Parallel Trade in Pharmaceuticals: Reconsidering the Underlying European Community Policies

Commentary on the Opinion of AG Francis Jacobs in Case C-53/03 Bayer/Adalat

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A. Introduction

Parallel trade in medicines has troubled the European pharmaceutical industry since the 1970s. With the accession into the European Community (hereinafter the 'Community') of poorer states, such as Spain, Portugal, and Greece, parallel traders have exploited price differences and freedoms of the Community to enrich themselves at the expense of pharmaceutical manufacturers in high-priced States. Under the auspices of free movement of goods competition reigns and the level of parallel traded goods continues to increase with additional harmonization measures in the Community.

Pharmaceuticals manufacturers have at many times turned to the European Court of Justice (hereinafter the 'Court' or 'ECJ'), but in *Centrafarm v. Winthrop*, the Court held that the irregularities created by price differences must be remedied by legislation as provided by the European Community (EC) Treaty, and not be remedied by the Court. The Court further elaborated upon this notion in the recent *Bayer/Adalat* case where it questioned the Commission of the European Communities' (hereinafter the 'Commission') attempt to create a single market in prescription medicines through parallel trade.

The *Bayer/Adalat* case opened the doors for pharmaceutical companies to limit parallel trade by means of "unilateral measures" that fall outside the ambit of Article 81(1) EC. As a result, wholesalers had to look for other legal grounds, such as Article 82 EC, against unilateral measures limiting parallel trade where appropriate. In 2003, the Greek Competition Commission (GCC) approached the Court with a preliminary reference from the *Syfiat v. GSK* case (hereinafter the "GSK case"). The preliminary reference requested the Court to elaborate on the application of Article 82 EC to the pharmaceutical sector. The GCC raised the question whether, considering the specific regulatory framework in

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pharmaceuticals, the refusal to supply orders in full by a dominant pharmaceuticals manufacturer would constitute abuse within the meaning of Article 82 EC and, if so, what factors would indicate such abuse.

Because the Court rejected the case as inadmissible for jurisdictional reasons, there remains considerable uncertainty regarding the legitimacy of refusals to supply under Article 82 EC. Up to now, neither the Commission nor Community Courts have considered the substantial economic and regulatory arguments within the dispute between pharmaceutical industry and parallel traders. Nor has there been any case on the assessment of dominant position and refusal to supply by a pharmaceutical manufacturer. Therefore, the only authority in the dispute is the highly criticized Advocate General Jacobs' Opinion, of 28 October 2004, in which he elaborated that a supply restriction having the intention to limit parallel trade is not *per se* abusive considering the economic and regulatory particularities of the pharmaceutical industry.

This paper, without going into detailed economic aspects of assessing dominance or analysis of demand and supply as required in Article 82 EC cases, analyzes first the dispute between the industry and the parallel traders and then the contradictory interrelation between the Community intellectual property policy and the principle of free movement of goods. The author argues for a more balanced application of policy areas in parallel trade cases.

B. Facts and the Procedural History of Recent Parallel Trade Landmark Cases

I. The Notion of Parallel Trade

The technical term for the purchase of products in a lower-priced state for resale in a higher-priced state is 'arbitrage trade'. "It is known as 'parallel' to the extent that it takes place outside and – in most cases – in parallel with the distribution network that the manufacturers or original suppliers have established for their products at a Member State[.]"[1] Opportunities for parallel trade in pharmaceuticals stem from the differences in Member State public health policies and regulatory frameworks,[2] the principle of free movement of goods, the principle of exhaustion of intellectual property rights, and the fluctuations in

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[1] Communication from the Commission, Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, COM(2003)839 final of 30.12.2003, at 6.

[2] The first cases on parallel trade appeared in the 1970s with the accession of new and much poorer member states such as Spain, Greece, and Portugal. The Accession Treaties provide a specific mechanism to deal with parallel imports from the new member states. It provides that patents and supplementary protection certificates may be used for their duration to prevent parallel imports of pharmaceutical products from the new member state if the product could not have obtained "such" protection in the new member states.

currency. Parallel trade generally occurs with patent-protected pharmaceutical products, as the competitive market created for these original products is the most advantageous.

The key driver of parallel trade is the price differences between Member States that can be as high as 40% to 50% for some products.[3] However, parallel trade can be profitable even with a difference as low as 15% to 20%.[4] Although the costs and regulatory requirements of marketing in the import state are high, parallel trade will occur as long as price differentials and demand make it economically viable. Because its government does not regulate prices of pharmaceuticals, parallel trade is the highest in the United Kingdom, accounting for more than 17% of total sales in medicines.[5] In the Netherlands, Denmark, Germany, and Sweden, parallel imports account for 10% to 12% of the sales in pharmaceuticals.[6] On the other hand, Belgium, France, Italy, Portugal, Spain, and Greece are mainly 'export states' of cheap medicines to the rest of the European Union because their national governments exercise price regulation.

According to the Commission, Spanish Pharma SA, an individual wholesaler of pharmaceutical products, in 1997 achieved a turnover of €10.8 million (ESP 1.8 billion), of which three quarters was derived from exports to other Member States.[7]

The Commission promotes the notion of parallel trade as a legitimate trade within the internal market based on the principle of free movement of goods. This is of little surprise as the Commission has always taken a pro-integration approach advocating greater market integration and attacking any measures aimed at dividing national markets.

Two lines of cases have arisen regarding suppliers' methods to combat parallel trade. Suppliers have brought attempts to prevent parallel trade on the grounds of protection of their intellectual property rights to the Court numerous times and a very wide range of guidance is available on the subject matter.[8] The other line

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3 European Association of Euro-Pharmaceutical Companies, *Who actually gains from parallel trade?*, at http://www.eaepc.org.

4 IMS-Global, *Parallel Trade – The Number One Concern in Europe* (2002), at http://www.ims-global.com.

5 In 1997, parallel trade in the United Kingdom was 7%; in 2001, 14%; and, in 2002, 17.6% of total sales in medicines. European Association of Euro-Pharmaceutical Companies, *How widespread is Parallel Trade?*, at http://www.eaepc.org; EurActiv, *Parallel Trade in Medicines* (2003), at http://www.euractiv.com; IMS-Global, *Parallel Trade – The Number One Concern in Europe* (2002), at http://www.ims-global.com.

6 *Id*. Parallel trade in 1997: the Netherlands, 14%; Denmark, 11%; Germany, 2%. In 2001: the Netherlands, 14%; Denmark, 12%; Sweden, 10%; Germany, 5%. In 2002: the Netherlands, 10.4%; Denmark, 12.2%; Germany, 7.1%; Sweden, 10.2%. All percentages are of total sales in medicines.

7 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 EAEPC (complaint), OJ 2001 L 302, 17.11.2001, para. 3(b). (Commission Decision of 8 May 2001 on GSK Spain.)

8 The general rule is that once a product is legally placed on the market in a Member State by the owner of the intellectual property rights or with his consent, the owner cannot rely on these rights to hinder the further sale of the product within the EEA. *See* cases C-267/95, Merck *v.* Primecrown,

of cases involves compliance with the competition rules. A more specific and not yet developed legal basis for attack under ECJ case law is the application of Article 82 EC against pharmaceutical companies that exercise dominance over a particular product.

With the fight between manufacturers and wholesalers becoming legally more advanced, new issues keep arising that require clarification. After the Court's controversial decision in *Bayer/Adalat* case, its decision in *GSK* was greatly anticipated by the parties, the industry, and intermediaries, to serve as the landmark case on the issue. There was hope that the decision would not only clarify the legal aspects of the issue but also give some indication about the interrelation of the Community policies governing the issue.

1. Presentation of the *Bayer/Adalat* and *GSK Greece* Cases

a) The Bayer/Adalat case

This case came to the Court when Bayer, a pharmaceuticals manufacturer that was incurring losses because of parallel trade in its product Adalat, introduced a quota system without informing the wholesalers of its reasons for limiting supplies. As a result, the legal discussion before the Court concentrated on the definition of 'an agreement' within the meaning of Article 81 EC Treaty.

Both the Court of the First Instance and the ECJ concluded that Article 81 EC does not cover unilateral conduct because there must be a "concurrence of wills" in order for an agreement to be in place.[9] The Court further noted that despite the fact that the effects of such unilateral action are the same as those of an export ban; it was not prohibited *per se* by Article 81 EC.[10]

There is a clear indication from the ECJ that the Commission's claim that parallel trade is a legitimate means of integrating the pharmaceutical markets no longer withstands critique.

> [U]nder the system of the Treaty, it is not open to the Commission to attempt to achieve a result, such as the harmonization of prices in the medicinal products market, by enlarging or straining the scope of [EC Competition rules], especially since that Treaty gives the Commission specific means of seeking such harmonization where it is undisputed that large disparities in the prices of medicinal products in the Member States are engendered by the differences existing between the state mechanisms for fixing prices and the rules for reimbursement.[11]

[1996] ECR I-6285; C-436/93, Bristol Myers *v.* Paranova, [1996] ECR I-3457; Case 16/74, Centrafarm *v.* Winthrop, [1974] ECR 1183. The latest decision in *AstraZeneca* has once again proved that measures foreclosing competition or parallel imports of their protected products are not admissible. EUROPA Press Release IP/05/737 of 15 June 2005, Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs.

9 Case T-41/96, Bayer/Adalat, [2000] ECR II-3383, para. 173-4; Case C-2/01, Bayer/Adalat appeal decision of 6 January 2004, para. 97.

10 *Id*., Bayer/Adalat appeal, para. 88.

11 Bayer/Adalat, *see supra* note 9, para. 178.

The Court finds that there exists no Community principle on restriction of measures meant to prevent parallel trade:

> [C]ontrary to what the Commission claims, [previous case law] does not in any way presume a general prohibition on preventing parallel exports applying not only to Member States but also, and in all cases, to undertakings.[12]

By finding that parallel trade is not protected as a kind of trade[13] and that it is not the appropriate means provided by the Treaty for the Commission to achieve price harmonization, the *Bayer/Adalat* judgment provides a new line of interpretation of competition rules and the principle of free movement of goods.[14]

The reading of the judgment is also important when considering parallel trade cases under Article 82 EC. Because the Court clears the right of a pharmaceuticals manufacturer to take unilateral actions with the intent of combating parallel trade, it implies that it does not recognize creation of obstacles to parallel trade as a *per se* abuse. This means that a particular measure must come within the ambit of Article 81 or 82 EC by meeting other material criteria apart from having this particular intent or effect. Furthermore, the Court rejects the notion that measures against parallel trade are anti-competitive by definition by dismissing the Commission's argument that in order for a discussion on the compelling reasons for impeding parallel trade to be relevant it must take place in the context of Article 81(1) and 82 EC applicability.[15]

b) The GSK Greece case

This case concerns a preliminary reference made by the GCC in proceedings brought against GlaxoSmithKline (GSK), a pharmaceuticals manufacturer, by a number of wholesalers. The wholesalers claimed that GSK abused its dominant position by refusing to meet their orders in full and supplying only quantities sufficient for the national Greek market.

The wholesalers were exporting large quantities of GSK products to the United Kingdom. To prevent such exports, GSK changed its system of distribution by meeting national orders and, at one point, supplying hospitals and pharmacies directly. Although the number of orders was obviously too high for the Greek national market the implementation of the new distribution system led to shortages of medicines in the Greek market. After GSK carried out all orders following interim measures adopted by the GCC, the competition authority reported that demand and supplies exceeded the consumption needs of the domestic market

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12 *Id*., para. 178.
13 *Id*., paras. 174, 179.
14 P. Rey & J. S. Venit, *Parallel Trade and Pharmaceuticals: a Policy in Search of Itself*, 29 ELRev, 153, at 155 (2004).
15 Case IV/34.274, Adalat, [1996] OJ 2001 L201/1; EUROPA Press Release M. Monti, Member of the European Commission in charge of competition policy, EC Antitrust policy in the Pharmaceutical sector, 26 March 2001, at 9.

and indeed were considerably higher than before November 2000.[16] This led GSK to apply for a negative clearance for its refusal to cover more than 125% of Greek demand.[17]

In its reference for a preliminary ruling, the GCC asked whether a refusal to meet all orders in full by a dominant pharmaceutical undertaking with the intention to limit parallel export amounted to a *per se* abuse of its dominant position.[18]

Considering the outcome of cases brought against the pharmaceutical manufacturers and the *Bayer/Adalat* case, wholesalers would not be able to bring claims successfully without the determination of dominance.[19] Advocate General Jacobs addressed this in his opinion on this case, arguing that it was not GSK's market dominance that allowed it to adopt a new distribution system.

In his opinion, the Advocate General contests the claim that a dominant undertaking automatically abuses its dominant position if it refuses to supply with the intent of limiting or excluding actual or potential competitors from the market thereby reinforcing its position on the market or with the intent of restricting intra-Community trade.[20] He argues that, considering the specific nature of the pharmaceutical sector, GSK's measures constituted a proportionate protection of its legitimate business interests and partition of the market is just an inevitable consequence of its actions.

