

PHARMACEUTICALS INDUSTRY IN TURKEY IN THE LIGHT OF
EC COMPETITION LAW

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1. INTRODUCTION

Turkish pharmaceuticals industry is increasingly becoming dependent on imports. The domestic industry sees parallel trade as the key to increasing exports to the EU in order to cover the increasing imports. However, the parallel trade is not permitted for Turkish wholesalers by the Association Council Decision No 1/95. This study aims to examine whether the opening of parallel trade could really be a cure to the industry or whether there is another trend in the EU that the Turkish industry should follow as well.

Parallel trade in pharmaceuticals is a highly debatable issue in the EU. Parallel trade in general is encouraged by the Commission, mainly because it is thought to contribute to the achievement of the single market. However, concerning specifically the pharmaceutical market, there is an ongoing discussion between the pharmaceutical industry and the Commission on whether this industry has any special characteristics which makes it different from the other industries. The pharmaceutical industry defends that its parallel trade has the result of benefiting only the importer and harming the industry, consumers and the government health system. The Commission is emphasizing on the other hand that pharmaceutical products are not different than the other products when it comes to parallel trade. In this regard, the Commission kept on taking decisions finding infringements of Article 81(1) EC when manufacturing companies engage in agreements with their wholesalers prohibiting exports or restricting supply. In line with the Commission's established case-law regarding other products as well as pharmaceuticals, the concept of an agreement has been defined very broad, including even the wholesalers' tacit acquiescence with manufacturer's policy of preventing parallel imports in the absence of a written agreement. Although the Commission was accused by some scholars of using the rules on competition law excessively in order to achieve the integration of the single market, these decisions were upheld by the European Court of Justice up to the Bayer decision¹.

¹ 96/478/EC, Commission Decision of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty (Case IV/34.279/F3 - ADALAT), OJ L 201/1, 09.08.1996 (hereinafter: "Bayer decision").

The judgment of the Court of First Instance² in *Bayer*³ which is recently upheld by the European Court of Justice⁴ on 6 January 2004⁵ has been welcomed with enthusiasm among the European pharmaceutical industrialists. It is now believed that there is a way out for preventing parallel trade which the companies has long been accusing of being detrimental to the achievement of the industry's long-term objectives. The judgment does not overrule the previous case-law but instead draws the line between what can be considered as a unilateral policy adopted by a non-dominant firm and what can be considered as an agreement. As a result, it is from now on possible for non-dominant pharmaceutical firms to restrict supplies to their wholesalers with the obvious aim of impeding parallel trade as long as they do not impose an export ban either as a part of a written agreement, or by penalizing the wholesalers who continue exporting. The Commission's response to this new development is yet to come. However, while it is not expected to deviate from its well-established position against the companies that attempt to impede parallel trade, its vast powers in finding an agreement seems to be limited by the CFI and the ECJ.

The Commission might be expected to develop new ways of collecting evidence to prove that the quotas put by the manufacturer is determined on the basis of the destination of the products, rather than on objective criteria. However, it may be anticipated that the pharmaceutical companies will be extra careful not to give any signal to their wholesalers that the restriction of supply is actually governed by a system of sanctions. Furthermore, it will be very hard for the Commission to prove this, given that it is difficult to trace the destination of the products.

Health care is an area under the competence of the Member States. Although different price controls in different Member States cause distortions to competition, the Commission does not consider using Articles 95 and 96 EC to achieve harmonization. In the absence of harmonization of pricing, parallel trade will continue to exist and frustrate the manufacturers. In its communication on the single market in pharmaceuticals dated

² Hereinafter: "CFI".

³ Case T-41/96 *Bayer AG v Commission* [2000] ECR II-3383 (hereinafter: "*Bayer*").

⁴ Hereinafter: "ECJ".

⁵ Joined Cases C-2/01 and C-3/01 *Bundesverband der Arzneimittel-Importeure eV and Commission v Bayer AG* [2004] ECR I-23 (hereinafter: "*Commission v Bayer*").

25 November 1998⁶, the Commission already pointed out that the competition in the pharmaceuticals can be furthered also by trying to achieve relaxation of price controls rather than only continuing with the present situation of fighting against individual cases with the help of Article 81 EC. If the Commission would be able to rely on Article 81 EC to prevent companies from impeding parallel trade not as much as it used to do, it might choose to put more emphasis on this. The Commission has already developed another proposition by inviting the Member States to open the market for medicines neither purchased nor reimbursed by the state to full competition, in its Communication dated 1 July 2003, namely “Call for action: A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient”⁷. In this way, relaxation of government control on the prices may be another solution to achieving single market without referring to Article 81 EC excessively. The analysis on the use of Article 82 EC shows that it is much more limited for cases concerning pharmaceutical sector than the use of Article 81 EC, because of the specific economic conditions of this sector.

Since, the use of both Article 81 EC and Article 82 EC is limited in the Commission’s fight against manufacturers’ efforts to prevent parallel trade, the manufacturers will be able to restrict parallel trade without infringing the EC competition law. Therefore, the Turkish manufacturers would face the opposition of the European manufacturers in case the parallel trade is made available and they would like to take advantage of the parallel trade. Relaxation of government control on prices seems to be suggested also by the Commission and should be adopted by Turkish authorities in order to increase competitiveness of the industry without having to rely on parallel trade.

2. PHARMACEUTICALS INDUSTRY IN TURKEY

Pharmaceuticals industry in Turkey is one of the most important sectors in Turkey. On the demand side, the principal buyers of pharmaceutical products are the Social Security Institutions. The share of these institutions in the pharmaceutical market has been

⁶ Commission Communication on the Single Market in Pharmaceuticals COM(98)588 final (hereinafter: “1998 Communication”).

⁷ Commission Communication on a Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action COM(2003)383 final (hereinafter: “2003 Communication”).

increasing consistently in the past few years. Their share increased from 35% in 1996, to 47% in 2002⁸. Emekli Sandığı and Bağ-Kur has reimbursement systems, whereas Sosyal Sigortalar Kurumu (SSK) supplies pharmaceutical products to its members through the pharmacies it owns. The pharmacies belonging to SSK get the pharmaceutical products either from its own manufacturing facilities or through mass purchases from other companies⁹.

On the supply side, there are 134 companies active in this sector, of which 84 are manufacturers of pharmaceutical products, 12 are manufacturers of raw materials used in the industry and 38 are importers. Whereas there were only 10 companies with foreign capital in 1990, this number has increased to 36 by the year 2000. The increase in the number of foreign capital companies is due to the Customs Union established between Turkey and the EU in 1996. After the Customs Union the barriers to import pharmaceuticals have been removed from the market and more foreign companies chose to invest in Turkey. Furthermore, the foreign pharmaceutical companies, that were giving licenses to domestic producers, now became importers themselves or through an office in Turkey¹⁰.

The imports of Turkey have increased considerably after the Customs Union. The imports have increased 173 % between 1996 and 2000. In 2003, the increase in imports has become as much as 125 % compared to the year before. The imports constituted 28 % of the pharmaceutical products market in Turkey, in 2003. This increase in imports is not solely the result of the Customs Union. The advanced progress in the innovative pharmaceutical industry and the increased use of biotechnological products, which cannot be manufactured in Turkey, are the other factors lying under this development. Although the exports still cannot cover the imports, the exports of Turkey are also increasing. This has been particularly evident in 2003, in which the exports have increased by 114 %. The

⁸ Top, M. and Tarcan M., “Türkiye İlaç Ekonomisi ve İlaç Harcamaları: 1998-2003 Dönemi Değerlendirmesi”, 2004, p.8, available at <http://www.econturk.org/Turkiyeekonomisi/ilac.doc> .[accessed on 02.06.2005]

⁹ Ibid.

¹⁰ İstanbul Sanayi Odası, “Avrupa Birliği’ne Tam Üyelik Sürecinde İstanbul Sanayi Odası Meslek Komiteleri Sektör Stratejileri Geliştirme Projesi: Kimya Sektörü”, December 2004, p.2.

industry is aiming to increase exports and considers parallel trade as a way of increasing exports to the EU¹¹.

The price of the pharmaceuticals is controlled by the Ministry of Health in Turkey. The Except in very exceptional cases, the prices of pharmaceuticals manufactured in Turkey are much below the similar products manufactured in the EU¹². This price difference can be the principal motive for parallel trade. However, parallel trade is prohibited to the wholesalers in Turkey by the Association Council Decision No 1/95. Thus the representatives of the domestic industry defend that the opening of the EU pharmaceuticals market for parallel trade would be for their benefit.

3. CHARACTERISTICS OF THE PHARMACEUTICALS MARKET

Parallel trade is the result of price differences between different Member States of the European Union, therefore it is important first of all to examine the factors underlying the determination of prices in different Member States concerning pharmaceutical products.

Why is the pharmaceuticals market considered to be a special market in terms of pricing? In order to answer this question, main features of demand and supply in the pharmaceutical market should be highlighted.

3.1 Structure of the demand: government as the principal purchaser

The peculiarity of the demand for pharmaceuticals is the result of the roles different actors play in this market. Unlike other product markets, in pharmaceuticals market there are several “third parties” involved on the demand side besides the ultimate users of the products. These are third-party payers and prescribing physicians¹³. In most of the Member States the third party payer is the government through its public health system. The result is that, the government pays for the product that the patient is going to use but the physician prescribes to him and he can exercise no control in choosing due to lack of knowledge in this field. Therefore, the patient is not a “consumer” within the meaning of

¹¹ Ibid. p. 4.

¹² Devlet Planlama Teşkilatı “İlaç Sanayii Özel İhtisas Komisyonu Raporu” 2001, p.37.

¹³ See Kanavos P, “Overview of pharmaceutical pricing and reimbursement regulation in Europe”, 2001, p. 2, available at <http://pharmacos.eudra.org/F3/g10/docs/synthesis.pdf> [accessed on 02.06.2005].

the word in other product markets¹⁴. Its contribution to the determination of the product is very limited. The choice of which pharmaceutical products to use is made by the physicians. Studies show that the physicians that prescribe the products do not take into account economic factors as long as they will not be paying for the costs¹⁵. Often, it is neither the patient that is going to pay for the costs. Since the government makes most of the actual purchasing or reimbursement of the costs, it may choose and almost always chooses to exert monopsony power on the suppliers¹⁶. Therefore they exercise control over prices.

