and taxpayers have saved annually about €4.7 million in Denmark and about €2.7 million in Norway on Losec – an anti-ulcer drug – as parallel trade has pushed the product's price down to a level corresponding to that charged in other European countries.

2.4 OVERVIEW OF PARALLEL TRADE IN THE EU SINGLE MARKET

In EU parallel trade has developed more or less consistently in all sectors[27]. However, in the pharmaceutical market the economic driver of this business is particularly strong: indeed, price differentials for drugs may be significant, up to 30 percent and more. The flow of goods originally occurred from southern European countries to northern European countries, as Member States of the Mediterranean area applied direct cost containment policies that kept prices down, whereas northern European countries always allowed free pricing. However, recently, price variation is becoming more and more diverse, and countries that historically were exporters are now also importers. This is the case, for example, with both France and Italy. Furthermore, the EU's enlargement in 2004 contributed to the integration of new markets and the expansion of the concept of parallel import to the accessing countries. Contrary to popular perception, trade flows are re-directed to these Member States because they surprisingly experience high prices for some products.

Parallel trade increased significantly with the maturing of the Internal Market and from the mid 1990s the share of parallel imports grew in a range from 7 to 17 percent, especially in countries like Denmark, Sweden, United Kingdom, Germany and The Netherlands. However, data from the last years show that the business is overall stable and partly decreasing. The principle reasons relate to the dependency of the business on the availability of supplies, on the size of the target market and on the substitution rate at the pharmacy level. In this regard, the penetration of generics and the different strategies adopted by pharmaceutical companies to prevent such a form of competition could explain the decreasing trend.

However, in comparison to parallel trade in other goods, the overall level of parallel trade in medicines is low. Various estimates by independent economic consultants on the share of the prescription pharmaceutical market in the EU taken by parallel-traded products from 1990-2000 put it at 2 percent, with a peak of 4 percent in 2002.

In EU parallel trade started out as a simple south-north process – this is no longer the case. Almost all countries of EU are involved, either as the source of the medicine or the destination. Many countries act simultaneously, with various medicines, as both source and destination. This is because prices have become

[27] See Table 2.1.2

relatively fluid – some prices in a "low-price" country are higher than those for the same product in a "high-price" country.

The Netherlands, United Kingdom and Germany have the longest exposure to parallel trade. More recently, Denmark, other Nordic countries and Ireland have seen more parallel-traded products appearing. And this is also now the case in Austria, Belgium, Italy and Spain. There are some countries which still have barriers to incoming parallel trade, notably France.

Table 2.4.1 Share of Parallel Trade in Pharmacy Market, 2002 [28]

Country	% share
Denmark	12.2
Germany	7.1
Netherlands	10.5
Norway (share of total market)	6.3
Sweden	10.2
United Kingdom	17.6

Further, the analysis of the biggest pharmaceuticals market is provided.

Germany is the largest pharmaceutical market in Europe. As the biggest pharmaceutical market in the European Union by volume and value (and the third largest market worldwide), Germany is a prime target for parallel trade. This has been exacerbated by recent policy initiatives to substitute re-imported products and generics for brand names. Parallel trade has grown exponentially since 2000 following the enactment of a law requiring pharmacists to replace brand names with re-imported drugs when the latter are at least 10 percent cheaper. Between 1998 and 2001, the parallel trade more than trebled, from 260 to more than 800 million euros. The market share of re-imported drugs increased from 1.8 percent in 1998 to 5.8 percent in January 2002. German parallel traders also enjoy considerable support from legislators in achieving such growth. A law introduced in 2001 makes it mandatory for pharmacists to supply low-priced alternatives (re-imported products or generics) whenever possible. This substitution practice forces pharmacies to have a minimum sales quota of re-imports of 5.5 percent in 2002, increasing to 7 percent in 2003.

It is estimated that 90 percent of UK pharmacists source products through parallel trade. According to the Consumers' Association, this would save the National Health System (NHS) approximately £80 million a year. The United Kingdom is indeed a major destination for re-imports in Europe with an estimated drug expenditure of $8.4 billion in 2000. One source indicated that by late 2002, 20 percent of all UK prescriptions would be re-imports.

As regards to Sweden, the first re-import license was granted there in 1996 and the first parallel traded product appeared on the market in early 1997 (the anti-ulcer medicine Losec). The number of PIPLs increased exponentially in 1998-2000, but decreased in 2001 as the market expanded. In 2000, parallel imports

[28] Source EFPIA, www.eaepc.org

included 137 products and 8.6 percent of total pharmaceutical sales (or SEK 1.7 billion).

The Netherlands probably has the highest penetration of parallel imports in the EU in 2001: 15 percent of the total market, forecast at 16 percent in 2006 (or $ 1bn).

Due to relatively low drug prices, France is essentially a parallel exporter of medicines to other EU countries. Prices are close to the European average, although more than 20 percent lower than in the UK and Germany, and more than 30 percent above Spanish prices. By comparison, an identical drug will be sold at € 10 in France, € 7.5 in Spain and Portugal and at € 12 in the UK and Germany.

2.8 REGULATORY FRAMEWORK FOR PARALLEL TRADE IN THE EUROPEAN SINGLE MARKET

Parallel trade of medicines in the EU is absolutely legal. Because, a main goal of the EU's founding Treaty of Rome is the creation of a single, internal market through which goods, services, people and capital can freely pass and it is thoroughly regulated through Articles 28-30 of that Treaty. It says that:

"Quantitative restrictions on imports and all measures having equivalent effect shall be prohibited between Member States". [29]

"Quantitative restrictions on exports, and all measures having equivalent effect, shall be prohibited between Member States".[30]

However article 30 of the treaty provides some exceptions:

"The provisions of Articles 28 and 29 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States".[31]

On the basis of its policy on freedom of movement of goods, pursuant to Articles 28-30 of the EC Treaty, the European Union applies the principle of "exhaustion of intellectual property rights".

Intellectual property rights (IPRs) are limited rights conferred by the state for certain ideas and expressions – products of the intellect. Examples include patents, which protect inventions, copyright, which protects expressions of ideas (primarily artistic, literary or musical, but also such things as computer code), and trademarks, which protect brands.

Patents confer on inventors the right to exclude competitors from producing, selling and distributing their inventions for the duration of the period of protection, which is usually 20 years after filing. Copyright confers a similar right on artists to

[29] Article 28 of the Treaty Establishing the European Community
[30] Article 29 of the Treaty Establishing the European Community
[31] Article 30 of the Treaty Establishing the European Community

exclude others from producing, selling or distributing their expressive works for the duration of their life plus seventy years. Meanwhile, trademarks give their owner the right to prevent others from using identical or confusingly similar marks and names on their products. Trademarks are normally renewable perpetually, but may under some circumstances be revoked (e.g. if a product name has become generic). Patents, copyright and trademark are all transferable.

Parallel traders say that patents ensure monopolistic pricing and huge profits for industry, but patents do nothing for poorer consumers who would be better off with cheap imports. Parallel trade ensures that price differentials are reduced. As a result, the EU has responded by giving preferential status to parallel traded products in order to bring down healthcare expenditure and introducing the above-mentioned "exhaustion".

The "exhaustion of intellectual property rights" occurs when a product is put on the market for the first time. From that moment the product can freely circulate along the distribution chain within a given market and in those countries where the manufacturer did not apply for the intellectual property right.

There are known three types of "exhaustion":

- National exhaustion. Under the doctrine of national exhaustion, rights are exhausted upon first sale within a nation but the ability of IPRS owners to prevent parallel trade between countries remains intact. The treatment of exhaustion is a core component of a nation's protection for, and regulation of, intellectual property rights. Because IPRS are provided on a territorial or national basis, the global approach to date has been to permit each nation to establish its own policy covering parallel trade.
- Regional exhaustion. Rights are exhausted within a group of countries (single market), thereby permitting parallel trade among them, but are not exhausted outside the region.
- International exhaustion. Under the doctrine of international exhaustion, rights are ended upon first sale anywhere in the world and parallel trades are permitted. Some have suggested that a global regime of international exhaustion would enhance welfare by enabling consumers everywhere to take advantage of lower prices. Others have argued that a global regime of international exhaustion would lower welfare of many, especially those in poor countries, because it would actually raise prices in those markets to the international average price.

Here are some examples of international and regional exhaustion. The U.S. applies the "international exhaustion", but it is known there as the 'first sale doctrine.' According to this, once a good has been first placed on market, the seller or manufacturer forfeits all rights to determine how that product will subsequently be disposed of. This effectively rules out price discrimination against American consumers, since a purchaser would always possess the right to resell into the U.S. However, U.S. law makes an exception of pharmaceutical products since it prohibits the importation of pharmaceutical products by anyone other than the manufacturer.

The European Union follows a policy of regional exhaustion in all IPR fields within the Community but bars parallel imports coming from outside its territory.

Historically, national intellectual property law in countries such as the U.K. and France has given exporters who possess a patent or trademark the right to prohibit such parallel trade. This can be done, for example, simply by marking the goods "not for resale in the U.K." or "not for resale in France."

More recently, the European Union has overridden this national law by adopting a policy known as 'Community Exhaustion,' meaning that once goods have been placed on the market in the European Union, the holder of the intellectual property right no longer has the right to restrict the further movement of the goods anywhere inside the European Union. The term 'exhaustion' is used because the rights of the owner of the intellectual property are said to be 'exhausted' once the goods have been placed on the market. Under Community Exhaustion, a U.K. exporter could not prevent the resale of AIDs drugs first sold in France back into the U.K., but could prohibit the re-entry of products made available for sale at low prices in Africa.

On this basis, once a good is legally produced and placed on the market within the European market by the owner of the rights, the latter cannot use its trademark or patent right to hinder the further sale of the product elsewhere in the EU, except in very exceptional circumstances where, for example, public health is at risk. This rule is implemented through the Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, which I will examine further.

Initially, in order progressively to establish the free movement of proprietary medicinal products, the Council has adopted four Directives essentially relating to the conditions in which the Member States deliver marketing authorizations for these products: 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[32]; Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products; 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; Directive 78/25/EEC of 12 December 1977.

Furthermore, in the "De Peijper" case the Court of Justice of the European Communities, to which the matter was referred under Article 177 of the EEC Treaty, has delivered a judgment on parallel trade of medicinal products. This judgment gives the Commission interpretative rulings enabling it to exercise more stringent checks on the application of the rules of the Treaty on free movement of

[32] Directive 65/65/EEC1 was the first European pharmaceutical directive. The directive was a reaction to the Thalidomide tragedy in the early 1960s, when thousands of babies were born with deformities as a result of their mothers taking thalidomide during pregnancy. The directive aimed to establish and maintain a high level of protection for public health in Europe. The idea behind the directive was that no medicinal product should ever again be marketed in the European Union without prior authorisation

goods, in particular the provision of Articles 28 to 30 of the EEC Treaty. As well, a direct consequence of free movement is the Cassis de Dijon doctrine of the European court of Justice (case C-120/78), which says that a product lawfully placed on the market of one member state must be allowed to circulate freely throughout the EU. This principle has been extended to also cover Iceland, Liechtenstein and Norway.

In case "De Peijper", the Court had to give a ruling on a set of health regulations relating to the marketing of medicinal products that prevented the marketing of a medicinal product introduced as a parallel import.

The Court first of all established that national rules or practices which result in imports being channelled in such a way that only certain traders can affect these imports, whereas others are prevented from doing so, are caught by the prohibition set out in Article 28 of the EEC Treaty.

The Court went on to reaffirm the Member States' right, in pursuance of Article 30 of the EEC Treaty, to decide, subject to the limitations imposed by the Treaty, on the level of protection they wish to afford for the health and life of persons, in particular the stringency of the checks to be carried out. It nevertheless immediately stressed the general context in which this competence of the Member States was to be exercised:

- National rules or practices which do restrict imports of pharmaceutical products or are capable of doing so are only compatible with the Treaty to the extent to which they are necessary for the effective protection of health and life of humans.
- National rules or practices do not fall within the exception specified in Article 30 if the health and life of humans can be as effectively protected by measures which do not restrict intra-Community trade so much.

In particular Article 30 cannot be relied on to justify rules or practices which, even though they are beneficial, contain restrictions which are explained primarily by a concern to lighten the administration's burden or reduce public expenditure, unless, in the absence of the said rules or practices, this burden or expenditure clearly would exceed the limits of what can reasonably be required.

In the case in point the competent national authorities intended to prevent a parallel importer from marketing a medicinal product that was similar to a medicinal product which had already been authorized and was produced by the same manufacturer for two reasons.

First, the parallel manufacturer was not able to provide the authorities with the complete file relating to the quality, efficacy and safety of the product in general, which the manufacturer's authorized importer had already supplied to those same authorities with a view to obtaining a marketing authorization for that medicinal product.

Secondly, the parallel importer could not, unlike the authorized importer, obtain from the manufacturer the reports on checks made on each manufacturing batch.

In the judgment on the "De Peijper" case, the Court ruled that "national rules or practices which make it possible for a manufacturer of the pharmaceutical

product in question and his duly appointed representative, simply by refusing to produce the documents relating to the medicinal preparation in general or to a specific batch of that preparation, to enjoy a monopoly of the importing and marketing of the product, must be regarded as being unnecessarily restrictive, unless it is clearly proved that any other rules or practices would obviously be beyond the means which can be reasonably expected of an administration operating in a normal manner …"[33]

In other words, the only measures which a national regulatory authority were justified in taking as regards parallel trade, the Court said, were those intended to verify that such products were identical with the version already marketed in that country by the domestic trade mark owner, or that the difference had no therapeutic effect. Following the de Peijper judgement, the European Commission produced a text outlining the basic principles for an abbreviated form of marketing authorisation for parallel-traded medicines in its 1982 Communication (Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted).

The Commission recommended that the information supplied by the importer should be sufficient to ensure that the medicine is covered by an existing authorisation in the country of destination. The parallel-traded version must therefore:

- contain the same active ingredient(s)
- be administered to patients through the same route
- have the same therapeutic effects
- have a common origin

The Commission admitted that the parallel trader may be required to supply the competent authorities in the Member State into which the product is imported with certain information, particularly:

- the product name and where it is sourced
- the name and address of the holder of the full marketing authorisation, both in the member state of origin and in the member state of destination
- the name and address of the parallel trader
- the product's marketing authorisation number in the source country
- the product's summary of product characteristics
- specimens or mock-ups of the product in the form in which it will be sold in the member state of destination

The Commission also suggested a period of a maximum of 45 days for the authorities to assess an application. In reality this period is often very much longer and suggested some additional requirements:

- Parallel traders are required to keep records of the origin, quantity and batch numbers of all products they sell
- If they are involved in modifying the outer packaging to enable the product to enter the local supply chain they need a manufacturing authorisation,

[33] ECJ 20.05.1976, case C 104/75 (Adriaan de Peijper v Kantongerecht Rotterdam-Netherlands), operative part, paragraph 2 European court reports 1976, page 00613

which involves periodic government inspection and the requirement to have substantial insurance cover

- In most countries it is also a requirement for importers to hold a wholesale dealing authorisation, as well as a manufacturing authorisation, if pharmacies are supplied directly. This involves implementing measures to ensure an audit trail for product traceability, maintaining suitable premises for the storage of medicines and the establishment of approved product recall procedures.

