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**Abuse of a Dominant Position by
Pharmaceutical Undertakings in EC
Law**

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Summary

In June 2005 the Commission imposed a €60 million fine on AstraZeneca for abusing its dominant position. This was followed in December 2005 by the Discussion Paper on the application of Article 82 EC, issued by the Directorate-General for Competition of the European Commission. This thesis discusses the interpretation of Article 82 EC and does this from the perspective of pharmaceutical undertakings.

The second chapter presents an overview of the pharmaceutical industry and its characteristics that make it unique – prices regulated by national authorities, very high R&D costs and reliance on patents, patients' low price elasticity and the public service obligations of pharmaceutical undertakings.

The third chapter analyzes the aim of Article 82 EC, the concept of an undertaking and the market definition in Article 82 EC cases. The analysis refers to problems that emerge when applying EC competition rules on the abuse of dominance to pharmaceutical undertakings. The chapter thereafter concentrates on the concept of dominance and concludes that it is crucial that the Commission's assessment regarding the relevant market and dominance would take into account all the relevant facts and apply the "rule of reason".

The fourth chapter deals with abuse of dominance and lays down principles set forth in the Discussion Paper. Thereafter the author presents the facts of the *AstraZeneca* case and his assessment to the Commission's interpretation of Article 82 EC in that particular case.

The author concludes that pharmaceutical undertakings must be able to protect their legitimate business interests. Conduct that is objectively justified must not be caught by Article 82 EC. The Commission understates the importance of R&D and buyer power in the pharmaceutical industry. The Commission's favourism on parallel trade and generic drugs in Article 82 EC cases is not economically rational and would not in the long run (due

to likely smaller investments in R&D and uncertainties for pharmaceutical undertakings) benefit neither generic producers nor consumers. The conduct of AZ was legitimate and objectively justified.

Abbreviations

AG	Advocate General
AZ	AstraZeneca
CFI	Court of First Instance
Decision	Commission Decision from the 15th of April 2005 Relating to a Proceeding Under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 AstraZeneca)
Discussion Paper	DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses
EC	European Community
ECJ	European Court of Justice
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
FEFIN	Federación Española de Empresas de Tecnología Sanitaria
FN	Footnote
GSK	GlaxoSmithKline
H2 blocker	Histamine receptor antagonist
MUPS	Multiple unit pellet system
Notice	Commission Notice on the Definition of the Relevant Market for the Purposes of Community

	Competition Law
PPI	Proton pump inhibitor
R&D	Research and development
SPC	Supplementary protection certificate
Treaty	Treaty Establishing the European Community

1 Introduction

1.1 Objective

The purpose of this research has been to present an overview of the concept of an abuse of a dominant position from the perspective of pharmaceutical undertakings.

This subject is pertinent for three reasons:

1. In December 2005 the Directorate-General for Competition of the European Commission issued a discussion paper on the application of Article 82 EC.¹ The Discussion Paper sets forth an interpretation of Article 82 of the Treaty² which is not legally binding, but must be taken into consideration by the pharmaceutical undertakings, since it is likely that the Commission shall apply methods set forth therein.
2. The recent opinion of AG Jacobs in *Syfait*³ presents an interpretation of Article 82 EC that is specific to the pharmaceutical industry. This interpretation, if upheld by the ECJ in the future, would signify that in applying Article 82 EC to pharmaceutical undertakings, normal rules apply to them only to a limited extent.
3. In June 2005 the Commission imposed a €60 million fine on AstraZeneca for abusing its dominant position by misusing national

¹ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses." Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 11th of April 2006.

² Consolidated Version of the Treaty Establishing the European Community, ([2002] OJ C 325/33).

³ Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AVEE*, opinion of AG Jacobs delivered on the 28th of October 2004, [2005] ECR-I 4609.

patent systems and national procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug “Losec”. The version of this Decision as proposed by the addressees of the Decision was very recently made available for the public.⁴ AZ has appealed the Decision to the CFI.⁵

It is consequently more important than ever to analyze what are the limits of applying Article 82 EC to pharmaceutical undertakings and whether (or how) the pharmaceutical undertakings can defend their business interests.

The objective is therefore to present the situation, point out problems and provide possible solutions for the future using the *AstraZeneca* case as an example. In order to achieve this goal, the possible application of Article 82 EC is analyzed in light of the characteristics of the pharmaceutical industry, taking into account the Discussion Paper, decisions of the Commission, case-law of the ECJ and the CFI and arguments put forth by the pharmaceutical industry.

1.2 Method and Material

The method of the research was to analyze legal acts and case-law relevant for the application of Article 82 EC and to present legal reasoning as to how the said acts and case-law should in the opinion of the author be interpreted in relation to possible problems that have already arisen and could arise for pharmaceutical undertakings.

⁴ See Commission Decision from the 15th of April 2005 Relating to a Proceeding Under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 *AstraZeneca*). Available at http://ec.europa.eu/comm/competition/antitrust/cases/decisions/37507/prov_version.pdf. Visited on the 13th of May 2006.

⁵ See notification of action brought by Astra Zeneca on the 25th of August 2005 — *AstraZeneca/Commission* in case T-321/05, ([2005] OJ C 271/24).

The background information was acquired, using relevant literature, various articles from journals and internet resources. Of significant importance was the paper published by EFPIA on how Article 82 EC can be applied to control sales by pharmaceutical manufactures to wholesalers,⁶ and of course, the Decision.

Legal acts adopted by the European institutions were accessed over the internet but reference was made to the relevant publication in the Official Journal. In referring to Articles in the Treaty, reference was made to the numbering adopted by the Treaty of Amsterdam. Style of reference to articles is based on that used by the ECJ and the CFI.⁷

Case-law of the ECJ and CFI was analyzed using documents available from the internet. However, reference was made to the relevant pages and paragraphs in the European Court Reports.

Decisions and other legal acts of the Commission were similarly accessed over the internet; reference was made either to the Official Journal where the decision was published or to the respective internet site.

1.3 Delimitations

In writing the thesis, I assumed that the audience has background information of the European Union and at least basic knowledge of the EC competition policy and competition rules.

⁶ EFPIA paper “Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?” Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 11th of April 2006.

⁷ See Note on the Citation of Articles of the Treaties in the Publications of the Court of Justice and the Court of First Instance, ([1999] OJ C 246/1).

The principles of competition law and specific meanings of EC competition provisions are analyzed only insofar as they serve to present problems facing the pharmaceutical industry.

Even though the thesis refers to many important issues for the pharmaceutical industry such as parallel trade in pharmaceuticals and generic medicines, these problems are alike described only in such detail that it would enable the average legal professional who has knowledge of EC competition rules, to understand the predicament facing the pharmaceutical industry.

Since the author had no access to the *AstraZeneca* file, analysis is based solely on the text of the Decision and the notice about the appeal by AZ. It is presumed that the facts set forth in the Decision and factual claims by AZ in the notice about appeal are correct. The author disputes the conclusions that the Commission or AZ derives from the facts.⁸

It is inevitable that in analyzing the application of Article 82 EC, and taking into account the span of the thesis, a choice had to be made between different legal problems to be presented. Accordingly, many interesting questions which could have been included in this thesis were either touched upon only in brief or left out.

⁸ See FN 5.

2 Pharmaceutical Industry

2.1 Introduction

This chapter will start with a short description of the pharmaceutical industry. Thereafter various characteristics that are specific to it and particularly to the European pharmaceutical industry are presented. These characteristics will be analyzed in more detail in the following chapters, discussing the possible application of Article 82 EC to pharmaceutical undertakings.

2.2 Pharmaceutical Undertakings

Pharmaceuticals is a large, high-growth, globalised, and innovation intensive industry. Its products – drugs – are directed to satisfy consumer needs in an area – health care –, which is vital for society. Health care and therapeutics are among the most relevant issues in the definition of the concepts of welfare and democracy in the new century. Thus, the pharmaceutical industry is clearly a strategic sector for Europe.⁹

Besides driving medical progress and improving health within Europe and worldwide, the research-based pharmaceutical industry is a key asset to the European economy. The pharmaceutical industry is one of Europe's best performing high-technology sectors.¹⁰ The pharmaceutical industry amounts

⁹ Gambardella, A. *et alia*, Global Competitiveness in Pharmaceuticals, A European Perspective, November 2000. Report prepared for the Enterprise Directorate-General of the European Commission, page 1. Available at http://europa.eu.int/comm/enterprise/library/enterprise-papers/pdf/enterprise_paper_01_2001.pdf. Visited on the 11th of April 2006.