Another feature of the demand is that it is constantly on the rise as a result of ageing population, higher patient expectations, and better products as a result of technological advances. This means that the expenditure on health care is increasing even if the prices are not increasing. This expenditure is considered to grow at a faster rate than the economies are growing¹⁷. Thus, this creates an extra incentive for most of the Member States to come up with price control in this market.

One other very important aspect of this market on the demand side is that there is no price competition. The pharmaceutical companies work hard to differentiate their products from the others on the basis of high quality rather than lower price¹⁸. Since the pharmaceutical products are complex products with several therapeutic elements, it is always possible to stress on the product differentiation. The pharmaceutical companies are relatively free to charge very high prices for their products, without the demand for their products being affected too much. This is because the patients cannot decide on which product to buy, and the physicians, who are making the decisions are free of any economic concerns in prescribing medicines. Furthermore, most of the time, the patients are concerned about only the costs not reimbursed by the government. Therefore,

¹⁴ Ibid. p. 22.

¹⁵ Jacobzone, S., "Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals", 2000, p. 16, available at <http://pharmacos.eudra.org/F3/g10/docs/OECDpharma.PDF> [accessed on 02.06.2005].

¹⁶ Ibid. p. 9.

¹⁷ Supra note 13, p. 3.

¹⁸ Hancher, L., "The European Pharmaceutical Market: problems of partial harmonization", 1990, 15 ELR 9, p. 10-11.

governments intervene in the market to prevent companies from using this liberty to charge very high prices.

Government intervention may take the form of direct price control or indirect control through reimbursement, or co-payment schemes. Although in partial reimbursement and co-payment schemes, the patients are also required to contribute, it is still in the government's interest to keep these prices low since health policy necessitates maximizing patients' benefits and it is a highly political field as well. The Member States have different levels of per-capita income and this has changed even more dramatically with the enlargement. This affects priorities of the governments as well.

3.2 Significance of research and development for the industry

On the supply side what distinguishes this market among the other product markets is the significance of research and development for the competitiveness of the industry. The only way to be competitive in this global market is to invest in innovation. However this proves to be very costly considering that many attempts fail in the process of developing a new product. The result is "a market where the 'winners' have to pay for the 'losers'."¹⁹ The pharmaceutical companies have to reflect their costs in their prices and research and development costs make up for most of it. They have to finance their investment costs from their revenues. This has been accepted by the Commission in its Communication outlining an industrial policy for the pharmaceutical sector in the European Community dated 1994²⁰. It is stated in this report that 90% of the research and development spending is financed by the industry itself. Therefore, the success of the pharmaceutical companies depends on their ability to finance for their research and development activities with the revenue they get from the successful products on the market.

¹⁹ Kon, S. and Schaeffer, F., "Parallel Imports of Pharmaceutical Products: A New Realism, or Back to Basics", 1997, 3 ECL 123, p. 124.

²⁰ Communication on the outlines of an industrial policy for the pharmaceutical sector in the European Community COM(93)718 final.

According to a study made by Pammoli for the Commission²¹, the competitiveness of the European pharmaceutical industry is diminishing compared to its global rival, USA. This is in large part because the European industry invests less in research and development²². The Commission makes suggestions for increasing firms' research and development efforts in both its 1998 Communication and 2003 Communication. To increase the competitiveness of the industry is to the benefit of the consumer as long as the innovation should result in technologically improved products.

3.3 Dilemma of governments: cheap drugs or competitive industry?

In this framework, the Member States are faced with a dilemma. Opposed to the previously stated goal of making pharmaceutical products at the lowest cost possible for the patients and thus cutting the government expenditure, there is the challenge for the governments to support research and development efforts of the pharmaceutical companies. The dilemma is between two major public policy goals; health policy and industrial policy. To establish the difference in policy orientations of different Member States is important in order to understand why pricing of pharmaceuticals varies so much within the European Community.

According to Hancher, this dilemma is solved by Member States, depending on the degree of their home-based pharmaceutical industries' development. Those Member States with well established, functioning and export-oriented industries (for eg. Germany and UK) choose to impose less control on the market. On the other hand, the Member States that mostly import and do not have a strong pharmaceutical industry (for eg. Belgium, Spain, Portugal, Greece and partially Italy) tend to impose stricter control²³.

According to a study made by Kanavos²⁴, the different policy orientation of countries is mainly determined by the traditional involvement of the government in the economy. The Member States that are traditionally directly involved in other sectors of the economy

²¹ Pammoli, F., Gamberdella, A., Orsenigo, L., "Global Competitiveness in Pharmaceuticals A European Perspective", 2000, available at http://pharmacos.eudra.org/F3/g10/docs/comprep_nov2000.pdf [accessed on 02.06.2005].

²² Ibid. p. 5.

²³ Supra note 18, p. 11.

²⁴ Supra note 13, p. 9.

have extensive government interference in this market. Belgium and Spain are given as examples for these countries. The prices are determined after negotiating with the pharmaceutical companies in these countries. Kanavos also mentions ways of indirect control in its study and gives UK as an example for exercising price control indirectly, through controlling the rate of return on capital invested. The last way of imposing price control is given as reference pricing exercised by the third group of Member States including Greece, Ireland, the Netherlands, Portugal and partly Italy. Although this method of price control can be considered as supportive of convergence of prices, nevertheless, the prices continue to vary. Which countries are chosen for taking reference determines the maximum prices in these countries. While some of them take as reference the average of prices in the neighboring countries, some (like Greece and Portugal) take the lowest price countries as a reference.

Price regulation of medicines is approved by the ECJ in *Roussel*²⁵. In this case, the ECJ maintained that price-setting in the pharmaceutical market does not violate any provisions of the Community law as long as this does not give rise to discrimination against the imported products. As a result, the pharmaceuticals market is regulated in all Member States albeit with different considerations and priorities causing the prices to vary very much in the Community. This situation is unlikely to change in the future since in the 1998 Communication even the Commission agrees to the fact that achieving harmonization in pricing will be unlikely²⁶.

4. RECENT DEVELOPMENTS IN THE EC COMPETITION LAW: PARALLEL TRADE OF PHARMACEUTICALS AFTER THE *BAYER* JUDGMENT

4.1 Commission's position against prevention of parallel trade

In the 1998 Communication, parallel trade is defined as “an important driving force for market integration and, consequently, for achieving the Single Market”²⁷. In the words of Commissioner Monti, “[F]rom the early sixties the Commission has pursued a merciless policy against companies which – one way or the other - clipped the wings of parallel

²⁵ Case 181/82, *Roussel Laboratoria v. Netherlands*, [1983] ECR 3849, at paras 18-19.

²⁶ 1998 Communication, p. 11.

²⁷ 1998 Communication, p. 4.

traders”²⁸. The Commission took decisions to prevent also pharmaceutical companies from impeding parallel trade. However, it has been criticized by the pharmaceutical companies for not taking into consideration the peculiar characteristics of the industry, which in their view, cause benefits of parallel trade pronounced for other sectors not to apply in this sector. The latest decision of the Commission applying Article 81 EC to the pharmaceutical sector, *Glaxo*²⁹, illustrates the arguments of both of the parties to the discussion well, and is also significant because the industry brought before the Commission for the first time the arguments for justifying restrictions to parallel trade with economic and consumer welfare arguments³⁰.

Glaxo decision was taken after Glaxo Wellcome has notified to the Commission its new sales conditions for its Spanish wholesalers. The new conditions concerned having different prices for products that are going to be exported and the products that are going to stay in the Spanish market. Glaxo Wellcome was asking for negative clearance or an exemption for this dual-pricing system. However, the Commission agreed to give neither negative clearance nor an exemption, adhering to the idea that likewise other types of conditions with the object of restricting parallel trade, dual-pricing systems and export bans constitute “restrictions by object” and are forbidden without even the need to prove their anticompetitive effects.³¹

4.1.1 Application of competition rules to an already regulated area

There is an idea among the pharmaceutical industry and those who advocate prevention of parallel trade that it is not possible to apply regular rules of competition to a field that

²⁸ Speech by Commissioner Mario Monti European Commissioner for Competition Policy Competition and Consumer: the case of Pharmaceutical Products European Competition Day in Antwerpen, 11.10.2001, available at

<http://europa.eu.int/rapid/pressReleasesAction.do?reference=SPEECH/01/450&format=HTML&aged=0&language=EN&guiLanguage=en> [accessed on 02.06.2005].

²⁹ 2001/791/EC, Commission Decision of 8 May 2001 relating to a proceeding pursuant to Article 81 of the EC Treaty Cases: IV/36.957/F3 Glaxo Wellcome (notification), IV/36.997/F3 Aseprofar and Fedifar (complaint), IV/37.121/F3 Spain Pharma (complaint), IV/37.138/F3 BAI (complaint), IV/37.380/F3 EAEPIC (complaint) (notified under document number C (2001) 1202), OJ L 302/1, 17.11.2001 (hereinafter “*Glaxo*”).

³⁰ Kliemann, A., “Commission Decision prohibits Glaxo Wellcome’s Spanish pricing system”, 2001, available at http://europa.eu.int/comm/competition/publications/cpn/cpn2001_2.pdf [accessed on 02.06.2005].

³¹ *Glaxo*, at recital 125.

is so much regulated. Parallel trade will contribute to the convergence of prices and therefore market integration only if the market is open to perfect competition. In the present situation of intense market regulation where the prices are not determined by market conditions, it will not be possible for the manufacturer to adjust its prices in the low-price country, and the result will be forcing towards harmonization at the cheapest price³².