The Advocate General concludes first, that in specific circumstances a dominant undertaking may have an obligation to supply; second, that such obligation is subject to various limitations; and third, that a finding of abuse is highly dependent on the specific economic and regulatory context in which the case arises. The Advocate General suggests that according to the case law of the ECJ, any refusal to deal under Article 82 EC must be assessed considering the factual and economic context of each case; therefore, there is no concept of *per se* abuse of a dominant position.[21]

The Advocate General's approach suggests that the procedure of assessing abuse of a dominant position under Article 82 EC does not require first finding an abuse and consequently determining if there was an objective justification for the abuse.[22] The Advocate General instead applies a balancing test that addresses both

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16 Judgment of 31 May 2005 in Case C-53/03 Reference for a preliminary ruling from the Epitropi Antagonismou *in* Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others *v.* Glaxo-SmithKline plc and Others, para. 16, not yet published (hereinafter Syfait *v.* GSK).

17 Syfait *v.* GSK, para. 18.

18 *Id.*, para. 48.

19 In fact, the case law under Article 81 EC indicates that economic pressure exercised by one of the undertakings and/or unilateral interest in the agreement is not necessarily characteristic of Article 82 EC. According to ECJ jurisprudence, the only difference between Articles 81 and 82 EC in the area of contractual practices is the holding of a dominant position. For a more thorough analysis, *see* E. Rousseva, *Modernizing by Eradicating: How the Commission's New Approach to Article 81 EC Dispenses With the Need to Apply Article 82 EC to Vertical Restraints*, 42 CMLR 587, at 620-637 (2005).

20 AG Jacobs Opinion of 28.10.2004 *in* Syfait *v.* GSK, para. 50.

21 Syfait *v.* GSK, *supra* note 16, paras. 53-69.

22 *Id.*, para. 72.

the effects of restrictions on competition and the benefits to consumers, resulting in one final verdict: abuse or no abuse. Therefore, remarks on the inconsistency of the Advocate General's line of argumentation are unfounded.[23]

The proposed legal and economic factors that must be addressed are the pervasive regulation of price and distribution in the sector,[24] the likely influence of uncontrolled parallel trade upon pharmaceutical undertakings in the light of the economics of the sector,[25] and the effect of such trade upon consumers and purchasers of pharmaceutical products.[26]

The Advocate General's Opinion attempts to change the long-standing approach of the Commission in cases challenging the legitimacy of measures aimed at impeding parallel trade. Although some of the arguments of the Advocate General are only theoretical,[27] he manages to detect and assess the main factors that would affect the balancing of the Community's policies on competition and free movement of goods with the rights of a dominant undertaking.

However, after the highly debated Advocate General's Opinion, the ECJ unexpectedly terminated the proceedings in the *GSK Greece* case, finding that it had no jurisdiction to answer the question referred by the GCC.[28] Therefore, the analysis of the Commission and Advocate General Jacobs remain the two colliding authorities in the dispute over the legitimacy of measures taken by a dominant undertaking to limit parallel trade in its products.

Considering the above stated factual and procedural context of disputes that have arisen with regard to parallel trade issues, the next sections elaborate on issues proposed by Advocate General Jacobs and the core Community policies and legal issues that collide in parallel trade cases.

C. Elaborating on Advocate General Jacobs' Opinion

I. Bringing a Case under Article 82 EC

Contrary to Article 81 EC, Article 82 EC is specifically concerned with unilateral actions by undertakings carried out in an abusive manner. Although a unilateral action carried out by a dominant undertaking simply for the reason of dominance may come under the prohibition of Article 82 EC, specific attention must be paid to the particular circumstances where the behavior arises. The Court's

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[23] Ch. Koenig & Ch. Engelmann, *Parallel Trade Restrictions in the Pharmaceuticals Sector on the Test Stand of Article 82 EC, Commentary on the Opinion of Advocate General Jacobs in the Case Syfait/GlaxoSmithKline*, 6 ECLR 338, at 340, 343 (2005).

[24] AG Jacobs, *supra* note 20, paras. 77-88.

[25] *Id.*, paras. 89-95.

[26] *Id.*, paras. 96-99.

[27] *Id.*, paras. 86, 91.

[28] The Greek Competition Commission considers that it meets the criteria within the meaning of Article 234 EC in the light of the ECJ case law. Greek Competition Commission Decision of 28 February 2002, part IV. The Commission of the European Communities agrees on the admissibility, AG Jacobs, *supra* note 20, para. 19.

stance in the *Bayer/Adalat* case that a pharmaceuticals manufacturer has a right to limit parallel trade as a characteristic business practice means that the permissibility of a unilateral action pursued by a dominant undertaking must not be underestimated.

The hardship in bringing the GSK case under Article 82 EC lies in assessing the dominance of an undertaking in a particular market and the effects of the actions taken by GSK on the market of import.[29] As indicated by the GCC in its preliminary reference, the specific regulatory framework and economic considerations put forward by the industry require additional guidance.[30]

II. No Abuse of Dominant Position

According to the facts of the case, the GCC measured GSK's dominant position based solely on the Greek national market and only with regard to one of the three products about which the wholesalers had complained.[31] Two members of the GCC argued that the dominance could only be assessed by considering the geographic market of the whole European Union because parallel trade means that the final consumer can be located in any Member State. They were of the opinion that government intervention does not mean that every Member State is a different national market.

Article 82 EC prohibits only abuse of a dominant position within the "common market insofar as it may affect trade between member states." The EC competition rules do not prohibit the status of merely having a dominant position in the common market; they prohibit the abuse of that position.[32] Neither the Treaty nor the case law of the ECJ provides a definition of an abuse or a definite test to apply or even a list of criteria to consider. Therefore, the competition authorities and courts must assess the possible prospects of abuse on a case-by-case basis

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[29] For more detailed analysis *see, for example,* European Association of Euro-Pharmaceutical Companies, *Understanding Competition in the Distribution of Pharmaceutical Products in Europe. An Analysis of the Application of Article 82 EC to Supply-restrictions in the Pharmaceutical Sector* (2005), at http://www.eaepc.org; Department of Health and the Association of the British Pharmaceutical Industry, *PPRS: The Study into the Extent of Competition in the Supply of Branded Medicines to the NHS* (2002), at http://www.dh.gov.uk/Home/fs/en; P. Kanavos *et al.*, *The Economic Impact of Pharmaceutical Parallel Trade in European Union Member States: A Stakeholder Analysis* (2004), at http://www.lse.ac.uk/.

[30] Because the national authorities are responsible for applying Community competition rules through Regulation 1/2003, Article 3, they are in need for interpretation guidelines of Article 82 EC, especially regarding the pharmaceutical industry. *See also* A. Jones & B. Sufrin, EC Competition Law, Text, Cases and Materials 254 (2004).

[31] In majority of cases of pharmaceutical sector, the relevant market due to state intervention and the therapeutical uses for the competing products has been defined as the national markets. In the *Bayer/Adalat* case, the Commission identified the United Kingdom as the primary relevant market since the agreements directly affected it by protecting it from parallel imports, and further identified France and Spain, from where the parallel imports originated, as secondary markets. Commission decision of 10 January 1996, Case IV/34.279/F3 – Adalat, paras. 153, 154.

[32] Dominance in a single Member State is probably enough to constitute a substantial part of the common market, even in a European Union with twenty-five or more Member States. *See* Jones & Sufrin, *supra* note 30, at 269.

considering all relevant economic and regulatory factors. According to the GCC, GSK had abused its dominant position according to Article 82(b) EC by limiting production and national markets to the prejudice of consumers.[33]

In the *United Brands* and *Hoffman-La Roche* cases, the ECJ defined dominance as:

> [A] position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.[34]

This definition says that a dominant undertaking's position on the market means that it can act independently from its competitors and consumers and that, by its presence, it is able to impede effective competition on the relevant market. However, due to state intervention, GSK does not have power over prices in Greece nor in other states. Furthermore, because GSK is a manufacturer, Greek national law and Community acts regulate its independence from wholesalers, as explained more fully below.[35]

1. No *per se* Abuse of Dominance

The GCC suggests that a *per se* abuse of dominance exists when the actions taken by a dominant undertaking have the intent of limiting or excluding actual or potential competitors from the market and restricting intra-brand competition in the market of import. However, Advocate General Jacobs in his Opinion argues for an assessment of GSK's actions in light of specific regulatory and economic factors of the case.[36] The ECJ has always looked for an objective justification and to the proportionality of a challenged behavior.[37]

Courts must pay particular attention to the regulatory and economic factors of the case because an incorrect assessment of measures that a dominant undertaking implemented in response to market activities may lead to an incorrect finding of an abusive conduct under Article 82 EC. Such incorrect judgments could create a disincentive to companies that would otherwise attempt to achieve superiority on

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[33] Article 82(b) EC Treaty. *See* for similar cases, Cases 40/73, Suiker Unie *v.* Commission, [1975] ECR 1663; Case 226/84, British Leyland *v.* Commission, [1986] ECR 3263; 88/138/EEC, Commission Decision of 22 December 1987 relating to a proceeding under Article 86 of the EEC Treaty, IV/30.787 and 31.488 – Eurofix-Bauco *v*. Hilti, OJ 1988 L65/19; 98/538/EC, Commission Decision of 17 June 1998 relating to a proceeding pursuant to Article 86 of the EC Treaty, IV/36.010-F3 – Amministrazione Autonoma dei Monopoli di Stato, OJ 1998 L252/47 of 12 September 1998

[34] Case 27/76, United Brands *v.* Commission, [1978] ECR 207 paras 38, 65; Case 85/76, Hoffmann La Roche *v.* Commission, [1979] ECR 461, para. 38.

[35] Directive 2004/27/EC of the European Parliament and the Council of 31 November 2004 amending Directive 2001/83 on the Community code relating to medicinal products for human use, OJ 2004 L 136/34 of 30 April 2004.

[36] AG Jacobs, *supra* note 20, para. 50-72.

[37] R. Wish, Competition Law 180 (2001). Case 311/84, Centre Belge d'Etudes de Marche Tele-Marketing *v.* CLT, [1985] ECR 3261, para. 27. "An abuse within the meaning of Article [82] EC is committed where, without any objective necessity, an undertaking holding a dominant position […] [acts] with the possibility of eliminating […] competition."

the market, for example by launching a patent right. Although the EC Competition rules have often recognized the power to limit output as a characteristic anti-competitive behavior, the pharmaceutical market involves two specific factors that may make that standard indication of abuse inapplicable. First, national governments intervene considerably in the competition on prices, and, second, "the pharmaceutical industry has a different economic structure in comparison to other industries, so that excessive prices are not necessarily curbed through a reduction in demand."[38]

2. The 'Special Responsibility'

The Commission and the Community Courts frequently hear complaints that Article 82 EC protects the competitors rather than maintaining the competitive process.[39] Even a dominant undertaking that is acting legitimately still affects the structure of competition in a manner that may come under prohibition of Article 82 EC; therefore, a dominant undertaking has a 'special responsibility' to the competitive process.[40] Assessment of its behavior requires application of a stronger proportionality test.[41]

The question is whether GSK's actions to protect its business interests caused harm to competitors or to the process of competition and, if so, if such harm that arose as an inevitable consequence of a legitimate act can constitute an abuse. Consideration must be given to the assessment of dominance and other particular circumstances of the case.[42] Therefore, the factors regarding the specific regulatory and economic circumstances of the pharmaceutical industry are necessary to assess the effect of GSK's actions on the existing competitive processes.

The limitation of output as a legitimate commercial response to commercial threat despite having a limiting effect on the competition in the markets of importation does not constitute an abuse. First, the specific pharmaceutical industry regulatory framework in each of the Member States causes manufacturers to carry out their business considering each Member State individually. Second, in light of *Bayer/Adalat* case, the specific public service obligation and the fact that parallel trade as such does not bring the efficiency gains to the industry or patients, parallel trade cannot be considered a desirable form of competition and therefore cannot create a 'special responsibility' for dominant undertakings of the protection of such trade.

3. Public Service Obligation under EC and National Law

The principle of public service obligations limits the obligation upon a manufacturer to provide supplies regardless of its market power or the 'special

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[38] European Parliament Resolution on the communication from the Commission to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community, OJ 1996 C 141/63, 13 May 1996.

[39] Wish, *supra* note 37, at 149.

[40] Jones & Sufrin, *supra* note 30, at 279.

[41] United Brands *v.* Commission, *supra* note 34, para. 190.

[42] Jones & Sufrin, *supra* note 30, at 279.

responsibility' of a dominant undertaking. The Directive on the Community code relating to medicinal products for human use (hereinafter the 'Directive') defines the public service obligation as:

> [T]he obligation placed on wholesalers to guarantee permanently an adequate range of medicinal products to meet the requirements of *a specific geographical area* and to deliver the supplies requested within a very short time over the whole of the area in question.[43]

First, Member States are individually responsible for running their national health care systems. The fact that they choose different approaches to limit their health care expenditures supports the notion of separate national markets for pharmaceuticals.[44] Second, because the wholesalers are obliged to provide supplies only for a specific geographic area, the manufacturers' obligation to supply is mandatory only within the limits of the wholesalers' obligations.

In that regard, the Directive defines the supply obligation by requiring the holders of marketing authorization to ensure appropriate and continued supplies *so that the needs of patients in the Member State in question are covered*.[45] This further confirms the notion of distinct national markets for pharmaceuticals because pharmaceuticals' manufacturers and wholesalers have this mandatory obligation only for the needs of patients of the relevant Member State, that is, the amount sold to the public by pharmacists within the territory of a member state. Furthermore, because the obligation concerns only a limited area it is clear that there is a specific level of demand that is characteristic or traditional to the named territory.