¹⁰ EFPIA paper "The Pharmaceutical Industry in Figures, 2005 update," page 3. Available at http://www.efpia.org/6_publ/infigures2005.pdf. Visited on the 11th of April 2006.

to about 3.5% of the total EU manufacturing value added and about 17% of the total EU business R&D expenditure.¹¹

It is useful to define from the start the concept of “pharmaceutical undertakings” used in this thesis, to clarify which undertakings are included therein, and respectively, which undertakings do not fall within the definition. To this end, I shall turn to EC legislation.

One of the key legal acts to regulate the pharmaceutical industry in the EC is Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use.¹²

Article 1 (2) of the said directive defines a medicinal product as “any substance or combination of substances presented for treating or preventing disease in human beings.” Even though medicinal products are also used for treating or preventing disease in animals,¹³ this thesis shall focus on medicinal products as they are used for human beings.

“Pharmaceutical undertakings” for the purposes of this thesis are thus understood as undertakings that produce, market or sell medicinal products as they are defined in directive 2001/83/EC.¹⁴

¹¹ *Id.*, page 7.

¹² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, ([2001] OJ L 311/67).

¹³ See definition in Article 1 (2) of Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, ([2001] OJ L 311/1).

¹⁴ See FN 12.

2.3 Regulated Prices

One of the most important characteristic of the pharmaceutical industry for applying Article 82 EC is how and to what extent can pharmaceutical undertakings determine prices.

Article 4 (3) of directive 2001/83/EC¹⁵ stipulates that “the provisions of this Directive shall not affect the powers of the Member States’ authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.”

The regulation and prices of pharmaceuticals are subject only to limited harmonization by EC legislation. Under Council Directive 89/105/EEC¹⁶ Member States are obliged to ensure that decisions on pricing and reimbursement are taken transparently and within a precise time frame.

In its 1998 communication on the single market in pharmaceuticals the Commission concluded that the option of adopting a centrally administered European pricing system for medicines was undesirable and at that time impracticable.¹⁷ As a result, Member States have clear competence to take national measures in order to control healthcare expenditures. For the time being, prices – both ex-factory and retail – are widely divergent amongst Member States.¹⁸ Lower price countries typically include Belgium, France,

¹⁵ See FN 12.

¹⁶ See Articles 8 and 10 of Council Directive 89/105/EEC of 21 December 1988 Relating to the Transparency of Measures Regulating the Prices of Medicinal Products for Human Use and their Inclusion in the Scope of National Health Insurance Systems, ([1989] OJ L 40/8).

¹⁷ Commission Communication on the Single Market in Pharmaceuticals, Brussels, 25th of November 1998, COM(98) 588 final, page 11. Available at http://europa.eu.int/comm/enterprise/library/lib-regulation/doc/com-98-588_en.pdf. Visited on the 11th of April 2006.

¹⁸ Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: “A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action,” Brussels, 1st of June 2003, COM(2003) 383 final, page 14. Available at

Italy, Spain and Greece. Higher price countries typically include the United Kingdom, Germany, The Netherlands and Sweden.¹⁹

The launch price of pharmaceutical products is not freely determined, but negotiated with national governments in the EU, which essentially determine the market value of a drug before it is marketed. In the absence of harmonization at the EU level, significant differences in the way that Member States regulate price and reimbursement levels for medicines create opportunities for intra-Community parallel trade. Other issues raised by price regulation include the *ex ante* determination of the social value of the new drug, and the extent to which it can be reflected in its price and the depressing effect regulated prices have on R&D.²⁰

Consequently, the prices for pharmaceutical products are subject to different regulations in different Member States. The pharmaceutical undertakings cannot determine freely the prices of pharmaceutical products. This means that the price of one pharmaceutical product in one Member State could differ largely from the price of the same pharmaceutical product in another Member State. The difference in prices could cause parallel trade *i.e.* third parties from the low priced Member State could import the pharmaceuticals to the high priced Member State to gain profit and to reduce the sales and produce loss to the pharmaceutical undertaking in the high priced Member State.²¹

http://mednet3.who.int/prioritymeds/report/append/22c_apx.pdf. Visited on the 11th of April 2006.

¹⁹ EFPIA paper “The Pharmaceutical Industry in Figures, 2005 update,” FN 2 and 3. Available at http://www.efpia.org/6_publ/infigures2005.pdf. Visited on the 11th of April 2006.

²⁰ *Id.* page 13.

²¹ In joint cases C-2/01 P and C-3/01 P *Commission of the European Communities v. Bayer AG (Adalat)*, [2004] ECR I-23, para. 3 it was stated that: “Because of those price differences, wholesalers in Spain exported Adalat to the United Kingdom from 1989 onwards. French wholesalers followed suit as from 1991. According to Bayer, sales of Adalat by its British subsidiary, Bayer UK, fell by almost half between 1989 and 1993 on

2.4 Reliance on Patents and High R&D Costs

Another important feature of the pharmaceutical industry, when applying Article 82 EC, is the significance of patents and the R&D costs for producing pharmaceuticals.

Pharmaceutical industry has an unusually high rate of R&D, which implies a high rate of technical change, critical importance of patent protection, potential for market power and novel price and product competitive strategies.²²

Pharmaceutical R&D is:

1. Lengthy: By the time a medicinal product is placed on the market, an average of 12-13 years will have elapsed since the synthesis of the new active substance;
2. Costly: The cost of researching and developing a new chemical or biological entity was estimated at €870 million in 2001;
3. Of a high risk nature: On average, out of every 10,000 substances synthesized in laboratories, only one or two will successfully pass all the stages to become marketable medicines.²³

Despite popular misconceptions about the invariable profitability of pharmaceutical companies, most marketed drugs fail to cover their R&D costs. According to a 1994 study of drugs introduced between 1980 and

account of the parallel imports, entailing a loss in turnover of DEM 230 million for the British subsidiary, representing a loss of revenue to Bayer of DEM 100 million.“

²² Danzon, P. M., *The Pharmaceutical Industry*, The Wharton School – University of Pennsylvania, 1999, page 1055. Available at <http://hc.wharton.upenn.edu/danzon/PDF%20FILES/5880book.pdf>. Visited on the 12th of April 2006.

²³ EFPIA paper “The Pharmaceutical Industry in Figures. 2005 update,” page 18. Available at http://www.efpia.org/6_publ/infigures2005.pdf. Visited on the 12th of April 2006.

1984, for every ten drugs that came to market, only three covered the average development costs.²⁴

Even the largest pharmaceutical companies cannot diversify the underlying research and development-based investment risk. They must rely upon a handful of flagship products for the majority of their sales, and the commercial life of a drug – from market launch to patent expiration – is generally less than seven years. Consequently, even major companies must develop a block-buster every two to three years, or face massive financial contraction. The frequency of mergers of research-based companies is a direct consequence of this basic market dynamic. As market conditions have become increasingly competitive, this dynamic has become even more significant.²⁵

2.5 Patients' Low Price-Elasticity

With credence goods consumers cannot judge the quality they receive compared to the quality they need. The needed quality can only be observed by an expert seller who may exploit the information asymmetry by cheating.²⁶

Medicinal products are credence goods. Patients are often uncertain of the value of prescribed products and play a limited role in selecting appropriate drugs. Customers in this market are relatively insensitive to prices and may not always be able to express their preferences. The fact that patients rely on

²⁴ Glover, G. J., Competition in the Pharmaceutical Marketplace, March 19, 2002, page 4. Available at <http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf>. Visited on the 12th of April 2006.

²⁵ *Id.*

²⁶ Dullec, U. and Kercshbamer, R., Where are the Problems with Credence Goods? January 2000, page 1. Can be downloaded from <http://ideas.repec.org/p/ecm/wc2000/1441.html>. Visited on the 12th of April 2006.

third party payer (different health care systems) relaxes their budgetary constraints and contributes to patients' low price-elasticity.²⁷

This, of course, has implications on the supply and demand structure of any pharmaceutical product and must be deemed of importance, when analyzing a case under Article 82 EC.

2.6 Public Service Obligations

Article 1 (18) of the directive 2001/83/EC²⁸ defines public service obligation as “the 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.”

Article 81 (2) of said directive states that “the holder of a marketing authorization for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State in question are covered.”

So, the pharmaceutical undertakings are not entirely free to determine the quantity of pharmaceutical products they can place on the market. They must quickly meet the needs of patients in all Member States and in all parts of Member States, even if it would turn out that selling pharmaceutical

²⁷ EFPIA paper “Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?” page 14. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 12th of April 2006.

²⁸ See FN 12.

products is not profitable or when part of the products are exported by third parties to other Member States where the price of pharmaceuticals is higher.

2.7 Summary of Pharmaceutical Undertakings

It is clear that the pharmaceutical sector exhibits a number of specific features that cannot be ignored in assessing practices under Article 82 EC. The pharmaceutical undertakings are not free to set prices and rely heavily on innovation and patents to make profit. The supply and demand of pharmaceuticals is not governed by the “invisible hand”, but to a large extent by regulatory authorities. The decisions of purchase in the pharmaceutical markets are not made by patients, but to a very large extent by regulatory authorities and health care professionals.