In line with this thought, an argument that the dual-pricing system should be established for compensating a distortion of competition caused by Spain was raised also by Glaxo Wellcome in asking for negative clearance. Glaxo Wellcome argued that since the prices are already fixed for the Spanish market, to open the way to charge different prices for exports from this market will only mean opening the market to competition³³. However, the Commission rejected this argument³⁴. First, the Commission reminded that in *Merck v Primecrown*³⁵ the ECJ has established that distortions of competition that are caused by a Member State should not be a reason to justify derogation from the principle of free movement of goods³⁶. In this respect, the Commission states that existence of price controls in Member States does not mean that they can give undertakings the right to prevent importation of goods that are lawfully marketed in another Member State. Therefore, if Member States' legislation cannot give this right to derogate from free movement of goods, an agreement which meets the conditions of Article 81(1) EC should not be permitted to impose restrictions on free movement of goods.³⁷ This is based on the fact that both Article 28 EC and Article 81 EC aim to achieve market integration. This illustrates clearly the Commission's attitude towards the interaction of principles of free movement of goods and competition rules in the struggle against parallel trade. An undertaking, once become a party to an agreement within the meaning of Article 81(1) EC, is subject to the same rules of free movement of goods as the Member States are.

³² Supra note 19; Vicién, C. F., "Why Parallel Imports of Pharmaceutical Products Should be Forbidden", 1996, 4 ECLR 219; Rey, P. and Venit, J., "Parallel trade and pharmaceuticals: a policy in search of itself", 2004, 29(2) ELR 153.

³³ *Glaxo*, at recitals 79-82.

³⁴ *Glaxo*, at recital 127.

³⁵ Joined Cases C-267/95 and C-268/95, *Merck & Co. Inc. v Primecrown Limited* [1996] ECR I-6285 (hereinafter: "*Merck v Primecrown*").

³⁶ *ibid.*, at para 47.

³⁷ *Glaxo*, at recital 129.

Secondly, the Commission drew a comparison with the other sectors and does not agree with Glaxo Wellcome in finding that pharmaceutical industry is peculiar in terms of government involvement. In the Commission's view, in other sectors such as the car sector, there is also government involvement (through tax levels) and although this creates differences in prices as well, it has never been accepted by the Commission as a reason for justifying restrictions on parallel trade. Furthermore the Commission even indicates an advantage pharmaceutical industry has over other sectors and this is their involvement in deciding on the price together with the government at the negotiation stage.³⁸

Therefore it can be concluded that the Commission does not support the view that distortions to competition should be corrected by undertakings.

4.1.2 The effect of parallel trade on companies' R&D efforts

A very common argument put forward by the pharmaceutical manufacturers and the advocates of prevention of parallel trade is that since companies depend almost entirely on their revenues for their R&D expenditure, the loss of revenue through parallel trade impedes their research and development efforts. In their article, Kon and Schaeffer give reference to a report prepared for DG IV by REMIT consultants³⁹ where parallel traders are described as entrepreneurs who do not have any R&D programmes or concern for industry's long-term future. In the authors' view, it is impossible for the pharmaceutical industry to go on with its R&D investments if the parallel trade continues⁴⁰. Rey and Venit support this argument and furthermore state that parallel imports have three negative effects on R&D⁴¹. Not only do they reduce the funds available for current projects and cause companies' incentives to invest in R&D to decrease, but also, they interfere with the policies of those governments that support innovation efforts against restraining government spending on health care. When the products are imported from

³⁸ *Glaxo*, at recital 132

³⁹ REMIT Consultants, "Impediments to Parallel Trade in Pharmaceuticals within the European Community", 1992.

⁴⁰ *Supra* note 19, p. 124-125.

⁴¹ Rey, P. and Venit, J., "Parallel trade and pharmaceuticals: a policy in search of itself", 2004, 29(2) ELR 153, p. 167.

low price countries to high price countries, the policy of supporting the industry is affected in the high price country.

Glaxo Wellcome attempted to use this argument to justify its dual-pricing system under an exemption provided by Article 81(3) EC. It claimed that parallel trade causes the firm's R&D efforts to decrease. This in turn results in less technical progress and diminished consumer benefit. However, this argument was rejected by the Commission, which stated that the causal link between a decrease in R&D expenditure and impact of parallel trade has not been established by Glaxo Wellcome. In the Commission's view, while it is true that parallel trade may decrease the revenues of a manufacturing company, this does not necessarily mean that the decrease in revenues will directly result in a decrease in R&D spending.⁴² As the proof of its argument, the Commission stated that in the last 20 years in which parallel trade has been a reality, the R&D expenditure has continued to grow enormously⁴³.

4.1.3 Who benefits from parallel trade?

Opponents of parallel trade in pharmaceuticals often cite the Commission stating "Unless parallel trade can operate dynamically on prices, it creates inefficiencies because most, but not all, of the financial benefit accrues to the parallel trader rather than to the health care system or patient."⁴⁴ Although the Commission goes on stating why parallel trade "must equally be seen" as promoting market integration⁴⁵, those who are against parallel trade argue that in pharmaceuticals it does not result in increasing consumer welfare as it does in other sectors where the prices are not regulated and furthermore, it doesn't cause a remarkable decrease in government spending.

When this argument was raised by Glaxo Wellcome, the Commission rejected it right away and stated that patients have direct benefits from parallel trade when partial reimbursement and co-payment exist in the health-care system.⁴⁶ Furthermore, the

⁴² *Glaxo*, at recital 155.

⁴³ *Glaxo*, at recital 158.

⁴⁴ 1998 Communication, p. 4.

⁴⁵ *Ibid.*

⁴⁶ *Glaxo*, at recital 184.

Commission extended the notion of consumer in terms of consumers in the pharmaceuticals sector and stated that parallel trade benefits wholesalers, pharmacies, national health budgets, and insurance schemes by contributing to cost-savings. According to the Commission, the countries that the parallel traders choose as destination even give incentives to parallel trade to achieve more cost-savings.⁴⁷

4.2 Use of Article 81 EC in Preventing Parallel Trade

In order to be able to fight against impediments to parallel trade caused by undertakings, the Commission needs to take decisions addressing undertakings. To guarantee the achievement of the single market in which the competition rules are respected it has to ensure that the undertakings are abiding by the rules. By the EC Treaty, the Commission is empowered to take decisions addressing undertakings using only either Article 81 EC or Article 82 EC. Until now the Commission has not taken any decisions applying Article 82 EC to the pharmaceutical sector. On the Commission's initiative, Article 81 EC was used against companies in two decisions.

The two decisions applying Article 81 EC to the pharmaceutical sector were Sandoz decision⁴⁸ in 1987 and Bayer decision in 1996. In both of these decisions, the companies were fined for entering into an agreement with their wholesalers about fixing an export ban. Both of the pharmaceutical companies challenged these decisions. The Commission's decision in Sandoz was upheld by the ECJ⁴⁹ while its decision was annulled in *Bayer* by the CFI and this judgment was upheld by the ECJ⁵⁰.

Sandoz concerned the parallel trade of the products of Sandoz from Italy to other Member States. The Italian subsidiary of Sandoz was fined for trying to impede this parallel trade through imposing an export ban. There was no explicit agreement between Sandoz and its customers. However, the fact that the invoices sent by Sandoz contained the words

⁴⁷ *Glaxo*, at recitals 185 and 186.

⁴⁸ 87/409/EEC, Commission Decision of 13 July 1987 relating to a proceeding under Article 85 of the EEC Treaty (IV/31.741 - Sandoz), OJ L 222/28, 10.08.1987.

⁴⁹ Case C-277/87 *Sandoz prodotto farmaceutici SpA v Commission* [1990] ECR I-45 (hereinafter: "*Sandoz*").

⁵⁰ *Supra* note 5.

“export prohibited” was enough to show that “continuous commercial relationship” was set up between Sandoz and its customers⁵¹. The Commission states that “[T]he fact that the invoices have been constantly and systematically used leads to the conclusion that Sandoz PF's clients implicitly agreed with it and accepted it.”⁵² The Commission was not able to establish the existence of a restriction of supply policy aimed at preventing parallel trade⁵³. However, the words on the invoices were accepted as sales conditions. Although Sandoz argued that this invoice was sent to the customer only after the deal has been made, and that the so called export ban was not a precondition of the purchasing, this argument was rejected by the Commission who stated that the systematic use of this condition made it a part of a continuous business relationship. The Commission found that even the tacit acquiescence of the distributors meant that an agreement existed. The ECJ has upheld the decision and agreed with the Commission in finding an agreement.

In the view of Jakobsen and Broberg⁵⁴ this was a very far-reaching judgment. The Commission and the ECJ have disregarded the fact that the clause was contrary to the interests of the distributors and in fact several of them have actually re-exported the product nevertheless. It is true that there was no evidence to show that the customers who would actually export the products were going to be penalized. It is worth emphasizing at this point that, later on, in *Bayer*, the CFI looked for a system of sanctions in order to prove that the interests of the wholesalers in continuing with the conditions of Bayer lied in fear of sanctions.

The main issue of *Bayer* concerned the restriction of supply exercised by the Spanish and French subsidiaries of Bayer on their wholesalers. The wholesalers were supplied with products as much as it was consumed in their geographical area. The Commission stated that Bayer infringed Article 81(1) EC by imposing an export ban as part of its commercial relations with its wholesalers⁵⁵. There was no explicit agreement between Bayer and its wholesalers. The Commission based its finding about the existence of an

⁵¹ Supra note 48, at para 25.

⁵² Supra note 48, at para 26.

⁵³ Supra note 48, at para 30.

⁵⁴ Jakobsen, P.S., and Broberg, M., “The Concept of Agreement in Article 81 EC: On the Manufacturers’ Right to Prevent Parallel Trade Within the European Community”, 2002, 3 ECLR 127.

⁵⁵ Bayer decision, at recitals 155-159.

agreement on two points. First, there was an export ban imposed by Bayer and second, the wholesalers showed tacit acquiescence to Bayer's policy of restricting supply and imposing an export ban. Bayer appealed the decision before the CFI.