Following, a series of European Court of Justice rulings and opinions has played a key role in establishing and regulating parallel trade. This legal discipline is consolidated through robust case law developed over forty years and through detailed regulation, both at national and Community level. The European Court of Justice has over time repeatedly condemned Member State measures or corporate conducts that, without any appropriate justification (such as the protection of the industrial and commercial protection and of public health), restrict exports, however, at the same time, creating regulatory framework for parallel trade. For example, joint cases C-427/93, C-429/93, C-436/93 Bristol-Myers Squibb v. Paranova.[34] This is the case between between, on the one hand, Bristol-Myers Squibb, C.H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S (hereinafter "Boehringer"), and Bayer Aktiengesellschaft and Bayer Danmark A/S (hereinafter "Bayer"), which are pharmaceutical manufacturers, and, on the other hand, Paranova A/S (hereinafter "Paranova"), which imports into Denmark certain products manufactured by those companies, on the interpretation of Article 7[35] of the First Council Directive (89/104/EEC) of 21 December 1988 to approximate the laws of the Member States relating to trade marks, and of Article 36 of the EC Treaty.

In this case, for the purposes of sale in Denmark, Paranova repackaged all the medicines in new external packaging with a uniform appearance and its own style. That packaging displayed, inter alia, the respective trade marks of the manufacturers and the statement that the product had been manufactured respectively by "Bristol-Myers Squibb", "Boehringer Ingelheim" and "Bayer", together with the indication "imported and repackaged by Paranova".

Following, Bristol-Myers Squibb and Boehringer brought proceedings against Paranova claiming, that the defendant should be obliged to recognize that it had infringed the plaintiffs' trade marks by affixing them without the plaintiffs'

[34] ECJ 11.07.96, case Bristol-Myers Squibb v Paranova A/S (C-427/93) and C. H. Boehringer Sohn, Boehringer Ingelheim KG and Boehringer Ingelheim A/S v Paranova A/S (C-429/93) and Bayer Aktiengesellschaft and Bayer Danmark A/S v Paranova A/S (C-436/93).

[35] Article 7 of Directive 89/104, entitled Exhaustion of the rights conferred by a trade mark, provides:

1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent.

2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods, especially where the condition of the goods is changed or impaired after they have been put on the market.

consent to products it offered for sale, and that the defendant should be ordered to stop from affixing those trade marks to the products it repackaged and marketed.

The Court has ruled, that article 30 of the Rome Treaty as well as Article 7(2) 89/104/EEC of the directive must be interpreted as meaning that a trade mark owner may legitimately oppose the further marketing of a pharmaceutical product where the importer has repackaged it and reaffixed the trade mark, unless the four conditions set out in the Hoffmann-La Roche judgment[36], cited above, have been met:

- it is established that reliance on trade mark rights by the owner in order to oppose the marketing of repackaged products under that trade mark would contribute to the artificial partitioning of the markets between Member States; such is the case, in particular, where the owner has put an identical pharmaceutical product on the market in several Member States in various forms of packaging, and the repackaging carried out by the importer is necessary in order to market the product in the Member State of importation, and is carried out in such conditions that the original condition of the product cannot be affected by it; that condition does not, however, imply that it must be established that the trade mark owner deliberately sought to partition the markets between Member States; As well, In cases subsequent to Hoffmann-La Roche, in particular in Bristol-Myers Squibb and Others and Upjohn, the Court clarified what may constitute artificial partitioning of the markets between Member States. In certain circumstances, where repackaging is necessary to allow the product imported in parallel to be marketed in the importing State, opposition of the trade mark proprietor to the repackaging of pharmaceutical products is to be regarded as constituting artificial partitioning of markets.
- it is shown that the repackaging cannot affect the original condition of the product inside the packaging; such is the case, in particular, where the importer has merely carried out operations involving no risk of the product being affected, such as, for example, the removal of blister packs, flasks, phials, ampoules or inhalers from their original external packaging and their replacement in new external packaging, the fixing of self-stick labels on the inner packaging of the product, the addition to the packaging of new user instructions or information, or the insertion of an extra article; it is for the national court to verify that the original condition of the product inside the packaging is not indirectly affected, for example, by the fact that the external or inner packaging of the repackaged product or new user instructions or information omits certain important information or gives inaccurate information, or the fact that an extra article inserted in the packaging by the importer and designed for the ingestion and dosage of the product does not comply with the method of use and the doses envisaged by the manufacturer;

[36] ECJ 23.05.1978, case C-102/77 (Hoffmann-La Roche&Co. AG v Centrafarm), operative part

- the new packaging clearly states who repackaged the product and the name of the manufacturer in print such that a person with normal eyesight, exercising a normal degree of attentiveness, would be in a position to understand; similarly, the origin of an extra article from a source other than the trade mark owner must be indicated in such a way as to dispel any impression that the trade mark owner is responsible for it; however, it is not necessary to indicate that the repackaging was carried out without the authorization of the trade mark owner;
- the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; thus, the packaging must not be defective, of poor quality, or untidy; and
- the importer gives notice to the trade mark owner before the repackaged product is put on sale, and, on demand, supplies him with a specimen of the repackaged product.

In the similar case C-443/99 between Merck, Sharp & Dohme GmbH and Paranova Pharmazeutika Handels GmbH[37], the Court has ruled that replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabeled pharmaceutical products and as well repeated paragraph 14 of the judgment in Case 102/77 Hoffmann-La Roche, that the proprietor of a trade mark right which is protected in two Member States at the same time is justified, for the purposes of the first sentence of Article 30 EC, in preventing a product to which the trade mark has lawfully been applied in one of those States from being put on the market in the other Member State after it has been repacked in new packaging to which the trade mark has been affixed by a third party. That paragraph also states, however, that such prevention of marketing will constitute a disguised restriction on trade between Member States, within the meaning of the second sentence of Article 30 EC, where it is established, in particular, that the use of the trade mark right by the proprietor, having regard to the marketing system which he has adopted, will contribute to the artificial partitioning of the markets between Member States.

In the Case C-143/00 Boehringer Ingelheim GmbH, Glaxo Group Ltd and others v. Dowelhurst Ltd and Swingward Ltd[38], the Court supplemented the Bristol-Myers Squibb v. Paranova judgment and ruled that the Article 7(2) of First Council Directive 89/104/EEC of 21 December 1988 to approximate the laws of the Member States relating to trade marks, as amended by the Agreement on the European Economic Area of 2 May 1992, must be interpreted as meaning that a trade mark proprietor may rely on its trade mark rights in order to prevent a parallel importer from repackaging pharmaceutical products unless the exercise of

[37] ECJ 23.04.02, Case C-443/99 (Merck, Sharp & Dohme GmbH v Paranova Pharmazeutika Handels GmbH)
[38] ECJ 23.04.02, case C-143/00 (Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham plc, Beecham Group plc, SmithKline & French Laboratories Ltd and Eli Lilly and Co. v Swingward Ltd and Dowelhurst Ltd)

those rights contributes to artificial partitioning of the markets between Member States. And that the replacement packaging of pharmaceutical products is objectively necessary within the meaning of the Court's case-law if, without such repackaging, effective access to the market concerned, or to a substantial part of that market, must be considered to be hindered as the result of strong resistance from a significant proportion of consumers to relabeled pharmaceutical products. As well, a parallel importer must, in any event, in order to be entitled to repackage trade-marked pharmaceutical products, fulfill the requirement of prior notice. If the parallel importer does not satisfy that requirement, the trade mark proprietor may oppose the marketing of the repackaged pharmaceutical product. It is incumbent on the parallel importer himself to give notice to the trade mark proprietor of the intended repackaging. In the event of dispute, it is for the national court to assess, in the light of all the relevant circumstances, whether the proprietor had a reasonable time to react to the intended repackaging.

Then, in Joined Cases C-267/95 and C-268/95[39] Merck & Co. Inc., Merck Sharp & Dohme Ltd, Merck Sharp & Dohme International Services BV and Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta, Necessity Supplies Ltd, and between Beecham Group plc and Europharm of Worthing Ltd, the Court has ruled that articles 28 and 30 of the EC Treaty preclude application of national legislation which grants the holder of a patent for a pharmaceutical product the right to oppose importation by a third party of that product from another Member State in circumstances where the holder first put the product on the market in that State after its accession to the European Community but before the product could be protected by a patent in that State, unless the holder of the patent can prove that he is under a genuine, existing legal obligation to market the product in that Member State.

As you see, since the adoption of the 1982 Communication, the European Court of Justice has developed significantly its jurisprudence on the field and has clarified a number of issues regarding the requirements and procedures for licensing parallel trade, the use of national patent rights and regarding repackaging, re-labelling and the use of national trade-marks.

As a result, the European Commission adopted new communication[40]. This communication, based mainly on the development of the jurisprudence of the Court, does not address issues dealt with by other Community legislation, especially regarding the marketing for the first time of a medicinal product, competition or issues dealt with by the 1998 Commission Communication on the Single Market in Pharmaceuticals, unless such issues have been addressed by the Court in its jurisprudence regarding parallel trade. Specific reference is made to more recent judgements that clarify the conditions where repackaging of the

[39] ECJ 5.12.96, case C-267/95 and 268/95 (Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd.)

[40] COM(2003)839 final "Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted", Brussels, 30.12.2003.

medicinal product, imported in parallel, is objectively necessary so that it can gain access to the Member State of destination.

It updates the 1982 Commission Communication on the same subject and aims at giving some guidance on the practical application of the jurisprudence of the European Court of Justice to national measures relating to parallel trade, from one Member State to another, of proprietary medicinal products[41] for which marketing authorisations have already been granted in the Member State of destination. This communication consists of four statements.

The first statement is that parallel importation of a medicinal product is a lawful form of trade within the Internal Market based on article 28 of the EC Treaty and subject to the derogations provided by article 30 of the EC Treaty.

The second statement is that a medicinal product may be imported in parallel on the basis of a license granted according to a 'simplified' procedure under which the applicant needs to provide less information than is required for an application for a marketing authorization if: the imported product has been granted a marketing authorisation in the Member State of origin; the imported product is essentially similar to a product that has already received marketing authorisation in the Member State of destination.

Parallel importation of a medicinal product is still possible even when the reference authorisation has been withdrawn and the parallel imports licence may not be revoked unless such a measure is justified by reasons relating to the protection of public health.

The third statement is regarding to "exhaustion of intellectual property rights" and it says that the owner of an industrial and commercial property right protected by Member State legislation may not rely on that legislation to oppose the importation of a product which has been lawfully placed on the market in another Member State by, or with the consent of, the proprietor of that right. However, the Court has ruled that the derogation to the free movement of goods justified on the grounds of protection of industrial and commercial property is only admissible when it is justified for the purpose of safeguarding rights, which constitute the specific subject matter of the property. The specific subject matter of the industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention with a view to manufacturing industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well as the right to oppose infringements, Case C-15/74 Centrafarm v Sterling Drug (1974) ECR 1147 as confirmed by joint cases C-267/95 and C-268/95 Merck v. Primecrown (1996)).

[41] Proprietary medicinal product is any ready-prepared medicinal product placed on the market under a special name and in a special pack; medicinal product is any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

The forth statement is regarding to the protection of trade marks and repackaging and based on the judjment of ECJ in the Bristol-Myers Squibb v. Paranova case. The proprietor of the trade mark may not use his trade mark right in order to prevent repackaging when: -the use of the trade-mark right by the owner will contribute to the artificial partitioning of the markets between Member States; -the repackaging cannot adversely affect the original condition of the product; -it is stated on the new packaging by whom the product has been repackaged and manufactured; -the presentation of the repackaged product is not such as to be liable to damage the reputation of the trade mark and of its owner; and -the proprietor of the trade mark receives prior notice before the repackaged product is put on sale.

Generally, parallel trade is regulated at several levels:

- at the level of the exporting wholesaler to be authorised to store and distribute medicines
- at the level of the parallel distributor with respect to three aspects:
    - wholesaling - authorisation to store and distribute medicines
    - manufacturing - activities of repackaging and re-labelling
    - individual products - marketing authorization/EMEA parallel distribution notice

The wholesalers are required to hold a pharmaceutical wholesaling authorisation issued (in accordance with Article 77 of Directive 2001/83/EC, as amended by Directive 27/2004/EC) by the competent authority in the Member State in which they are located. In accordance with the wholesaling authorization, the exporters are obliged to follow Good Distribution Practice (GDP) guidelines pursuant Article 84 of the mentioned Directive, to employ a EU Responsible Person and are subject to periodic inspection by the competent authority. Separate and additional authorization must be obtained from the relevant competent authority in order to handle and distribute controlled drugs (narcotics).

Medicines, when parallel traded, are subject to a second process of approval: the first time when the manufacturer applies for the marketing authorisation in the originating Member State; subsequently a second regulatory assessment takes place before the distribution in parallel can start. It follows that the parallel distributors in the country of destination need to have in the first place a marketing authorisation (or licence) to be able to commercialise imported products. However, the type of licence needed depends on the adopted approval process. If the directly distributed product has been subject to the national approval process, pursuant the Directive 2001/83/EC (as amended), then the parallel distributor must obtain a parallel import marketing authorisation from the same competent authority for the product to be distributed in parallel. Together with any applicable fee, the applicant must indicate the EU source country and the product's marketing authorisation number there. The competent authority then conducts checks, in conjunction with the competent authority in the source country, to assure itself that there are no differences of therapeutic significance from the directly-distributed product covered by a full marketing authorisation in the country of destination. The general principles to be considered by national competent authorities when granting

simplified marketing authorisations for parallel-distributed products were first outlined in a 1982 Communication from the European Commission[42]. At the stakeholder meeting of 29 November 2006, the Commission had explicitly referred to the "Kohlpharma ruling" related to the questions of common origin. If the directly distributed product has been approved centrally by the European Commission, following a positive opinion from the European Medicines Agency (EMEA) and in accordance with Regulation 726/2004 (It is the Reg. (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.), then no further regulatory approval is necessary as the product on the market is, by definition, authorised and identical in every Member State. However, a linguistic compliance check on the pack labelling and patient package leaflet of the parallel-distributed product by the EMEA is required in accordance with Article 57.1(o) of Title IV of the Regulation, resulting in the issue of a Parallel Distribution Notice.