At this point it is appropriate to quote AG Jacobs: “In my view it is impossible [...] to ignore the pervasive and diverse regulation to which the pharmaceutical sector is subject both at national and Community levels, and which appears to me to set it apart from all other industries engaged in the production of readily traded goods.”²⁹

I shall now continue with the assessment of Article 82 EC and analyze how it should be interpreted with respect to the above special features.

²⁹ Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEEV*, opinion of AG Jacobs delivered on the 28th of October 2004, [2005] ECR-I 4609, para. 77.

3 Dominant Undertakings

3.1 The Objective of Article 82 EC

3.1.1 The Aim of Protection

Article 82 EC stipulates that “any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;
- (b) limiting production, markets or technical development to the prejudice of consumers;
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”³⁰

Article 82 EC is a central provision of the competition regime established by the Treaty. It is one of the pillars of the “system ensuring that competition in the internal market is not distorted”, set down in Article 3 (1) (g) EC. It is generally understood as a system in which superior business performance should be the decisive factor for the success of an undertaking (principle of competition on the merits). In such a system,

³⁰ See FN 2.

efforts of business to anticipate and satisfy customers' needs in the best possible fashion are stimulated and rewarded, thus also assuring the most efficient use of scarce resources.³¹

It is safe to assume that the main goal of Article 82 EC is to protect competitive process and to this extent also the opportunities of competitors to compete on the merits. This objective, and the efficiencies presumed to be associated with such a system of undistorted competition, are however not a goals in themselves, but are ultimately pursued for the benefit of the consumer.³²

The landmark case of *Continental Can* supports this interpretation. ECJ found that “as may further be seen from letters (c) and (d) of Article 8[2] (2), the provision is not only aimed at practices which may cause damage to consumers directly, but also at those which are detrimental to them through their impact on an effective competition structure, such as is mentioned in article 3 [(1) (g)] of the Treaty.”³³

The Discussion Paper adopts this construction. It states: “With regard to exclusionary abuses the objective of Article 82 is the protection of competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resources. Effective competition brings benefits to consumers, such as low prices, high quality products, a wide selection of goods and services, and innovation. Competition and market integration serve these ends since the creation and preservation of an open

³¹ Eilmansberger, T., How to Distinguish Good From Bad Competition Under Article 82 EC: In Search of Clearer and More Coherent Standards for Anti-Competitive Abuses, *Common Market Law Review* No 42, February 2005, page 132.

³² *Id.* page 133.

³³ Case 6/72 *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities*, [1973] ECR 215 para. 26.

single market promotes an efficient allocation of resources throughout the Community for the benefit of consumers.”³⁴

3.1.2 Medical Professionals as “Consumers”

As noted above, in the pharmaceutical industry, patients rely on third parties, mainly doctors, in order to make a decision, which medicinal products to buy. The patient (consumer) in the pharmaceutical industry has a limited role in making decisions. So how can one evaluate, whether the allocation of resources actually benefits the patient or not?

I find that in the pharmaceutical industry one should not look only at the patient on the demand side, but also include doctors and pharmacists. Even though they themselves do not buy the products, they make most decisions concerning which products are bought and assess the efficiency of pharmaceuticals.

Pharmaceutical undertakings do not sell their products only to patients, but in many cases “sell” them to doctors or pharmacists so that they would recommend their products to patients. This fact is evidenced by restrictions that have been enacted in the EU with respect to advertising medicinal products to doctors and pharmacists and giving them free samples of products.³⁵

To my mind, in relation to pharmaceutical undertakings, the object of Article 82 EC is not only to guarantee the effective allocation of resources for the benefit of customers, but also to guarantee that the resources are

³⁴ European Commission Directorate General for Competition, “DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses,” para. 4. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 12th of April 2006.

³⁵ See Articles 94-96 of the Directive 2001/83/EC referred in FN 12.

effectively allocated in the opinion of healthcare specialists, who make most decisions and evaluate the efficiency of the product.

3.1.3 Article 82 EC and the Common Market for Pharmaceuticals

One of the tasks of the European Community is to insure a system that competition in the internal market is not distorted.³⁶ How does this task relate to the pharmaceutical industry, where prices in Member States differ considerably?

Economists agree that when monopolist discriminates buyers based on their willingness to pay, then if discrimination makes possible a large volume of new sales, it can lead to an increase in welfare.³⁷ The efficiencies result primarily from the fact that buyers willing to pay less than the uniform price would still receive the product, whereas, in the case of a uniform price, they would not.³⁸

Consider, for example, a case of two consumers: One is willing to pay €20 for a product, and the other €5. For simplicity's sake, assume that the marginal cost of providing the product is zero. If the firm supplying the product were required to sell at a uniform rate to both consumers, it would clearly find it most profitable to set a rate of €20. If, however, the firm could price the product differently to both classes of consumers, it would find it most profitable to sell to the high-value user at a price of €20 and the low-

³⁶ See Article 3 (1) (g) of the Treaty.

³⁷ Schmalensee, R., *Output and Welfare Implications of Monopolistic Third-Degree Price Discrimination*, Massachusetts Institute of Technology, 1980, page 8. Available to be downloaded from <https://dspace.mit.edu/handle/1721.1/1956>. Visited on the 13th of April 2006.

³⁸ EFPIA paper "Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?" page 15. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 13th of April 2006.

value user at a price of €5. Forcing a producer to sell to everyone at the same price may thus be superficially appealing, but it can lead the producer to sell only to the high end of the market. In contrast, differential pricing gives the producer an incentive to supply the product to anyone willing to pay the incremental cost of production.³⁹

Although consumers in the initially high price country may appear to benefit from lower prices under a uniform price policy, in the long run these consumers are worse off if these low prices result in lower expected returns to R&D and hence fewer new medicines than they would have been willing to pay for, had different pricing been feasible. Consumers in traditionally low price countries are unambiguously worse off because the uniform price exceeds their initial low price. At the higher prices, governments tend to limit access to costly medicines, in order to stay within budget targets. At the limit, countries that have relatively elastic demand may not be served at all because their demand at the higher price is insufficient to cover the company's incremental costs of launch in that country, including fixed costs. If the company considers launch at a lower price, the expected net revenue from that country, after covering all country-specific incremental costs, must exceed the revenue loss that its low price would cause through parallel trade or international price comparisons in other markets.⁴⁰

For this reason, it is evident that due to different regulations and prices for pharmaceutical products in different Member States, the common market and common prices for pharmaceuticals cannot and should not at this stage of the Community be achieved. The efficient allocation of resources and maximizing welfare in the pharmaceutical industry means – at least for the

³⁹ *Id.*

⁴⁰ Danzon, P. M., Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU. *International Journal of the Economics of Business*, November 1997, no 4, page 307.

time being – that pharmaceutical undertakings must be able to charge in different Member States different prices for their products.

3.2 Pharmaceutical “Undertaking” under Article 82 EC

3.2.1 The Concept

Article 82 EC refers to “undertakings”. Must this concept be understood in traditional legal terms *i.e.* the same way as a legal entity or does it have an independent meaning?

It is clear from settled case-law that, in competition law, the term undertaking must be understood as designating an economic unit for the purpose of the subject-matter in question even if in law that economic unit consists of several persons, natural or legal.⁴¹ The courts have also emphasized that, for the purposes of applying the competition rules, formal separation of two companies resulting from their having distinct legal identity, is not decisive. The test is whether there is unity in their conduct on the market.⁴² Moreover, in EC competition law the concept of an

⁴¹ Case 170/83 *Hydrotherm Gerätebau GmbH v Compact del Dott. Ing. Mario Andreoli & C. Sas*, [1984] ECR 2999, para. 11, Case T-234/95 *DSG Dradenauer Stahlgesellschaft mbH v Commission of the European Communities*, [2000] ECR II-2603, para. 124, Case T-66/99 *Minoan Lines SA v Commission of the European Communities*, [2003] ECR II-5515, para. 121.

⁴² Case 48/69 *Imperial Chemical Industries Ltd. v Commission of the European Communities*, [1972] ECR 619, para. 140, Case T-66/99 *Minoan Lines SA v Commission of the European Communities*, [2003] ECR II-5515, para. 123.

undertaking covers any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed.⁴³

For that reason, the fact that parent company divides various national markets between its subsidiaries, cannot make Article 81 (1) EC applicable. On the other hand, the courts have also underlined that such unilateral conduct could fall under Article 82 EC if the conditions for its application, as laid down in that article, are fulfilled.⁴⁴

As discussed above, dividing national markets in case of pharmaceutical undertakings is at this stage of the development of the Community inevitable and should not bring about liability under Article 82 EC. Pharmaceutical companies should be able to divide national markets between its subsidiaries and have different marketing conditions for the same medicinal product in different Member States.