What Bayer has accepted in the case before the CFI was that it had restricted supply to its wholesalers with the aim of restricting parallel trade⁵⁶. What it did not accept was that it exercised this policy in agreement with its wholesalers and that it imposed an export ban. Bayer claimed that it was placing quotas on the quantities ordered unilaterally. These quotas were determined on the basis of the wholesalers' orders in the previous year, allowing an increase of about 10% per year in accordance with the increase in consumption⁵⁷. Furthermore, it has emphasized that its sales personnel was strictly instructed to give to the wholesalers "stock shortages" as the reason for these quotas. Bayer made it clear that when the wholesalers became aware of the true reason behind this restriction; they pretended to comply with the new situation while at the same time they continued to look for alternative ways to circumvent the quota and in fact the parallel exports continued⁵⁸. Furthermore, in case the wholesalers chose to export the products allocated to them instead of supplying to the internal market, Bayer has assured that it was going to supply itself to those areas of the internal market where there was shortage of its products⁵⁹. Therefore, the wholesalers were left free even to stop their activities in their geographical areas in favour of exporting the goods in their quota.

The Commission found existence of an export ban in its decision by identifying first the existence of a monitoring system for detecting exporting wholesalers and second by showing that these exporting wholesalers were facing reductions in the amounts supplied to them by Bayer. Therefore, according to the Commission, the wholesalers were threatened to have a decrease in their supplies if they would continue exporting⁶⁰. However, the CFI found that the Commission has not proved that there was systematic

⁵⁶ *Bayer*, at para 34.

⁵⁷ *Bayer*, at para 35.

⁵⁸ *Bayer*, at para 30.

⁵⁹ *Bayer*, at para 141.

⁶⁰ Bayer decision, at recitals 160-170.

monitoring of the final destination of the products or that there were sanctions or threats applied by Bayer against the wholesalers⁶¹.

Not having accepted the Commission's argument that an export ban had existed, the CFI went on to show why the behaviour of the wholesalers cannot be regarded as implicit acquiescence. In this regard, unlike the ECJ in *Sandoz*, the CFI did not find that this restriction formed part of continuous commercial relations between Bayer and its wholesalers. The Commission's argument that the wholesalers even adjusted their conduct according to this ban was rejected by the CFI. The CFI maintained that far from being a proof of an agreement, the wholesalers' efforts to circumvent these quotas can only mean that there was no tacit acquiescence⁶². The CFI stated that when the de facto conduct of the wholesalers are contrary to the policy adopted by the manufacturer, the mere fact that the commercial relations continue does not mean that there is an agreement.⁶³ Therefore the CFI concluded that there was neither an agreement between the parties nor an export ban enforced by Bayer.

The Court of First Instance has decided that Commission was wrong in finding an agreement and annulled the Commission's decision. In its judgment, the primary focus of the Court was that the Commission has not supplied enough evidence in order to prove the existence of an agreement. Not surprisingly, the Commission has concentrated in showing the existence of an agreement in its appeal. The ECJ held that the CFI was right in examining whether compliance of its policy was required by Bayer as a condition for continuing the relations with its wholesalers⁶⁴. It further established that the CFI was correct in making a distinction between the declared intention and the genuine wishes of the wholesalers. According to the ECJ as well, the actual attitude of the wholesalers was more important in finding whether they showed tacit acquiescence⁶⁵. The ECJ makes it clear that "the mere fact that a measure adopted by a manufacturer, which has the object or effect of restricting competition, falls within the context of continuous business relations between the manufacturer and its wholesaler is not sufficient for a finding that

⁶¹ *Bayer*, at para 109.

⁶² *Bayer*, at para 155.

⁶³ *Bayer*, at para 173.

⁶⁴ *Commission v Bayer*, at para 103.

⁶⁵ *Commission v Bayer*, at para 124.

such an agreement exists.”⁶⁶ Therefore, the European Court of Justice upheld the judgment of the Court of First Instance.

4.2.1 Concept of “agreement” in case-law

In *Bayer* and its appeal, the CFI and the ECJ put down the line between what constitutes a unilateral policy and what can be assumed as an agreement within the meaning of Article 81 EC. This is important because the rules applying to undertakings in the EC Treaty require for either a dominant position of a single undertaking or an agreement between at least two undertakings. A unilateral policy adopted by a non-dominant firm cannot be subject to these rules even if the aim of this policy is explicitly restriction of competition. This is why the Commission is inclined to interpret the concept of agreement in a broad way and has regarded some seemingly unilateral practices as in fact constituting an agreement. Until *Bayer* judgment, this approach was upheld by the European Court of Justice. Examples of such agreements concerned export bans⁶⁷ and resale bans⁶⁸ as well as refusals to supply. When these decisions were appealed before the Court of Justice, the decisions were challenged by the companies who claimed that they were engaged in unilateral actions and not agreements. The Commission referred to examples of these judgments regarding refusal to supply in asking the CFI to uphold its *Bayer* decision. It is worth mentioning the CFI’s answer to this, since it shows how the present case should be distinguished from the established case-law.

The earliest case mentioned by the Commission is *BMW Belgium v Commission*.⁶⁹ This case is differentiated from *Bayer* by the fact that BMW Belgium made its intentions to prohibit exports of new BMW products from Belgium through the circulars it has sent to the BMW dealers. The existence of such circulars was evaluated within the framework of the pre-existing agreement with its dealers and it’s concluded that an agreement existed. There were no such circulars in *Bayer*.

⁶⁶ *Commission v Bayer*, at para 141.

⁶⁷ See for eg 88/172/EEC, Commission Decision of 18 December 1987 relating to a proceeding under Article 85 of the EEC Treaty (IV/31.503 - Konica), OJ L 78/34, 23.03.1988.

⁶⁸ See for eg 90/38/EEC, Commission Decision of 13 December 1989 relating to a proceeding under Article 85 of the EEC Treaty (IV/32.026 - Bayo-n-ox), OJ L 21/71, 26.01.1990.

⁶⁹ Cases 32/78 etc *BMW Belgium SA v Commission* [1979] ECR 2435.

Two cases mentioned by the Commission in *Bayer* considered selective distribution systems. The main distinction between them and *Bayer* was seen in this fact. In *AEG*⁷⁰ and *Ford*⁷¹ there were selective distribution systems. The Commission has found an agreement in both of them because the distributors were not admitted to the system if they did not accept, tacit or expressly, the policy of the supplier⁷². In *AEG*, AEG wanted to preserve high prices and exclude modern channels of distribution and had developed a policy accordingly. The distributors who accepted this policy were supplying products with high prices whereas the retail-outlets who were not accepting to have high prices were not accepted to the system. In *Ford*, the issue was Ford's refusal to supply right-hand drive cars to its distributors in Germany in order to avoid their exportation to UK.

What differentiated *Ford* from *AEG* is that the distributors had no advantage in complying with this policy. Although they were found to be part of an agreement because they accepted the condition, this was not an agreement in the usual sense in which both parties benefit. In Jakobsen and Broberg's view, the fact that Ford refused to supply should be considered as a breach of the agreement and thus a unilateral act of Ford.⁷³ However, the ECJ decided that refusal to supply was a part of the main distributor agreement. In fact this situation is almost always the case in agreements concerning prevention of parallel trade. Whereas the manufacturers have an interest in limiting parallel trade, their wholesalers or distributors in the exporting country would prefer to go on since it is increasing their sales. Then the question must be; if the distributor or wholesaler does not have an interest in applying the manufacturer's policy, then why should it agree to comply? The answer is given by Jakobsen and Broberg as the motivation by the fear of sanctions imposed by the manufacturer⁷⁴. Therefore, it is essential to prove that there is control and a system of sanctions imposed by the manufacturer, in order to conclude that the wholesaler entered into an agreement with the manufacturer.

⁷⁰ Case 107/82 *AEG-Telefunken v Commission* [1983] ECR 3151 (hereinafter: "*AEG*").

⁷¹ Joined Cases 25 and 26/84 *Ford - Werke AG and Ford of Europe Inc. v Commission* [1985] ECR 2725 (hereinafter: "*Ford*").

⁷² *AEG*, at para 38; *Ford*, at para 21.

⁷³ *Supra* note 54, p.130.

⁷⁴ *Supra* note 54, p. 134.

*Tipp-Ex*⁷⁵ was another case referred by the Commission which was distinguished from *Bayer* because of the sanctions involved. This case concerned an exclusive distribution agreement. The refusal to supply was demanded by the manufacturer from the wholesaler to be applied to those customers that re-sell the products to other Member States. Whereas the Commission made a parallel between this case and *Bayer*, the CFI has decided that the subsequent checks carried out by the manufacturer made a crucial difference in finding an agreement in this case. The distributor had to increase its prices only to its customer that was exporting the products, because the manufacturer adopted a penalty in case the distributor chose not to comply with its request. After establishing this, the CFI concluded that the refusal to supply was the result of an agreement.

Perhaps the case that resembled *Bayer* the most was *Sandoz*. They both concerned practices adopted by big pharmaceutical companies in order to prevent parallel imports of their medicinal products. In both cases the manufacturers chose to restrict supplies to their wholesalers. In both *Bayer* and *Sandoz*, there were no explicit agreements between the manufacturers and wholesalers regarding this refusal of supply and the Commission relied on the existence of an export ban inserted into a series of continuous commercial relations between the manufacturer and the wholesalers in order to find the existence of an agreement. However, according to the CFI, there were two crucial differences between the two cases and they corresponded exactly to what the Commission set out to prove in its decision. First difference was in proving the existence of an export ban, and the second one was in proving the tacit acquiescence of the wholesalers.

According to the CFI, in *Sandoz*, what made the crucial difference was the fact that the words “export prohibited” were printed on the invoices sent to the customers. As a result, the existence of an export ban was proved together with the tacit acquiescence of the wholesalers. The absence of such a manifestation in *Bayer*, either verbally or written, made it even more important for the Commission to prove the existence of an export ban through a system of monitoring and sanctions. However, as discussed before, its findings

⁷⁵ Case C-279/87 *Tipp-Ex GmbH v Commission* [1990] ECR I-261 (hereinafter *Tipp-Ex*).

in this respect were not enough for the ECJ to prove that Bayer conducted a system of control to ensure that its wholesalers abided by its policy of preventing exports.

In *Sandoz*, since the invoices were sent to wholesalers in each purchase regularly, it was found to be part of a continuous commercial relation. However, in *Bayer* there was no such relation. The Commission is criticized for maintaining that when parties maintain their commercial relations, the existence of an agreement is proven. According to the CFI, it is important to distinguish the de facto behaviour of the wholesalers after a new policy is adopted unilaterally by the manufacturer. If the wholesalers act contrary to the new policy even though on the appearance they seem to agree, this may not account for concurrence of wills⁷⁶.