In accordance with Article 76.3 of Directive 27/2004/EC, importers are required to notify the full marketing authorisation holder and the competent authority in the Member State of destination of their intention to parallel distribute a product. In addition, under trademark law, the importer must also notify the trademark owner. Moreover, importers also have to adapt the packaging/labelling of every incoming batch to access the local market, in accordance with the marketing authorisation, national law and decisions of the ECJ. To this effect, they need a manufacturing authorization (In UK the licence for repacking/re-labelling is called a 'manufacturers (assembly only)' licence.) issued by the competent authority in the country of operation. Holders of manufacturing authorizations are obliged to follow Good Manufacturing Practice guidelines, to employ an EU Qualified Person and are subject to periodic inspection by the competent authority. The EU Qualified Person has to be a person who has received the relevant education and training (in accordance with Article 48 of the Directive), usually a pharmacist with industry experience, or a chemist, with responsibility to personally ensure that a quality system is implemented and maintained. If a parallel distributor does not repack or re-label goods in his own facility, he will have to subcontract these processes to an authorised re-packer, who will have to demonstrate that he is in possession of a manufacturing authorisation and operates under Good Manufacturing Practice conditions. In these cases, all legal and technical requirements that must be observed by the parallel importer/distributor will be laid down in a technical agreement between him and the repacker. This ensures full compliance with all legal and technical requirements under Good Manufacturing Practice.

In other words, every parallel traded product has in fact been approved twice – its producer obtains a marketing authorization to place it first on the market and

[42] Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted OJ No C 115 of 6. 5. 1982, p. 5.

then each parallel trader requires an abbreviated marketing authorization to sell it. In addition, any trader that repackages or re-labels parallel trade has a manufacturing authorization, employs a legally-responsible EU Qualified Person, and is subject to Good Manufacturing Practice regulations and periodic government inspection.

Table 2.5.1 Overview of EU regulation applied to wholesalers, parallel trader and re-packers

	Type of license	Guidelines	Obligations	Inspections	Batch recordin
Wholesaler (export)	Wholesaling authorization (Art. 77 Dir. 2001/83/EC, as amended by Directive 2004/27/EC)	Good distribution Practice	Employments of an EU responsible person (Dir. 2001/83/EC)	+	+
Parallel trader (import)	Product level: Abbreviated marketing authorization (Dir. 2001/83/EC) for nationally approved medicines Parallel distribution notice (Art. 57.1 (o) of Title IV f the Reg. 726/2004) for EMEA approved medicines Activity level: Manufacturing authorization Wholesaling authorization	Good manufacturing practice and good distribution practice	Employment of an EU qualified Person (i.e. a pharmacist or a chemist, according to art. 48 of Dir. 2001/83/EC)	+	+
Repacker only	Manufacturing authorization	Good Manufacturing practice (in case repacking/relabelling	Employment of an EU qualified	+	+

		is outsourced)	person (i.e. a pharmacist or a chemist, according to art. 48 of Dir 2001/83/EC)		

2.6 SHORTCOMINGS OF THE REGULATORY FRAMEWORK FOR PARALLEL TRADE

Unfortunately there still some shortcomings in the regulation of parallel trade. First of all it is due to different national frameworks.

For example, implementation of the trademark rules varies from country to country, requiring parallel distributors to follow complicated procedures to fulfill the demands of trademark owners and authorities. A label produced by the parallel importers can (and must often), depending on national regulation, contain a window so that the trademark remains visible. This is complicated by the new regulations on Braille[43] and by the old problem of different trademark names in different markets for identical medicines. Some Member States require that the imported medicine be sold in the importing States under the branded name on that market. Other MS insist that the parallel distributor maintains the imported products' names and forbid name changes, although case law would suggest otherwise.

The procedures for abbreviated marketing authorisation for parallel imports are in place in all countries, including new Member States. However, the timelines to issue marketing authorisations vary significantly and are only in very few cases in line with the Recommendation of the Commission.

For example, Denmark now issues marketing authorisations on average within 56 days, which is a considerable improvement of the situation with respect to a few years ago. In this sense Denmark constitutes a very good example and a benchmark for other authorities. In Sweden, according to law, issue of parallel import marketing authorizations should take maximum 120 days. However, authorities do not manage to stay under this limit and declared that the target time for issuing an authorization is 210 days. Despite this extension, in 2004 this target was met only for 76 percent of the applications, in 2005 for 40 percent and in 2006 for 15 percent. Currently the average of days needed to issue a licence is 223 days. Poland is an example of proactive approach of health authorities. Lead times for parallel import marketing authorisations shrunk from 9-12 months in 2005 to 6-8

[43] Compliance with the Braille provisions presents an extra challenge to parallel importers/distributors. This stems from the fact that the Braille version of the product name is often embossed on top of the surface also containing the branded or trademark name of the product. Normal practice requires the Braille of the original package to be re-labelled to fit with country of import conditions, which is usually done with extra thick paper labels or transparent labels. However, in some countries trademark rules do not permit the original name to be covered with a label. This is particularly relevant if and when the Braille expresses a foreign product name. In such a case, the importer must cover that Braille. Also the inclusion on some packs of the pharmaceutical form or additional information in Braille needs to be covered, if source product has a different brand name.

months in 2006/2007. The timelines can vary, however, with respect to the source country, as discussed above. In Austria the PI licence depends on the master licence (manufacturer marketing authorisation) and if the latter is withdrawn, the former ceases to exist. This does not seem to be consistent with EU case law. The issue of the marketing authorisation in Italy is generally a bureaucratic procedure that takes from one to two years.[44]

In addition to vast differences among Member States with regard to waiting periods for marketing authorisations, there are also differentials in applicable fees. UK has by the most expensive parallel trade regime in the EU (see Table 12). For example, one licence under the new pricing regime will total £3977 (EUR 5767) per annum from April 2007 (application cost £1718, plus one variation fee per year £342, plus the annual maintenance fee £1917), the most expensive in the Community.

Table 2.6.1 Differences in parallel trade license approval procedures and fees[45]

Country	Approvals	Application fee (€)	Length of procedure (month)	Estimated agency earnings ('000 €)
Austria	-	390	6-36	-
Belgium	-	1,5000	-	-
Denmark	~900	2,185	3-4	-
Finland	200	1,680	7-14	336
Germany	10,200	2,934	6-12	20,538
Ireland	450	1,516	3-6	455
Italy	14	629	12-24	8
Netherlands	1,500	1,465	2	2,198
Norway	~2000	1,502	3-4	-
Poland	170	777	9-10	132
Sweden	425	1,626	4	-
United Kingdom	15,000	2,500	12-18	37,500

As well, practical experience provided that there is often a lack of effective administrative procedures among national authorities. For example in the area of marketing authorisation issuance, importing companies in the UK, Germany, and the Nordic countries complain that their national authorities have particular difficulty in getting responses from the Italian and Spanish regulators. This dialogue is necessary in order to establish the required therapeutic similarity criteria between the exporting and importing Member States. If we were to rank Member States slowness in responding, Italy beats the rest by far and Spain has

[44] European Association of Euro-Pharmaceutical Companies 30.03.07, EAEPC Submission DG Enterprise Consultation on Safe Medicines in Parallel Trade

[45] European Association of Euro-Pharmaceutical Companies 30.03.07, EAEPC Submission DG Enterprise Consultation on Safe Medicines in Parallel Trade, p. 12

recently fallen back in response time. France ranks in the middle, and Portugal and Greece respond fast. For the solution of this problem, EAEPC provides some recommendations, for instance:
"A more automated, electronic system could contribute substantially to improving the exchange of information between parallel distributors and the authorities, as well as among national authorities (although the obligation of submitting samples of repacking, or mock-ups, still requires direct communication). The electronic procedures of notification established by the EMEA are a good example.

Authorities of the importing country should send or ask for administrative support from the sourcing countries immediately upon receipt of the application."[46]

Moreover, barriers to free movement of goods are created by differences in required pack sizes. There is clearly an element of market segmentation in maintaining differences in pack sizes. Trademark rules do not authorise parallel trader to make theirs own pack to adjust to national regulations and product requirements of the destination markets. Sometimes also reimbursement rules create constraints on pack size modifications. Germany requires that parallel importers supply their products in pack sizes identical to those of the brands available on the German market. To achieve this, import packs have to be stock up, or blisters have to be removed from original packaging, or two or more original packages have to be bundled. Only those blisters removed in the course of repackaging can be distributed in a re-box because there is no other way to distribute these blisters. In order to avoid an obstacle to market access, the importer uses its own packaging.

Generally, the all pharmaceutical supply chain in Europe is complex, with millions of medicine packs moving around the EU each year. Its fragmentation, as well as the overwhelming growth of wholesaler intermediaries and traders involved in the European flow of medicines is resulting on a decrease of transparency of the supply chain, and an increase in the difficulties to track and trace medicines. Furthermore, the growing problem of counterfeiting, particularly in some third markets, raises a significant threat within the current supply chain system.

And the medicines supply chain is continuing to fracture, with different coding solutions implemented in different Member States, each with its own objectives and motivation. Opportunities to improve patient safety at a European level and enhance the control of the supply chain are being lost, while the multiplication of systems adds incremental production costs for manufacturing and increase further both the complexity and differentiation across the European market.

The solution is provided by EFPIA: "The standardised and unique coding of medicines can lead to opportunities to improve patient safety and enhance the security and efficiency of the medicines supply chain, with better traceability of medicines in Europe and worldwide. "

[46] European Association of Euro-Pharmaceutical Companies 30.03.07, EAEPC Submission DG Enterprise Consultation on Safe Medicines in Parallel Trade, p. 13

All above-mentioned create a great obstacles for parallel trade. However this is not the only one barrier, because more obstacles can be created by manufacturers that you will see in third part of my work.

2.7 IMPORT FROM THIRD COUNTRIES

Today, the E.U. policy only extends as far the E.U.'s borders. The most important part of that policy for parallel trader is that, once a product protected by a trademark has been put on the market in the Community by the trademark owner or with his consent, the owner's proprietary rights are "exhausted" throughout the Community and the rules of free movement must prevail. This law developed was codified in Article 7 of the Trade Marks Harmonisation Directive. Article 7 of the Directive provides that: 1. The trade mark shall not entitle the proprietor to prohibit its use in relation to goods which have been put on the market in the Community under that trade mark by the proprietor or with his consent. 2. Paragraph 1 shall not apply where there exist legitimate reasons for the proprietor to oppose further commercialisation of the goods especially where the condition of the goods is changed or impaired after they have been put on the market.

Article 13 of the Community Trade Mark Regulation (Council Regulation on the Community trade mark, 40/94/EEC.) is in identical form save that it is drafted with reference to the Community trade mark.

However, prior to the adoption of Article 7 of the Directive, there was an open question as to whether Articles 28 and 30 (former 30 and 36) of the EC Treaty had any application to cases involving the parallel importation of goods first placed on the market outside the EU. In practice, the approach taken by the Member States varied, with some applying a rule of international exhaustion and others applying a rule of Community exhaustion only. In very broad terms (and subject to exceptions), there was a north-south split in approach, with the northern European countries tending to follow the principle of international exhaustion and the southern European countries being more restrictive in their approach and thereby favouring brand owners who wanted to prevent parallel imports of their products.

Even after implementation of the Directive, the lawyers argued with each other and in the national courts about whether the Directive entitles the owner to prevent parallel importation of its goods from outside the EU or not. The answer could have been found in the political debate which took place between the original proposal for these two pieces of legislation and the text that was eventually adopted. The approach that was initially proposed was explained in the Explanatory Memorandum for the Directive, published as part of the Proposal[47]:

"The rule under which the right to a trade-mark is exhausted with the first use of the mark effected or authorised by the proprietor is a direct consequence of its function as an indicator of origin. The place where the marked product is put on the market is not important in this respect. The principle laid down in Article 7

[47] COM (80) 635, Explanatory Memorandum.

thus applies regardless of whether the product bearing the Community trade-mark was put on the market inside or outside the Community.

Moreover, the application of the principle of the exhaustion of the right to the trade-mark ties in with the attaining of two tasks which are entrusted to the Community by the Treaty: the removal, as between Member States, of obstacles to freedom of movement for goods and services, and the institution of a system ensuring that competition in the common market is not distorted. The latter obligation could clearly not be observed if the Commission were to propose rules laying down the principle that the proprietor of a Community trade-mark had the right to use it in order to compartmentalise the world market. There is a real danger that undertakings whose principal place of business could well be in a non-member country would prevent their products from being imported into the Community at more favourable prices, which would be detrimental to Community consumers. It is only in particular cases, therefore, that the rule relating to the exhaustion of the right to a Community trade-mark may be varied. These are listed in paragraph 2. One of the legitimate grounds which a proprietor may invoke under paragraph 2(a) to oppose the importation into the common market of goods marked in a nonmember country with his consent is the fact that he has been prevented by the authorities of the exporting country from controlling the quality of the goods produced there by his licence."

The intention at this stage was quite clearly to introduce a Community doctrine of international exhaustion for both the new Community trade mark and the harmonized national trademark systems. However, the parliamentary process led to an about-turn by the Commission and the introduction of the words "in the Community," based on the view expressed in particular by the Economic and Social Committee that the absence of reciprocity in countries outside the Community would result in discrimination against industry within it.

In particular, the Explanatory Memorandum to the amended Proposal for the Community Trade Mark Regulation published in 1984 stated[48]:

"On the question of international exhaustion of the rights conferred by a Community trade mark, the Commission has formed the opinion that the Community legislator should refrain from introducing this principle and make do with the rule of Community-wide exhaustion. The Community must, however, be empowered to conclude, at some future time with important trading partners, bilateral or multilateral agreements whereby international exhaustion is introduced by the contracting parties. The restriction to Community-wide exhaustion, however, does not prevent national courts from extending this principle, in cases of a special nature, in particular where, even in the absence of a formal agreement, reciprocity is guaranteed."

The commentary on the equivalent amendment to the Directive cross-referred to the above comments, stating that the Commission had decided not to introduce international exhaustion, "in line with the proposals made by the Economic and Social Committee and Parliament".