Under Greek law, GSK had an obligation "to supply to the domestic market quantities at least equal to current prescription levels … plus an amount (25%) to cover any emergencies and changes of circumstance."[46] The law requires meeting orders only for the needs of the Greek market, and, as identified by the GCC, the orders clearly exceeded the traditional consumption needs of the domestic market.[47] Orders were out of ordinary because wholesalers exported a substantial portion of product to the United Kingdom.[48] The 25% emergency margin is not part of the national demand for every single order, because in the light of public service obligation upon manufacturer, it is not the primary mandatory obligation.[49] Consequently, GSK had neither a legal nor a moral obligation to supply more than is necessary for the national market consumption.

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[43] Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001 on the Community code relating to medicinal products for human use. OJ 2001 L 311/67 of 28 November 2001, Article 1(18).

[44] AG Jacobs, *supra* note 20, para. 85.

[45] Directive 2004/27/EC amending Directive 2001/83 on the Community code relating to medicinal products for human use, *supra* note 35, Article 81.

[46] Syfait *v.* GSK, *supra* note 16, para. 17.

[47] *Id*., para. 16.

[48] *Id*., para. 11.

[49] Where an emergency situation would be established, other rules take effect, such as prohibition of discrimination among the orders as a type of abuse, as elaborated more in Case 77/77, Benzine Petroleum Handelmaatschappij BV *v.* Commission, [1978] ECR 1513.

In addition, the alleged responsibility of a manufacturer to meet all demands in full is not an economically sound requirement considering the regulatory complexity of putting a medicinal product into most of the Member States' national markets. A manufacturer's decision to supply a national market is economically viable only in amounts sufficient to meet the national demands because the manufacturer negotiates a price for that territory only. In other words, the agreement between a manufacturer and the government is valid only within the territory of a single Member State where the product is on the market for domestic consumers. The actions of parallel traders therefore hamper the realization of so-called negotiated contracts with the governments.

Furthermore, there is no duty under competition rules to maximize output against a company's own free will, even if it is a dominant undertaking.[50] In particular, a wholesaler may not require a manufacturer to respond to unlimited demands and to produce product for export if the manufacturers' policy is to produce only within the limits of national demand. Both low- and high-priced member states have imposed the public service obligation upon manufacturers. Because GSK's dominance was determined only relative to the Greek market, the argument that its refusal to fully supply wholesalers' orders would have a negative impact on the supply structure in the Member State of import is unreasonable because GSK's responsibilities do not extend outside Greece even under the principle of the 'special responsibility' of a dominant undertaking.

It is not incumbent on the competition authorities to intervene based on competition laws into the process of making a business decision with whom to deal and to what extent. According to ECJ jurisprudence, competition law interference with the freedom of contract must be limited to the extent of adjudicating only abusive contracts or behavior.[51] The competition rules may not interfere with the "company's freedom to organize its commercial activities in the manner it sees to fit best."[52] Therefore, the principle that a dominant undertaking cannot refuse supplies *per se* or as a matter of 'specific responsibility' of dominant undertaking does not withstand critique.

4. The Action of Limiting Output

It should be noted that refusal to meet all orders in full is not an action undertaken solely due to a manufacturer's market power nor is it a purely anti-competitive action like a threat or punishment to competitors. On the contrary, refusal to supply is a normal business practice within the sector and is an inherent action of defense against parallel trade. Abuse must be assessed in light of these considerations.

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[50] European Federation of Pharmaceutical Industries and Associations, *Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?* (2005), at 51, at http://www.efpia.org.

[51] AG Jacobs Opinion of 28 May 1998 *in* Case C-7/97, Bronner *v.* Mediaprint, [1998] ECR I-7791, paras. 56-58.

[52] EFPIA, *supra* note 50.

The Court has stated that the concept of abuse is an objective concept and intent is not an element in defining abuse.[53] Therefore, a finding of abuse requires an actual or potential effect of hindering the maintenance of the level of competition. In the *BPB Industries* case, the Court held that a dominant undertaking is entitled to protect its commercial interests if it is attacked and only actual intent to strengthen or abuse its dominant position would be sanctionable.[54] The intent of GSK's actions was to provide consumers in Greece with products as required by national legal and moral obligations of a pharmaceutical manufacturer without prejudicing its ability to fund research and development and without distorting its ability to compete based on price, service, and efficiency throughout the Community.[55] Furthermore, as in *AKZO*, the Commission has submitted, "it does not consider an intention even by a dominant firm to prevail over its rivals as unlawful;"[56] therefore, GSK's intent to protect its legitimate commercial interests in other States does not constitute an anti-competitive intent.

a) Effect on competition

It is argued that measures of a dominant undertaking aimed at preventing exports of its products constitute abusive behavior in the meaning of Article 82 EC as they limit the competition with their products in States of import and act contrary to the policy of market integration as foreseen in the EC Treaty.

Hoffman-La Roche provides that a manufacturer abuses its dominant position where it uses:

> [M]ethods different from those, which condition normal competition in products or services on the basis of the transactions of commercial operators, that has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.[57]

It follows that in order to conclude that an abuse has occurred, the actions must have the effect of hindering the maintenance or growth of competition on the relevant market and be a result of methods different from 'normal competition'.

Commercial Solvents provides that refusal to supply would amount to abuse if the direct result of such refusal were potential elimination of the competition, and consequent strengthening of a dominant position.[58] GSK's actions did not eliminate a true competition on the markets of import.[59] Parallel trade, as recognized by the Court in *Bayer/Adalat*, is not a protected type of trade and must be considered only as a side effect of the government intervention within the competition as a matter of public policy. The actions of GSK did not harm any effective competition

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53 Hoffman-La Roche, *supra* note 34, para. 91.

54 Case T-65/89, BPB Industries and British Gypsum *v.* Commission, [1993] ECR II-389, Case C-310/93P, [1995] ECR I-865.

55 Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 21.

56 Case C-62/86, AKZO *v.* Commission, [1991] ECR I-3359, para. 81.

57 Hoffman-La Roche, *supra* note 34, para. 91.

58 Case 7/73, Commercial Solvents *v.* Commission, [1974] ECR 223; United Brands *v.* Commission, *supra* note 34, para. 201.

59 More fully discussed below in section D.

as the competition posed by the parallel traders in the states of import is not a competition on the merits (e.g. price, quality, and functionality) and furthermore, it does not bring the efficiency gains to the industry that are expected to result from competitive processes. The particular regulatory framework of the industry does not foresee any competition with regard to prices after they have been negotiated with the governments. For that reason, even where GSK decided to supply hospitals directly the elimination of effective competition in the Greek market cannot be inferred.[60] The limitation of availability of products for export also does not result in less competition in states of import because parallel traded products coming from Greece are not considerably cheaper than are those coming from other states and the products of GSK in the United Kingdom are faced with more effective free market competition by other manufacturers.

According to the jurisprudence of ECJ, the following arguments against disproportionate effects on the market caused by parallel trade can be provided for the defense of pharmaceutical manufacturers in general and GSK in particular. Applying *Metro I* facts and reasoning to the *GSK Greece* case, parallel traders in states of import have an unfair competitive advantage over GSK's United Kingdom suppliers just as SABA (a German producer of consumer electronic devices) wholesalers had an advantage over SABA retailers.[61] Because the costs of production differ according to the particular marketing system the wholesaler operates, manipulations of the system would give that party at an unjustified competitive advantage. Therefore, the ECJ cleared the prohibition on manipulating within the SABA structure under competition rules. Similarly, parallel traders have gained an unjust competitive advantage in relation to GSK's United Kingdom manufacturers by acquiring pharmaceuticals in highly regulated markets and re-selling them in markets open for competition.

Likewise, in the *Distillers* case, the agreement forbidding the sale of duty-free products in normal channels of trade is accepted as not infringing Article 81(1) EC.[62] Otherwise, it would create distortions in the Common market. The Commission itself recognized that only trade in small portions of duty-free products could occur in normal channels of trade without creating distortions to the Common market.[63] If analogizing those facts to the parallel trade in pharmaceuticals cases, it is clear that, due to government intervention, the low-priced pharmaceuticals distort competition in high-priced states where competition takes place on merits. The reference to trade in small portions is similar to the rights that any national of a Member State may exercise under the free movement principles by traveling to another country and acquiring the goods individually.[64]

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60 AG Jacobs, *supra* note 20, para. 6.

61 Case 26/76, Metro *v.* Commission, [1977] ECR 1875, paras. 28, 29.

62 80/789/EEC: Commission Decision of 22 July 1980 relating to a proceeding under Article 85 of the EEC Treaty, IV/26.528 - The Distillers Co. Ltd – Victuallers.

63 *Id*., para. 16.

64 The same approach is adopted also by US Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, recital 30.

Also, GSK did not act purely to strengthen its dominant position. Because companies in the pharmaceuticals sector compete on ability to innovate, GSK's intention of limiting its output in low-priced states is more to ensure its ability to fund its research and development funds Community-wide than to merely strengthening its dominant position in Greece or the United Kingdom. Refusal to supply is not a common action in managing business where fierce competition is present; rather it is a means of protection. Refusal to supply as means of protecting legitimate commercial interests on the part of a non-dominant company has been cleared by the Court in the *Bayer/Adalat* case. The Court has recognized this method as a business practice for pharmaceutical manufacturers responding to growing parallel trade activities.[65] Manufacturers are forced to deviate from the normal business practices, such as responding to demands in full, as long as there is government intervention on prices.

Furthermore, GSK argues that a dominant undertaking may refuse orders that are out of ordinary or excessive, in line with *United Brands*.[66] The excess must be determined considering the factual and regulatory context and taking into account the market specificity. GSK did not refuse all orders but only those that were clearly out of the ordinary and excessive and that did not comply with the national public service obligations. Such behavior is supported also by the *Boosey & Hawkes* case,[67] stating that a company has no duty to subsidize a competition against itself especially where the company has to work on a mandatory basis.

In addition, it is highly questionable that the relevant wholesaler deals only with the dominant manufacturer. The GCC determined the dominance of GSK only in Greece, not on the whole Common market or even in the United Kingdom. In order to fulfill their public service obligations, wholesalers must have a variety of sources in order to guarantee full stocks. Furthermore, it has been argued that parallel traders who are involved in pure arbitrage trade are not affected by refusals to supply as they are able to switch to other products easily.[68] It has also been argued that where the relevant product market would be determined as the "arbitrage market," any product of the same price range is substitutable for parallel trade activities.[69] If that were taken into account, the possible market share, the prospects for the abuse, and possible effects on the market would be unlimited.

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[65] The companies have adopted this approach not only in Europe but also in the United States where parallel trade as such is prohibited but consumers manage to order products from Canada via the internet. J. Arfwedson, *Parallel Trade in Pharmaceuticals*, July 2003, at 15-28, at http://www.cnehealth.org.

[66] United Brands, *supra* note 34; Case C-311/84, CBEM *v.* CLT and IPB, [1985] ECR 3261, para. 182.

[67] 87/500/EEC: Commission Decision of 29 July 1987 relating to a proceeding under Article 86 of the EEC Treaty, IV/32.279 – BBI/Boosey & Hawkes: Interim measures. OJ 1987 L286/36.

[68] EFPIA, *supra* note 50.

[69] The commission did not distinguish between first and second-generation drugs for the same therapeutic indication, even though the second-generation drug required less frequent dosing. Non-opposition to a notified concentration of 8 May 2000 in Case COMP/M.1846. Glaxo Wellcome/Smithkline Beecham, OJ 2000 C170.

Moreover, the potential effect of GSK's actions within the state of import is weakened by the fact that the industry is very competitive, especially in the usual states of import, whose regulatory frameworks attract higher competition and consequently a greater availability of substitutes.[70] In addition, the competition within the national markets is intensified when a patent expires and generic products are able to copy branded drugs at a lower price. The generic goods, in contrast to parallel trade, do contribute to effective competition in the market because producers are competing on increased efficiencies such as lower costs of production.[71]

b) Effect on consumers[72]

In assessing the challenged exclusionary conduct the 'limitation of production to the prejudice of consumers' must be detected, that is, it must be shown that the conduct reduces consumer welfare by reducing overall output. It has been argued that abuse will occur if the conduct has "a material adverse effect on consumer in the form of exploitation of market power."[73] Consequently, where no reasonably material harm is created for consumers and where actions have the aim of achieving long-term benefits for the consumers, the limitation of production available for export is not prohibited under Article 82(b) EC.[74]

The refusal to supply orders that are out of the ordinary would have the potential to have a negative effect on consumers in the national market if the unusual orders reflected the real needs of the national market. The European Association of Euro-Pharmaceutical Companies (EAEPC) indicates that it is morally questionable to limit supplies and cause a shortage of products for national consumers.[75] However, the fact that its refusal to supply excessive orders caused a shortage of

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[70] Moreover, GSK may not decrease the prices in states of import as it then would not be able to compensate for the low revenues in low-priced states. High costs spent on marketing is just another indication that the competition is fierce in the market. G. Hopkins, *Does The Regulation Of Pharmaceutical Drug Prices Discourage Innovation?*, at 10-12, at http://www.agecon.ucdavis.edu.

[71] This is illustrated by the fact that when GlaxoWellcome's Zantac product patent expired and production of generic substitutes decreased the product's price, the previously intense parallel trade disappeared at once. EFPIA, *supra* note 50, at 32.