3.2.2 Public Undertakings

Another question that arises, is whether undertakings under Article 82 EC include only private undertakings *i.e.* companies, or does Article 82 EC also apply to public undertakings and to undertakings to which Member States have granted special or exclusive rights?

ECJ has held in that regard, that the important factor is carrying out a business activity. If a public undertaking or an undertaking to which

⁴³ Joined Cases C-159/91 and C-160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon*, [1993] ECR I- 637 para. 17.

⁴⁴ See case C-73/95 P *Viho Europe BV v Commission of the European Communities*, [1996] ECR I-5457 para. 17.

Member States have granted special or exclusive rights carries out a business activity, it is subject to rules under Article 82 EC.⁴⁵

Article 82 EC in combination with Article 86 EC may also be infringed where a Member State adopts or maintains in force measures, which create a situation in which such undertakings are led to, or cannot avoid, abusing their dominant position. The conditions of applying Article 82 EC to such abuses and the conditions for their justifications are laid down in Article 86 EC.⁴⁶

Article 10 EC obliges Member States to take all appropriate measures to ensure fulfillment of the obligations arising out of the Treaty. This article, which imposes on the Member States a duty to cooperate, read in conjunction with Articles 81 EC and 82 EC, requires the Member States not to introduce or maintain in force measures, even of a legislative or regulatory nature, which may render ineffective the competition rules applicable to undertakings.⁴⁷

The question whether an organization managing the national health system can be considered as an undertaking within the meaning of Article 82 EC is the subject of ECJ pending case no C-205/03 P.⁴⁸

The dispute originates in a decision of the Commission of 26th of August 1999 not to allow a complaint submitted by FENIN, which is an association of the majority of the undertakings which market the medical goods and equipment used in Spanish hospitals, seeking a declaration that 26 public bodies, including three ministries of the Spanish Government, which run the

⁴⁵ See e.g. case 41/83 *Italian Republic v Commission of the European Communities*, [1985] ECR 873 paras 18-20.

⁴⁶ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 9. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 13th of April 2006.

⁴⁷ *Id.* para. 10.

⁴⁸ See notification of application in ([2003] OJ C 184/19).

Spanish national health system, had infringed Article 82 EC by paying sums invoiced to them by FENIN only after a considerable delay, amounting to 300 days on average, even though they settled their debts to other suppliers within a far more reasonable period of time. That discrimination, according to FENIN, was attributable to the fact that the organizations which manage the Spanish national health system enjoy a dominant position in the Spanish market for medical goods and equipment which enables them to delay paying for such goods and equipment without their creditors being able to exert any commercial pressure on them to put an end to that practice.⁴⁹

The CFI found that it is the activity consisting in offering goods and services on a given market that is the characteristic feature of an economic activity. An organization which purchases goods - even in great quantity - not for the purpose of offering goods and services as part of an economic activity, but in order to use them in the context of a different activity, such as one of a purely social nature, does not act as an undertaking simply because it is a purchaser in a given market. Whilst an entity may wield very considerable economic power, even giving rise to a monopsony, it nevertheless remains the case that, if the activity for which that entity purchases goods is not an economic activity, it is not acting as an undertaking for the purposes of Community competition law and is therefore not subject to the prohibitions laid down in Articles 81 (1) EC and 82 EC.⁵⁰

FENIN appealed the decision on a single ground of appeal, alleging that the CFI incorrectly interpreted the concept of an undertaking within the meaning of EC competition law.⁵¹

⁴⁹ Case T-319/99 *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental v. Commission of the European Communities*, [2003] ECR II-357 para 1.

⁵⁰ *Id.* paras 36-37.

⁵¹ See application, FN 48.

AG Maduro first submitted in his opinion that in seeking to determine whether an activity carried on by the State or a State entity is of an economic nature, the ECJ is entering dangerous territory, since it must find a balance between the need to protect undistorted competition on the common market and respect for the powers of the Member States. The power of the State which is exercised in the political sphere is subject to democratic control. A different type of control is imposed on economic operators acting on a market: Their conduct is governed by competition law. He found that there is no justification, when the State is acting as an economic operator, for relieving its actions of all control. On the contrary, it must observe the same rules in such cases. It is therefore essential to establish a clear criterion for determining the point at which competition law becomes applicable. In principle, the rules of competition law apply only to economic operators who participate on a market and not to States, save where they pay aid to undertakings (Articles 88 EC to 92 EC). However, the need for consistency means that if a State ratifies decisions taken by undertakings or if it conducts itself in practice as an economic operator, Articles 81 EC to 86 EC may apply to it. He added that Article 86 (2) EC would be rendered redundant if competition law were no longer to apply as soon as the State is present on a market.⁵²

As for the case at hand, he noted that Spanish national health system both provides compulsory health insurance cover to its members and is required to provide them with health care services free of charge. He pointed out that it is essential to consider each activity carried out by an organization separately, in order to determine whether it should be classified as an economic activity. A separate classification, on the basis of each activity undertaken, is all the more necessary where a public body is concerned, as it

⁵² Case 205/03 P *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental v. Commission of the European Communities*. Opinion of AG Maduro delivered on the 10th of November 2005. n.y.r., para 26.

can act as an economic operator in relation to only one activity, while at the same time carrying on functions that are non-economic in nature. He concluded that in classifying the Spanish national health system from a global perspective, without considering its activity as a provider of free health care separately, the CFI erred in law.⁵³

He thus proposed that the ECJ should uphold the second part of the appeal and refer the case back to the CFI for it to make the findings of fact necessary to determine whether or not the activity of the organizations managing the Spanish national health service is economic in nature and, accordingly, whether the rejection by the Commission of the European Communities of the complaint submitted by the FENIN was well founded.⁵⁴

It therefore seems (if the opinion is followed by the ECJ) that organizations managing national health care services are not automatically excluded from the scope of Article 82 EC. Article 82 EC applies to them, if they conduct themselves in practice as an economic operator.

It is appropriate to repeat that the launch price of pharmaceutical products is not freely determined, but negotiated with national governments. If the opinion of AG Maduro is upheld, it could open a door for pharmaceutical undertakings to claim – when in their economic interests – that in demanding a too low price for pharmaceuticals or imposing other unfair trading conditions, a body of a Member State has acted as an economic operator and infringed its dominant position under Article 82 EC.

⁵³ *Id.* paras 41-44.

⁵⁴ *Id.* para. 70.

3.3 Market Definition

3.3.1 The Importance of Market Definition

For the purposes of Article 82 EC, the proper definition of the relevant market is a necessary precondition for any judgment as to allegedly anti-competitive behavior, since, before an abuse of a dominant position is ascertained, it is necessary to establish the existence of a dominant position in a given market, which presupposes that such a market has already been defined.⁵⁵

The given market or the relevant market is determined by applying the Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law.⁵⁶ That Notice should serve as the basis for market definition issues also for the application of article 82 EC.⁵⁷

Market definition is a tool to identify and define the boundaries of competition between firms. It allows to establish the framework within which competition policy is applied by the Commission. The main purpose of market definition is to identify in a systematic way the competitive constraints that the undertakings involved face. The objective of defining a market in both its product and geographic dimension is to identify those actual competitors of the undertakings involved that are capable of

⁵⁵ Case T-62/98 *Volkswagen AG v Commission of the European Communities*, [2000] ECR II-2707, para. 230.

⁵⁶ Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, ([1997] OJ C 372).

⁵⁷ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 12. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 19th of April 2006.

constraining their behavior and of preventing them from behaving independently of an effective competitive pressure.⁵⁸

Markets do not always have clear limits, and the insistence on definition rather than analysis may be misleading. There may be substitutes that are not perfect; in which case selecting a narrow definition will overstate the market power of a firm supplying a large proportion of the defined product. It may not be able to raise prices above the competitive level without losing too many sales for it to be profitable. A wide definition will usually indicate a smaller market share which understates the firm's market power. Market definitions are often arbitrary and should not determine whether the firm has market power but they do focus attention on the factors relevant to appraising market power.⁵⁹

The definition of the relevant market in both its product and geographic dimensions often has a decisive influence on the assessment of a competition case.⁶⁰ The more narrowly the relevant market is defined, the more likely it is that the undertaking in question is deemed to be in a dominant position.

If an undertaking is not deemed to be in a dominant position, it escapes the rule under Article 82 EC. Subsequently, it is difficult to underestimate the importance of defining the relevant market.

3.3.2 Basic Principles of Market Definition

Firms are subject to three main sources of competitive constraints: demand substitutability, supply substitutability and potential competition. From an

⁵⁸ Notice, para. 2.