[48] COM (84) 470, Explanatory Memorandum

Despite the arguments of the parallel importers' lawyers, it should not have been a surprise, therefore, when the ECJ interpreted Article 7(1) of the Directive in the case of Silhouette v. Hartlauer (Silhouette, an Austrian company that sold spectacles under its trademark, sold an outdated batch to a Bulgarian company for resale in the Former Soviet Union. However, the distributor then tried to put them on the market in Austria, and the court upheld Silhouette's right to prevent this under its trademark)[49] as meaning that:

"…national rules providing for exhaustion of trade mark rights in respect of products put on the market outside the EEA under that mark by the proprietor or with his consent are contrary to Article 7(1) of the Directive, as amended by the EEA Agreement."

In other words, the trademark owner is able to rely on the trademark rights granted to him under national law to prevent the importation of goods bearing that trademark, which have been first placed on the market outside the EEA by him or with his consent. Any other interpretation was said to be contrary to the scheme and purpose of the Directive.

However, it took some time for the national courts to interpret these provisions in any consistent way.

The German Federal Supreme Court (Bundesgerichtshof) was the first to preempt the interpretation now settled by the ECJ, despite having had a policy of international exhaustion under the old national law. In a 1995 case involving parallel
imports of LEVI'S jeans from the United States[50], the Court granted LEVI'S a prohibition expressly on the basis that the implementation of Article 7 imposed an exhaustion principle intentionally limited to the EEA.

At around the same time, the District Court of the Hague concluded that the history behind the Directive, taking into account the travaux préparatoires (preliminary works), left no room for doubt that Novell would have been entitled to object to parallel imports of its software from the United States, based on its trademarks, had Article 7 by then been implemented (which unfortunately for Novell it had not at that point). Again, this was despite the prior application of international exhaustion in the Netherlands.

Austria was a country which applied a rule of international trademark exhaustion. However, the Austrian Supreme Court was sufficiently uncertain of the position under the Directive that it made the reference in Silhouette. Once its questions were answered by the ECJ, the Court followed the guidance with a judgment in favour of Silhouette, and continued to apply EEA-wide exhaustion thereafter.

Italy's courts remained divided between Community/EEA-wide and international exhaustion prior to Silhouette, but since then they have generally unified against international exhaustion. Prior to the development of the pre-

[49] Case C-355/96, Silhouette International Schmied GmbH & Co. KG v. HartlauerHandelsgesellschaft GmbH

[50] Joined cases C-414/99, C-415/99, C-416-99, Zino Davidoff v. A&G Imports and Levi Strauss v.Tesco and Costco

Directive European case law discussed above, the courts in France did not apply any exhaustion principle, making this an attractive jurisdiction for brand owners to prevent parallel imports.

However, the French courts changed their approach to that of European exhaustion as early as the 1970s, and now comply strictly with the limitation of exhaustion to goods put on the market within the EEA by the trademark proprietor or with his consent.

The Greek courts also observe the principle of EEA-wide exhaustion.

The path taken in Spain has been somewhat complicated. Having developed a doctrine of international exhaustion through long-established case law, legislation was brought in on November 10, 1988, supposedly enacting (in advance) Article 7 of the Directive, but in fact limiting trademark exhaustion to the territory of Spain. Despite this, some cases continued to be decided in accordance with international exhaustion, but the tendency gradually shifted towards Community/EEA exhaustion during the 1990s. Article 7 was correctly enacted in 2001 and has since then consistently been applied to allow parallel imports to circulate within the EEA but to prevent those coming in from outside.

The English courts made the most "noise" before toeing the ECJ line. Prior to the Directive, the position appeared to be that a rule of international exhaustion applied to parallel imported goods of the same quality as the local UK goods, whereas UK trademarks could be relied on to prevent the importation from outside the Community of goods of inferior quality to the UK equivalents. In the latter case, the courts felt that the parallel goods would damage the UK trademark, whereas the same could not be said for the former. Even after the Silhouette decision, the English judges were reluctant to permit a brand owner to rely on its trademarks to prevent parallel imports of its own products from outside the EU, on the basis that to do so is incompatible with the function of a trademark of identifying origin. This was in line with sentiments expressed by the national press and consumer bodies who suspected that brand owners only wanted to prevent parallel imports in order to preserve artificially high prices in the UK.

The High Court judge, Mr Justice Laddie, identified a potential lacuna in the Silhouette judgment. He argued in Davidoff case[51] that, while the Court had laid down the principle that no Member State may impose international exhaustion, it had not ruled out the possibility of a particular proprietor consenting directly or indirectly to parallel importation of his products when he markets them outside the EU. He then said that the question of whether a proprietor had so consented was to be determined under the relevant law of the contract under which the goods were put on the market.

In this case it was English law. Laddie J. then applied principles derived from a 19th century patent case to conclude that Davidoff was to be treated as having consented to the parallel imports, despite having imposed an express written territorial restriction on sale on the relevant distributor in Singapore. This

[51] Joined cases C-414/99, C-415/99, C-416-99, Zino Davidoff v. A&G Imports and Levi Strauss v.Tesco and Costco

position was found by the ECJ to be wrong under EC law, but the case highlights the strength of feeling in certain parts of the English judiciary that the effect of the Directive is "wrong" whether as a matter of law, policy or principles of fair trade.

It is interesting to note that a Scottish judge had no such difficulty with applying the ECJ decision in Silhouette, when asked by Davidoff to grant an injunction against parallel importers of perfume from outside the EU. Unlike Laddie J, he concluded from the harmonisation aim of the Directive that it should not be open to any Member State to adopt an approach which made it easier for international exhaustion to be established.

Sweden is another country whose courts have found it hard to come to terms with the forced abandonment of its old principle of international exhaustion. When the Directive was first implemented in Swedish trademark law, Article 7 was not included because it was neither in line with the traditional Swedish approach to free trade nor did it satisfy the aims of Nordic Harmonisation (given that Finland and Norway both then applied an international exhaustion rule). The Swedish Government intervened in the Silhouette case, arguing that individual Member States should be permitted to apply an international exhaustion rule. However, having failed to persuade the ECJ of this, Sweden inserted a new provision in its trademark law to implement Article 7, as from July 1, 2000. Nevertheless, the courts displayed their continuing reluctance to allow brand owners to use their trademarks to stop parallel imports in the case of Levi Strauss & Co. v. COOP Sverige AG. The District Court of Stockholm (Stockholm's tingsrätt) decided against Levi's on the basis that the importation had taken place prior to the date on which Sweden implemented Article 7 of the Directive. Since international exhaustion applied under national case law, the need for legal predictability at the time meant that the defendant could not be held liable for infringement by retroactive application of territorial exhaustion.

By a majority decision, the Court of Appeal (Svea hovrätt) agreed, adding that the introduction of criminal penalties for trademark infringement by parallel importation made it all the more important to decide the case on the basis of legal predictability. The dissenting judge agreed with the application of the legal predictability rule, but argued that people's reasonable expectations as to the legality of parallel importation should have changed after Silhouette and therefore the critical date was that of the ECJ's decision, 16 July 1998, rather than that of the new Swedish trademark law.

It is presumed that the Levi's case was specific to its facts in terms of the relevant importation dates, and would not be repeated. However, like the English cases, it highlights a national tendency to identify and lean towards any legal argument which might justify a global exhaustion rule for "pure" parallel imports.

Prior to the Silhouette case, the courts in both Denmark and Finland also applied the principle of international exhaustion. However, since then, they have effected the transition to regional exhaustion, as required by the ECJ's interpretation of the Directive.

All the other EU Member States are known to have implemented the Directive and to be applying the decisions of the ECJ so as to prevent the parallel

importation of goods bearing protected trademarks from outside the EU, in the absence of unequivocal evidence of consent.

In contrast to the prescriptive approach under EC law, as interpreted by the ECJ, the EFTA countries which are also members of the EEA (Norway, Liechtenstein and Iceland) are free to decide whether to adopt international trademark exhaustion rather than restrict this to goods first put on the market with the proprietor's consent in the EU.

However, for any parallel traders who are determined to continue their trade from outside the EU despite Article 7 of the Directive, there may be cases in which they can rely on Article 81[52] or 82[53] to defend an infringement action.

There are two significant cases in which this has happened in the past, but which are not well-publicised in the trademark community.

The first is the Javico case[54] in which the question posed was whether a restriction imposed on an EU-based distributor (Javico), to the effect that it could only sell Yves Saint Laurent ("YSL") goods in Russia, Ukraine and Slovenia was contrary to Article 85(1) (now 81(1)). The goods concerned were manufactured within the EU and exported by Javico to the listed countries and then re-imported into the EU in competition with the equivalent goods put on the market through YSL's selective distribution arrangements for the EU (which had been expressly exempted under Article 85(3) – now 81(3)).

The ECJ found that the restriction on sale or re-importation into the EU in the agreement between YSL and Javico could be precluded under Article 81(1) if that prohibition had the effect of preventing, restricting or distorting competition within the Community and was liable to affect the pattern of trade between Member States. Examples of when these conditions might occur were given, as follows:

- where the Community market in the products in question is characterised by an oligopolistic structure, or by an appreciable difference between the prices charged for the contractual product within the Community and those charged outside the Community; and
- where, in view of the position occupied by the supplier of the products and the extent of the supplier's production and sales in the Member States, the prohibition entails a risk that it might have an appreciable effect on the pattern of trade between Member States such as to undermine attainment of the objectives of the common market.

There was clearly much further work to be done in that case to determine whether the territorial restriction did in fact have that effect, which was a matter for determination back in the national court.

---

[52] Article 81: 1.The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerned practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distribution within the common market.

[53] Any abuse by one or more undertakings of a dominant position within the common market or in a sunstantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between MS.

[54] Case C-306/96, Yves Saint Laurent v. Javico

Another case, in which the price differential between an exporting non-EU country and an EU member was a key factor, is that of Micro Leader Business v. Commission.[55] In that case, Micro Leader took a complaint under both Articles 85 and 86 (now 81 and 82) to the Commission against Microsoft in relation to its attempts to prevent parallel importation of French language software from Canada into France, such attempts comprising inter alia territorial restrictions in Microsoft's distribution agreements with Canadian distributors and notices to the trade in France to the effect that Canadian parallel imports were unlicensed. Micro Leader alleged that Microsoft's actions resulted in the direct or indirect fixing of purchase or selling prices of software within the Community and the maintenance of artificially high prices on the French market.

The Commission rejected the complaint under Article 85 (81) on the basis that the conduct complained of amounted to no more than unilateral attempts by Microsoft to enforce its copyright in the imported software, and that no evidence had been presented of an agreement or concerted practice. The Article 86 (82) complaint was also rejected, primarily on the basis that Micro Leader had not presented sufficient evidence to support a case of abuse. Micro Leader brought an action before the Court of First Instance, asking the Court to rule that the Commission had failed to conduct a proper investigation into Microsoft's conduct and to require the Commission to revisit the case.

The Court reviewed the Commission's decision and affirmed its rejection of the complaint under Article 85 (81) for the reasons given. However, it concluded that the Commission had made a manifest error of assessment in relation to the Article 86 (82) aspect of the case. The evidence presented by Micro Leader constituted "at the very least, an indication that, for equivalent transactions, Microsoft applied lower prices on the Canadian market than on the Community market and that the Community prices were excessive." The Court then referred to the Magill case as authority for the proposition that the enforcement of intellectual property rights may in exceptional cases involve abusive conduct.

The Micro Leader case was therefore sent back to the Commission for further investigation of the complaint under Article 86 (82), which investigation is technically still outstanding, though very inactive (perhaps not least because of a subsequent reduction in Microsoft's French prices as well as other Commission investigations into the company).

However, arguments such as those presented in the Javico and Micro Leader cases are only available in a limited set of circumstances and actually it is very nard for parallel trader to use it with success.

For detaining of parallel traded products from outside the EU, there exists the customs authorities. The Customs authorities in the EU are responsible inter alia for controlling the entry into the EU and the export and re-export from the EU of goods infringing certain intellectual property rights. These powers were introduced by Council Regulation (EC) No. 3295/94, which was recently

[55] Case T-198/98 [1999]

superseded by Council Regulation (EC) No. 1383/200392, taking effect from July 1, 2004 ("the Customs Regulation").

Most of the EU Member States also have their own national laws governing their Customs' activities, which may in some cases cover parallel imports.

However, they should certainly not act against parallel imports moving around within the EU, and will rarely do so for incoming goods either. The Subcommittee members are aware that the Customs authorities in Austria, Benelux and Italy will not seize parallel imported goods if they know them to be such. On the other hand, both French Germany from outside the EEA. Also, although Spanish Customs have traditionally not done so, there may be a role for this in the future, since the Spanish Criminal Code was recently changed so as to make dealing in parallel imports a criminal offence in Spain. In the case of the UK, the Customs authorities will not seize suspected parallel imports under their general powers, but they will detain such goods on entry into the UK from outside the EU (or from within the EU but not having been entered for free circulation) if the trademark proprietor has lodged a formal notice in relation to the specific consignment of goods. While this provision is better than nothing, it is only of any use in cases where the trademark owner has been tipped off about an expected consignment.

In practice, even in countries where Customs will not act to detain parallel imports from outside the EU, such goods are sometimes detained and notified to the trademark owner on suspicion of being counterfeit goods. In such a case, the owner is given information about the provenance and intended destination of the goods, as well as a sample to check. If he concludes that the goods are not counterfeit, but are unauthorised parallel imports, it is then generally open to him to apply to the relevant civil court for an order that the goods should be released to him or to an independent third party to be held until a trademark infringement claim against the importer can be determined.

Implementation of regional exhaustion and as a consequence the limitation of parallel trade from outside the EU, usually results in the maintenance of high prices. For instance, prior to entering the E.U., Sweden operated a system of international exhaustion, permitting importers to source parallel traded goods from anywhere in the world. For example, if Levi jeans could be purchased more cheaply in America than in Europe, a Swedish importer wasn't free to purchase in America and resell in Sweden, even if the goods had originally been intended (by Levi Strauss & Co.) for sale in America (this specific issue arose in the European Court in the case of Davidoff v. A&G Imports and Levi Strauss v. Tesco (Case C-414/99). Tesco, a U.K. retailer, attempted to circumvent the E.U. distribution channels of Levi Strauss by buying direct from U.S. wholesalers – the court upheld the right of Levi Strauss under their trademark to prohibit these imports.)

However, on entering the E.U., Sweden was obliged to respect the rights of any holder of a Community trademark to prevent parallel trade from outside the E.U. A study by the Swedish Competition Authority (1999) estimated that parallel traded goods in sectors such as motor cycle spare parts, tyres, clothing, footwear, pharmaceuticals, sports equipment and snow scooters were between 10 and 30

percent cheaper than domestically sourced goods and that the elimination of parallel trade from outside the E.U. had increased domestic prices by between 0.4 and 5 percent on average.