[72] First, it is necessary to agree upon a definition of a consumer. The question is whether it is a consumer in the national Greek market or does it also include potential consumers in other Member States where the product may find its way through the channels of parallel trade. For the purpose of this article, the primary consumer will be considered the Greek customer but consideration is given also to arguments defining a consumer as being located anywhere in Europe.

[73] J. T. Lang & R. O'Donoghue, *The Concept of an Exclusionary Abuse under Article 82 EC, Global Competition Law Centre Research papers on Article 82 EC*, 38, at 47 (2005), at http://gclc.coleurop.be.

[74] The actions are suspected under Article 82 EC both if they cause direct damages to consumers as well as indirect resulting from impact on effective competition structure. *Case 6/72*, *Europemballage and Continental Can*, [1973] ECR 215, para. 26.

[75] European Association of Euro-Pharmaceutical Companies, *Understanding Competition in the Distribution of Pharmaceutical Products in Europe. An Analysis of the Application of Article 82 EC to Supply-restrictions in the Pharmaceutical Sector* (2005), at http://www.eaepc.org.

medicine in Greece was not GSK's responsibility. GSK complied with its public obligation and fulfilled all orders that were necessary for the market. Rather, it was the wholesalers' activities that caused shortages in the national market and whose activities must be assessed under the Directive on the Community code relating to medicinal products for human use.[76] For example, GSK started supplying hospitals directly because it was not sure whether the products supplied to intermediaries would end up with the consumer that most needed them – the national consumer. While it is not the responsibility of the manufacturer to guard whether the market players comply with their obligations under law nor it is for the manufacturer to enforce these obligations, but a manufacturer may react to the market players' activities in order to avoid disturbances and to protect its legitimate business interests.

The wholesalers have argued that refusal to supply medicinal products for export resulted in the reduced availability of effective substitutes and higher prices in the state of import. GSK's refusal to supply additional quantities does not affect the product variety in the state of import because wholesalers and suppliers are obliged under the public duties in the respective Member States to guarantee full stock at all times. The duty implies the necessity for wholesalers to deal with many suppliers. In addition, the pharmacies that supply the final consumer deal with several wholesalers. Because the price difference between parallel traded products and the legitimately imported products is minimal, it cannot be established that this particular refusal would have had any direct effect on consumers. Furthermore, because GSK enjoys dominance only on the Greek national market and because it has traditionally answered only to Greek national demand there cannot be sufficient link of consumer dependency such that the refusal to supply some extra quantities would have a detrimental effect on consumers in the state of import.

The wholesalers maintain that parallel trade and government intervention are the only reasons that "the prices of innovative medicines are not spiraling out of control."[77] The statistics show that manufacturers in states of import do not lower their prices as a result of parallel trade, because then they would not be able to offset the low revenue from low-priced states and the expenses for research and development that are constantly growing. Moreover, prices have a general tendency to increase. Furthermore, the increase in supplies is unlikely to affect consumer prices, because the parallel traders keep the majority of the difference and the national health care systems keep the rest. On the contrary, if parallel trade were unrestricted, the decrease in manufacturers' ability to fund innovations would adversely affect future consumer choice.

It is also argued that "parallel trade is a cure for governments and consumers looking to pay less for drugs."[78] Although governments may indeed take

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[76] Directive on the Community code relating to medicinal products for human use, *supra* note 45, Article 81.

[77] European Association of Euro-Pharmaceutical Companies, *Why Do Prices Differ Between Countries?,* at http://www.eaepc.org.

[78] D. Macarthur, *Written Statement to HHS Task Force on Drug Importation* (2004), at http://www.hhs.gov.

advantage of other Member States' policies, the partitioning of markets as enacted by a Member State does not foresee extending the national policies to other Member States. Nor do Member States envisage that companies would compete on regulated prices to provide consumers with cheaper drugs, because it is for the governments themselves to negotiate a price they can bear. The savings for the national health systems due to parallel trading are estimated in 2002 in six major import states to account for 0.3% - 3% of national health system budgets, representing just €100 million[79] and higher according to other sources.[80] In contrast, the profits accrued by parallel traders are estimated around €648 million or higher.[81] All studies and the Commission agree that most, but not all, of the financial benefit accrues to the parallel trader rather than to national health systems or patients and that creates inefficiencies.[82] Where parallel traders work in cooperation, the profits can be even greater. For example, Spanish parallel trader Unyexport Medicamentos SA received revenues of €75 million in 1997, and in 2000 received €200.9 million.[83]

c) Effect on trade between Member States

Because parallel trade arises under the principle of free movement of goods, it is clear that any actions aimed at altering the activities of parallel traders will have an effect on trade between Member States. The assessment of effect on trade of this particular case, however, must be carried out in light of the *Bayer/Adalat* decision and considering the specific regulatory context of the sector.

First, in the *Bayer/Adalat* case, the Court specifically clarified that there is no presumption of a general prohibition on preventing parallel exports.[84] As more fully discussed below, parallel trade as such does not represent a protected trade or desirable competition. Therefore, considering the market power of GSK in Greece, its actions are legitimate as long as they are reasonable and proportional to the threat posed by parallel traders despite the effect of its actions on trade between Member States.

Second, according to public service obligations, GSK is required to respond to orders only of national demand; therefore, the notion of separate national markets is already foreseen by Community acts. In addition, the highly regulated nature of the national markets does not provide incentives to outgrow low-priced national markets as it would undermine its innovation activities on a Community scale. Furthermore, it is not GSK or the industry as such that would derive benefits

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[79] The study has been taken with regard to limited amount of products and six major destination countries. London School of Economics, *EU Pharmaceutical Parallel Trade - Benefits to Patients?* (2002) at http://www.lse.ac.uk.

[80] Macarthur, *supra* note 78.

[81] The study has been taken with regard to limited amount of products and six major destination countries. *See supra* note 79.

[82] Commission Communication on the Single Market in Pharmaceuticals, COM(98)588 final of 25 November 1998, at 4.

[83] *See* Financials of Unyexport Medicamentos SA, at http://www.informa.es; Rey & Venit, *supra* note 14, at 164.

[84] *Bayer/Adalat*, *supra* note 9, para. 178.

from making products more available for export through parallel trade because in most of the national markets the prices are already considerably higher than those in Greece and parallel traders do not belong to the industry. Therefore, pharmaceutical manufacturers protect their commercial interests by limiting the production for export without there being a consideration of market foreclosure.

As a result, the obstacles to parallel trade arise only because of the realization of legitimate business interests. However, it is the abuse that must affect trade between Member States.[85] When a limitation on parallel trade arises as an inevitable consequence of legitimate business behavior of a dominant undertaking; it would not be an abuse and would not be deemed to inhibit trade between Member States.

III. Prospects for Objective Justification

Having identified the negative effects that unrestricted parallel trade brings to the industry, GCC enquired the Court: what are the criteria of the objective justification to be used in evaluating whether the refusal to supply by a dominant undertaking is justifiable by protecting its legitimate commercial interests?[86] Although Article 82 EC does not explicitly mention elements of justification, the Court has consistently looked for such elements.[87] Therefore, the Commission's opinion that restriction to supply should not be capable of justification at all or only in very limited circumstances is not acceptable. In addition, the Court has accepted the defense of objective justification because of the specific regulatory nature of television sector in the *CBEM* case.[88] The same pattern also applies to the pharmaceuticals sector because it too lacks normal market mechanisms due to government intervention.[89]

According to the *Michelin II* case:

> [A]n undertaking in a dominant position cannot have recourse to means other than those within the scope of competition on the merits […] without objective economic justification.[90]

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[85] Commission's Guidelines on the Effect of Trade Concept Contained in Article 81 and 82 of the Treaty, OJ 2004 C101/81, 2004, at 17.

[86] AG Jacobs, *supra* note 20, paras. 13-14.

[87] Wish, *supra* note 37, at 207; *See, e.g.*, Commercial Solvents, *supra* note 58, para. 28; CBEM *v.* CLT and IPB, *supra* note 66, para. 26; Case T-30/89, Hilti AG *v.* Commission, [1991] ECR II-1439, paras. 102-119; Case T-83/91, Tetra Pak International SA *v.* Commission, [1994] ECR II-755, paras. 136-140; Case 333/94, Tetra Pak International SA *v.* Commission, [1996] ECR I-5951, para. 37.

[88] CBEM *v.* CLT and IPB, *supra* note 66, para. 26.

[89] In addition, Parliament notes that "the pharmaceutical industry has a different economic structure in comparison to other industries, so that excessive prices are not necessarily curbed through a reduction in demand." European Parliament resolution on industrial policy for pharmaceutical sector, *supra* note 38.

[90] Case T-203/01, Manufacture Frnacaise des Pneumatiques Michelin *v.* Commission of 30 September 2003, paras. 97, 107, 110.

ECJ case law identifies three types of 'objective justification'.[91] According to the factors indicated by Advocate General Jacobs, the GSK case falls within the ambit of defense of protection of legitimate business behavior.[92] Similarly, the conduct of a dominant undertaking must pursue a legitimate aim, be reasonable, and be proportional to the desired aim. Previous Court decisions under Article 82 EC imply that it is not proportional to terminate supplies in full suddenly, or involve products which are indispensable for the commercial activities of the weaker party.[93] Neither of these factors are present in the GSK case.

The characteristic factors of the pharmaceutical industry that provide grounds of objective justification for refusal to supply orders in excess are as follows: first, government intervention in competition by setting prices; second, the negative effect of unlimited parallel trade on the prospects of innovation of the industry; and, third, the negative effect of parallel trade upon consumers in long run. The uniqueness of the sector requires analyzing the measures taken according to their prospective long-term effects on the industry.

First, in order to assess the conduct of a dominant undertaking within the meaning of Article 82 EC, consideration must be given to the regulatory and economic circumstances in which the undertaking operates because that constitutes the basis for the undertaking's reactions. As comprehensively indicated by Advocate General Jacobs, the regulatory framework of the pharmaceutical industry is unique and differs from other industries engaged in the production of readily traded goods because, despite high national and Community regulations on distribution of the products, the normal conditions of competition such as competition on prices are not present or, more accurately, are not foreseen. Pharmaceutical manufacturers have adapted to this particular structure by deviating from normal business practices and gaining profit by sale in separate markets only and not producing products for export in states with high intervention. The means to carry out such policies involve refusing to supply excessive orders that are clearly out of ordinary and traditional needs of a particular market.

Second, the Commission has recognized on various occasions that innovation is the most important parameter of competition in the pharmaceuticals industry.[94] By its nature, the pharmaceuticals industry is expensive, risky and time consuming, even under effective competition.[95] However, the products yield significant benefits to the final consumer and to Community welfare in general. Therefore, by adopting a limited supply strategy in low-priced states, GSK protected its legitimate commercial interests and the long-term interests of the industry.

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[91] P. Lowe, *DG Competition's Review of the Policy on Abuse of Dominance*, *in* B. E. Hawk (Ed.), International Antitrust and Policy: Annual Proceedings of the Fordham Corporate Law Institute, at 170-171 (2003); Jones & Sufrin, *supra* note 30, at 282-283.

[92] P-J. Loewenthal, *The Defence of 'Objective Justification' in the Application of Article 82 EC*, 28 World Competition 464 (2005).

[93] Commercial Solvents, *supra* note 58; CBEM *v.* CLT and IPB, *supra* note 66.

[94] *See* Chapter on Conflict of Policies. Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 155.

[95] Competition Commission of the Government of South Africa, *Comments On The Regulations Relating To a Transparent Pricing System For Medicines And Scheduled Substances* (2004), at http://www.compcom.co.za.

Advocate General Jacobs, in his Opinion, posed concerns that unlimited parallel trade could lead to manufacturers applying protective strategies by choosing not to market certain products in states that they would then find hard to withdraw from or by choosing to delay the launch of new products in those states.[96] Such considerations would not take place in an open market with competition on prices. For that reason, the characteristics of the pharmaceutical industry are sufficient to represent exceptional circumstances, as argued by Advocate General Jacobs.

The GCC itself had doubts about the efficiencies that unrestricted parallel trade would bring to the industry. Although the Commission has stated that it had not been given any convincing evidence on effects of parallel trade on a manufacturer's research and development budget, the GCC notes that:

> [S]uch trade can seriously undermine the financial and organizational interests of pharmaceuticals manufacturers, eroding their revenues and disrupting their organizational arrangements in those States which receive the parallel imports.[97]

Any losses in expected profits have an effect on all parts of the budget including spending on research and development. The burden of proof to show the causal link is on GSK, but it must be evident that the government intervention in most of the states and high parallel trade are factors that make it difficult to calculate the expected future profit on investments made today. Furthermore, wholesalers argue that most of the spending of pharmaceutical companies is for marketing of the products; one of the Commission's first concerns is to decrease the spending in pharmaceutical marketing.[98] This is an indication of where the real competition occurs. In addition, most parallel traders repackage the original products in a way to attract more patients to their product, thereby contributing to the high industry spending on marketing.

Third, the assessment of abuse requires balancing the effects of GSK's measures on competitors against the further effects on consumer welfare, such as the effects on prices, output, and choice.[99] The GCC agrees with the Commission and the Parliament that "the benefit of the parallel trade would appear to accrue mainly to the undertakings engaged in such trade rather than the end consumers of the products traded."[100] As community welfare relies on the prospects of development and innovation activity of the industry, it is essential to balance the short-term harms to the wholesalers against long-term benefits to consumer when assessing the behavior of GSK under Article 82 EC.