4.2.2 Reflections on the Bayer judgment

The judgment was welcomed by the pharmaceutical industry⁷⁷. The industry was advocating for a long time the negative effects of parallel trade and disagreeing with the Commission's policy of furthering parallel trade. In a media briefing of the Association of British Pharmaceutical Industry, parallel trade is accused of costing 6 pounds for every pound the government health system saves and consequently complain that in the long term this may cause the British pharmaceutical industry to contribute less to trade balance and employment⁷⁸. President of the European Federation of Pharmaceutical Industries and Associations (EFPIA) states that parallel trade is undermining European pharmaceutical competitiveness and claims that it benefits neither the patients nor the social security systems. Furthermore, according to him, parallel trade causes not only the European pharmaceutical companies' ability to invest in R&D to decrease but also discourages global companies to invest in Europe⁷⁹.

⁷⁶ *Bayer*, at para 173.

⁷⁷ Press release of The European Federation of Pharmaceutical Industries and Associations (EFPIA) on 6 January 2004, available at http://www.efpia.org/3_press/20040106.htm [accessed on 02.06.2005].

⁷⁸ Association of British Pharmaceutical Industry, "Parallel Trade in Medicines", available at http://www.abpi.org.uk/press/media_briefings/pdfs/2001/PARALL_TRADE.PDF [accessed on 02.06.2005].

⁷⁹ Press release of The European Federation of Pharmaceutical Industries and Associations (EFPIA) on 10 February 2004, available at http://www.efpia.org/3_press/20040210.htm [accessed on 02.06.2005].

However, the industry was unable to prevent parallel trade because it was legal in Europe based on the principle of free movement of goods and the exhaustion principle of intellectual property rights. As explained above, the Commission regards parallel trade as an important element for market integration and is determined to fight with undertakings which try to impede parallel trade of their products. In this setting, the CFI's annulment of the Commission's Bayer decision is very important in three aspects. First, it established that pharmaceutical companies may take unilateral actions to prevent parallel trade as long as they do not have a dominant position and that parallel trade must not be protected in all cases. Second, by limiting the concept of agreement it showed a way which the pharmaceutical industry may use to restrict parallel trade of medicines without infringing competition rules. Third, it rejected the Commission's argument that parallel trade will bring about in the long term the harmonization of prices in the pharmaceuticals market.

First of all, the answer the CFI gives to the Commission's claim that parallel trade must be protected in all circumstances is worth mentioning. This argument was raised by the Commission based on the ECJ's judgment in *Merck v Primecrown*. As mentioned above, this case established that distortions of competition that are caused by Member States should not be a reason to justify a Member State's attempts to prevent parallel trade. However, in *Bayer*, the CFI rejects the Commission's attempt to widen the meaning of this statement and maintains that it does not mean that there is a general prohibition on preventing parallel exports applying also to undertakings⁸⁰. In this respect, the CFI is firm in distinguishing between the rules applying to undertakings and rules applying to Member States. In *Merck v Primecrown* the issue concerned law on the free movement of goods which applies to Member States. However in *Bayer*, the issue concerns Article 81 EC, which applies to undertakings. Whereas Article 81 EC is also aiming at achievement of a single market, it is clear from its wording that in order to apply this article, first there must be an agreement. Therefore, it is limited to agreements and does not apply to all restrictions of competition capable of affecting trade within the Community. Thus, in *Glaxo*, the Commission reformulated its perception of the principle put down by the ECJ in *Merck v Primecrown* and maintained that a parallel between principles on free

⁸⁰ *Bayer*, at para 178.

movement of goods and competition rules can be drawn based on *Merck v Primecrown* when and only if there is an agreement within the meaning of Article 81 EC⁸¹, which was certainly the case in *Glaxo*.

Therefore the CFI in *Bayer* has established that solely unilateral practices of undertakings are outside the application of competition rules. Furthermore, the CFI made a very important statement that the manufacturer's right to take measures, when he is faced with a situation which is damaging its interests, is limited only as far as Articles 81 and 82 EC apply⁸². In the CFI's own words, "provided that does so without abusing its dominant position and there is no concurrence of wills between him and his wholesalers, a manufacturer may adopt the supply policy which he considers necessary, even if, by the very nature of its aim, for example to hinder parallel imports, the implementation of that policy may entail restrictions on competition and affect trade between Member States."⁸³

The CFI accused the Commission of attempting "enlarging or straining the scope of the Section 1 (Rules applying to undertakings) of Chapter 1 of Title VI of the Treaty"⁸⁴. According to the CFI, it's not open to the Commission to remedy distortions to competition by different price legislations in different Member States by using Article 81 EC or Article 82 EC. It is maintained that differences in price controls in a Member State must be resolved by Community authorities.⁸⁵ Furthermore the Commission is criticized for extending the scope of Article 81(1) EC so much that refusal to sell would be penalized in situations where a non-dominant firm merely exercises a unilateral policy, whereas under Article 82 EC, a dominant firm would be penalized for refusal to supply only if this constitutes an abuse. The CFI reminds in this regard the case-law which establishes that even an undertaking with a dominant position may adopt a policy entailing restriction of supply.⁸⁶

⁸¹ *Glaxo*, at recital 129.

⁸² *Bayer*, at para 176.

⁸³ *Ibid.*

⁸⁴ *Bayer*, at para 179.

⁸⁵ *Ibid.*

⁸⁶ *Bayer*, at para 180.

After *Bayer*, it became clear for the pharmaceutical industry, that in principle, they have the right to prevent parallel imports. How important it may be for the integration of the single market, it is still not possible to prohibit unilateral actions of undertakings based on the competition rules of the EC Treaty and the rules on free movement of goods apply only to the Member States. According to Rey and Venit, with this judgment, the CFI, followed by the ECJ, has for the first time questioned the suitability of achieving single market using competition rules⁸⁷. They evaluate the CFI's answer as recognizing that a policy of encouraging parallel trade should be avoided since it will distort competition in pharmaceuticals. However, it would be too far to think that the CFI actually recognized parallel trade as causing distortion to competition. Whereas it is true that it has acknowledged the manufacturer's right to prevent parallel trade, it has reasoned this conclusion by the existence of a manufacturer's right to act to protect its own interests as long as he complied with Articles 81 and 82 EC⁸⁸. The CFI maintains that according to the established case-law of the ECJ, free enterprise is safeguarded when applying the competition rules of the Treaty.⁸⁹

The second important aspect of *Bayer* is that it limited to concept of agreement to open a way to the pharmaceutical companies to prevent parallel trade. If the non-dominant undertakings would like to prevent parallel trading of their products, they might do so by restricting the supplies to their wholesalers. As a result the manufacturers may restrict supply even with the obvious aim of preventing its exports but this prevention may not become in the form of any kind of an export ban imposed on the wholesalers. Therefore, in operating this policy, manufacturers need to be cautious in not giving information about this policy, either written or verbal, to their wholesalers and ensuring that they do not operate any form of control on the final destination of their products and sanction the wholesalers who actually export the products. Case-law, as it is once again maintained in *Bayer*, establishes that in order for concurrence of wills to be established it is enough to have either a written notice sent by the manufacturer to the wholesaler⁹⁰, or a system of

⁸⁷ Supra note 41, p. 174.

⁸⁸ *Bayer*, at para 176.

⁸⁹ *Bayer*, at para 180.

⁹⁰ See for eg *Sandoz*.

penalties to those wholesalers who export the products supplied⁹¹. According to Whish, the judgment is extremely important because if the Court had not annulled the Commission's decision, it would mean that consensus between the parties is no longer a requirement to find an infringement of Article 81(1) EC. This would give the Commission an enormous power to be able to prevent parallel trade⁹². After *Bayer*, it is definitely emphasized that if there is no consensus between the parties either because of common interests, fear of sanctions or even simply tacit acquiescence, an agreement cannot be found to exist.

Lastly, it is significant that the CFI rejected the Commission's argument that parallel imports will in the long term bring about harmonization of the prices of pharmaceuticals⁹³. CFI did not elaborate on this statement and contented with stating that it is "devoid of all foundation"⁹⁴. There are some arguments for explaining why the CFI adopted such a stance, which will be discussed below. However, what is so important about this is that the CFI refused the Commission's policy of achieving harmonization of prices through parallel trade instead of through Community measures. Harmonization of prices in health care is a very sensitive issue and requires Member States' consent if any step is to be taken. Although it is crucial to attain a single market which is going to increase the competitiveness of the pharmaceutical industry⁹⁵, it seems unlikely that the Member States are going to agree on it in the near future. Commission wanted to overcome this difficulty by using parallel trade instead, but this was rejected by the Court.

4.2.3 Possible factors underlying the Court's change of approach

In Rey and Venit's view, the CFI's approach in *Bayer* amounted to "an important constitutional objection to the Commission's use of its power under the competition rules to attempt to create a single market."⁹⁶ The CFI did not use the economical reasoning to come to this conclusion but according to Rey and Venit, it entailed an implicit

⁹¹ See for eg *Tipp-Ex*.

⁹² Whish R, "Competition Law", 2003, LexisNexis Butterworths, UK, p. 106.

⁹³ *Bayer*, at para 181.

⁹⁴ *Ibid*.

⁹⁵ 1998 Communication.

⁹⁶ *Supra* note 41, p. 174.

recognition by the Court of how parallel trade of pharmaceuticals can disturb the projected outcome of governments' policy choices. When the CFI rejected the Commission's argument that parallel trade will bring about harmonization in pricing of pharmaceuticals, Rey and Venit argues that, it implicitly based this on the consideration that this way of harmonization will in the long term have damaging effects on social welfare. Rey and Venit point out that contrary to what the CFI stated, the idea of achieving price harmonization through parallel trade has foundation in economic theory. However, economic theory also emphasizes the negative consequences this kind of harmonization will have on social welfare, such as transfer of revenues from R&D based manufacturers to traders, harm caused to policies of those governments that aimed to encourage R&D investment and development of less number of innovative medicines⁹⁷. According to them, the CFI opted for avoiding harmonization through parallel trade in order to prevent these negative consequences.