3 COMPETITION IN THE PHARMACEUTICAL INDUSTRY

3.1 CHARACTERISTICS OF THE PHARMACEUTICAL INDUSTRY

Before starting to analyze the competition in the pharmaceutical market I would like to describe the specificity of pharmaceutical industry. As I mentioned before, the pharmaceutical industry is not like normal industry, for next reasons:

- An industry protected by patents: because drug molecules are easy to copy, patents are a necessary and even fundamental condition for development of new drugs. (Some high-tech industries have such high fixed costs that their products may only be copied by a handful of competing firms and with delay; therefore, patent protection becomes in fact less relevant. Some sectors also develop so rapidly that the competitive advantage amounts to being first on the market, which makes patent expiry of little interest.)
- A research-intensive industry: pharmaceutical companies develop and market new products in order to maintain and increase their market share; innovation is accordingly paramount to survival. Research and development costs have risen very rapidly over the past three decades. In 1970, annual R&D expenditure in the US pharmaceutical industry amounted to $ 600 million, to $ 9.6 billion in 1991 and to $ 11.1 billion in 1992. Unfortunately, this rise has not yielded a proportional increase in the number of new drugs: in the 1970s, 30-40 new drugs were put on the market each year, compared to 10-20 in the 1980s.
- A highly regulated industry: the therapeutic nature of pharmaceuticals leads governments to establish strict rules before a new drug is approved for sale. The result is new medicines are delayed in reaching the market and R&D costs increase due to rigorous testing procedures. The flipside of regulations is that healthcare policies in industrialised countries mean that patients only pay a fraction of real drug costs. This does not encourage doctors, hospitals and patients to seek out the most cost-effective drugs.
- A competitive industry: increasingly, brand-name manufacturers have to tackle competition from generic producers once patents expire. Marketing of generic products may in some cases reduce the prices of branded drugs by at least 50 percent. In 1992, generic products represented 43 percent of prescription drugs in the UK
- An industry seeking new markets: due to saturated and highly regulated markets in the West, the pharmaceutical industry is increasingly searching for new outlets in the newly industrialised countries and in developing countries.

The protection of intellectual property rights lies at the foundations of R&D investment in the pharmaceutical industry. There is some evidence that intellectual

property rights, in the form of patents and trademarks, are relatively more important in the pharmaceutical industry than in other sectors. This may be due to the fact that patents on prescription drugs are a more effective means of raising imitation costs than patents on other products.

The value of patent protection depends upon the length of the period of exclusivity. Although patent life is fixed by international agreement at 20 years from the date on which the patent application is filed, in practice, due to the delay between patenting and obtaining marketing approval, the "effective life" of a patent is much less than 20 years. As a consequence, both the US and the EU have adopted special legislative provisions extending the life of pharmaceutical patents. In the case of the US, the Waxman-Hatch Act extended patent protection on name-brand drugs for up to five years, but also limits the total period of exclusivity following marketing approval to 14 years. Within the EU, patent life can be extended by up to five years by means of a so-called "supplementary protection certificate".

Patents play a very important role in stimulating and rewarding research and innovation in the pharmaceutical industry. However, it is useful to recall that patent protection of pharmaceuticals (like patent protection of other products) has both advantages and disadvantages. The primary disadvantages of patent protection are its rigidity as a policy instrument and the resulting market power which it generates. The primary advantages are that patents provide the right incentive for R&D investment and, in the process, they make new innovations public information.

The process of pharmaceutical research and development (R&D) is a complex, costly, risky and long undertaking. It requires a sustained mobilisation of substantial human and financial resources over long period of time before a new drug finally reaches the patient. On average, this process takes between 10-15 years and the estimated average cost of developing a new medicine exceeds $800 million. In the course of the R&D process, more than 8,000 compounds are tested on average, of which only one is developed into a potent and safe drug.[56]

Pharmaceutical R&D is a multi-step process which in general terms can be divided in two parts:

- research, during which a molecule with specific and potentially useful characteristics is identified;
- development, when such a simple molecule undergoes numerous steps of stringent testing in order to develop it into a final product.

An important implication of this fact is that very different skills and capacities are required in order to go through the whole cycle of R&D. In practice, only the pharmaceutical industry is capable to complete the entire R&D cycle. This fact makes the pharmaceutical industry the driving and vital component of pharmaceutical innovation.

The contribution of public research (government and academic) to the process of pharmaceutical R&D is limited to the very early stages of the research

[56] www.ifpma.org, Research&Development

phase. "Basic or fundamental research" provides for invaluable discoveries enabling further “targeted” drug research. However, "applied research" is the step that brings new products to the patients. Development remains the most important component of the R&D process as it consumes over 70 percent of the entire R&D budget. This phase of the process is dominated by large-scale, multi-step clinical trials.

The process of pharmaceutical R&D is dynamic. In order to be successful, it requires continued investment by pharmaceutical companies. Their human and financial capacities, expertise, know-how and technological excellence guarantee the sustainability of this process and result with a constant flow of innovative medicines.

Manufacturers invest considerable sums in research and development of new products. The latter is estimated to amount to 15-20 percent of revenues. The R&D costs have increased substantially in recent decades; a 2003 study by the Tufts Center for the Study of Drug Development puts the cost of developing and marketing a new pharmaceutical product at approx. $ 900 million. [57]

3.1.1 Overview of pharmaceutical industry in EU

Europe is a strong base for Pharmaceutical companies to do business. Profits of the biggest multinational pharmaceutical manufacturers continue to grow and most of the big companies achieved double-digit growth rates in 2003 and with profit margins ranging from 11percent to 25 percent the research-based pharmaceutical sector is amongst the most profitable of all industries in spite of research spending. At the same time, pharmaceutical companies’ spending on sales and marketing in Europe is growing. Between 2002 and 2003, spending in Germany increased by 25 percent, in Spain by 26 percent and in Italy by 20 percent.

Table 3.1.1.1 The top-10 most profitable pharmaceutical companies in the world in 2002 of European origin.[58]

Company	Sales ($)	Operating profit ($)	Net income ($)	Marketing costs ($)	R&D costs ($)
Pfizer	45,2 bill		3,9 bill	15,2 bill	7,1 bill
J & J	41,9 bill	29,7 bill	7,2 bill	14,1 bill	4,7 bill
Bayer	€ 28,6 bill	€ -1,2 bill	€ -1,4 billl	€ 6,5 bill	€ 2,4 bill
GSK	35,2 bill	11,1 bill	7,8 bill	12,4 bill	4,5 bill
Novartis	24,9 bill	5,9 bill	5,0 bill	7,9 bill	3,8 bill
Roche	22,7 bill	4,6 bill	2,6 bill	6,9 bill	3,8 bill
Merck&Co	22,5 bill		6,8 bill	6,4 bill	3,2 bill

[57] Jacob Arfwedson “Parallel trade in pharmaceuticals”, July 2003
[58] 2003 annual reports of the companies

Aventis	22,1 bill	4,5 bill	2,4 bill	6,7 bill	3,6 bill
Bristol Myers	20,9 bill		3,1 bill	4,7 bill	2,3 bill
AstraZeneca	18,8 bill	4,1 bill	3,0 bill	6,9 bill	3,5 bill
Takeda	8,7 bill	2,6 bill	2,3 bill		
Sanofi	€ 8,0 bill	€ 3,1 bill	€ 2,1 bill	€ 2,5 bill	€ 1,3 bill

Europe's share of world pharmaceutical sales in 2003 also grew. According to IMS Health, this robust growth is expected to continue, despite pressure on prices and a number of blockbuster medicines going off-patent.

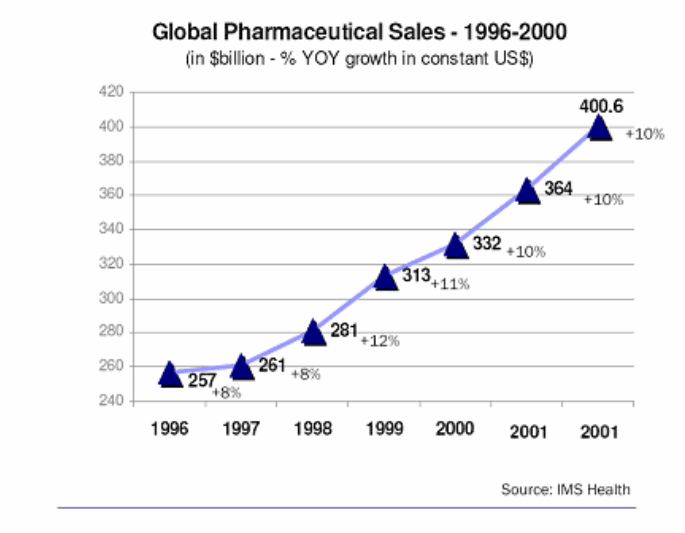

Table 3.1.1.2 Pharma Sales & Growth across Europe by value[59]

Country	Total market		Domestic brand	
	value bil euro	growth 2003-2004	value bil euro	growth 2003-2004
total	80.5	6.8%	63.1	5.5%
Germany	20.1	5.5%	12.8	4.4%
UK	12.1	10.0%	9.2	5.6%
France	16.8	6.2%	13.8	4.9%
Nederlands	3.0	4.5%	2.2	3.3%
Spain	8.0	9.7%	7.1	9.1%
Italy	11.6	4.5%	10.2	4.4%
Portugal	2.1	8.4%	1.8	5.7%
Belgium	2.5	7.4%	2.3	6.1%
Austria	1.6	5.7%	1.4	4.7%
Norway	1.0	4.1%	0.9	2.9%
Czech R	0.8	10.5%	0.7	11.7%
Ireland	0.9	17.5%	0.8	17.8%

[59] IMS health, www.imshealth.com

The majority of manufacturers spend more financial resources on marketing and sales than on R&D. In addition, more enlightened industry experts recognise that there are underlying economic trends behind the loss of competitiveness of some of European pharmaceutical manufacturers which are independent of parallel distribution.

Table 3.1.1.3 Spending on Marketing and R&D

Company	Marketing costs ($)	R&D costs ($)
Pfizer	15,2 bill	7,1 bill
J & J	14,1 bill	4,7 bill
Bayer	€ 6,5 bill	€ 2,4 bill
GSK	12,4 bill	4,5 bill
Novartis	7,9 bill	3,8 bill
Roche	6,9 bill	3,8 bill
Merck&Co	6,4 bill	3,2 bill
Aventis	6,7 bill	3,6 bill
Bristol Myers	4,7 bill	2,3 bill
AstraZeneca	6,9 bill	3,5 bill
Sanofi	€ 2,5 bill	€ 1,3 bill

In fact the percentage of revenue that manufacturers are investing in marketing and sales is growing despite their claims of decreasing profits and difficulties in finding cash for R&D investment. According to IMS Health promotional expenditure in 2003 amounted to:

Table 3.1.1.4 Promotional expenditure

Country	€ mill	Change to 2002 in %
Germany	1,914.93	+24.6%
Italy	1,041.71	+20.3%
France	890.57	+12.7%
Spain	515.78	+26.1%
UK	316.81	+15.3%

Apart from the UK, medical representatives accounted for more than 90 percent of these costs.

Moreover, according to a study by the National Institute of Health from February 2000, “Public researchers often tackle the riskiest and most costly research, which is basic research, making it easier for industry to profit.” The report discovered that only 14 percent of total R&D spending by the manufacturer went to basic research, while 38 percent was dedicated to applied research and 48 percent was spent on product development.

As you see pharmaceutical companies spend a west of money for developing and promoting new drugs, as a result these companies are very sensitive to competition.

3.2 COMPETITORS ON THE PHARMACEUTICAL MARKET

Generally, there are four competitors in the pharmaceutical market:

- Manufacturers: research-based pharmaceutical and vaccines companies, relying on patent protection to recoup their investments;
- Parallel trader: companies selling branded OTC (over the counter) medicines;
- Manufacturers of generic products (selling branded or unbranded versions of off-patent products);
- Companies selling copies of patented products, and in certain cases counterfeit products. Some companies break patent and other laws but some manufacturers of unlicensed copies of on-patent medicines, such as Ranbaxy, Cipla and Dr. Reddy's in India, operate legally because there is currently no patent protection for products in India.

But the most important competitors of the manufacturers are generics and parallel trader.

3.2.1 Generics

A generic medicine is a product using the name of the active ingredient (e.g. aspirin, which used to be a trademark).

Generic drugs are now an important aspect in all principal pharmaceutical markets and the growth rate in this industry is much higher than for branded pharmaceuticals. Further to this nine of the top ten fastest growing pharma companies are generic. In 2005 of over 10500 drug listed on the FDA's Orange Book over 7600 had generic counterparts. In addition to this, all healthcare systems are examining ways to reduce their respective drug bills and low priced generics are seen as an obvious solution. In 2004 the total world market for generic prescription drugs was $39.6bn with a growth rate of 12 percent from the previous year and this rate will increase to reach a peak of 14 percent in the period 2008-2010. It is estimated that over 39 major drugs will come off patent in this period leading to high generic growth as generic products enter these markets to replace these off-patented drugs.

The generics market is a low price high volume system. Generic companies have a low mark-up on their products but make profit through high volume sales. Unlike branded drugs whose main competitive factor is through drug efficacy and low side effects profile, the overwhelming principal competitive effect in the generics market is through price. This is not only the price difference between competing generic drugs but the price differential between the branded drugs and their generic equivalents. Generics flourish best in markets where branded drugs are very expensive such as in UK and Germany. In those countries where branded drugs are less expensive such as in Italy and Spain the generics market is very small. If the price difference between branded and generics drugs is small then there is little incentive to prescribe them. Table shows some of the average branded/generic price differentials in several leading European countries. As can

be seen from the table those countries that have the highest generic penetration by value have the largest branded/generic price differential.

Table 3.2.1.1 Branded and Generics price differentials in selected leading European countries, 2004[60]

Country	Average price difference between branded and generic drugs (%)	Generic market share (%) by value
UK	80	20,60
Netherlands	50	19,80
Germany	30	22,70
France	30	6,35
Italy	25	2,05
Spain	25	5,16

The major drivers in the generics markets are:

- Patent expirations
- Branded drug prices
- Cost containment by national governments

The most important growth factor for the generics market is the expiration of branded patents which obviously then allows for the marketing of a generic alternative. Following the expiration of a patent, the patent-holder can no longer prevent other manufacturers from producing and distributing copies of the patented drug. Drugs which are bioequivalent to formerly patented drugs are known as "generics". The competitive impact of generics can be quite substantial and prices, after their introduction, can fall by 30-50 percent.