⁵⁹ Korah, V., EC Competition Law, Hart Publishing Limited, 2001, page 82.

⁶⁰ Notice, para. 4.

economic point of view, for the definition of the relevant market, demand substitution constitutes the most immediate and effective disciplinary force on the suppliers of a given product, in particular in relation to their pricing decisions. A firm or a group of firms cannot have a significant impact on the prevailing conditions of sale, such as prices, if its customers are in a position to switch easily to available substitute products or to suppliers located elsewhere. Basically, the exercise of market definition consists in identifying the effective alternative sources of supply for the customers of the undertakings involved, both in terms of products/services and geographic location of suppliers.⁶¹

The competitive constraints arising from supply side substitutability and from potential competition are in general less immediate and in any case require an analysis of additional factors. As a result, such constraints are taken into account at the assessment stage of competition analysis.⁶²

3.3.3 Demand Side Substitution

3.3.3.1 Demand Side Substitution in General

In *Hoffman-La Roche* ECJ stated that the concept of the relevant market implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use [emphasis added] of such products is concerned.⁶³

⁶¹ *Id.* para 13.

⁶² *Id.* para 14.

⁶³ Case 85/76 *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, [1979] ECR 461 para 28.

The ECJ found in *United Brands* that for the banana to be regarded as forming a market which is sufficiently differentiated from other fruit markets it must be possible for it to be singled out by such special features distinguishing it from other fruits that it is only to a limited extent interchangeable [emphasis added] with them and is only exposed to their competition in a way that is hardly perceptible.⁶⁴ The ECJ found that a very large number of consumers having a constant need for bananas are not noticeably or even appreciably enticed away from the consumption of this product by the arrival of other fresh fruit on the market and that even the personal peak periods only affect it for a limited period of time and to a very limited extent from the point of view of substitutability. ECJ concluded that the banana market is a market which is sufficiently distinct from the other fresh fruit markets.⁶⁵

The assessment of demand substitution entails a determination of the range of products, which are viewed as substitutes by the consumer.⁶⁶

Demand-side substitution is usually analyzed by applying the so-called “SSNIP” test. Under the SSNIP-test it is asked whether the customers of the undertaking(s) concerned would switch to readily available substitutes or to suppliers located elsewhere to such an extent that it would be unprofitable to implement a small but significant (normally in the range 5%-10%), non-transitory increase in relative prices for the products and the areas being considered. If answered in the affirmative, additional substitutes and areas are added to the relevant market until such a price increase would be profitable. At that point, a hypothetical single seller of the now included products and within the now included areas would be able to profitably raise

⁶⁴ Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, [1978] ECR 207, para. 22.

⁶⁵ *Id.* paras 34-35.

⁶⁶ Notice, para. 15.

prices by 5%-10%, signifying that the products and areas in question constitute a market that is worth monopolizing.⁶⁷

SSNIP-test normally is based on the assumption that prevailing prices constitute the appropriate benchmark for the analysis. This assumption often does not hold in Article 82 cases. The very notion of dominance involves an assessment of whether or not the undertaking in question is subject to effective competitive constraints. The appropriate benchmark for this assessment is the competitive price, which may not be the prevailing price.⁶⁸

For that reason the Commission uses additional tools to check whether the market has been defined too widely so as to include false substitutes. Those methods include:

- 1) reconstructing the competitive price to apply the SSNIP test,
- 2) examining the characteristics and intended use of the products concerned to assess whether they are capable of satisfying the inelastic consumer need and
- 3) comparing prices across various regions to determine the geographic and product market.⁶⁹

3.3.3.2 Demand Side Substitution in Medicinal Products

The application of the SSNIP test is difficult, if not impossible, in the pharmaceutical sector given national regulation of pharmaceutical prices

⁶⁷ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 14. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 19th of April 2006.

⁶⁸ *Id.* para. 15.

⁶⁹ *Id.* paras 16-19.

and reimbursement levels. More specifically, comparing the extent to which price variations in one product affect demand for another product is not possible in practice when final consumers are insensitive to price levels due to the existence of State reimbursement in one form or another. Manufacturers will also be constrained, directly or indirectly, by national regulations on pharmaceutical prices. Therefore, the basic assumptions underlying the SSNIP test regarding the ability of a firm or group of firms to profit-maximize by increasing price realistically cannot be applied. In these circumstances, particular emphasis should be placed on non-price factors.⁷⁰

The Commission stated in *Sandoz* that European pharmaceutical market is large in total but is divided along both national and regional lines. The reasons behind this division stem mainly from differences in Member States' laws for the regulation of prices and the admission of pharmaceutical products to markets.⁷¹

It seems that the Commission acknowledges that in defining the relevant market in the pharmaceutical sector the same medicinal products from one Member State are not interchangeable with medicinal products from another Member State. But what about therapeutic substitution between products?

In the pharmaceutical sector, product markets are usually defined by reference to medical conditions, on the basis that patients use a drug suitable for treating a particular illness. Traditionally, competition authorities have based this assessment on the World Health Organization's Anatomical Therapeutic Classification (ATC), which groups products by reference to their composition and therapeutic qualities. The third level (therapeutic indication) is most commonly used, although a narrower market definition

⁷⁰ EFPIA paper "Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?" page 21. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 19th of April 2006.

⁷¹ 87/409/EEC: Commission Decision of 13th of July 1987 relating to a proceeding under Article 85 [now Article 81] of the EEC Treaty (IV/31.741 - *Sandoz*), section D, ([1987] OJ L 222/28).

may be adopted if there is a relatively wide range of indications in the particular group.⁷²

This approach leads to a large number of pharmaceutical companies being regarded as potentially dominant in at least some of the markets in which they are active. So is the ATC approach to market definition correct? While its use is generally accepted in merger investigations, which are concerned with markets' future development, practitioners have started to ask whether the same approach is always appropriate when determining whether a company has abused a dominant position. To date, almost all of the cases in which level 3 of the ATC has been used to define markets have been merger investigations. It is predominantly national competition authorities, such as the UK's Office of Fair Trading in the *Napp* and *Genzyme* cases, which have applied the same reasoning to dominance cases.⁷³

However, at national level there has also been a case where it has been suggested that a single medicine itself may constitute a separate market.⁷⁴ Even though the Commission does not state it explicitly, this also seems to be the Commission's position in the *AstraZeneca* case.⁷⁵

This essentially means that any pharmaceutical undertaking, which has marketed a medicine, could be in a dominant position and potentially liable under Article 82 EC. I find that such a narrow definition ignores the fact that most illnesses can be cured using different medicinal products and different methods of treatment *e.g.* traditional medicine. The competition authorities must take into account substitutes for medicines from the demand side.

⁷² Lawrance, S., Treacy, P., *Legal Uncertainties Leave Pharma Companies in Limbo, Managing Intellectual Property*, London, September 2005.

⁷³ *Id.*

⁷⁴ See EFPIA paper "Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?" page 3. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 19th of April 2006.

⁷⁵ See Decision, paras 378-379, 504.

For instance, instead of prescribing a medicine such as “Losec” for ulcer, a doctor could (having regard the price of the medicine) suggest the patient alternative competing medicines such as “Zantac” or cheaper traditional medicines for treating stomach aches. Though the Decision tries to explain in detail, that “Losec” and “Zantac” are not interchangeable, the arguments of AZ and especially the study carried out by it, which demonstrates that this assessment is not true, is equally convincing.⁷⁶ It is for the CFI to establish whether the Commission’s assessment of the relevant market was correct or not.

3.3.3.3 Are Original Drugs and Generic Drugs Interchangeable?

In the context of drugs suitable for treating a particular illness, the question arises whether original drugs and generic drugs are interchangeable or not.

Article 10 (2) (b) of Directive 2001/83/EC⁷⁷ gives a generic medicinal product the following definition: “‘generic medicinal product’ shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy of the various salts, esters or

⁷⁶ See Decision, paras 329-357.

⁷⁷ As amended by 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, ([2004] OJ L 136/34).

derivatives of an authorized active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriate detailed guidelines.”

It follows that original medicinal products and generic medicinal products have same qualitative and quantitative composition in active substances and should as such be normally interchangeable from the perspective of patients.

However, owing to the fact that original products and generic products could have differences in composition, one or the other drug could be more effective (for instance due to the combination of the active substance with other substances) or have less side effects for treating patients. So, doctors, who prescribe pharmaceuticals, could view them as not interchangeable.

3.3.4 Supply Side Substitution and Potential Competition

Supply side substitution means that suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risks in response to small and permanent changes in relative prices. When these conditions are met, the additional production that is put on the market will have a disciplinary effect on the competitive behavior of the companies involved. Such an impact in terms of effectiveness and immediacy is equivalent to the demand substitution effect.⁷⁸

⁷⁸ Notice, para. 20.