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96 AG Jacobs, *supra* note 20, para. 91.
97 AG Jacobs, *supra* note 20, para. 13.
98 Communication from the Commission to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community, COM(93)718 final of 2 March 1994.
99 Lang & O'Donoghue, *supra* note 73, at 47.
100 AG Jacobs, *supra* note 20, para. 13.

IV. Summary

In assessing the behavior of GSK and other similarly situated manufacturers towards the parallel traders, a specific consideration must be attributed to the notion that "the Competition rules under the Treaty require that the conditions under which competition takes place remain subject to the principle of fairness in the market place."[101]

Although a dominant undertaking is limited in its responsibilities towards the competitors under the so-called 'special responsibility' principle, the limitations must be reasonable so that undertakings that, due to their efficiency, have achieved greater market power are not overburdened. Because GSK's activities are already regulated by public service obligation under both national and Community acts, the 'special responsibility' to parallel traders must be interpreted within the ambit of those obligations and should not exceed them. Otherwise, by broadly interpreting the principle and public service obligations the competition authorities would intervene in a company's freedom to organize its commercial activities such as output.

It is a legitimate business behavior within the pharmaceutical sector for a manufacturer to adopt a strategy of supplying production only for the use of a national market and not producing for export. Refusal to supply excessive orders in response to parallel traders' 'free rider' activities is a reasonable and proportional behavior to protect the manufacturer's legitimate interests.

The assessment of possible abuse involves a balancing of efficiency gains and anti-competitive effects.[102] The activities of GSK cannot be considered to have a negative effect on competition processes in states of import, as there is no competition envisioned due to member state contribution in separating the national markets. Parallel traders cannot be considered desirable competitors because: first, the open market elements are not present; second, lower prices do not reflect better use of resources, but more aggressive national regulations; and, third, the benefits from parallel trade are accrued by the traders instead of being passed to the consumers or the industry to enhance further welfare. Furthermore, it has been recognized by the *Bayer/Adalat* case that parallel trade is not a protected means of trade; therefore, it cannot be considered that the refusal to supply excessive orders would amount to elimination of a competitor. For the same reasons, and the fact that it is an inherent right of a company to produce supplies only for national markets separately, the effect on trade between Member States is out of consideration.

The refusal to supply by manufacturers in low-priced States is also consistent with the interests of consumers because it safeguards the long-term interests of consumers by ensuring continuous innovation that may result in the availability of new medicines for patients. This is also in line with the proportionality principle and the balancing of interests because when considering the effect on long-term

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[101] D. Hildebrand, The Role of Economic Analysis in the EC Competition Rules. The European School 15 (2002).

[102] Jones & Sufrin, *supra* note 30, at 287.

perspectives, the short-term benefits to consumers are insignificant. Prohibiting refusals to produce and supply for export would deprive the pharmaceutical companies from incentive to invest in research and development. A prohibition would also, as indicated by Advocate General Jacobs, lessen the motivation to improve markets where governments intervene in pricing as part of their public health policy. For those reasons, the conduct of GSK can be considered to be objectively justified and not constituting abuse despite impairing the opportunities of parallel traders.

It is important to note that the Greek courts have already cleared another pharmaceutical manufacturer's refusal to supply quantities for exports under both Articles 81 and 82 EC as a protection of legitimate economic interests.[103] A similar case in France was decided in favor of the pharmaceuticals manufacturer as the wholesalers failed to prove the restraint effects of the refusal on competition.[104] In Spain, a manufacturer's refusal of supply was not found to be abusive as it was not a total interruption of supply: other, more expensive alternatives were available; and, reduction in supplies was objective and proportionate.[105]

D. The Conflict of Policies

I. The Community Single Market in Pharmaceuticals

1. Member State Public Health Policies

Under Article 152 EC, Member States are solely responsible for organization and delivery of national health services. Because the states are the real consumers that pay for prescription drugs and because they must ensure that pharmaceutical expenditures do not become excessive, it is in their interest to contribute to setting prices.[106]

Different states have different rationales behind their national health policies and different means for their realization.[107] In countries like France, Spain, and Greece, consumer and government allowances take priority irrespective of the effects on the industry; therefore, the national authorities have adopted the system of negotiations with the manufacturers in order to have control over prices.[108] On the other hand, the governments in the United Kingdom and Italy regulate manufacturers by imposing upon them profit control or 'reference price limits'

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[103] Athens Administrative Court of Appeal on appeal by the plaintiff against final judgment No.5857/2003 of the Multi-Member First Instance Court of Athens, Servier. EFPIA, *supra* note 50.

[104] *Id*., Conseil de la concurrence, Decision 04-D-05, 24 February 2004, Phoenix Pharma (interim measures).

[105] *Id*., Case R 558/03, Spain Pharma/SmithKline, Spanish Competition Service.

[106] Study of the European Association of Euro-Pharmaceutical Companies, *supra* note 75.

[107] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 4.

[108] Study of the European Association of Euro-Pharmaceutical Companies, *supra* note 75, at 8, 10, Annex 1.

on reimbursements like they do in the Netherlands, Denmark, and Germany.[109] In the latter countries, one priority is the long-term policy that innovation and open markets foster competition. However, even a controlled profit margin has been identified as hampering the growth of the industry.[110]

Because the United Kingdom is the biggest market for parallel imports, it is of interest that it has actually introduced measures to fight the unjust enrichment of parallel traders. In fact, all pharmacists are considered to be involved in parallel trade and for that reason they are deprived of 4-5% of their benefits without considering whether they have actually been involved to that extent.[111] Such action by the government indicates that parallel trade is recognized as conduct that exploits the differences of national policies on pricing of pharmaceuticals in order to deprive the government and consumers of benefits.

2. Commission Communication

It follows that the restrictions that the Community may exercise under Article 3(m) and (n) EC are limited under Article 152 EC, which provides that the Community shall fully respect the responsibilities of Member States for the organization and delivery of health services and medical care. Therefore, Community action may only complement national policies excluding any harmonization of the laws and regulations of the Member States. On the other hand, under the rules of consumer protection, the Community may adopt harmonization measures in the context of the completion of the internal market.

In its 'Communication on the Single Market in Pharmaceuticals' (hereinafter the 'Single Market Communication'), the Commission intended to address the "totality of the regulatory, social and industrial interests in play" to ensure that consumers have access to medicines at an affordable cost and that appropriate incentives for innovation and industrial development exist.[112] Various Community institutions have issued several policy documents, all of them indicating the importance of balancing competing interests with the desired aims. The Commission has taken action or is requesting Member States to take further action concerning all aspects of the industry from pricing of the pharmaceuticals within the state price control systems to other measures that will complete the technical harmonization within the sector to a greater extent, thereby developing the necessary environment for parallel trade to take place.[113]

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[109] Hopkins, *supra* note 70, at 15.

[110] The OECD Report indicates that the Italian and French Antitrust Authorities believe the fixed margin system hampers the growth of the generics market in the industry. Competition Commission of the Government of South Africa, *Comments On The Regulations Relating To a Transparent Pricing System For Medicines And Scheduled Substances* (2004), at http://www.compcom.co.za.

[111] Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, paras. 49, 84 for an explanation of the functioning of the claw-back system introduced to fight unjust enrichment by parallel traders who import cheap medicines from Spain and sell in the UK for a higher price.

[112] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 2.

[113] The Commission's call for action to create a stronger industry for the benefit of patients has provided guidelines on the actions that Member States must consider in order to achieve a more balanced and coordinated regulatory base for the consumers and the industry. The Commission

In the 'Single Market Communication', the Commission first recognizes the concerns regarding the competitiveness of the European industry as compared to the market in the United States. Although Europe does not have a negative pattern in the industry's development, the differences in all aspects of the two markets are still considerable. The main reasons for these differences are the significantly higher overall profitability and the return on capital that are possible in the United States' market.[114] The Commission recognizes that Member State intervention "may necessarily distort the operation of the market leading to a reduction in the competitiveness of this sector in a global context."[115] The issue of parallel trade is one of the driving forces leading Community institutions to launch research projects and take measures in the sector because the Commission receives high pressure from both the governments and the industry.[116] The Commission, however, has taken a strange approach to address the issues of parallel trade. Initially it named parallel trade as "a conflict between the operation of price fixing mechanisms and the Single Market," indicating that it is an important tool for price integration.[117] The Commission seemed to see parallel trade as a temporary conflict that would disappear as soon as a single market existed. Then, it continued by stating that parallel trade actually creates inefficiencies by accruing all the benefit of such trade and not putting pressure on supposedly high prices.[118] Parallel trade has great potential to be the driving force for market integration and put pressure on the industry with regard to its pricing policy, but in reality, it does not. Furthermore, it is odd that the Commission reduces its responsibility for the pattern of effects that parallel trade produces in the industry by leaving identification of a solution to the Member States.[119]

In 1998, the Commission envisaged three possible ways to hamper discrepancies within the industry – by keeping the status quo, by achieving full integration, or by a middle way. At the time, the Commission showed its preference for a single market that would recognize different patterns for in different segments of the market, for instance, non-prescription, generic and patent-protected products.[120] In 2003, the Commission launched a call for action to create a strong and modern legislative framework that would ensure smooth operation of the industry.[121]

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has strictly set an objective to ensure that patients have faster access to innovative medicines by improving the marketing authorization procedure and creating a competitive non-prescription and generics market. Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action, COM(2003)383 final of 1 July 2003.

114 Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 3.

115 *Id*., at 7.

116 As governments are facing growing financial pressure on their health systems the Commission has taken the action of working to improve their efficiency, cost-effectiveness and quality. Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 8, 10.

117 *Id*., at 4.

118 *Id*., at 4.

119 *Id*., at 5.

120 *Id*., at 10-11.

121 Commission Communication – A Call for Action, *supra* note 113, at 29.

The Commission finally notes that, according to evidence for patent-protected products, there is a need to introduce normal market mechanisms, but that the "removal of mechanisms of price-setting" should not be considered a "prior requirement."[122]

It is clear that Commission has the aim of opening the market and that a balanced approach is necessary to ensure that all objectives and interests are considered.[123]

II. Conflict of Policies Regarding Parallel Trade

According to the subsidiarity principle, the Commission's involvement with regard to functioning of these national schemes is limited to the realization of its competences under Article 3(c), (g), and (h) EC; namely, the creation of an internal market, ensuring that competition in the internal market is not distorted, and approximation of laws of Member States.

The internal market is regarded as the key driving force for ensuring market integration, development of intra-brand trade and, consequently, increasing growth and competitiveness. Free movement of goods is one of the fundamental principles for the functioning of the single market. It is supported by a Community competition policy developed and enforced by the Commission and the ECJ under Articles 81 and 82 EC. The development of an internal market and maintenance of competitive markets are the cornerstones of the Community's competition policy.[124]

The current pattern of application of these particular policies by the Commission and the Court indicates an inconsistency with the goals that the Community has set for the development and competitiveness of the pharmaceutical industry within the common market and the world. In particular, the creation of more favorable circumstances for protection of parallel trade as a legitimate type of trade and competition within the ambit of the internal market and competition rules harm the long run prospects of the Community competition policy and its policy on innovation in pharmaceuticals. Therefore, when interpreting the application of competition rules and rules on free movement one must refer to the broader EC Treaty aims and objectives.[125]

1. Conflict with Competition and Free Movement Policy

The main objective of the Commission's internal market policy is to abolish inter-state barriers to the free movement of goods and restrictions on competition that

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[122] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 12.

[123] The Parliament commenting on the communication took an approach more oriented towards protecting the industrial interests noting that it will eventually lead to consumer benefits. European Parliament A4-0205/99 Resolution on the communication from the Commission on the Single Market in Pharmaceuticals (COM(98)588 – C4-0127/99), OJ 1999 C 279, 1 October 1999, at 79; Commission Communication – A Call for Action, *supra* note 113, at 12.

[124] Commission's XXIXth Report on Competition Policy (1999), points 2-4.

[125] Jones & Sufrin, *supra* note 30, at 244.

have negative effects on trade between Member States. From the Commission's perspective, parallel trade is "a lawful form of trade within the Internal Market based on Article 28 of the EC Treaty and subject to the derogations regarding the protection of human health and life and the protection of industrial and commercial property, provided by article 30 of the EC Treaty."[126] Under Articles 28 and 29 EC, the Member States are precluded from introducing administrative requirements[127] and laws[128] that would undermine parallel imports. To that extent, the Commission has taken certain action with regard to pharmaceuticals[129] and vehicles.[130] Furthermore, case law is well established that prohibits measures that impede parallel imports by partitioning the national markets through reliance on intellectual property rights (IPRs)[131] including patent and trademark rights.[132]

Exhaustion of intellectual property rights is a well-established legal principle[133] created to "eliminate any risk of the use of [IPRs] to establish artificial divisions within the Common market"[134] and any obstacles to the principle of free movement of goods.[135] When questioning the nature of parallel trade as a legal problem,

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[126] Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, *supra* note 1, at 3.

[127] Case 154/85, Commission *v.* Italy, [1987] ECR 2717; Case C-201/94, Smith & Nephew, [1996] ECR I-5819.