The price differential is also an important driver in this market. If there is no significant price differential between branded and generic drugs then there will be no substantial generics market.

Cost containment policies by governments influence generics market growth. When governments focus on generics as a solution to control their respective drug bill the market for generics will grow. However, this is dependent on the means by which governments use to persuade doctors to prescribe generics and the price differential existing between generics and branded drugs.

Pharmaceutical companies try to impede or delay entry by generics manufacturers. Legislation to prevent this has therefore emerged. In the EU, it is based on the fact that under EU law generic manufacturers do not need to replicate the extensive clinical trials necessary to obtain the original marketing approval of a new drug. Instead they only need to show "bioequivalence" with the original branded "reference" product provided that the reference product "is marketed in the member state for which the application is made". Recognising this, some manufacturers have taken to removing the original product from the market shortly before patent expiration and replacing it with a "new and improved" version.

[60] www.imshealth.org, IMS Health, visiongain, 2005

AstraZeneca has been accused of using this strategy to protect Losec, its valuable ulcer drug.

3.2.2 Parallel traders

Recently big research-based pharmaceutical companies have stepped up their complaints to regulators that the competitive effect of parallel trade limits their ability to invest in research and development (R&D) because it reduces their profit relative to other markets where there is no parallel trade, namely America.

Parallel trade are now reaching a significant percentage of the market in some European countries (e.g. UK, Netherlands, Denmark), and although difficult to calculate exactly, it is now estimated to affect sales of about € 5 billion per annum (value at ex-factory prices) – which represents about 5% of the total European pharmaceutical market. Parallel trade could be costing the R & D based industry over € 1 billion, much of which could have been reinvested in research and innovation.

Examples reported by research-based pharmaceutical companies highlight a series of safety and quality problems arising from the handling of pharmaceutical products by parallel traders, in addition to logistic problems and regular product shortages in some countries where medicines simply do not find their way to patients in need. This raises not only serious safety issues in terms of patient consumption, but also acts as an obstacle in case of product recalls. At the extreme end of the spectrum, there is also the risk of unlawful counterfeit medicines reaching patients under the guise of parallel trade.

As well, as demonstrated by Dr Panos Kanavos of the London School of Economics and Political Science in a recent study[61], the vast majority of the benefits from cross-border trade in branded medicines go directly into the pockets of the third-party companies that buy and resell these medicines, with modest savings for payers and zero or marginal benefits for patients. Parallel trade thus does not provide benefits for patients or social security systems, but its lucrative profits accrue mostly to the traders themselves, depriving the research-based pharmaceutical industry from valuable resources to fund the research and development of new products.

Against an obvious background of commercial interests, pharmaceutical companies try to limit the market share of parallel distributed medicines, sometimes even by obstructing the free movement of goods within the internal market and breaking community law. Initiatives taken include:

- “supply quotas” - limitation on supplies in countries where prices are low;
- “price corridor” strategies - a product is launched in different countries with prices that are inside a narrow "price corridor" making potential parallel trade not workable; "price corridors" however limit profitability of pharmaceutical companies and therefore are implemented quite seldom;

[61] Kanavos, P., Costa-i-Font, J., Merkur, S., Gemmill, M., “The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis”, LSE, January 2004.

- “dual pricing” policies - pharmaceutical companies offer their products at one - lower - price for the local market and at higher price for "exports"; such measures - implemented for example in Spain - have been questioned by the European Commission as contrary to the Treaty;
- different pack sizes - by differentiating pack sizes (for example 28 tablets in one country and 30 tablets in another one) pharmaceutical companies make life for parallel importers harder;
- different brand names, different colours and shapes of tablets - are to suggest that the same products are not identical;
- direct distribution - in some countries new distribution techniques have been introduced - direct supply from the manufacturer to pharmacies; such attempts are however subject to high costs, difficulties in delivering products on time and are not welcomed by pharmacists;
- specific mechanism - a special derogation was included in the Accession Treaty restricting the parallel trade of pharmaceuticals between 8 CEEC's (Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia) and "old" EU-15; the provisions of this Mechanism provide for pharmaceutical manufacturers for objecting to parallel trade from - for example - Poland to Germany, and probably also - for example - from Hungary to Poland; in worst case scenario these objections can be sustained until 2019.

Pharmaceutical companies justify the introduction of these measures with public health concerns while spreading incorrect myths about parallel distribution.

As you see pharmaceutical companies have been adopting different strategies to prevent parallel trade.

But the major challenges to parallel trade involve dual pricing, stock allocation schemes (supply restriction) and repackaging. Under a dual pricing system, a pharmaceutical company typically requires wholesalers or exporters to pay a higher price for products which they seek to export than the price which they pay when reselling the same products for consumption on a domestic market. Stock allocation schemes allocate supplies on the basis of actual local demand and sales growth forecasts, thereby tailoring the amount of product supplied to that actually consumed on the local market. Both of these practices have been challenged before the courts recently, with both challenges involving GlaxoSmithKline (GSK). These types of restriction of parallel trade are described more thoroughly through European case-law

There exists a nice hypothetical example of dual pricing in the report of Panos Kanavos:

For instance, a pharmaceutical company “ABC” manufactures product “A”. It sells the product in two EU countries X & Y at different prices:

Price in country X = 100

Price in country Y = 120

Given, the cost of parallel importing one unit of A from X to Y = 5

In normal conditions, the market potential for product A is as follows:

Country X = 4000 units

Country Y = 2000 units

There might be three following scenarios:

- Scenario 1: Ideal market conditions for the company. No parallel trade. Company is able to sell to the potential in both the markets.
- Scenario 2: Assume, a parallel trader purchases 1000 units of A from country X (for 100), exports it to country Y (incurring a cost of 5 per unit), and sells in country Y at 115 per unit. This way the customer benefits due to lower cost of purchase (120-115 = 5) per unit and the parallel importer benefits by earning a profit (115-(100+5) = 10) per unit. The transporter gets a share of his revenues. In this case, the total loss of revenue suffered by the company is distributed among the customer, the parallel trader and the transporter
- Scenario 3: The company tries to avoid parallel trade by making price changes (Selling price in country Y reduced from 120 to 110). In this case, though the company suffers the same loss as in Scenario 2, the entire benefit is enjoyed by the customers (120-110 = 10) per unit as there is no incentive for parallel trade.

Following table illustrate above-sited scenarios.

Table 3.2.2.1 Description of scenarios

Scenario	Scenario 1	Scenario 2	Scenario 3
Units sold in market X	4000	5000	4000
Units sold in market Y	2000	1000	2000
Price per unit in X	100	100	100
Price per unit in Y	120	120	110
Total revenue for ABC	640000	620000	620000
Loss of revenue to ABC	20000		20000
Share of Benefit:			
Customer	5000		20000
Parallel Trader	10000		0
Transporter	5000		0

However, any steps taken by pharmaceutical companies to control parallel trade will be subject to EC competition law. The relevant legal provisions prohibit two types of conduct: anti-competitive agreements between two or more companies and unilateral action by firms which amounts to an abuse of a dominant position. These rules are found in Articles 81 and 82 of the EC Treaty and have as a principal goal the market integration of the European Union, notably the development of trade and strengthening of competition. This rule has been proved a lot of times by the European court of Justice.

4 RESTRAINING AND LIMITATION OF PARALLEL TRADE

As I mentioned before there are three major methods of restraining parallel trade: dual pricing, supply restriction and re-packaging.

4.1 SUPPLY RESTRICTION

One of methods of fighting the parallel trade is supply restriction. When manufacturers discover that a customer has resold a drug to a third-country buyer, they impose limitations on the drug amounts for sale. The amount is reduced to the level which only meets the demand of the customers from the primary market.

The most famous case regarding "supply restriction" is the case of Bayer[62]. In October 2000, the European Court of Justice delivered its judgment on the case where Bayer had imposed supply restrictions in order to prevent parallel trade. The ECJ established that these restrictions did not contravene European competition rules as long as these were not adopted pursuant to a concurrence of wills between the manufacturer and domestic suppliers and did not amount to an abuse of dominant position.

The case dates back to 1991 when Bayer was first accused of limiting supplies of its anti-hypertensive drug Adalat in France and Spain. As prices for Adalat were lower in the latter countries, demand trebled suddenly which resulted in considerable parallel trade from France and Spain to the UK. Bayer reacted by introducing a policy of supplies corresponding to previous levels, allowing for a 10% increase compared to this level. The European Commission responded by claiming this policy reflected a tacit agreement between Bayer and its wholesalers with the aim of restricting exports from Spain or France.

The European Commission first fined Bayer €3 million ($3.4 million) for infringement of EU competition rules. This was later overruled by the Court of First Instance, which dismissed the contention of an export ban as unfounded; no such evidence could be found, nor of any intention by wholesalers to adopt Bayer's anti-parallel trade policy. The CFI observed that re-imports continued on a smaller scale after Bayer introduced its policy, and established that a non-dominant company should enjoy the freedom to lay down its activities as it sees fit, "providing […] there is no concurrence of wills between him and his wholesalers", even if the aim is to prevent parallel importers.[63]

Also, the Court observed that the Commission's proposition of extending competition rules would lead to the paradoxical situation where a refusal to sell would be penalised more severely (based on Art. 81 of the EC Treaty on restrictive agreements) than with regards to Art. 82 (abuse of dominant position). A refusal to supply is prohibited under Art. 82 only if it constitutes an abuse. In conclusion, the Court remarks that:

> "nor, finally, can the Commission rely in support of its argument upon its conviction, which is, moreover, devoid of all foundation, that parallel imports will in the long term bring about the harmonization of the price of medicinal

[62] Judgment of the court of first instance of 26 October 2000, case T-41/96 (Bayer v Commission), 2000, ECR II-3383

[63] Judgment of the court of first instance of 26 October 2000, case T-41/96 (Bayer v Commission), 2000, ECR II-3383, paragraph 173

products. The same applies to its claim that it is not acceptable for parallel imports to be hindered so that pharmaceutical undertakings may impose excessive rates in countries not applying any price control in order to compensate for lower profits in Member States which intervene more on prices."[64]

However, the Commission has appealed and is supported by the German Association of Importers of Pharmaceuticals (BAI) and the European Association of Euro-Pharmaceutical Companies (EAEPC)[65]. The Commission argues that the Court has departed from earlier case law by adopting too strict an interpretation notably of the term "export ban". However in its 2004 decision the court has dismissed the appeal. It follows that the Court of First Instance did not make any error in law by holding the case-law relied upon by BAI and the Commission inapplicable to the present case and it means that in the absence of a dominant position, a pharmaceutical manufacturer may unilaterally implement certain measures to limit parallel trade without infringing EU antitrust law.

More recently, GlaxoSmithKline has been criticized for threatening to cut short its supplies to Greek wholesalers and retailers in the case C-53/03[66].

The case came before the European Court of Justice in early 2003 upon referral from the Greek Competition Authority. It concerned the distribution by GSK of its prescription drugs Imigran, Lamictal and Serevent in Greece. A large proportion of GSK's supplies to Greek wholesalers was re-exported to other EU countries, especially the United Kingdom, because of the much lower prices in Greece. Faced with the prospect of significant shortages on the Greek market, GSK stopped meeting orders from wholesalers and started supplying Greek hospitals and pharmacies directly. Three months later, considering that supplies had to some extent been normalised and that the stocks of hospitals and pharmacies had been rebuilt, it restarted supplies to wholesalers but only up to the level of their domestic needs plus 10 percent. The wholesalers complained to the Greek Competition Authority that GSK's refusal to meet their orders in full constituted an infringement of Greek Law and EU competition rules. The Greek Competition Authority delivered that case to the ECJ.

The ECJ ruled that it had no jurisdiction to decide on the questions referred because the Greek Competition Authority was not a court or tribunal that under EU procedural rules had the right to refer such questions to the ECJ. However, the Advocate General Jacobs left his opinion about this case. Jacobs concluded that given the characteristics of the pharmaceutical market a refusal to supply with a view to limiting parallel trade is unlikely to infringe article 82, either because it

[64] Judgment of the court of first instance of 26 October 2000, case T-41/96 (Bayer v Commission), 2000, ECR II-3383, paragraph 181

[65] Judgment of the court of 6 January 2004, joined cases C-2/01 and C-3/01 (BAI, Commission v Bayer and European Federation of Pharmaceutical Industries' Associations)

[66] Judgment of the court of 31 May 2005, case-53/03 Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others, Panellinios syllogos farmakapothikarion, Interfarm – A. Agelakos & Sia OE and Others, K.P. Marinopoulos Anonymos Etairia emporias kai dianomis farmakeftikon proïonton and Others, v GlaxoSmithKline plc)

does not amount to an abuse on a proper analysis or because the abuse is in any event objectively justified.

On the question of abuse, he reflected that "in the present case, […] the partitioning of the market is not the primary intent, but rather an inevitable consequence, given the characteristics of the market, of the attempt by GSK to protect what it sees as its legitimate commercial interests […]" In any event, Jacobs added, EC case law gives dominant undertakings the possibility of demonstrating an objective justification for their conduct, even if it is prima facie an abuse. Given the characteristics of the sector, the advocate general found that a refusal to supply by a dominant pharmaceutical company in order to limit parallel trade was capable of justification "as a reasonable and proportionate measure in defence of that undertaking's commercial interests".

More specifically, Jacobs considered a refusal to supply capable of justification where the price differential giving rise to parallel trade is the result of state intervention in the member state of export to fix the price there at a level lower than that which prevails elsewhere in the EU, taking into account:

- the pervasive and diverse state intervention in the pricing of pharmaceutical products;
- obligations upon pharmaceutical undertakings and wholesalers to ensure the availability of adequate stocks of products in any given country;
- the potentially negative consequences of parallel trade for competition, the common market, and incentives to innovate, given the characteristics of the pharmaceutical industry; and
- the fact that end consumers of pharmaceutical products may not in all cases benefit from parallel trade and that public authorities in the member states, as the main purchasers of such products, cannot be assumed to benefit from lower prices, given that they are themselves responsible for fixing prices within their territories.

Hence, as long as the above conditions are fulfilled on the facts, a refusal to supply should not infringe article 82.

Meanwhile, the Greek Competition Authority has issued its decision in Syfait. It sides with Jacobs on the issue of per se abuse, finding that to establish an abuse the various conflicting interests should be weighed, having regard also to the principle of proportionality. Moving on to the assessment of abuse in this particular case, the Authority concluded that article 82 has not been infringed by GSK's decision to no longer supply wholesalers and instead deal directly with hospitals and pharmacies. The Greek Competition Authority makes three important findings in this respect.