The third source of competitive constraint, potential competition, is not taken into account when defining markets, since the conditions under which potential competition will actually represent an effective competitive constraint depend on the analysis of specific factors and circumstances related to the conditions of entry. If required, this analysis is only carried out at a subsequent stage, in general once the position of the companies involved in the relevant market has already been ascertained, and when such position gives rise to concerns from a competition point of view.⁷⁹

As discussed above, pharmaceutical undertakings spend a substantial part of their turnover on R&D and on the trials drugs must undergo before they can legally be released to the public. Yet it is easy to copy a drug once its therapeutic and side effects are known. Little research and development would be financed for products that can be reverse engineered if anyone could undercut the inventor by copying the intervention without incurring the costs of R&D and testing. Such people are often called “free riders” They take a “free ride” on the investment of the innovator.⁸⁰

To protect innovation, Article 10 (1) of Directive 2001/83/EC⁸¹ lays down that a generic medicinal product authorized pursuant to Article 10 shall not be placed on the market until ten years have elapsed from the initial authorization of the reference product.

Further, most original pharmaceutical products are patented. Article 28 (1) of the TRIPS convention lays down that a patent shall confer on its owner the following exclusive rights:

- (a) where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of:

⁷⁹ *Id.* para. 24.

⁸⁰ Korah, V. EC Competition Law, Hart Publishing Limited 2001, pages 17-18.

⁸¹ As amended by 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, ([2004] OJ L 136/34).

making, using, offering for sale, selling, or importing for these purposes that product;

- (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.⁸²

As a consequence, supply side substitution and potential competition in the pharmaceutical sector is very dependent on patent protection and regulatory protection of the original pharmaceuticals. During the time for patent protection and regulatory protection, the pharmaceutical product has no supply side substitutes and is relatively safe from potential competition, though it is possible that other companies could have developed independently an alternative cure for the same illness. Once the time for protection expires, the pharmaceutical product normally faces very strong competition from generic products.

After patents expire, generic producers are able to copy branded drugs at a low price. Manufacturing the drug itself is cheaper than the production of the branded version since generic producers do not incur the sunk costs associated with R&D expenditures. Generic producers are therefore able to enter the market easily and introduce therapeutically similar products at lower prices, which, under perfectly competitive conditions, lower the branded drug's market share.⁸³

⁸² Agreement on Trade Related Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

⁸³ EFPIA paper "Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?" page 40. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 23rd of April 2006.

3.4 Concept of Dominance

3.4.1 Undelying Principles of Finding Dominance

European competition law has developed under the influence of the ordoliberal school of thought, according to which the actual goal of competition policy is the protection of individual economic freedom of action as a value in itself or *vice versa* in the restraint of undue economic power. The concept of abuse under Article 82 EC also bears the imprint of ordoliberal thinking, which first influenced the development of an identical concept of abuse under German competition law. Then, mainly through the German concept, which had no counterparts in other Member States' laws, it influenced the judicial interpretation of Article 82 EC.⁸⁴

ECJ stated in *Michelin* that “the dominant position [...] relates to 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, its customers and ultimately of the consumers.”⁸⁵

The ECJ specified in *Hoffman-La Roche* that “the concept of abuse is an objective concept relating to the behavior of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of

⁸⁴ Rousseva, E., Modernizing by Eradicating: How Commission's New Approach to Article 81 EC Dispenses With the Need to Apply Article 82 EC to Vertical Restraints, *Common Market Law Review*; June 2005 no 42, pages 590-59.

⁸⁵ Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 3461 para. 38.

hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.”⁸⁶

ECJ furthermore laid down in *Michelin* that “a finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a **special responsibility** [emphasis added] not to allow its conduct to impair genuine undistorted competition on the common market.”⁸⁷

It is not difficult to trace its roots to ordoliberal notion that “the one who has power has no right to be free and the one who wants to be free should have no power”. In essence the concept of special responsibility means that dominant undertakings, simply by virtue of the market power they hold, are not allowed to perform certain activities on the market that other non-dominant undertakings are free to perform.⁸⁸

Unfortunately, the Community courts have never clarified the exact scope of this special responsibility. It has been used more as an axiomatic rule, enabling prohibition on the basis of dominance. So, although the Community courts profess to support the view that dominance *per se* is not prohibited, the special responsibility concept has the effect of reprimanding dominance itself.⁸⁹

In addition, the ECJ has failed to establish a clear relationship between the special responsibility concept and the degree of dominance. Once dominance is established, no matter how strong it is, the undertaking is

⁸⁶ Case 85/76 *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, [1979] ECR 461 para. 91.

⁸⁷ Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 3461 para. 57.

⁸⁸ Rousseva, E., *Modernizing by Eradicating: How Commission’s New Approach to Article 81 EC Dispenses With the Need to Apply Article 82 EC to Vertical Restraints*, *Common Market Law Review*; June 2005 no 42, pages 592-593.

⁸⁹ *Id.* page 593.

bound by its special responsibility. This may result in excessive intervention, especially of dominant undertakings that have a relatively weak dominant position.⁹⁰

3.4.2 Elements of Dominance

3.4.2.1 Elements in General

The Discussion Paper lays down that the definition of dominance consists of three elements, two of which are closely linked: (a) there must be a position of economic strength on a market which (b) enables the undertaking(s) in question to prevent effective competition being maintained on that market by (c) affording it the power to behave independently to an appreciable extent.⁹¹

The first element implies that dominance exists in relation to a market. It cannot exist in the abstract. It also implies that an undertaking either on its own or together with other undertakings must hold a leading position on that market compared to its rivals.⁹²

The second and third elements concern the link between the position of economic strength held by the undertaking concerned and the competitive process, *i.e.* the way in which the undertaking and other players act and inter-act on the market. Dominance is the ability to prevent effective competition being maintained on the market and to act to an appreciable extent independently of other players. The notion of independence, which is

⁹⁰ *Id.*

⁹¹ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 21. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 21st of April 2006.

⁹² *Id.* para. 22.

the special feature of dominance, is related to the level of competitive constraint facing the undertaking(s) in question. For dominance to exist the undertaking(s) concerned must not be subject to effective competitive constraints. In other words, it thus must have substantial market power.⁹³

Market power is the power to influence market prices, output, innovation, the variety or quality of goods and services, or other parameters of competition on the market for a significant period of time.⁹⁴

3.4.2.2 Market Share

The starting point for the analysis of market position of the allegedly dominant undertaking and its rivals is the market shares of the various players.⁹⁵

The ECJ recognized in *Hoffman-La Roche* that the significance of market share in determining dominance varies depending on the market structure. Nevertheless, a presumption of dominance may not arise even in case of very high market shares. Evidence of a high market share, even when it has been maintained for a long period, is insufficient to establish dominance.⁹⁶

The Commission stated in *AKZO* that “market share, while important, is only one of the indicators from which the existence of a dominant position may be inferred. Its significance in a particular case may vary from market to market according to the structure and characteristics of the market in

⁹³ *Id.* para. 23.

⁹⁴ *Id.* para. 24.

⁹⁵ *Id.* para. 29.

⁹⁶ EFPIA paper “Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?” page 37. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 21st of April 2006.

question. To assess market power for the purposes of the case at hand, the Commission must consider also all the relevant economic evidence.”⁹⁷

The Discussion Paper also stresses that the strength of any indication based on market share depends on the facts of each individual case and that market share is only a proxy for market power, which is the decisive factor.⁹⁸

For instance, in the merger case of *Sterling Drug* the Commission noted that the proposed combination of Sanofi and Sterling would lead to relatively high market shares ranging between 45% in the laxative market in Italy to 74% in the cold preparations (without anti-infectives) markets in the Netherlands. However, in assessing the importance of these market shares the Commission took into account other considerations and approved the merger.⁹⁹

3.4.2.3 Barriers to Expansion and Entry

If the barriers to expansion faced by rivals and to entry faced by potential rivals are low, the fact that one undertaking has a high market share may not be indicative of dominance. Any attempt by an undertaking to increase

⁹⁷ 85/609/EEC: Commission Decision of 14 December 1985 relating to a proceeding under Article 86 [now Article 82] of the EEC Treaty (IV/30.698 - *ECS/AKZO*), ([1985] OJ L 374/1, paras 68-69).

⁹⁸ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 32. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 21th of April 2006.