[128] Case C-249/88, Commission *v.* Belgium, [1997] ECR I-1275. *See also* Case 181/82, Roussel Laboratoria BV *v.* État néerlandais, [1983] ECR 3849; European Commission, DG Internal Market, Guide to the Concept and Practical application of Articles 28–30 EC, January 2001, at 9.

[129] EUROPA Press Release MEMO/04/7 of 19 January 2004, Commission communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, OJ 1982 C115, 06 May 1982, at 5; Commission brings Member States' attention to the relevant Treaty norms including the grounds for an exemption under Article 30 EC, ECJ judgments and the obligations of the national authorities to preserve the unity of the Community's Internal market. Communication on the compatibility with Article 30 EC of measures taken by Member States relating to price controls and reimbursement of medicinal products, OJ 1986 C310, 4 December 1986.

[130] Commission notice on procedures for the type - approval and registration of vehicles previously registered in another Member State, OJ 1996 C143, 15 May 1996, at 4.

[131] Communication on the compatibility with Article 30 EC of measures taken by Member States relating to price controls and reimbursement of medicinal products, OJ 1986 C310, 4 December 1986, at 21.

[132] These are referred to as "repackaging cases." For a comprehensive discussion of "repackaging cases" *see* P. Koutrakos, *In Search of a Common Vocabulary in Free Movement of Goods: The Example of Repackaging Pharmaceuticals*, 28 ELR, at 53-69 (2003); Hoffman-La Roche, *supra* note 34; Joined Cases C-427/93, C-429/93 and C-436/93, Bristol-Myers Squibb *v.* Paranova, [1996] ECR I-3457.

[133] Cases 56, 58/64, Consten and Grundig *v.* Commission, [1966] ECR 299. The Court expressly underlined the importance of the free movement of goods principle with regard to anti-competitive measures that "might tend to restore the national divisions in trade between MSs." The principle was first established with regard to copyrights by the *C*ase 78/70, Metro, [1971] ECR 487, para. 13. Exhaustion of patent rights was established in Centrafarm *v.* Winthrop, *supra* note 8, paras. 7-11; Exhaustion of trademark rights was established in Case 15/74, Centrafarm *v.* Sterling Drug, [1974] ECR 1183, para. 12.

[134] AG Capotorti Opinion *in* Case 102/77, Hoffman-La Roche *v.* Centrafarm, [1978] 1139, at 1173; Case 24/67, Parke, Davis *v.* Probel, [1968] ECR 55.

[135] Case 187/80, Merck *v.* Stephar, [1981] ECR 2063, para. 13. *See also* Case 19/84, Pharmon BV

one must question the limitations of intellectual property owner's rights over their products. Because exhaustion of intellectual property rights is the basis for parallel trade, it is of no consideration that parallel traders and manufacturers are not faced with the same market pressures for bringing the product into the market in the first place. However, a problem arises when products are put on the market in circumstances that restrict the discretionary power of the IPR owner to set the price of its own product. At the same time, high costs of research and development are incurred before the launch of a new product. Therefore, although there should not be an exemption to the principle of exhaustion of IPR for the pharmaceutical industry, the principle must be still considered in a different light when questioning what the long-term effects are if the manufacturers would not be able to limit such trade with clear intention but as a matter of unilateral actions. As a result, the manufacturers consider it their right to supply only in particular markets, thereby limiting the output and consequent trade in those products throughout the Community. The effects of this business practice are contrary to the goals of an internal market and inter-Community trade. Still, the Commission acknowledges, "differences in intellectual property laws have a direct and negative impact … on the ability of enterprises to treat the Common Market as a single environment for their economic activities."[136]

The Commission's policy in the field of competition is to maintain competitive conditions within the market because only then will customers be offered lower prices, higher quality or better service and only then will the efforts of competitors lead to greater innovation and efficiency.[137] In the context of enforcing competition rules, the Commission views measures aimed at impeding parallel trade as anti-competitive and in conflict with the goal of the internal market – market integration.[138] It often refers to such measures as anti-competitive and having a similar effect as an export ban[139] or as aiming at partitioning the national markets through discriminatory pricing[140] or distribution,[141] thereby depriving consumers of benefits such as low prices and greater availability of substitutes.

In order to achieve greater competition within the industry and greater availability of cheaper substitutes for consumers in states of import, or even

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v. Hoechst AG, [1985] ECR 2281; Case C-267/95, Merck *v.* Primercrown, [1996] ECR I-6285; Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 91.

[136] Completing the Internal Market: White Paper from the Commission to the European Council, COM(85)310 final in T. Hays, Parallel Importation under European Union 19 (2004).

[137] EUROPA Press Release SPEECH/01/450 of 11 October 2001, Speech by Commissioner Mario Monti European Commissioner for Competition Policy Competition and Consumer: the case of Pharmaceutical Products.

[138] EUROPA Press Release M. Monti, Member of the European Commission in charge of competition policy, EC Antitrust policy in the Pharmaceutical sector, 26 March 2001, at 9.

[139] Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, paras. 77-84; Decision of 10 January 1996 relating to a proceeding under Article 85 of the EC Treaty, Case IV/34.279/F3 – Adalat, paras. 155-159.

[140] Case 30/78, Distillers *v.* Commission, [1980] ECR 2229; Case C-277/87, Sandoz *v.* Commission, [1990] ECR I-45; Case T-41/96, Bayer *v.* Commission, [2000], not yet published.

[141] Case 26/76, Metro I *v.* Commission [1977] ECR 1875, Cases 96/82, IAZ *v.* Commission, [1983] ECR 3369; Case T-43/92, Dunlop *v.* Commission, [1994] ECR II-441.

to achieve price integration across Europe, the Commission tries to substitute government intervention and consequent non-competition on prices with the free movement of goods principle. However, this approach poses certain doubts as to whether it achieves its goals and whether it is reasonable because of the following arguments: (1) parallel trade cannot be considered a competition on merits and therefore is not a desirable competition within the meaning of competition rules; (2) parallel trade does not bring efficiency gains to the market such as lower prices; and (3) the incentive to innovate and the value of a patent is affected by the Community policies.

First, parallel trade as such does not result in greater efficiencies for the intra-brand trade because parallel traders keep most of the price difference. Therefore, the consumer benefits are negligible, and they deprive the industry of substantial profit. In other words, parallel traders use Community principles to free ride[142] on the intellectual property rights and innovative efforts of producers such as GSK.[143] Parallel traders do not have a sense of the pricing of medicinal products and they do not consider the innovation efforts involved in the invention process. They resell the products with only one consideration – that they offer products in states of import at a minimally cheaper price than the products of that state's manufacturer so that their products are more attractive to consumers. Therefore, parallel traders are not scrupulous competitors. Theirs is not a competition on merits, but an artificial one because parallel traders enter into competition only at the post-production level and only after state intervention, in contrast with the manufacturers. Their late entry into the market deprives the respective market players of the main tool for competition – individual price setting. This seemed to be the standing of the Court in *Bayer/Adalat* decision because the Court did not use the words of Commission and did not proclaim parallel trade to be a necessary element that would contribute to development of Internal Market.

Second, even limiting the possibility of having parallel traded products within the Community, the prices in the state of import would not increase nor would cheaper substitutes no longer be available. Usually the market of the state of import, particularly the United Kingdom, already has a strong competition among the producers on price because the expected profits on the market are higher. Furthermore, the Commission itself indicates that parallel traders do not operate dynamically on prices.[144] They do not affect the pricing of pharmaceuticals because the prices are negotiated between the government and the respective pharmaceutical manufacturers, not parallel traders. In addition, parallel trade penetration is not so high that their minor difference in price would cause

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[142] The Court has also recognized the free-riding nature of the parallel traders and noted that the replacement of a trademark aimed at securing commercial advantage for the parallel importer can be legitimately opposed under Article 30 EC. C-436/93, Bristol Myers *v.* Paranova, [1996] ECR I-3457, para. 44.

[143] For analysis on how price discrimination adopted by manufacturers increases the value of patents and thus increases the incentives for future development of new medicines, *see* D. Glynn, *Article 82 and Price Discrimination in Patented Pharmaceuticals: the Economics*, 3 ECLR 134 (2005).

[144] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 4.

manufacturers to reconsider their pricing. Prices of the parallel traded products in the states of import are usually set in response to and are dependent upon the pricing of the original products. This is another factor indicating that parallel trade does not come within the ambit of a welcomed type of competition as indicated by the *Bayer/Adalat* decision.

Furthermore, the promotion of parallel trade as a means to foster price integration in the Common market in pharmaceuticals is not compatible with the principle of subsidiarity.[145] Because the national laws regulate the trade in pharmaceuticals in accordance with Article 30 EC, the internal market is indeed partitioned by national regulations.[146] In the *Bayer/Adalat* case, the Court recognized the claims of the industry that in the absence of harmonized national regulations, the Commission cannot use parallel trade to achieve price integration for pharmaceuticals.[147] Until price regulation is in the sole responsibility of national authorities, the Commission's approach to extend the prohibition of unilateral private measures that impede parallel trade within the ambit of competition and free movement of goods rules would amount to intervention in the terms on which the relevant state and the industry had agreed upon. Excessive protection of parallel trade would impose fiscal and industrial policies adopted based on individual concerns of one Member State on another.

The Commission[148] and many other scholarly writers[149] argue that encouraging and protecting parallel trade would cause the prices of pharmaceuticals to achieve an average price throughout the Europe in the long term. While price changes have been reported, such changes have the following pattern: the prices start high due to the high costs of production and then decrease when the relevant patent has ended.[150] Furthermore, in its latest Communication, the Commission has stated that price differentials will increase even further because of the 2004 enlargement of the European Union.[151]

Third, it is not acceptable that the incentive to innovate and the value of the patent are negatively affected by the application of Community policies when the goal of the policies is to respect the involved interest groups in balance by finding a solution for the regulation of the industry. First, the reward for a patent differs among the Member States depending on their health policy priorities. Therefore, the producers of patented products are forced to offset the limited revenues accrued in low-priced states, such as Greece or Spain, against the benefits in

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[145] EUROPA Press Release IP/98/1038 of 25 November 1998, The Commission agrees a Communication on the Single Market in pharmaceuticals.

[146] Hays, *supra* note 136, at 389.

[147] Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 88.

[148] Communication on the Single Market in Pharmaceuticals, *supra* note 83, at 4, Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, paras. 182-186; Bayer/Adalat, *supra* note 9, at 181.

[149] *See* scholarly writings supporting the decrease in prices: M. Ganslandt & K. Maskus, *Parallel Imports of Pharmaceutical Products in the European Union* (2001), at http://swopec.hhs.se; Y. Chen & K. Maskus, *Vertical Price Control and Parallel Imports – Theory and Evidence* (2000), at http://wdsbeta.worldbank.org.

[150] Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 41.

[151] Commission Communication – A Call for Action, *supra* note 113.

high-priced states, such as the United Kingdom and Germany, that promote more research and development based pharmaceutical industry. Second, due to the principle of free movement of goods and the doctrine of exhaustion of intellectual property rights, the terms to which the producer has agreed in one state are altered by the interruption of parallel trade and the manufacturer may no longer rely on the certain revenue base that it had expected when it negotiated a price with the state. Contrary to the claims of the Commission, the current situation cannot be considered a stable and predictable environment to encourage therapeutic innovation.[152] As a result, the combination of Community-wide exhaustion of intellectual property rights and different state price lists decreases the value of the relevant patent and the incentive to innovate.[153] This factual and regulatory situation may indeed lead to the situation discussed by Advocate General Jacobs, namely, that producers are motivated to delay the launch of new products in low-price states where their innovative efforts are not adequately rewarded.[154]

Although free movement is recognized as the driving force for the integration of the common market in pharmaceuticals, the exercise of it must still be carried out in accordance with the other policies of Community, such as its competition policy.

2. Conflict with Competition and Exercise of Intellectual Property Rights

The Community's competition policy aims to make Europe a globally competitive knowledge–based economy "where the competition policy has a key role".[155,156] An essential prerequisite for inducing the process of innovation – the driving force of the industry – is completion of the internal market and maintenance of a competitive environment that ensures optimal allocation of resources.[157]

According to Articles 3(m) and (n) EC, the Community has the exclusive competence and the responsibility to strengthen the competitiveness of the Community industry and to promote research and technological development. Particularly, Article 157 EC requires the Community and the Member States to ensure that the conditions necessary for the competitiveness of the Community's industry exist. Moreover, Article 163(1) EC defines the Community objective of strengthening the scientific and technological bases of Community industry

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[152] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 1.

[153] Implied in the Conclusions of the Frankfurt Round Table on the Competition of the Single Market in Pharmaceuticals of 1997. Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 8.

[154] AG Jacobs, *supra* note 20, para. 91; *See also* Glynn, *supra* note 143. Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 8; Cambridge Pharma Consultancy: Delays in Market Access, December 2002 in COM(2003)383, at 13.

[155] Commission's XXVth Report on Competition Policy, 1996, point 15l.

[156] Commission Communication, Productivity: The Key to Competitiveness of European Economies and Enterprises, COM(2002) 262 final of 21 May 2002.

[157] Commission Communication, Industrial Policy in an Open and Competitive Environment: Guidelines for a Community Approach, COM(90)556 of 16 October 1990.

and encouraging it to become more competitive at an international level. The Community institutions have therefore a number of legal bases and factors to consider creating a balanced industrial policy for the pharmaceutical sector.