First, it considers that it would be wrong to apply article 82 to restrictions on trade between EU countries in circumstances where, due to the existing regulatory framework, prices are not freely set by the pharmaceutical companies. Restrictions on competition that are triggered by this regulatory framework should be tackled through legislative action rather than through antitrust enforcement. Second, on a

traditional assessment of refusals to supply, article 82 is not infringed because the wholesalers affected were neither put at a disadvantage nor eliminated from the market. Finally, GSK's conduct was objectively justified taking into account: (i) the reduced level of competition on the market due to state intervention on pricing; (ii) the fact that its supplies on the Greek market exceeded national consumption; (iii) the fact that parallel trade seriously affects GSK's profitability; (iv) the fact that consumers do not benefit from parallel trade; and (v) the general economic and regulatory framework within which pharmaceutical companies need to operate.

The Greek Competition Authority further decided that GSK's policy not to supply the full orders received from wholesalers, once it had resumed supplies to wholesalers, likewise did not infringe article 82 because it did not prevent the wholesalers from complying with their legal obligation to supply the domestic market at prevailing prescription levels plus 25 per cent in case of emergencies or changed circumstances.

4.2 DUAL PRICING

The main actor here is the GlaxoSmithKline. While Bayer was under investigation for supply restrictions, Glaxo Wellcome (now part of the merged GlaxoSmithKline) was also targeted by the European Commission for having signed an agreement with wholesalers in Spain. The dual pricing scheme involved on one hand the maximum price set by the Spanish government for products sold in Spain, and on the other a higher price in case the products were destined for export. Glaxo also notified the Commission about this arrangement and thus escaped the fines, which are otherwise imposed in case of breach of antitrust rules.

Nevertheless, the Commission decided that Glaxo's sales conditions did indeed amount to an export ban and that there was no increase in technical progress, nor any improvement in production or consumer benefits. Furthermore, the EC said there was no causality between parallel trade and reduced research and development efforts. The Commission banned the dual pricing scheme in May 2001 and maintains that Glaxo's policy contravenes EU competition rules. The company has appealed the Commission's decision to the Court of First Instance.

After a long time of waiting, on 27 September 2006, the Glaxo has received judgment of the European Court of First Instance (CFI).

The CFI partly annulled a 2001 decision of the European Commission finding that GSK's General Sales Conditions to its wholesalers in Spain infringed Article 81(1) EC (equivalent of Section 1 of the Sherman Act) and denying GSK an exemption under Article 81(3) EC. According to the CFI, the Commission erred in considering only the short-term, price-impact issues in its analysis in EC competition law while ruling out consideration of the issues raised by GSK as to the longer-term, anti-competitive impact on innovation of parallel traders' price arbitrage.

The CFI judgment is of particular interest to pharmaceutical companies as it examines the justification of steps they have taken to address the issue of parallel trade. Although the CFI considers that limitations on parallel trade may have

restrictive effects, even in industries like the pharmaceutical sector where manufacturers are often not free to determine the price of their own products, it also recognizes that such limitations may constitute efficiencies by preserving pharmaceutical companies' incentives to invest in R&D.

As such, the CFI judgment departs from the European Commission's customary approach that limitations on parallel trade should be considered as a quasi per se restriction of competition for which there exists no possible justifications. The judgment raises the standards of proof that the European Commission must respect in order to deny an Article 81(3) exemption to agreements between undertakings that may limit parallel trade in the pharmaceutical industry.

The case goes back to 1998, when GSK (then Glaxo Wellcome) notified its General Sales Condition for wholesalers in Spain to the European Commission. Under the General Sales Conditions, GSK's domestic sales to wholesalers were regulated by the prices imposed on products by the Spanish health authorities. However, GSK charged a higher price to wholesalers for products intended for export to other EU Member States.

The European Commission considered that GSK's General Sales Conditions infringed Article 81(1) EC and were ineligible for an Article 81(3) EC exemption because they introduced a 'dual' pricing 'system' that limited parallel trade between Spain and those EU countries where products were sold at prices higher than those in Spain, such as the United Kingdom. GSK appealed the European Commission's decision to the CFI.

The CFI did not accept the European Commission's conclusion that GSK's General Sales Conditions had the object of restricting competition. The CFI found, rather, that it cannot be automatically presumed that limitations of parallel trade in the pharmaceutical industry infringe Article 81(1) EC in the absence of an analysis of the effect of the agreement. The CFI pointed out that, in most EU countries, the pharmaceutical industry is shielded from the free play of supply and demand due to the existence of State-price regulations. In this context, it could not be inferred that parallel trade would automatically contribute to price reductions that would be passed on to end-users.

The CFI did, however, accept the European Commission's analysis that GSK's General Sales Conditions had some restrictive effects on intra-brand competition among wholesalers that could, in turn, deprive social security authorities and end-users from some cost and price reductions. In the CFI's view, GSK's General Sales Conditions limited the pressure that Spanish wholesalers could have exercised on the price of UK wholesalers/distributors. Even if this pressure was likely to remain 'marginal', the CFI concluded that the General Sales Conditions still contributed to the maintenance of some price rigidity, to the detriment of social security schemes and consumers' welfare.

Nevertheless, the CFI considered that the European Commission should have balanced this reduction of intra-brand price competition with the longer term 'efficiencies' that limitations of parallel trade may bring to inter-brand competition on innovation. In particular, the CFI found that GSK presented 'relevant, reliable

and credible' arguments that parallel trade had a negative impact on the company's incentives and ability to invest in R&D, which the Commission did not sufficiently take into account.

The CFI accepted GSK's arguments that the medicines sector is characterized by fierce competition on innovation and high fixed R&D costs, which pharmaceutical companies are required to fund themselves and are uncertain to wholly recover because of the different State-price regulated systems of the EU Member States. In this context, the CFI found that GSK had made a convincing case that parallel trade could lead to a loss of efficiency that would alter GSK's ability to recover R&D costs and discourage innovation. GSK had also convincingly argued that, in view of the fierce competition on innovation in the pharmaceutical industry, profit increases from limitations of parallel trade would likely be re-invested, at least in part, in R&D to the end-user's benefit.

The CFI therefore concluded that the European Commission had failed to 'seriously' examine GSK's arguments concerning investment in R&D and annulled that part of the European Commission's decision concluding that Article 81(3) EC was inapplicable in the present case. The CFI ordered the European Commission to reconsider GSK's request for an exemption under Article 81(3) EC. In light of the CFI's judgment, it will be interesting to see what conclusions the European Commission will draw in this respect.

The willingness of this key EU court to consider the broader macroeconomic impact as a core aspect of EC competition law will be welcomed by innovative pharmaceutical companies. This industry has been trying for some time, and with limited success, to communicate to authorities the adverse effect upon European competitiveness of permissive parallel trade policies, in a region where the prices drug companies can charge is often determined by governmental authorities. Coming, as it does, in the same month as the Commission's first European Pharmaceutical Forum on European innovation, the judgment supports the industry's view that the Commission's competition authority remit encompasses broad impact on innovation as well as narrow price arbitrage issues.

4.3 REPACKAGING

The trade mark owners had a lot of attempts to challenge both the parallel importers' rights to repackage their products, and the ability of the unauthorized importer to re-apply their trademark on the re-packaged goods.

However, according to EU law[67] parallel traders may and need to re-package the drugs. Before, that rule has been proved by series of rulings delivered by the European Court of Justice regarding repackaging of a product traded in parallel. The Court has clarified that the protection of a trade-mark right is not without limits, noting in particular that it may not contribute to the artificial portioning of the internal market. Therefore, the parallel importer may repackage a proprietary

[67] COM(2003) 839 final "Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted", Brussels, 30.12.2003

medicinal product and reaffix the trade-mark or indeed replace it with the trade-mark used in the market of destination, provided that repackaging does not adversely affect the original condition of the product or the reputation of the trade-mark and its owner and that there is a clear identification of importer and manufacturer on the box of re-imported drug. As well the parallel trader has to inform the trade mark owner that he intends to repackage the trade-marked product and to sell it in the Member state of importation.[68]

For instance, in a 1996 case - where drugs were being repackaged and imported into Denmark from Greece - the European Court was asked to decide whether the Danish parallel importer, Paranova, was entitled to apply the trademark of the pharmaceutical company concerned, Bristol-Myers Squibb, without its permission.

In the event, the Court decided that the free movement of goods principle overrode any trademark rights, provided the drugs themselves were not damaged.

In other words, the parallel importer was free to repackage the drugs so that they were fit for the Danish market. The effect of this decision, of course, is that the European Court has ignored the fact that the market is not level, and that the price of drugs is controlled nationally.

The European Court has, in fact, gone even further in eroding drug companies' rights in their trademarks, and has permitted the parallel importer not only to repackage the product but also to apply a different trademark to the one that was originally put on the drugs.

This matter was decided in 1997, in a case involving the pharmaceutical company Upjohn, which sold a drug under the trademark Dalacine in France, and under the name Dalacin in Denmark. When it discovered that a parallel importer was taking off the Dalacine mark, and replacing it with the Dalacin name when parallel importing the drug into Denmark, Upjohn objected.

However, the European Court concluded that such re-labeling was quite permissible if it was no more than 'necessary', and provided that the repackaging did not adversely affect the product and that prior notice was given to the proprietor of the trademark.

Nevertheless, the trade mark owners have not stopped their attempts to complicate repackaging by parallel traders. And in case C-348/04 (Boehringer Ingelheim and Others) the UK courts were asked to consider precisely this question.

At issue was the fact that the two importing companies Swingward Ltd and Dowelhurst Ltd were repackaging products manufactured by Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co. KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham plc, Beecham Group plc, SmithKline and French Laboratories Ltd and Eli Lilly and Co. (together ‘Boehringer Ingelheim and Others’), so that - in the case of Eli Lilly's product Prozac for instance - the blister packs were removed and re-boxed. Likewise,

[68] Joined Cases C-427/93, C-429/93 and C-436/93 Bristol-Myers Squibb [1996] ECR I-3457.

Glaxo's drug Serevent was being repackaged, and the information on it re-written in English.

The pharmaceutical companies argued that the parallel importers had exceeded their rights in applying their proprietary trademarks without their permission, because they had gone further than 'necessary' to re-box the products, and had not given the drug companies sufficient notice of their intention to repackage the products.

The UK judge, however, disagreed with the pharmaceutical companies' arguments, ruling that their view of the law conflicted with earlier judgments of the European Court. Nevertheless, he did decide to refer the issues to the European Court of Justice.

It is the second time the EU court has ruled on the drugmakers' eight-year-old challenge against parallel traders Swingward and Dowelhurst for re-boxing their drugs or putting new labels on the original boxes, a practice known as "overstickering". The tribunal said in 2002 that repackaging was necessary and permissible if it was essential for the parallel trader to access the U.K. market.

But the problem is that till today the subject of repackaging was unclear. And recent case is a corner-stone for repackaging.

"After 30 years of case-law on the repackaging of pharmaceutical products it should be possible to distil sufficient principles to enable national courts to apply the law to the constantly replayed litigation between manufacturers and parallel importers", the court's advocate general Eleanor Sharpston said in an opinion last April.[69]

This time, the Court interpreted article 7(2) of the First Council Directive 89/104/EEC more thoroughly.

According to ruling of the Court that article is to be interpreted as meaning that the trade mark owner may legitimately oppose further commercialization of a pharmaceutical product imported from another Member State in its original internal and external packaging with an additional external label applied by the importer, unless: it is established that reliance on trade mark rights by the proprietor would contribute to the artificial partitioning of the markets between Member States; it is shown that the new label cannot affect the original condition of the product inside the packaging; the packaging clearly states who overstickered the product and the name of the manufacturer; the presentation of the overstickered product is not such as to be liable to damage the reputation of the trade mark and of its proprietor; thus, the label must not be defective, of poor quality, or untidy; and the importer gives notice to the trade mark proprietor before the overstickered product is put on sale, and, on demand, supplies him with a specimen of that product.

The condition that the repackaging of the pharmaceutical product, either by reboxing the product and re-applying the trade mark or by applying a label to the

[69] Opinion of advocate general Sharpston delivered on 6 April 2006 for Case C-348/04 (Boehringer Ingelheim KG v. Swingward LTD and Dowelhurst Ltd), paragraph 3

packaging containing the product, be necessary for its further commercialisation in the importing Member State is directed solely at the fact of repackaging and not at the manner and style of the repackaging.

The condition that the presentation of the pharmaceutical product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor is not limited to cases where the repackaging is defective, of poor quality, or untidy.

It is for the national court to decide when and how parallel importer fails to make re-packaging etc.

In situations such as those in the main proceedings, it is for the parallel importers to prove the existence of the abovementioned conditions. As regards the condition that it must be shown that the repackaging cannot affect the original condition of the product inside the packaging, it is sufficient, however, that the parallel importer furnishes evidence that leads to the reasonable presumption that that condition has been fulfilled. This applies a fortiori also to the condition that the presentation of the repackaged product must not be such as to be liable to damage the reputation of the trade mark and of its proprietor. Where the importer furnishes such initial evidence that the latter condition has been fulfilled, it will then be for the proprietor of the trade mark, who is best placed to assess whether the repackaging is liable to damage his reputation and that of the trade mark, to prove that they have been damaged.

Where a parallel importer has failed to give prior notice to the trade mark proprietor concerning a repackaged pharmaceutical product, he infringes that proprietor's rights on the occasion of any subsequent importation of that product, so long as he has not given the proprietor such notice. It is for the national court to determine the amount of the financial remedies according to the circumstances of each case, in the light in particular of the extent of damage to the trade mark proprietor caused by the parallel importer's infringement and in accordance with the principle of proportionality.[70]

The most important is that the court placed the obligation on parallel traders to prove their packaging doesn't harm a drug maker's trademark by clearly stating who repackaged the product and ensuring the original condition of the medicine inside the box isn't affected. "The packaging must not be defective, of poor quality, or untidy", the court said. It left it up to national courts to decide, based on today's ruling, when a parallel trader has damaged a brand and the amount to penalize such a breach and ruled for more strict condition for notification.

By way of conclusion, the Bayer, Syfait, Glaxo dual-pricing and Boehringer cases have put green light for manufacturer by reducing the circumstances in which a restriction of parallel trade may amount to a breach of article 81 of the Treaty by: rejecting the European Commission's theory of per se infringement; pointing to the limited competition that derives from parallel trade, and laying down a high threshold for rejecting article 81(3) arguments. Moreover, its

[70] Judgment of the Court (Second Chamber) of 26 April 2007, case C-348/04 "Boehringer Ingelheim KG v Dowelhurst Ltd, and Swingward Ltd", the decision of the Court.

conclusions combined with the court's clear recognition of the specific circumstances of the pharmaceutical sector provide useful guidance also for the application of article 82 to parallel trade cases, much in line with Advocate General Jacobs' considerations in Syfait.