⁹⁹ Case no IV/M072 -*Sanofi/Sterling Drug*. Decision from the 10th of June 1991 pursuant to Article 4 of Council Regulation No 4064/89, paras. 24-25. Available at http://www.eu.int/comm/competition/mergers/cases/decisions/m72_en.pdf. Visited on the 21st of April 2006.

prices above the competitive level would attract expansion or new entry by rivals thereby undermining the price increase.¹⁰⁰

The Discussion Paper states that when identifying possible barriers to expansion and entry it is important to focus on whether rivals can reasonably replicate circumstances that give advantages to the allegedly dominant undertaking. Barriers to expansion and entry can have a number of origins relating to the legal or economic environment that pertains on the relevant market.¹⁰¹

There can be no doubt that one of those legal barriers in case of pharmaceutical undertakings is the protection afforded by the patents or other legislation. As long as the pharmaceutical products are afforded patent protection, it prevents other undertakings entry to the market to produce the same drug and gives the undertaking in question market power with respect to the drug.

In the *AstraZeneca* decision which will be discussed further below, the Commission held that AZ had supplied misleading information which did not allow several national patent offices to identify the date of first marketing authorization (as subsequently defined by the ECJ). As a result, AZ obtained extended protection of its “Losec” patent. The Commission found that this amounted to an abuse of AZ’s dominant position in Belgium, Denmark, Germany, the Netherlands, Norway and the UK as this practice prevented or delayed market access for generic products.¹⁰²

¹⁰⁰ European Commission Directorate General for Competition, “DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses”, para 34. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 23rd of April 2006.

¹⁰¹ *Id.* para. 40.

¹⁰² Simmons & Simmons newsletter of June 2005, Decision of the European Commission in COMP/37.507. Available at <http://www.simmons-simmons.com/docs/ecjuly.pdf>. Visited on the 23rd of April 2006.

3.4.2.4 Buyer Power

The Discussion Paper states that market position of buyers provides an indication of the extent to which they are likely to constrain the allegedly dominant undertaking. The presence of strong buyers can only serve to counter a finding of dominance if it is likely that in response to prices being increased above the competitive level, the buyers in question will pave the way for effective new entry or lead existing suppliers in the market to significantly expand their output so as to defeat the price increase. In other words, the strong buyers should not only protect themselves, but effectively protect the market.¹⁰³

Research has demonstrated that even an unregulated monopolist that faces no possible threat of entry may price competitively.¹⁰⁴ Buyer power is of particular relevance to the pharmaceutical sector because there is frequently a highly concentrated demand side, whether in the form of a single buyer, such as a national health authority, or of a few powerful purchasers, such as clinics or hospitals, that have sufficient leverage against the suppliers to affect price.¹⁰⁵

For instance in the merger case of *Johnson & Johnson/De Puy* the Commission found that budgetary constraints imposed on hospitals by Public Authorities (because of national reimbursement systems) are an

¹⁰³ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 41. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 23rd of April 2006.

¹⁰⁴ Engle-Warnick, J. and Ruffle, B. J., Buyer Countervailing Power versus Monopoly Power: Evidence from Experimental Posted-Offer Markets, April 2002. Available at <http://www.econ.bgu.ac.il/papers/154.pdf>. Visited on the 23rd of April 2006.

¹⁰⁵ EFPIA paper "Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?" page 41. Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 23rd of April 2006.

additional constraint that suppliers are to take into account when fixing price and approved the merger.¹⁰⁶

3.5 Summary of Dominant Undertakings

The finding of dominance must take into consideration the actual circumstances of each and every particular case. Even though high market shares could be an indicator of market power, other considerations such as low barriers of entry or buyer power could mean that the undertaking in question has actually no market power.

Similarly, defining the relevant geographic and product market must take into account possible substitutes on the demand side, supply side and potential competition.

This is all the more important in case of pharmaceutical undertakings where in any market there are many specific characteristics which should not be ignored by the authorities. It is crucial that the assessment of the Commission regarding the relevant market and whether the undertaking in question has dominance on the relevant market, would not be arbitrary but would apply the “rule of reason” and the underlying objectives of competition law.

I find that if a product has substitutes, the undertaking supplying the products is subject to public service obligations and the price of the product is determined by national authorities who have substantial buyer power, one should be careful to deem the undertaking dominant. It should be recalled

¹⁰⁶ Case no IV/M.1286 - *Johnson & Johnson / Depuy*. Decision from the 28th of October 1998 pursuant to Article 4 of Council Regulation No 4064/89 para. 36. Available at http://europa.eu.int/comm/competition/mergers/cases/decisions/m1286_en.pdf. Visited on the 23rd of April 2006.

that Article 82 EC might also be applicable against national health care authorities.

I shall now continue with the assessment of the “abuse” of a dominant position and analyze whether the Commission have paid due consideration to the facts of the *AstraZeneca* case – and more importantly – whether the Commission has properly construed Article 82 EC in light of those facts.

4 Abuse of Dominance

4.1 Central Concern

The essential objective of Article 82 EC when analyzing exclusionary conduct is the protection of competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resources. The concern is to prevent exclusionary conduct of the dominant firm which is likely to limit the remaining competitive constraints on the dominant company, including entry of newcomers, so as to avoid that consumers are harmed. This means that it is competition, and not competitors as such, that is to be protected. Furthermore, the purpose of Article 82 EC is not to protect competitors from dominant firms' genuine competition based on factors such as higher quality, novel products, opportune innovation or otherwise better performance, but to ensure that these competitors are also able to expand in or enter the market and compete therein on the merits, without facing competition conditions which are distorted or impaired by the dominant firm.¹⁰⁷

As the wording of Article 82 (2) EC clearly states, the list given therein is not inclusive *i.e.* other forms of an abuse of a dominant position may take place. This thesis does not analyze each and every example on the list, but concentrates on the abusive conduct as such. To that end, it analyzes the recent case of *AstraZeneca* and tries to assess whether the decision against AZ was justified or not.

¹⁰⁷ European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses," para. 54. Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 23rd of April 2006.

The Discussion Paper states that where a certain exclusionary conduct is clearly not competition on the merits, in particular conduct which clearly creates no efficiencies and which only raises obstacles to residual competition, such conduct is presumed to be an abuse. However, the dominant company will have the possibility to rebut that presumption. Such rebuttal can be brought by providing convincing evidence that the conduct does not and will not have the alleged likely exclusionary effect, or that the conduct is objectively justified.¹⁰⁸

It is of particular importance that in defining the presumption of abuse as “conduct clearly not competition on the merits”, the Discussion Paper makes a footnote reference to the *AstraZeneca* Decision. The final outcome of this case will be of utmost importance for interpreting the concept of “abuse” and in particular, setting the limits (if any) of applying Article 82 EC to pharmaceutical undertakings. This case will also make clear how extensive is the burden of proof of the allegedly dominant undertakings and what can serve as an “objective justification” under the Discussion Paper.

4.2 *AstraZeneca* Case

4.2.1 Facts and Arguments of the Parties

The Commission finds that from 1993 to 2000 AZ infringed EC and EEA competition rules by blocking or delaying market access for generic versions of the drug “ Losec ” and preventing parallel imports of “ Losec ”. Commission claims that AZ did this by:

- 1) giving misleading information to several national patent offices in the EEA resulting in AZ gaining extended patent protection for

¹⁰⁸ *Id.* para. 60.

“Losec” through so-called supplementary protection certificates (SPCs). In the specific case, the patent offices essentially relied on information supplied by AZ and they were not obliged – as in normal patent assessments – to consider whether the products were innovative. AZ’s misleading conduct amounted to an abuse in Belgium, Denmark, Germany, the Netherlands, Norway and the United Kingdom;

- 2) misusing rules and procedures applied by the national medicines agencies which issue market authorizations for medicines by selectively deregistering the market authorizations for “Losec” capsules in Denmark, Norway and Sweden with the intent of blocking or delaying entry by generic firms and parallel traders. At the time, generic products could only be marketed and parallel importers only obtain import licenses if there was an existing reference market authorization for the original corresponding product (“Losec”). The purpose of a market authorization is the right to sell a medicine and not to exclude competitors. Unlike patents, SPCs and data exclusivity, market authorizations are not intended to reward innovation and the finding of an abuse cannot therefore affect incentives to innovate. Subsequent changes in the applicable EU legislation have made it impossible to repeat this specific conduct.¹⁰⁹

AZ does not accept the Decision. In brief, the arguments of AZ are the following:

- 1) AZ has supplied detailed evidence negating the allegation that AZ occupied a dominant position in the appropriate market in the 1990s.

¹⁰⁹ See Commission’s press release IP/05/737. Available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/737&type=HTML&aged=0&language=EN&guiLanguage=en>. Visited on the 23rd of April 2006.