The characteristics of the pharmaceutical industry are so unique in their regulatory structure and sensitive for the entire European population that it is essential to ensure the best combination of the requirements and regulations to which the industry is subjected.[158] The aims and means of the industrial policy for the pharmaceutical sector have been set forth by various Community initiatives, but each initiative assessed the interests of a different interest group.[159] This shows the difficulty of the Commission in creating an industrial policy that would satisfy the interests of all economic players and the institutions themselves. For example, Parliament refused the 1993 Commission's proposal for development of the industry stating that it was lacking any consideration of basic aspects of a balanced policy.[160] On the Commission's 'Communication on the Single Market in Pharmaceuticals', the Parliament commented that a realistic industrial policy for the pharmaceutical sector must be based on the following principles: "encouraging innovation through a competitive market and an appropriate regulatory framework […] and focusing EU measures to promote research and innovation"; and that "this Single Market must take into consideration all legitimate interests."[161] It can be inferred from the communications among the institutions that there are two ends that the Community aims to achieve, namely, the protection of the economic interests of the consumers and the competitiveness of the European pharmaceutical industry in the world market; in other words, greater innovation and catching up to United States.

Almost 15 years after the first Commission communication on the subject[162] a vast harmonization has been done[163] in order to ease the trade of pharmaceuticals within the European Economic Area (EEA) market and make them more safe and available for the consumers. However, the Community has failed to fulfill its goals due to the cumulative effect of two factors. First, Member State intervention in price competition still does not allow the European industry to

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158 *Id*.

159 Commission communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted, OJ 1982 C 115 of 6 May 1982; Commission Communication on the outlines of an industrial policy for the pharmaceutical sector in the European Community, *supra* note 98; Communication on the Single Market in Pharmaceuticals, *supra* note 82; Commission – A Call for Action, *supra* note 113; Commission Communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, *supra* note 1.

160 Resolution on the communication from the Commission to the Council and the European Parliament on the outlines of an industrial policy for the pharmaceutical sector in the European Community, *supra* note 38.

161 European Parliament resolution on the communication from the Commission on the Single Market in Pharmaceuticals, OJ 1999 C 279, 1 October 1999, at 79.

162 Commission communication on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted, OJ 1982 C115, 06 May 1982.

163 Commission of the European Communities, *Review of Pharmaceutical Legislation,* at http://europa.eu.int.

grow with the swiftness of its United States-based counterpart because the market is not competitive enough. Second, with the level of harmonization achieved in marketing and selling the pharmaceuticals and parallel traders' licensing, unlimited parallel trade poses an even greater financial burden. Neither of these elements are present in the United States market and they certainly have an effect on the development of the industry. Consequently, the exercise of intellectual property rights becomes more burdensome.

First, a healthy competition is necessary to boost the development of the industry and make it more competitive for the benefit of consumers. Articles 152 and 153 EC provide for a high level of human health protection and include a specific reference for the protection of the economic interests of consumers. This clause is interpreted as requiring the availability of medicinal products for a reasonable price.[164] The protection of the economic interests of consumers can be best achieved both in short and long term only by strong and open competition within the industry.

The Parliament indicates that governments considering the introduction of cost containment measures[165] must make sure that those measures ensure the overall improvement of public health.[166] The overall improvement represents foremost the developments in the field of innovation and greater competition among the producers in the Europe. Therefore, the positive attitude of governments towards the parallel traded goods and the measures that they have introduced to foster the parallel trade must be considered with caution. Moreover, considering the uniqueness of the industry, the long-term benefits must be strongly considered when measuring the benefits for the consumers.

Second, the parallel traders argue that they provide consumers with the only competition for the products in the states of import. This argument is misleading because parallel trade is not the kind of competition within the industry that the EC Treaty promotes. Such competition must come from inside the industry, that is, from the members of the industry that are involved in the invention and creation of the products and are likely to achieve greater level of efficiency. Parallel traders are considered external players because they are not concerned with the process of creating the product and therefore do not pay attention to the pricing of the repackaged product. Parallel trade medicines do force lower prices for domestic equivalents and bring short-term benefits to the consumers and the national health services, but they have a harmful effect on the social welfare in general and result in the "steady decrease of Europe's contribution to global pharmaceutical R&D investment"[167] in the long-term.[168] If the patented product with a relatively

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[164] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 1-2.

[165] Charles River Associates, Innovation in the pharmaceutical sector. A study undertaken for the European Commission, 8 November 2004, at 84-85.

[166] European Parliament resolution on industrial policy for pharmaceutical sector, *supra* note 38.

[167] EUROPA Press Release IP/98/1038 of 25 November 1998, The Commission agrees a Communication on the Single Market in pharmaceuticals.

[168] The results of a lack of spending on R&D in long-term. Charles River Associates, *supra* note 164, at iv.

low value in low-priced state[169] undermines the realization of revenues for the same product in a high-priced state, manufacturers are well motivated[170] to remove that product from the low-priced markets[171] or to delay pursuing market authorization.[172] Consequently, parallel trade cannot be considered as a means for achieving healthy and necessary price competition against manufacturers in high-priced states.

The two goals of the industrial policy in pharmaceuticals as set by the Community institutions are really at odds if the government intervention of price-setting continues as a structural particularity of the sector. The Commission has addressed the issue and does agree with the industry that in order to create a competitive environment, Member State intervention must be decreased.[173] Therefore, the Commission's Action Plan has launched a reflection period to find alternatives for managing the expenditures of national health systems.[174] The main goal is to open the competition on prices as for any other product on the market while at the same time respecting the Treaty.

Another element to be addressed is the Commission's attitude about the use of intellectual property rights as stated in its working and policy papers. The creation and exercise of intellectual property rights is becoming burdensome for several reasons.[175] First, the ECJ's elaborated doctrine of exhaustion of IPRs. Second, the constant reduction in the useful life of pharmaceutical patents because of increasing delays in obtaining mandatory marketing approvals[176] and faster introduction of generic products.[177] Third, the costs and risks associated with the development of new medicinal drugs have increased:[178] (i) research and development costs have risen significantly in recent years; (ii) the development time for new drugs has increased; and, (iii) average returns on successful products have diminished.

The producers receive protection for their IPRs as a reward for being innovative. Returning to the parallel traders' argument that they provide consumers with the only competition for patented products, one must look back at the general intent of granting a patent right. A patent is a legitimate protection from competition of new entrants and it is the only means for pharmaceutical manufacturers to receive

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169 GSK Spain submits that the Spanish prices are artificially low. Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 55.

170 AG Jacobs, *supra* note 20, para. 93-95; Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, para. 83.

171 Case C-249/88, Commission *v.* Kingdom of Belgium, [1991] ECR I-01275, paras. 16-20.

172 Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 8.

173 The first attempt of the Commission was highly criticized by the Parliament, which said that the Commission has lost the connection with the reality because the Member State systems will stay in place for the foreseeable future. European Parliament resolution on industrial policy for the pharmaceutical sector, *supra* note 38, at 48.

174 Commission Communication – A Call for Action, *supra* note 113.

175 EFPIA, *supra* note 50.

176 Commission Communication – A Call for Action, *supra* note 113, at 13, 14. Cambridge Pharma Consultancy: Delays in Market Access, December 2002.

177 Communication on the Single Market in Pharmaceuticals, *supra* note 82.

178 Charles River Associates, *supra* note 165, at 68-76.

a reward for their creative effort.[179] A characteristic feature of the pharmaceutical sector is that it is an industry based in research and development.[180] Currently €21 billion or 15% of all research and development investment in Europe comes from the pharmaceuticals sector.[181] The innovation process involves considerable long-term financial inputs and takes many years. According to the Association of the British Pharmaceutical Industry,[182] the UK-based pharmaceutical industry spends more than £7 million a day in the research for new medicines. The length of a product discovery process usually takes 8-12 years with costs in range of $350-650 millions;[183] therefore, investment in research and development is a long-term policy for every producer. Often, research and development efforts do not even result in an actual drug innovation.[184] Therefore, constant fund-raising is obligatory if a manufacturer is to stay in the market. Because the manufacturers' ability to set adequate prices is limited, they are forced to offset the losses in one market with profits in another in order to keep the overall level of research and development spending sufficient to respond to the market forces. Patent protection is the only means for guaranteeing continuous financial means for innovation and for resistance of the competition.[185] The statistics show that, for example, in the United States in 2000, the cost of bringing a new product into the market was $800 million, which was almost 3.5 times higher than in 1987.[186] Research and development spending in the United States grew at twice the rate of that of the

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[179] The patent right is a reward for creative effort that grants an exclusive right to exclude others from making, using, and selling the product. The EC Treaty does not affect the existence of intellectual property rights granted by the Member States and provides a general exception to free movement principle under Article 30. However, the exercise of those rights is subject to Article 28 EC. P. Craig & G. de Burca, EU Law. Text, Cases and Materials 1091 (2003).

[180] In 1996, the top 10 pharmaceutical firms such as Merck & Co, Roche, and Novartis spent around $1500 millions on R&D. Glaxo-Wellcome, before its merger with SmithKline Beecham, in 2000 alone spent nearly $2000 million on research and development. Communication on the Single Market in Pharmaceuticals, *supra* note 82.

[181] The European Round Table of Industrialists (Ed.)*, Future European Research Policy: The ERT View* (2005), at http://www.ert.be.

[182] The Association of the British Pharmaceutical Industry, *Parallel Trade in Medicines,* at http://www.abpi.org.uk.

[183] According to a 1994 study of drugs that were introduced between 1980 and 1984, for every ten drugs that came to market, only three covered the average development costs. It takes approximately 15 years to develop a new drug today [2002], whereas it took 8.1 years in 1960, 11.6 years in 1970 and 14.2 years in 1980 and 1990. G. J. Glover, *Competition in the Pharmaceutical Marketplace*, presentation to the United States Department of Justice/Federal Trade Commission hearings on intellectual property and antitrust law, 19 March 2002, at http://www.ftc.gov; A. Gambardella, L. Orsenigo & F. Pammolli, *Global Competitiveness in Pharmaceuticals – A European Perspective, Report prepared for the Enterprise Directorate-General of the European Commission* 38 (2000), at http://europa.eu.int.

[184] European Parliament resolution on industrial policy for pharmaceutical sector, *supra* note 38.

[185] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 6.

[186] J. DiMasi, *Price Trends for Prescription: Pharmaceuticals: 1995-1999, Department of Health and Human Services Conference on Pharmaceutical Pricing Practices, Utilization and Costs* (2000), at http://aspe.hhs.gov.

European Union during the 1990s.[187] In order to compete with the United States pharmaceutical manufacturers, spending on research and development must be appropriately encouraged in Europe[188] or research bases may move to the United States.[189] [190] To that end, the Commission has set forth some goals for research and innovation by decreasing the contribution level that is to come from the industry itself to two-thirds from 90%.[191]

Furthermore, the producer's patent protection lasts for only a limited time after which the product is available for public use and for the generics to take over the market. The Commission continuously encourages increased use of generic medicines because that would bring significant savings to the states.[192] The Parliament has indicated, "companies should be authorized to begin, in advance of the expiry of the patent or supplementary protection certificate, […] so that such products may be made available on the market as soon as the legal protection expires."[193] The result is that even Member States that have not traditionally encouraged generics have started to promote them.[194]

It is also estimated that for United Kingdom-based pharmaceutical manufacturers, parallel trade caused a loss of expected profit of more than £770 million in 1997.[195] It is estimated that 90% of United Kingdom pharmacists source products through parallel trade.[196] For example, in the *Bayer/Adalat* case, it was submitted that more than 50% of United Kingdom sales of Adalat were from parallel trade imports.[197] Considering that approximately 20% - 30% of the lost sales revenue would have been devoted to research and development, the industry is losing at least one major project a year.[198]

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[187] Commission Communication – A Call for Action, *supra* note 113, at 5; Charles River Associates, *supra* note 165, at 60, 79-80.

[188] In 1990, the global research-based pharmaceutical industry still invested roughly 50% more in Europe than in the United States. Since then, research and development investment in the United States has risen fourfold while in Europe it only grew 2.6 times. Today, the global industry is investing 40% more money in research and development in the United States than in Europe. The European Round Table of Industrialists, *supra* note 181.

[189] Large foreign firms including the biggest in the European Union, e.g., Novartis and GSK, have begun locating their research activities in the United States. K. Hassett, *Pharmaceutical Price Controls in OECD Countries* (2004), at http://www.aei.org. *See* on pharmaceutical industry and prospects for R&D in US *in* P. Danzon, The Pharmaceutical Industry 5880-5887 (1999).

[190] Communication on the Single Market in Pharmaceuticals, *supra* note 82, at 3.

[191] 90% of research and development spending was financed by the industry itself in 1994. Commission Communication on the outlines of an industrial policy for the pharmaceutical sector in the European Community, *supra* note 98, at 5.

[192] Commission Communication – A Call for Action, *supra* note 113, at 16.

[193] European Parliament resolution on industrial policy for pharmaceutical sector, *supra* note 38.

[194] Charles River Associates, *supra* note 165, at 85-87.

[195] Charles River Associates, *supra* note 165, at 10, 30; S. Szymanski, *UK industry is the Loser from Parallel Trade in Pharmaceuticals* (2004), at http://www.esrc.ac.uk.