CONCLUSION

As followed from the given research there has been a hard battle between pharmaceutical manufacturers and parallel traders since the appearance of parallel trade. The parallel trade has been always a thorn for pharma-companies (drug companies argue that the parallel drug trade costs them about 5 billion euros a year and undermines their competitiveness.), so they used every opportunity to limit it. Pharmaceutical manufacturers have sought to restrict these parallel imports

through unilateral means and by agreement or concerted practice with their distributors. Such action is potentially in breach of EC competition law, either as a restrictive agreement (article 81 EC Treaty) in the case of concerted measures or as an abuse of a dominant position (article 82 EC Treaty) in the case of unilateral measures. Consequently, the European Commission has for many years sought to curb attempts by pharmaceutical companies to restrain parallel trade in their medicinal products. During that period, trade mark owners lost a lot of actions and money.

However, there have been several important EU antitrust developments in the pharmaceutical sector over the last year.

Finally, the Court of First Instance delivered its judgment in the long-awaited Glaxo dual-pricing case, providing further ammunition to pharmaceutical companies seeking to justify their parallel trade policy. Shortly before that, the Greek Competition Authority had issued its decision in Syfait, adding to the number of national decisions that have found a refusal to supply with a view to impeding parallel trade not to infringe EU competition rules. In particular from those cases follow that in the absence of a dominant position, a pharmaceutical manufacturer may unilaterally implement certain measures to limit parallel trade without infringing EU antitrust law and where there is an agreement, there may, in theory, be an infringement, however, in practice, both the CFI in Glaxo dual-pricing and Jacobs in Syfait suggest that the specific circumstances of the pharmaceutical industry may provide a basis upon which to justify these restrictions and hence avoid infringement of the EC competition rules. In other words the court recognized the specific circumstances of the pharmaceutical sector. Moreover, the court recognized that final consumers in the country of destination derive little benefit from parallel trade. Yet, to the extent that restricting parallel trade may prevent these limited benefits from being realized, and hence the welfare of final consumers diminished, such restrictions may nevertheless have the effect of restraining competition in breach of article 81(1) EC Treaty.

The Glaxo dual-pricing ruling and the decision by the Greek competition authorities may show that the tide is turning in the favor of the pharmaceutical industry in its long-running debate with parallel traders in Europe. This opens the door for pharmaceutical companies to claim that restrictions on parallel trade are justified. However, parallel traders say that it is bad news for government healthcare providers who could face higher medicine bills if competition provided by arbitrage trading is stamped out.

Anyway, those decisions may lead to changes in how drugs are sold in the 98.5 billion-euro ($125 billion) EU market.

As to the one more important case, regarding repackaging, this case as well provides new perspective for pharmaceutical industry. Pharmaceutical companies have been fighting for years against so-called parallel traders, which repackage and re-label their drugs from one EU nation and then import them to another. Till the Boehringer case, all types of parallel trade have been largely liberalized. But recent case makes it very clear what constitutes an infringement and may finally end the long debate between parallel importers and pharma-companies, as well now it is

clear where the responsibility of both sides lie. The court placed the onus on parallel traders to prove their packaging doesn't harm a drugmaker's trademark by clearly stating who repackaged the product and ensuring the original condition of the medicine inside the box isn't affected and it left it up to national courts to decide when a parallel trader has damaged a brand and the amount to penalize such a breach.

Therefore, according to recent rulings of |ECJ pharmaceutical manufacturers won't be able to prevent (lawfully) the traders from repackaging and reselling their products if all conditions coming from the recent Boehringer case are fulfilled, however they will be able to restrain parallel trade by methods provided in Glaxo dual-pricing case.

REFERENCES

Articles:

Bodoni Stephanie (April 26, 2007) "Glaxo, Lilly Get Parallel Trade Rules From EU Court (Update 2)", Bloomberg, www.bloomberg.com

Brett Hugh (2000) "Parallel imports in Europe", Thomson Scientific, www.thomsonscientific.com

Coumes Jean-Michel, Wright Elisabethann (2006) "The CFI's GSK Judgment", Brussels Legal/Law/Competition Law, www.brusselslegal.eu

Earl-Slater Alan (1997) "The pharmaceutical price regulation scheme", Financial Accountability Management, Vol. 13 N. 1

European Association of Euro-Pharmaceutical Companies (2007) "Parallel trade" www.eaepc.org

European Association of Euro-Pharmaceutical Companies (2007) "Safe medicines in parallel trade", www.eaepc.org

European Federation of Pharmaceutical Industries and Associations (2005) "Parallel trade of medicines", www.efpia.org

EurActiv: Health&Pharma (2006) "Parallel trade in medicines", www.euractive.com

FDA/Center for Drug Evaluation and Research (2004) "Generic Drugs: Questions and Answers", www.fda.gov

German Association of Research-Based Pharmaceutical Companies (2006) "The pharmaceutical market. Statistics 2006", www.vfa.de

Ganslandt Mattias, Maskus Keith (2004) "Parallel imports and pricing of pharmaceutical products: evidence from the European Union", Journal of Health Economics, Vol. 23, N. 5, pp 1035-1057

Haigh Janice (2004) "Parallel Trade in the EU", www.eyeforpharma.com

Humer Franz (2005) "Parallel tarde medicines are a clear symptom of the failure of Europe's pharmaceutical policy", European Pharmaceutical Executive, www.efpia.org

IMS (2007) "Parallel trade in Europe-Assessing the Reality of Payer and Patient Savings", IMS Insights, www.imshealth.com

IMS (2007) "Parallel trade: A Global Pharma Worry", IMS Insights, www.imshealth.com

IMS (2007) "What EU Expansion Means for the Pharmaceutical Industry", IMS Insights, www.imshealth.com

Jacob Arfwedson (December, 2004) "The high cost of cheap drugs", AEI-Brookings Joint Center, www.aei-brookings.org/policy/page.php?id=202#top

Kanavos Panos, Joan Costa-i-Font, Sherry Merkur, Marin Gemmill (2004) "The Economic Impact of Pharmaceuticals Parallel Trade in European Union Member States: A stakeholder Analysis", LSE Health and Social Care, pp 24-135 http://www.lse.ac.uk/Depts/lsehsc

Konijn Paul (2007) "Pharmaceutical products – comparative price levels in 33 European countries in 2005", Statistic in Focus: Economy and Finance, KS-SF-07-45-EN, http://ec.europa.eu/eurostat/

Kobelt Heinz, Kaufholz Christian (2006) "EU court not convinced by Glaxo's arguments", European Association of Euro-Pharmaceutical Companies, www.eaepc.org

Kobelt Heinz (2006) "Statement by the EAEPC on the commission appeal in Glaxo dual-pricing case", European Association of Euro-Pharmaceutical Companies, www.eaepc.org

Knox Daniel, Richardson Martin (2002) "Trade policy and parallel imports", European Journal of Political Economy, N. 19, pp 133-151

Li Changying, Robles Jack (2007) "Product innovation and parallel trade", International Journal of Industrial Organization, N 25, pp 417-429

Li Changying, Maskus Keith (2006) "The impact on investments in cost-reducing research and development", Journal of International Economics, N 68, pp 443-455

Macarthur Donald (2004) "The myths of parallel trade in medicines", Consumer policy review, Vol 14, N 1, pp 13-17

Macarthur Donald (2002) "Why do medicines have different prices across Europe?", Tribune, www.eaepc.org

McKay Anna (2005) "The End of Pharmaceutical Parallel Imports?-Syfait/GlaxoSmithKline", www.annamckay.com

Newman Matthew (September 27, 2006) "Glaxo Wins Review of EU Order on Spanish Drug Sales (Update 4)", Bloomberg, www.bloomberg.com

No author (2007), "Parallel Imports Europe FAQ (Frequently Asked Questions)", Parallel imports Europe, www.parallelimportseurope.com

No author (May 14, 2007) "Pfizer, EU parallel traders clash over bogus drugs", Reuters UK http://investing.reuters.co.uk

No author (September 1, 2007) "ECJ Judgment C-348/04 on parallel imports of medicinal products", Parallel imports Europe, www.parallelimportseurope.com

No author (April 20, 2007) "Parallel trade companies ask ECJ to confirm benefits of their activity", Business Portal for Poland, www.pharmapoland.com

No author (2006), "EU against double pricing", Business Portal for Poland, www.polishmarket.com

No author. Parallel trade. Poland "Parallel trade", www.handelrownolegly.pl

No author (May 12, 2007) "What conditions I need to respect on parallel imports in Europe? (part 1)", Parallel imports Europe, www.parallelimportseurope.com

Philipson A. guide to the concept and practical application of articles 28-30 EC, Commission of the European Communities, DG Enterprise, Brussels, January 2001

Raff Horst, Schmitt Nicolas (2007) "Why parallel trade may raise producers' profits", Journal of International Economics, N. 71, pp 434-447

Sandra Ma (2004) "EU pharmaceutical parallel trade-benefits to patients?", The London School of Economics and Political Science, www.lse.ac.uk

Sandra Ma (2003) "New LSE study contradicts accepted benefits of EU pharmaceutical parallel trade", The London School of Economics and Political Science, www.lse.ac.uk

Sinner Michele, Hirschler Ben (2006) "Glaxo wins partial victory in EU drug export case", The Boston Globe, www.boston.com

Szymanski Stefan, Tommaso Valetti (2005) "Parallel trade, price discrimination, investment and price caps", Economic Policy Vol. 20 N. 44, pp 705-745

Tommaso Valletti, Stefan Szymanski (2006) "Parallel trade, international exhaustion and intellectual property rights: a welfare analysis", Journal of Industrial Economics Vol. 54 N. 4, 499-526

Van Kerckhove Marleen (2007) "Recent EU antitrust developments in the pharmaceutical field: from parallel trade to generic entry", Global Competition Overview, www.globalcompetitionreview.com

Wilen Hakan (2007) “R&D in enterprises”, Statistics in focus: Science and Technology, KS-SF-_07-39-EN, http://ec.europa.eu/eurostat/

Wikipedia (2007) “Parallel import”, www.wikipedia.org

Wikipedia (2007) “Single market”, www.wikipedia.org

Reports

AstraZeneca PLC (2006) “Annual report 2006”, www.astrazeneca.com

Eurostat (2007)“Gross domestic expenditure on R&D by source of funds - industry”, http://epp.eurostat.ec.europa.eu

GlaxoSmithKline “Corporate Responsibility Report 2006”, pp 26-28, www.gsk.com

IMS(2007) “IMS Retail Drug Monitor – January 2007”, www.imshealth.com

IMS (2007) “IMS Retail Drug Monitor – February 2007”, www.imshealth.com

IMS (2002) “IMS Launches World Review for generic pharmaceutical industry”, www.imshealth.com

IMS (2007) “Parallel trade”, www.imshealth.com

MedTRACK (2005) “Industry statistics”, www.medtrack.net

Merck(2004) “Annual Report 2004”, p. 27, www.merck.com

Pfizer(2006) “2006 Annual review”, www.pfizer.com

The Association of the British Pharmaceutical industry (2005) “Facts&Statistics from the pharmaceutical industry”, www.abpi.org.uk

The EU Subcommitee of the Parallel Imports Committee (2005) “Parallel imports: Summary of EC law and its Application in the EU Member States”, International Trademark Association

Regulations

Council Regulation N 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, OJ No L 214 of 24/08/1993

Directives

Directive 89/104/EEC of 21 December 1988 "to approximate the laws of the Member States relating to trade marks, as amended by the Agreement on the European Economic Area of 2 May 1992

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"

Directive 75/318/EEC of 20 May 1975 "on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products"

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"

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"

COM

COM(2003) 839 final "Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted", Brussels, 30.12.2003

COM(98)588 final "Commission Communication on the Single Market in Pharmaceuticals", Brussels, 25th/11/1998

Cases

ECJ 27.09.2006, Case T-168/01 (GlaxoSmithKline Services V Commission), OJ C 275, 29.9.2001

ECJ 26.04.2007, Case C-348/04 (Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co. KG v Swingward Ltd, and Boehringer Ingelheim KG, Boehringer Ingelheim Pharma GmbH & Co. KG v Dowelhurst Ltd, and Glaxo Group Ltd v Swingward Ltd, and Glaxo Group Ltd, The Wellcome Foundation Ltd v Dowelhurst Ltd, and SmithKline Beecham plc, Beecham Group plc, SmithKline

& French Laboratories Ltd v Dowelhurst Ltd, and Eli Lilly and Co. v Dowelhurst Ltd)

Opinion of advocate general Sharpston delivered on 6 April 2006 for Case C-348/04 (Boehringer Ingelheim KG v. Swingward LTD and Dowelhurst Ltd)

ECJ 23.04.02, case C-143/00 (Boehringer Ingelheim KG, Boehringer Ingelheim Pharma KG, Glaxo Group Ltd, The Wellcome Foundation Ltd, SmithKline Beecham plc, Beecham Group plc, SmithKline & French Laboratories Ltd and Eli Lilly and Co. v Swingward Ltd and Dowelhurst Ltd)

ECJ 31.10.74, case C-105/74 (Centrafarm BV et Adriaan de Peijper v Sterling Drug Inc.)

ECJ 31.05.2005, case C-53/03 (Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others, Panellinios syllogos farmakapothikarion, Interfarm – A. Agelakos & Sia OE and Others, K.P. Marinopoulos Anonymos Etairia emporias kai dianomis farmakeftikon proïonton and Others, v GlaxoSmithKline plc)

ECJ 6.01.2004, joined cases C-2/01 and C-3/01 (BAI, Commission v Bayer and European Federation of Pharmaceutical Industries' Associations)

ECJ 26.11.2000, case T-41/96 (Bayer v Commission), 2000, ECR II-3383

ECJ 5.12.96, joined cases C-267/95 and C-268/95 (Merck & Co. Inc., Merck Sharp & Dohme Ltd and Merck Sharp & Dohme International Services BV v Primecrown Ltd, Ketan Himatlal Mehta, Bharat Himatlal Mehta and Necessity Supplies Ltd and Beecham Group plc v Europharm of Worthing Ltd.), paragraph 47

ECJ 20.05.1976, case C 104/75 (Adriaan de Peijper v Kantongerecht Rotterdam-Netherlands), operative part, paragraph 2 European court reports 1976, page 00613