It is true that in its evaluation, the CFI has not explicitly touched upon the economic arguments which have long been advocated by the pharmaceutical industry. It has avoided differentiating this sector from the other sectors in which parallel trade is frequently seen. It is very much arguable if the CFI really took peculiar characteristics of the pharmaceutical sector into account in giving this judgment. However, it is also true that Bayer's principal argument was not this in asking for an annulment. Bayer based its arguments on the fact that an agreement did not exist between it and its wholesalers. The CFI was able to avoid answering this by finding a ground for annulment in Bayer's first plea.

Since the CFI does not get into economic grounds and the peculiar characteristics of the pharmaceutical industry in order to explain why it is not possible to attain harmonization of prices through parallel trade, it sets a general rule for avoiding the Commission to use competition rules to prevent parallel trade in all sectors. This will have effects not only in the pharmaceuticals sector but also in other sectors in which parallel trade is seen. After this judgment, it is expected that the companies in other sectors as well would be defending themselves by stating that they were implementing a unilateral policy when

⁹⁷ Supra note 41, p. 175.

they receive a Commission decision accusing them of engaging in an agreement with their wholesalers or distributors for preventing parallel trade. The CFI and the ECJ must be well aware that this judgment will be interpreted as a way out for preventing parallel trade for manufacturers in all sectors. Therefore, it can be concluded that the Court really intended to show where the Commission's powers end in fighting against parallel trade rather than to disguise a special decision for the pharmaceuticals sector under the seemingly constitutional argument.

Furthermore, it can be assumed that the CFI deliberately chose not to reason its decision with an economic one based on pharmaceuticals industry particularly, because this could have far-reaching consequences for the pharmaceutical industry. It is important that the CFI did not oppose the Commission's efforts to preserve parallel trade in pharmaceuticals in principle. However, it asked the Commission to do so within the limits of its powers given by the EC Treaty. If the CFI would have accepted the pharmaceutical industry's arguments that parallel trade is harmful for this industry particularly, it could have the consequence of legalizing the efforts of those pharmaceutical companies who wish to have the right to prevent parallel trade in any way – even a way that is infringing Article 81(1) EC or Article 82 EC. Instead, the CFI still left it open for the Commission to find infringements of Article 81(1) EC when pharmaceutical manufacturers impose an export ban on their wholesalers and their wholesalers do not oppose it, or to find infringement of Article 82 EC when a dominant pharmaceutical company attempts to prevent parallel trading of its products by abusing its dominant position.

4.3 How might the Commission change its policy after *Bayer*?

After *Bayer*, the Commission gave another decision applying Article 81 EC to the pharmaceutical industry in *Glaxo*. Because Glaxo Wellcome asked for an exemption under Article 81(3) EC, the Commission had to evaluate the peculiar characteristics of the pharmaceuticals industry in order to decide if they justify an exemption. The response of the Commission to this notification was given on 8 May 2001, that is to say after the Court of First Instance's *Bayer* judgment but before the European Court of Justice's answer to the Commission's appeal. The Commission has rejected Glaxo Wellcome's request for negative clearance or an exemption in the alternative. The Commission's

arguments in rejecting this request have been discussed above in detail. Looking at these arguments, it is clearly seen that the Commission has not given up its position against prevention of parallel trade in pharmaceuticals. It continues to deem parallel trade as an important tool for market integration, it does not believe that pharmaceuticals industry is in any way peculiar to justify a derogation from competition rules and it is determined to prohibit prevention of parallel trade when the existence of an agreement restricting parallel trade cannot be questioned. This approach is also found in one of the speeches of Commissioner Monti in which he emphasizes the importance of the fact that in *Bayer*, the Court has not questioned the application of Article 81(1) EC in case of “contractually agreed obstacles to parallel trade within the Community”⁹⁸. What was questioned in *Bayer* was only the existence of an agreement. The CFI agreed with the Commission on the need to apply Article 81(1) EC when there is an agreement aiming to impede parallel trade.

4.3.1 Finding of an infringement under Article 81(1) EC

In view of the fact that the Commission’s attitude towards parallel trade has not changed when the existence of an agreement cannot be questioned, it is worth discussing the possible situations in which the existence of an agreement will not be as obvious. Since the CFI found that the Commission has not come up with enough proof to show that a control mechanism was established by *Bayer*, the Commission might be expected to collect more evidence to prove the existence of such a mechanism for the next case it will have. However, it must be admitted that it will be very hard to trace the destination of the products and it will not be easy for the Commission to prove that the manufacturer is engaged in such a job. It might be expected that from now on, the pharmaceutical companies will be extra careful not to create a situation in which existence of an agreement can be claimed by the Commission. Therefore, they would be refraining from giving written or oral information to their wholesalers about their new policy. In addition they would refrain from establishing a control mechanism for the final destination of their products and deciding on how much each wholesaler will be supplied based on whether that wholesaler exports the product or not.

⁹⁸ Monti M, Speech on EC Antitrust Policy in the Pharmaceutical Sector, 26.03.2001, available at http://europa.eu.int/comm/competition/speeches/text/sp2001_013_en.pdf [accessed on 02.06.2005].

As a result, it became harder for the Commission to find an infringement of Article 81(1) EC and to stop companies from exercising a restriction of supply with the aim preventing parallel trade. This means that the Commission's vast powers in finding existence of an agreement are limited now and this might mean that the Commission will be referring to Article 81 EC less in the future in its fight against prevention of parallel trade.

4.3.2 Further European harmonization

The Commission advocates parallel trade in pharmaceuticals to achieve market integration and it aims to achieve market integration to make companies invest more on R&D in Europe as well as to improve consumer choices in pharmaceuticals at affordable costs. These two objectives may be conflicting, since whereas companies would be looking for assurance of higher revenues to invest in R&D, provision of medicines to all citizens would require having medicines at the lowest costs as possible. Therefore, just as Member States do, the Commission faces a difficult situation in which it needs to find the balance between these two contradictory objectives⁹⁹. The Commission has to consider also the characteristics of this sector in striving to achieve a single market.

The Commission has already acknowledged in the 1998 Communication that if the Commission leaves the current situation to develop, this would require it to exercise important monitoring activities in the market, such as applying the competition rules to companies trying to impede parallel trade¹⁰⁰. It is stated that this will not be enough to improve the global competitiveness of the European pharmaceutical industry. To fight against individual cases concerning infringement of Article 81(1) EC without taking any steps to change the circumstances creating a lucrative parallel trade business is not going to help the European pharmaceutical industry. Therefore, the Commission itself is not counting on using Article 81 EC excessively in order to achieve a single market in pharmaceuticals.

⁹⁹ 1998 Communication, p. 1-2.

¹⁰⁰ 1998 Communication, p.10.

In the alternative, as already suggested in *Bayer*, in order to achieve a single market, harmonization of prices in the medicinal products by the Community institutions may be a solution for correcting distortions caused by different price legislations in Member States¹⁰¹. According to Snell¹⁰² this does not seem possible for three reasons. First, the Commission believes this falls within the competence of the Member States entirely. Second, because health care is a politically sensitive area, reaching an agreement between Member States will be very difficult. Third, harmonization may be undesirable, since to have a uniform legislation may not be the best solution to find the best practice for all in a Community of countries with diverse needs and priorities. It is true that full harmonization seems unlikely. Although both Snell and Nazzini believe that contrary to what the Commission seems to advocate, it has competence under Article 95 and 96 EC to correct market distortions in this area¹⁰³, it seems highly unlikely that the Member States will agree on a common position.

In the 1998 Communication, the Commission suggests “staged introduction of normal market mechanisms”¹⁰⁴. This may entail different levels of harmonization in different segments of the market. In the “in-patent products” sector of the market in which there is the greatest price control, removal of price control totally is not suggested by the Commission. Rather than this, according to the Commission, relaxation of price control should be balanced against the benefits of having some control over prices. In this regard, also Nazzini points out that the Commission may encourage all Member States to adopt a system in which the prices of pharmaceutical products will be negotiated with the industry. In this way, the prices will be determined together with the industry in all of the Member States and there won’t be such high differences between prices of different Member States. Nazzini also indicates that this opportunity was mentioned briefly by the Commission in *Glaxo*¹⁰⁵.

¹⁰¹ *Bayer*, at para 179.

¹⁰² Snell, J., “Free Movement of Pharmaceutical Products: An Overdose of Cheap Drugs?”, 2003, 14 EBLR 507, p. 520.

¹⁰³ *Ibid* and Nazzini, R., “Parallel Trade in the Pharmaceutical Market”, 2003, 26(1) World Competition 53, p. 74.

¹⁰⁴ 1998 Communication, p.11.

¹⁰⁵ *Glaxo*, at recital 132.

4.3.3 Dual –pricing of pharmaceuticals

Another way to prevent differences between prices of different Member States may be dual-pricing of pharmaceuticals; opening the market to free competition when the goods are not purchased or reimbursed by the state. The Commission might be expected to encourage this method of imposing relaxation of price controls. This can be done either by the undertakings pursuing a dual-pricing policy or by Member States allowing for this as a general rule. However, Commission's decision in *Glaxo* clearly demonstrates that it is against dual-pricing done by manufacturers in agreement with their wholesalers. Commission's decision has been appealed by Glaxo Wellcome.¹⁰⁶ The answer of the Court in *Glaxo* will be important to see if its stance will diverge from the Commission's. It will also be important to find out if what is claimed by Rey and Venit is actually true and the Court will really – this time explicitly – accept that the economic conditions of the pharmaceutical industry necessitate a special exemption for this industry's efforts to prevent parallel trade. It seems like this case will be an opportunity for the CFI to clarify the factors underlying its *Bayer* judgment.