[196] J. Arfwedson, *Re-importation (Parallel Trade) in Pharmaceuticals, Institute for Policy Innovation* (2004), at http://www.ipi.org.

[197] Bayer/Adalat, *supra* note 9, para. 176.

[198] It has been concluded by the Commission in its decision on GSK Spain, para. 160 that the losses could not be over estimated and that it could be lost only one project.

Although recognizing the link between current revenues, the research and development spending, and the effect on future innovation; the Commission has refused the argument that manufacturers in low-priced Member States would incur any losses or that they would therefore cut back on research and development spending.[199] The industry does not refute that and, in fact, it cannot afford to cut back on research and development. However, the prices are still artificial and are rising even in the low-priced Member States.[200]

The conclusion still remains that the industry needs both national and Community measures acting as catalysts for industrial competitiveness and incentives to innovate in future.[201] Results of the United States pharmaceutical industry in terms of research and development spending and registration of new medicinal products may always be considered as the goal to reach. Still, the main lesson is that by increasing the returns of innovation, the European Union may be able to compete with the United States. Moreover, the first step in that direction would be finding an alternative to national cost containment measures. To do this, the current situation where the pharmaceutical manufacturers have the double burden of responsibility for the national and Community-wide welfare as well as innovation but parallel traders enjoy a free ride under the auspices of the principle of free movement of goods must be changed.

3. Learning from the United States Approach

When considering a possible solution for the dispute in European Union and because both parties in the *GSK Greece* case refer to the United States' experience in different aspects, it is informative to look into the United States' regulatory context and their experience with parallel trade.

Because there are no government price-control systems and the governments rely on the market for the development of the pharmaceutical sector,[202] the prices in the United States are considerably higher than in European Union. As a result, there is great pressure upon the legislature, especially on the issue of re/importation of medicines that has been allowed only to manufacturers. Recently, the Food and Drug Administration (FDA) was asked to reconsider the system and grant rights of importation or re-importation of FDA-approved prescription drugs from foreign countries to individuals, pharmacists, and wholesalers.[203] The main concerns that arose if the scope of importers were to be extended were the impact of the imported products on the industry, how any savings that such

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[199] Commission Decision of 8 May 2001 on GSK Spain, *supra* note 7, paras. 155-169.

[200] *Id*., para. 41, 42.

[201] Commission Communication, Industrial Policy in an Open and Competitive Environment Guidelines for a Community Approach, *supra* note 157.

[202] For more information on the United States pharmaceuticals market structure, *see* Organization for Economic Co-operation and Development, Directorate for Financial, Fiscal and Enterprise Affairs, Committee on Competition Law and Policy, *Competition and Regulation Issues in the Pharmaceutical Industry*, 06 February 2001, at 307-326.

[203] K. Mulligan, *Drug Re-importation Bill Wins House Vote*, 38 (16) Psychiatric News, at 6 (2003), at http://pn.psychiatryonline.org.

imports create would be shared, and how the protection of the consumer would be ensured. [204]

Importation does result in consumer savings, especially for those not covered by insurance, but at the same time, the FDA raised concerns over safety issues that cannot be appropriately safeguarded.[205] Because the main concern raised by unlimited imports is the safety of consumers, all medicines to be allowed for import must be approved according to a New Drug Application by the FDA. However, the estimated volume of drugs to be imported is so great that there are no appropriate mechanisms for keeping an accurate count.[206] For example, importation of medicinal products from Canada via the Internet by customers themselves has increased dramatically in recent years, bringing vast evidence of consumer risks. Furthermore, the actual beneficiaries of simpler importation must be considered. The 2000 policy initiative on importation indicated that such "imports apart from meeting safety requirements must also result in savings to US customers" in order to be at all welcome. [207]

It is beyond question that the United States takes the lead for research and development spending and the launching of new products and is therefore attracting more businesses than the European Union. At least part of the success of United States' pharmaceutical industry must be attributed to the absence of parallel trade. The supporters of parallel trade have argued that if parallel trade could be legitimately restricted, the consumer would not be protected from the high prices of medicinal products, as they are not protected in the United States. However, the industry has a tendency to become more expensive even with fierce competition present. Furthermore, the level of competition and the rise in the market share of non-prescription products in the European Union does not indicate consumer abuse through excessive pricing.[208]

As described more fully above, the curtailing of parallel trade is in the interests of the industry in every market because the introduction of parallel trade brings the same issues into play. United States-based manufacturers have taken similar actions to reduce imports from Canada as those taken by the manufacturers in the European Union, including refusal to supply by quota systems.[209] This is raising new issues of their compliance with United States' antitrust laws and their exercise of intellectual property rights. For example, there are already corporate and consumer class actions against manufacturers that limit supplies to Canada in order to decrease the products available for import back to United States customers.[210]

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[204] A. Wearing *et al.*, *Parallel Trade in the EU and US Pharmaceutical Markets*, Life Sciences 2004/05, at http://www.arnoldporter.com.

[205] Hom. Ron Paul of Texas in the House of Representatives, *Re-importation of Prescription Drugs* (2003), at: http://www.house.gov/paul/congrec/congrec2003/cr072403.htm.

[206] Espicom Business Intelligence Ltd., *US Drug Re-importation: Prospects & Opportunities,* at 126 (2005), at http://www.espicom.com.

[207] Wearing *et al.*, *supra* note 204.

[208] Commission Communication on the Single Market in Pharmaceuticals, *supra* note 82, Annex 11.

[209] Arfwedson, *supra* note 65, at 25-26.

[210] Wearing *et al*., *supra* note 204.

Although it would seem that the United States is fully enjoying its competitive victory in the world market, internally it does have some issues with product affordability. At the same time, the European Union-based pharmaceutical industry might be even a step ahead in dealing with parallel import cases. Furthermore, a common concern for both the United States' and European Union's health care systems and authorities charged with ensuring consumer safety is the growing use of electronic commerce.[211]

III. Need for a Balance

The main conflict within the policy of a single market in pharmaceuticals seems to arise when attempting to achieve the goal of availability of innovative and affordable products while preserving Member States' intervention on price setting. Despite the wide Community action in harmonizing and easing the functioning of the sector, the available facts do not show a considerable inflow of investments or increase of competitiveness within the market. On the contrary, some firms have moved their headquarters to the United States, the major competitor to the European Union. Furthermore, the issue of parallel trade must be addressed to resolve its free-riding effect on the industry.

The role of parallel trade in Commission's working papers is somehow twofold. Both the Commission and the representatives of parallel trade state: first, parallel trade has a considerable effect on the pricing of pharmaceuticals in states of import; and, second, it avails the consumers of cheaper substitutes. At the same time, there is enough evidence that, in practice, parallel trade does not result in higher competition as it could in theory. Consequently, there are certain side effects that create discussion when applying Community competition rules and rules on free movement of goods.

The enforcement of competition and free movement of goods rules must be in balance with the national measures and policies adopted in compliance with the EC Treaty. Therefore, state intervention must be considered as a factor showing that markets are already partitioned and that manufacturers' actions limiting their export output are a legitimate aim according to a national legal framework.

The aims of competition policy are to preserve the level of competition to bring about greater efficiency and lower prices reflecting optimal allocation of resources.[212] This is the goal that the presence of parallel traded products would need to achieve in the states of import in order to be considered as a desirable competition. However, parallel traders do not act as true competitors and therefore bring only inefficiencies to the market. Therefore, where Articles 81 and 82 EC come in question, strong consideration must be given to a proportionality test assessing the possible effect of manufacturer's actions on a particular competitor

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[211] The European Commission has addressed the importance of electronic commerce as a means of cutting state expenditures on pharmaceuticals. It is a part of the action to cut pharmacy service costs that currently amount to 25% of the final cost of a pharmaceutical. The Commission acknowledges both the security issues and advertising that is prohibited under European Union law. Commission Communication on the Single Market in Pharmaceuticals, *supra* note 82.

[212] Commission's XXVth Report on Competition Policy (1996), point 15.

and other benefits that the actions would bring to the market and consumers in the long term. The Commission's statement that "a non-balanced application of Community acts to highly restrictive businesses at national levels may not result in a growth in competition" requires strong consideration over other aims the pharmaceutical sector has to achieve.[213]

The conflict with the principle of free movement of goods is rooted in the discussion over the intellectual property rights and the limits of their exercise as an exception to that principle. The attempts of finding a balance between the competing goals have been almost entirely judicial[214] – a confusing way to link the needs of market integration with the reach of IPRs.[215] Still, manufacturers' unilateral measures restricting their output to national markets are in compliance with the territorial nature of intellectual property rights.

As state intervention in pricing will continue to exist in the near future (with possible amendments as a result of closer Member State cooperation within the ambit of Directive), more cases like that of GSK will arise before national authorities. By raising the question of objective justification, the GCC seems to have adopted the approach in favor of the industry representatives, but the wholesalers will always question such standing before EU institutions.

E. Conclusion

The Commission has addressed the issues of parallel trade for more than forty years; nevertheless, the Courts have yet to address every question raised by parallel trade. As the internal market develops, new questions keep emerging and old answers need further clarification.

The Commission has adopted a comprehensive basis for the single market, has issued guidelines on industrial policy for the pharmaceutical sector, and strongly enforces the principle of free movement of goods and competition rules to encourage and protect inter-Community trade by condemning measures aimed at partitioning the national markets.

The Commission's competition and free-movement policies are applied hand-in-hand to protect parallel trade as a form of trade that develops intra-brand trade and brings efficiencies such as low prices and substitutes to consumers around the Europe. Following the *Consten & Grundig* case,[216] the Commission and the Courts have condemned measures taken by suppliers to mitigate the effects of the exhaustion of IPRs and differences in prices by impeding parallel trade in their products through contractual clauses or refusal to supply.

The Commission's traditional approach against the measures adopted by non-dominant pharmaceutical companies with the aim of impeding parallel trade was dismissed by the final decision in *Bayer/Adalat*. The ECJ recognized the legitimate

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[213] Commission Communication, Industrial Policy in an Open and Competitive Environment: Guidelines for a Community Approach, *supra* note 157.
[214] Hays, *supra* note 136, at 18.
[215] *Id*., at 387.
[216] Consten and Grundig, *supra* note 133.

right of pharmaceutical companies faced with actions harmful to their interests to restrict parallel trade on the condition that those measures comply with the rules of competition. The Court also provided a new interpretation on the extent to which free movement and competition rules as enforced by the Commission can influence Member State public policy in determining their national health system. The ECJ once again refused to accept the Commission's attempts to create a single market in pharmaceuticals by enforcing competition and free movement rules instead of using means available under the EC Treaty as indicated by the *Centrafarm v. Winthrop* case.

This has led to discussion of reconsidering the approach to Article 82 EC cases as initiated by Advocate General Jacobs, but only regarding the pharmaceutical sector. It has been argued that refusal to supply excessive orders is a normal business practice of a pharmaceutical manufacturer that is competing Community-wide and whose products are subject to parallel trade due to state intervention. Refusal to supply excessive orders is a legitimate measure because the behavior is in compliance with the national and Community legal acts that impose supply obligation only for the national demand and because it does not result in elimination of efficient competition or prejudice to consumers. Furthermore, it is also proportional to the threat posed by parallel traders.

As a rule, in parallel trade cases Community institutions consider the needs of market integration to be predominant over the needs of intellectual property owners. However, "EC Competition policy does not exist in vacuum: it is an expression of the values and aims of society."[217] Under the EC Treaty, competition rules must be applied having the prerogative of effective competition and consumer welfare in the light of the Community's other policies, such as its industrial policy, taking into consideration both short and long-term perspectives.

There is a clear indication from the ECJ in the *Bayer/Adalat* case that the Commission's reasoning that the parallel trade is claimed as a legitimate means for the integration of the pharmaceutical markets no longer withstands critique because parallel trade in pharmaceuticals does not bring the efficiency gains to the market that normally result from trade. As the necessary competition envisioned for boosting the competitiveness of the industry does not correspond to the type of competition provided by parallel trade, it cannot be considered a desirable market influence. The minimal benefits that it brings to consumers do not outweigh the damage it creates to the industry and the long-term Community welfare because the loss of expected income is a loss to the industry and has a negative effect on the innovative activity and attractiveness of the sector as a target for investments. Therefore, considering the specific characteristics of the pharmaceutical industry, parallel trade in prescription medicines is socially undesirable.

In addition, the increased level of parallel trade decreases the value of patents and hence the prospects for innovative activity in future. It is not necessarily true that pharmaceutical companies must be shielded from the free-movement-of-goods principle in order to balance out the negative effects of the restrictive Member state regulations and parallel trade on their capacity to innovate. However,

[217] Wish, *supra* note 37, at 17.

the long-term objectives and defined priorities must be agreed upon between the industry and the national and Community authorities and a more liberal attitude towards unilateral measures combating parallel trade must be taken to change the oppressive effect that regulated prices have on research and development incentives.

Because Member State intervention will not be terminated in the near future and further harmonization is expected, the prospects for parallel trade will increase. The current pattern of case inflow before the ECJ shows that more and more cases will be brought to the attention of national competition authorities that will require interpretation of Articles 81 and 82 EC. In line with the *Bayer/ Adalat* case and Advocate General Jacobs' Opinion, it is therefore the right time for considering not only the legal but also the moral aspects of parallel trade in pharmaceuticals and its effects on the industry.