The CFI might force the Commission to provide exemption for dual-pricing systems if it accepts Glaxo Wellcome's arguments in the appeal brought by it. With the appeal, Glaxo Wellcome is arguing mainly that the new sales conditions do not constitute an infringement of Article 81(1) EC since they are counteracting the distortions to competition caused by Spain, and in the alternative is asking for an exemption under Article 81(3) EC. This point of view is also supported by Nazzini, who advocates that dual-pricing systems of companies should be given an exemption under Article 81(3) EC¹⁰⁷. According to him, to enable products to compete under free market conditions when they are marketed outside public health schemes creates consumer benefits enough to justify an exemption. The answer of the CFI will determine the future application of Article 81(3) EC. Clearly, the Commission is rejecting this argument. However, at the same time it is inviting Member States to make it possible for all the pharmaceutical

¹⁰⁶ Case T-168/01 *GlaxoWellcome plc v Commission* (judgment pending). As a further source see "Action brought on 23 July 2001 by Glaxo Wellcome plc against the Commission of the European Communities", OJ C275/17, 29.9.2001.

¹⁰⁷ Nazzini, R., "Parallel Trade in the Pharmaceutical Market", 2003, 26(1) *World Competition* 53, p.73.

companies to compete in a free market for products neither purchased nor reimbursed by the State. This is stated by the Commission in its 2003 Communication¹⁰⁸.

It seems that the Commission finds it unacceptable to apply Article 81(3) EC to the pharmaceutical sector, but agrees that dual-pricing system is a feasible solution to achieving a single market. The Commission might be assuming that to accept to give an exemption to an agreement restricting parallel trade in pharmaceuticals might have implications for other sectors as well. As mentioned by the Commission in *Glaxo*, pharmaceuticals is not the only sector in which the government exerts control over prices. In the other sectors as well, such as the car sector, there is also government influence on prices, for instance through tax levels. Manufacturers in the car sector might claim an exemption as well for dual-pricing of their products that are going to be exported, based on this decision. It is true that government's involvement in prices would not be the only reason behind this exemption and the dual-pricing will not explicitly mean different prices will be charged for products to be exported. However, in any case, this will mean that dual-pricing of companies with the implicit aim of preventing parallel trade can be justified.

Another complication that prevents the Commission from agreeing on an individual exemption for dual-pricing may be its possible future implications on the pharmaceutical industry. In case the Commission reasons its decision with the particular characteristics of the pharmaceutical industry, then it might cause the industry to rely on this declaration to ask for an exemption for other (perhaps more severe) restrictions on parallel trade. Taking these into consideration, this might be why the Commission preferred to come to a solution together with Member States instead. It is also worth noting that this communication was adopted by the Commission in response to the report prepared by the High Level Group on Innovation and the Provision of Medicines (called "G10 Medicines") set up by the Commission¹⁰⁹. This solution was proposed by this Group, to provide for "more patient choice at a more affordable cost"¹¹⁰, which is the same aim

¹⁰⁸ 2003 Communication, p. 15-16.

¹⁰⁹ Final report of the G10 Medicines Group, 7.05.2002, available at <http://pharmacos.eudra.org/F3/g10/docs/G10-Medicines.pdf> [accessed on 02.06.2005].

¹¹⁰ 2003 Communication, p. 15.

parallel trade has. Therefore, it is also true that the recent study prepared with the contribution of the industry and academicians came up with this solution to increase competitiveness of the European pharmaceutical industry, recognizing the Commission's considerations in pursuing a policy favouring parallel trade.

4.3.4 Use of Article 82 EC

After the European Court of Justice's judgment was delivered in *Commission v Bayer*, European Association of Euro-Pharmaceutical Companies (EAEPC) made a statement that it supported the Commission's attempts in going after restriction of supply practices¹¹¹. What was noteworthy about this statement was that it mentioned about more than 40 complaints about supply quota systems were made before the Commission and asked the Commission to handle them under Article 82 EC as well as Article 81 EC.

It is true that the Commission has never taken a decision on infringement of Article 82 EC in the pharmaceutical industry up to now. The only case brought so far before the ECJ about the use of Article 82 EC was the *Syfait*¹¹² case in which the Greek Competition Authority was asking for a preliminary ruling. In this case, the Greek pharmaceutical wholesalers are accusing Glaxosmithkline of infringing Article 82 EC Treaty by restricting supplies of its three proprietary medicinal products to the Greek wholesalers. Greek Competition Authority is asking the ECJ whether a dominant firm's refusal to supply in full the orders of the pharmaceutical wholesalers would amount to an abuse and how is it possible to assess when a conduct of a dominant pharmaceutical firm is abusive. Unfortunately the ECJ has concluded just very recently that the Greek Competition Authority did not have the characteristics of a national court and therefore did not accept the case as admissible. This caused disappointment in the industry, which was waiting for the answer with much interest to clarify the possibility of using Article 82 EC in order to prevent parallel trade of pharmaceuticals¹¹³. However, Advocate

¹¹¹ EAEPC Press Statement, 06.01.2004, available at http://www.eaepc.org/news_and_press/press_releases.php?n=3&start=5&id=31 [accessed on 02.06.2005].

¹¹² Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnaias (Syfait) and Others v Glaxosmithkline AVEE* [2005] (not yet reported) (hereinafter: "*Syfait*").

¹¹³ The decision of the ECJ not to answer the preliminary reference questions caused disappointment for both the wholesalers engaged in parallel trade and the innovative pharmaceutical manufacturers. See EAEPC Press Statement, 31.05.2005, available at

General Jacobs had delivered his opinion on 28 October 2004 and considering the case as admissible, has made very important contributions to the debate whether refusal to supply by a dominant firm in order to prevent parallel trade should be considered as abusive.

Article 82 EC prohibits undertakings that have a dominant position in the market from abusing their position. In order to evaluate whether Article 82 EC can be used by the Commission to pursue companies that intend to prevent parallel trading of their products, the individual elements of Article 82 EC should be examined; the relevant market, dominance and what constitutes an abuse. To begin with, identifying the relevant market is very important in order to determine the dominance. Unfortunately, in Advocate General Jacobs's opinion, the dominance of Glaxo in the relevant market has been taken as granted, and neither the definition of the relevant market nor the dominance has been elaborated by Jacobs. In this respect and since also the Commission has not yet adopted a decision based on Article 82 EC in the pharmaceutical sector, the only case law we have at hand is in the field of merger control. In merger control cases, the relevant market is determined by the Commission based on the products' therapeutic effects. However, according to the Commission's Notice on the Definition of the Relevant Market¹¹⁴, the main purpose of market definition is to identify the competitive constraints.¹¹⁵ Therefore, as Van Kerckhove states, merger cases and cases examining Article 82 EC do not pose similar competitive constraints to be able to define the market similarly¹¹⁶. Some other methods should be used in defining the market for cases examining undertakings under Article 82 EC.

According to the Notice, the first step in determining the relevant market is to establish the products that are substitutable with each other for the consumer, in terms of their price, characteristics and intended use¹¹⁷. According to a study undertaken by EFPIA, a

http://www.eapc.org/news_and_press/press_releases.php?n=3&id=246 and Press release of EFPIA on 31.05.2005, available at http://www.efpia.org/3_press/20050531.htm for further details [accessed on 02.06.2005].

¹¹⁴ Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, OJ [1997] C372/5 (hereinafter: "the Notice").

¹¹⁵ the Notice, at para 2.

¹¹⁶ Van Kerckhove, M., "Parallel Trade in Pharmaceutical Products Following the ECJ's Bayer Judgment: Can a Case Be Made Under Article 82 EC Treaty?", 2005, available at http://www.globalcompetitionreview.com/ear/eu_pharma.cfm [accessed on 02.06.2005].

¹¹⁷ the Notice, at para 36.

very important question regarding the pharmaceutical products is to take the wholesalers as the buyers or the national health authority¹¹⁸. As mentioned above, the peculiar characteristics of the pharmaceutical industry permits both of them to be treated as buyers. However, because these two buyers have very different priorities in buying the product, what they would consider as substitutes changes. The national health authorities and doctors would consider the therapeutic effects of the pharmaceutical product, whereas the wholesalers would take into account the profitability margin – the price difference between the two products in deciding on the substitutes. According to national health authorities, the market definition becomes similar to the market definition the Commission uses for merger cases. If this product market definition is accepted, the geographical market should then be taken as the national market of each Member State, since the national health authorities' reimbursement systems and pricing differ in each Member State¹¹⁹. In contrast to national health authorities, the wholesalers would define the market as all the pharmaceutical products capable of profitable parallel trade. This view is advocated by Jenny in his paper presented before the Hellenic Competition Authorities¹²⁰. According to Jenny, all pharmaceutical products, for which there exist price differences in different Member States big enough to cover the costs of parallel trade constitute the relevant market. This would make the geographical market all the importing countries in which the wholesaler is able to conduct parallel trade.

In defining the relevant market for cases in the pharmaceutical sector, another difficulty arises in using the SSNIP test method, which is also included in the Notice. This test aims to assess the buyer's reaction to the price increase in the product and whether or not the supplier would find it profitable to increase the price between 5 and 10 % above the good's price. It assumes both that the supplier would be able to increase the price as much as it wants and that the buyer would decide on its own which product to buy. Since, both of these assumptions are not correct in the pharmaceutical sector, to use the SSNIP

¹¹⁸ EFPIA, "Article 82 EC: Can It Be Applied to Control Sales By Pharmaceutical Manufacturers to Wholesalers?", November 2004, available at http://www.efpia.org/6_publ/Article82ECNov04.pdf (hereinafter: "EFPIA's study") [accessed on 02.06.2005].

¹¹⁹ Ibid.

¹²⁰ Jenny, F., "Pharmaceuticals Competition and Free Movement of Goods", paper presented to the Hellenic Competition Authorities EU competition law and policy conference, 19.04.2002, p.6.

test is not possible. Therefore, as also it is pointed out in the EFPIA's study, in identifying the relevant market, SSNIP test cannot be used as a "reliable method"¹²¹.

After identifying the relevant market, dominance of the undertakings should be examined. In EU case law, the definition of dominance is "a position of economic strength enjoyed by an undertaking which enables it to hinder the maintenance of effective competition on the relevant market by allowing it to behave to an appreciable extent independently of its competitors and customers and ultimately of consumers"¹²². In the pharmaceutical sector, dominance should be assessed in two relevant markets that were identified before. Therefore, first, dominance in the relevant market identified according to the products' therapeutic effects will be examined and secondly the dominance in the relevant market proposed by Jenny will be elaborated.

Although the market share constitutes the starting point of analysis, other factors are more determinative. A relatively high market share does not necessarily have to mean that the undertaking would be able to act independently. In the first relevant market, since the price is controlled in this highly regulated sector, the manufacturers are not in a position to decide independently on their prices and profit margins. Therefore, as also stated in the EFPIA's study, the dominance cannot be assessed by the ability of the undertakings to increase prices independent of their competitors¹²³. This view is shared by Van Kerckhove, who concludes that it would be "difficult" to establish dominance of an undertaking if the relevant market is defined as such¹²⁴.

In the second relevant market, it must be examined whether the manufacturing pharmaceutical firms are able to act independently and restrict the competition. The constraint on determining the price is relevant also for this definition of the market. Furthermore, EFPIA's study shows that the manufacturers of pharmaceuticals were not able to prevent activities of parallel traders by taking restrictive actions. EFPIA's study refers to a research conducted by the Commission, which establishes that the business of

¹²¹ EFPIA's study, p. 5.

¹²² *Case 27/76 United Brands v Commission* [1978] ECR I-207.

¹²³ EFPIA's study, p. 7.

¹²⁴ *Supra* note 116.

the wholesalers was not affected by the unilateral supply quotas of the manufacturing undertakings¹²⁵.

After these findings, both Van Kerckhove and EFPIA's study conclude that the in whatever relevant market definition is chosen, the dominance of the undertakings cannot be established, since the undertakings are not in a position to act independent of competitive constraints. Glynn does not share this view and after establishing that in general in the pharmaceutical sector, the purchasing power of the customer is strong, there is high degree of regulation and price control and there are high barriers to entry and exit, deduces that in this situation both the supplier and the buyer have dominant positions¹²⁶. Glynn points out that Article 82 EC can be successfully used against the abusive behaviours of the undertakings.

If Glynn's view is accepted and it is established that dominance of the pharmaceutical companies can be maintained in the relevant market, the next issue to be considered in examining the case under Article 82 EC is the existence of abuse. What is prohibited by Article 82 EC is not the dominance but the abuse of dominance by the dominant undertaking. In *Bayer* judgment, the CFI has concluded that "The case law of the Court of Justice indirectly recognises the importance of safeguarding free enterprise when applying the competition rules of the Treaty where it expressly acknowledges that even an undertaking in a dominant position may, in certain cases, refuse to sell or change its supply or delivery policy without falling under the prohibition laid down in Article 82."¹²⁷

Advocate General Jacobs has agreed with the CFI's statement in his opinion and affirmed that "a dominant pharmaceutical undertaking which restricts the supply of its products does not necessarily abuse its dominant position within the meaning of Article 82 EC merely because of its intention thereby to limit parallel trade". After examining the case law, Jacobs has made three conclusions. First, the dominant firm has an obligation to

¹²⁵ EFPIA's study, p. 7.

¹²⁶ Glynn, D., "Article 82 and Price Discrimination in Patented Pharmaceuticals: the Economics", 2005, 3 ECLR 136.

¹²⁷ *Bayer*, at para 180.

supply its products or services in order not to harm competition in very exceptional cases¹²⁸. Secondly, the dominant firm is not obliged to meet in full the orders which are out of the ordinary to defend its commercial interests¹²⁹. Thirdly, what determines whether a dominant firm has the obligation to supply or does not have to supply is the specific economic and regulatory context of the case¹³⁰.

Jacobs goes on to clarify the criteria to be used in order to understand when a conduct can be considered abusive. In this analysis, Jacobs takes into account the specific characteristics of the pharmaceutical sector; such as the regulation of price and distribution, the impact of parallel trade on the innovative pharmaceutical industry and the consequences of parallel trade for consumers and purchasers in the importing Member State. Jacobs concludes that a restriction of supply by a dominant firm in order to prevent parallel trade is objectively justifiable, reasonable and proportionate to defend the undertaking's commercial interests. However, he makes it clear that this conclusion is strictly related only to the pharmaceutical industry in its present condition and the characteristics of the specific case¹³¹. Furthermore, Jacobs emphasizes that if the refusal to supply by a dominant pharmaceutical firm results in any other negative consequences for competition other than restriction of parallel trade, the Court may find an abuse¹³².

Jacobs has made a significant contribution to the arguments of the innovative pharmaceutical industrialists, by considering the economic arguments they were also defending against parallel trade as decisive in finding out whether a dominant pharmaceutical firm's refusal to supply is abusive or not. It might be assumed that the Commission would take this Opinion into account although the ECJ has answered the questions neither in line with the Advocate General's Opinion nor against it. Given the previously examined difficulties in establishing the relevant market and dominance in the pharmaceutical sector, the Commission might be expected not to refer excessively to Article 82 EC instead of Article 81(1) EC.

¹²⁸ Opinion of Advocate General Jacobs, Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnaias (Syfait) and Others v Glaxosmithkline AEEVE* delivered on 28 October 2004, (hereinafter "Syfait Opinion"), at para 66.

¹²⁹ *Syfait* Opinion, at para 67.

¹³⁰ *Syfait* Opinion, at para 68.

¹³¹ *Syfait* Opinion, at para 101.

¹³² *Syfait* Opinion, at para 104.

In one of his speeches, Commissioner Monti touches upon the increasing possibility of using Article 82 EC in the pharmaceutical industry in the future¹³³. However, he mentions only the use of intellectual rights of companies to create entry barriers as the abusive practice under examination of the Commission. Furthermore, Commissioner Monti considers the misuse of intellectual property rights as “the most thorny” topic of the competition related topics of pharmaceutical industry. Therefore, it seems that the Commission is preoccupied with this aspect of abuse of dominance rather than prevention of parallel trade. Moreover the Commission cannot consider Article 82 EC as an alternative to Article 81 EC in order to prevent impediments to parallel trade.

5. IMPLICATIONS OF THE RECENT DEVELOPMENTS ON THE PHARMACEUTICAL INDUSTRY IN TURKEY

Since the analysis of the role of Articles 81 and 82 EC in preventing manufacturing pharmaceutical firms from restricting parallel trade will be very much limited in the future, the opening of the Turkish market to parallel trade of pharmaceuticals would not result in increase of exports. The multinational manufacturers would be free to take strictly unilateral actions to prevent this parallel trade, or the dominant manufacturers would be able to impose restrictions of supply in order to protect their commercial interests.

It is understood that Turkish pharmaceuticals sector needs to take further radical measures in order to increase its competitiveness. The foremost impediment against the sector’s competitiveness is the strict price control that the government exercises. Price control is an issue for many of the EU Member States as well; however, the trend is towards liberalisation of the prices. Some Member States such as Denmark, the Netherlands, Germany, UK and Finland have already chosen to have relatively liberal prices. Other countries such as Spain and Italy have no price control on pharmaceuticals sold without prescription¹³⁴. This trend of exerting no price control on pharmaceuticals that are not prescribed and to be reimbursed is also supported by the Commission.

¹³³ Supra note 98.

¹³⁴ Supra note 12, p.41.

6. CONCLUSION

Single European Act entered into force on 1 July 1987. It laid down a rather ambitious plan for the final achievement of a single market. The first decision applying Article 81(1) EC to the pharmaceutical sector was taken on 13 July 1987¹³⁵. Therefore, it coincides with the times the Community's focus was on market integration. This decision was aiming to eliminate the obstacles to parallel trade in pharmaceuticals using infringement of Article 81(1) EC and its ultimate aim was achieving market integration through parallel trade. When it was appealed in the European Court of Justice, the Commission's approach was upheld by the ECJ in *Sandoz*.

On 2 March 1994 the Commission outlined the main framework for an industrial policy for the European pharmaceutical industry in a communication¹³⁶. In this Communication, the Commission's concern about the weakening competitiveness of the industry was pronounced. In the light of these findings, steps were taken to increase its competitiveness. However, in the 1998 Communication it is stated that further steps are needed. Pharmaceutical industry is an important industry in Europe, with its contribution to the economy and trade balance, the number of people employed in it and the social aspects. It is important to keep it competitive while at the same time enabling all European citizens access to safe and technically developed drugs at affordable costs. This is also what the Commission aims. It envisages parallel trade as an important tool in this respect. Therefore the Commission advocates preservation of parallel trade by all means despite the industry's claims that the conditions of the very much regulated pharmaceutical industry does not allow for the established benefits of the parallel trade to be seen in this sector. The Court, who supported the Commission in *Sandoz*, gave a judgment in *Bayer* which seemed to depart from the Commission for the first time.

It seems that the CFI's considerations were about finding existence of an agreement and not on the particular situation of pharmaceutical industry against parallel trade. The result is that this judgment made it possible for the pharmaceutical companies to prevent parallel trading of their products by exercising strictly unilateral restriction of supply

¹³⁵ Supra note 48.

¹³⁶ Supra note 20.

policy. There might be some other underlying considerations that the CFI took into account in giving this judgment. These are not maintained explicitly by the CFI in *Bayer* judgment. Therefore, it is expected to get answers in the CFI's judgment for the appeal of the Commission's *Glaxo* decision.

Certainly the pharmaceutical industry is right in arguing for the special characteristics of this industry for their position against parallel trade. It is true that the prices are regulated intensively by the Member States, with every Member State having a different priority. In the words of the Commissioner Monti pharmaceutical industry is "a truly global industry operating in distinct national markets"¹³⁷. To open up this industry, in which the rules of competition are not operating, to free competition might result in parallel traders getting most of the benefit and harming the R&D based industry.

These considerations result in the impossibility of preventing parallel trade through competition rules. In this sector, which has very specific conditions, the parallel trade will be able to be limited by the manufacturers. In this respect, and in the absence of any foreseeable harmonization at the Community level, the best solution seems to be opening the market of medicinal products that are neither purchased nor reimbursed by the State to free competition. This was also the policy adopted and the suggestion made by the Commission in its 2003 Communication. This should be the policy adopted by the Turkish pharmaceuticals industry as well.

¹³⁷ Supra note 28.

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