The Commission is adopting a narrow and unsustainable product market definition that fails to take account of the competitive constraints imposed on “Losec” by H2 antagonists and competing PPI’s. H2 antagonists were the first products used in the treatment of stomach acid disorders and were the established therapy at the later time of the introduction of “Losec”, the first PPI. The H2 antagonist “Zantac”, marketed by GSK, was a leader in this class of medicines. Patents for “Zantac” expired between 1997-2002 in the UK and US. In 1999, “Zantac” had worldwide sales of \$1.037bn;

- 2) AZ does not accept as alleged by the Commission, that AZ made any deliberate misrepresentations to patent offices or courts to obtain or preserve SPCs. Entitlement to SPCs was sufficiently complex that even the highest German court did not consider the interpretation of the law was clear and asked the ECJ for a ruling on interpretation that was eventually handed down in December 2003. The ECJ made no suggestion of deliberate misrepresentation on the part of AZ, and AZ maintains that a good faith, reasonable approach was taken at all times. Misleading representations made in the course of applications for intellectual property rights cannot in law amount to an abuse unless and until the dishonestly obtained rights are enforced or are capable of being enforced;
- 3) AZ does not accept that it infringed the competition rules through the introduction of the MUPS formulation or through the withdrawal of “Losec” capsules in some markets: These were legitimate business decisions by some of AZ’s local marketing companies. The MUPS formulation offers significant benefits over capsules for certain categories of patients and its launch in 48 countries worldwide belies Commission claims about its selective introduction in Europe. Product withdrawals were undeniably a part of normal business practice by AZ’s local marketing companies and were within the bounds of applicable law. Equally it was not unlawful to withdraw the registrations for those products;

- 4) Article 82 EC, properly interpreted, did not impose on AZ an obligation to maintain a marketing authorization for a product they no longer marketed, merely because it would make it easier for generics and parallel traders to compete with it;
- 5) The Commission has not taken into account the fact that generic companies, if they so wished, could have relied on published literature to secure their own marketing authorizations, irrespective of the existence (or not) of AZ's product registrations;
- 6) The Commission has not shown that the behavior complained of had any significant effect on competition or on trade between Member States.¹¹⁰

4.2.2 Assessment

4.2.2.1 Market Definition

I deem it necessary to repeat that in cases relating to Article 82 EC, market definition is of utmost importance. If an undertaking is not in a dominant position on the relevant market, it escapes Article 82 EC.

First, to better understand the problem, it is necessary to give a brief outline of most common treatments for stomach diseases – H2 blockers and PPI's. H2 blockers and PPI's are classes of medicines which proactively inhibit the acid secretion into the stomach. Acid is pumped into the stomach by a specific enzyme ("the proton pump") inside the so-called parietal cells along the stomach's wall. However, the H2 blockers only block the so-called

¹¹⁰ See Astra Zeneca's brief of alleged infringement of Article 82 EC. Available at <http://www.astrazeneca.com/sites/7/imagebank/typearticleparam511187/astrazeneca-ec-omeprazole-investigation-brief.pdf>. Visited on the 23rd of April 2006 and the application referred to in FN 6.

histamine receptors in the parietal cells and these histamine receptors are only one of the stimulus of the proton pump. In contrast PPI's reach deeper into the acid-producing parietal cells and pin-point the proton pump itself. In other words, whereas H2 blockers only operate indirectly on the proton pump, the PPI's do so directly.¹¹¹

In 1998, 1999 and 2000 "Losec" (the PPI patented by AZ) became the best selling prescription medicine ever with sales of, respectively USD 4.8 billion, USD 5.9 billion and USD 6.3 billion. In 1999 and 2000, "Losec" accounted for almost 40% of AZ's total sales.¹¹² The drug has in total 17 indications.¹¹³

The Commission claims that H2 blockers and PPI's are not interchangeable¹¹⁴ and PPI's constitute the most effective and appropriate remedy for stomach diseases *i.e.* these products are on a different product market.¹¹⁵

AZ does not agree with this assessment. It commissioned a study undertaken by the economic consultant Lexecon. The study was an economic estimation of the impact of specific competitive variables on the substitution among PPI's and H2 blockers in Germany and the United Kingdom. AZ claims that this study supports the hypothesis that H2 blockers constituted a significant constraint on PPI's in Germany and the United Kingdom.¹¹⁶

It is very difficult to assess, based only on the Decision, whether actually the H2 blockers and PPI's are interchangeable. It is common ground that both

¹¹¹ See Decision, para. 34.

¹¹² *Id.*, para. 9.

¹¹³ *Id.* para. 30.

¹¹⁴ *Id.*, para. 79.

¹¹⁵ *Id.* para 386.

¹¹⁶ *Id.* para 347.

can be used for treating stomach diseases; the disagreement between the parties is, whether these products are on the same or on a different market.

This disagreement shall be decided by the CFI. If it shall be ruled that there was an effective competition between the two drugs, it could lead to the annulment of the Commission's decision due to the fact that AZ was not a dominant undertaking in the relevant market (it had no market power) and as such can not be liable under Article 82 EC.

4.2.2.2 Giving Misleading Information

In 1993 and 1994 AZ submitted applications to a number of national patent offices within the EEA in order to obtain so-called supplementary protection certificates (SPCs). It did so on the basis of Council Regulation (EEC) No 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products.¹¹⁷ Such certificates effectively extend the basic patent protection for the active substance in a pharmaceutical product.¹¹⁸

A generic manufacturer can not launch a generic version without either obtaining the consent of the patent holder or committing patent infringement before the substance patent, extended as the case may be by an SPC, of the original reference product expires. The effect of the SPC protection is therefore to delay market entry for generic companies.¹¹⁹

AZ's 'misrepresentations' in its SPC applications are said to consist in providing the wrong date for calculating the duration of the supplementary protection. This meant that AZ gained an additional period of protection for

¹¹⁷ Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, ([1992] OJ L 182/1).

¹¹⁸ See Decision, para. 143.

¹¹⁹ *Id.* para. 148.

“Losec” on top of its legal entitlement. According to the Commission, AZ should have informed all national patent authorities of the date of the ‘first authorization’ for “Losec” in the EU. However, at the time at which AZ made the SPC applications, the meaning of ‘first authorization’ was unclear. National patent offices varied in their interpretation of the provision, with some taking the date to refer solely to the first grant of a marketing authorization in the EU/EEA and some picking the later date on which a price or reimbursement level has been agreed with the relevant national authority, as this is also a precondition to commercialization.¹²⁰

On the 16th of June 1994, when AZ submitted a new submission with the UK patent office, AZ claimed that “in practice, it is not possible to market a medicinal product until it appears in the Ministry of Health’s list of drugs that have received marketing authorizations. New drugs will not be prescribed by doctors or dispensed by pharmacists until they have received this list ... The date when as a practical matter the medicine could first have been placed on the market in the EEC is the relevant date.”¹²¹ So, AZ claimed that the date when the medicinal products could be actually marketed (not when the authorization was granted), is the relevant date for calculating the supplementary protection.

However, at the end of 2003 in *Hässle AB v Ratiopharm GmbH* the ECJ stated that “while the wording of Article 19 (1) of Regulation No 1768/92 does not make it clear that the first marketing authorization mentioned therein must be obtained in accordance with Directive 65/65,¹²² in the absence of an express reference to that directive, neither does that fact rule

¹²⁰ Lawrance, S. and Treacy, P., The Commission's AstraZeneca decision: delaying generic entry is an abuse of a dominant position, *Journal of Intellectual Property Law & Practice* 2005 vol 1 no 1 pages 7-9. Available at <http://jiplp.oxfordjournals.org/cgi/content/full/1/1/7>. Visited on the 23rd of April 2006.

¹²¹ Decision, para. 213.

¹²² Now Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, ([2001] OJ L 311/67).

out such an interpretation. (...) The first authorization to place ... on the market mentioned in Article 19 (1) of Regulation No 1768/92 refers only to the marketing authorization relating to provisions on medicinal products in accordance with Directive 65/65.”¹²³ It should be noted that Hässle AB is a fully owned subsidiary of AZ.

Abuse of a dominant position is an objective concept and requires no intent from the part of the dominant undertaking. AZ can not claim that it should escape Article 82 EC merely because it lacked the intent to abuse its alleged dominant position.

The Commission has confirmed that it is not alleging that Astra was in any way misusing its intellectual property rights.¹²⁴ What the Commission seems to be claiming is that Astra Zeneca used the legal uncertainty to its advantage to extend its patent protection for the detriment of the generic producers.

The CFI has held in *ITT Promedia* that “the ability to assert one's rights through the courts and the judicial control which that entails constitute the expression of a general principle of law which underlies the constitutional traditions common to the Member States and which is also laid down in Articles 6 and 13 of the European Convention for the Protection of Human Rights and Fundamental Freedoms of 4 November 1950 [...]. As access to the Court is a fundamental right and a general principle ensuring the rule of law, it is only in wholly exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an abuse of a dominant position within the meaning of Article 8[2] of the Treaty.”¹²⁵

¹²³ Case C-127/00 *Hässle AB v Ratiopharm GmbH*, [2003] ECR I-14781, paras 54 and 61.

¹²⁴ Astra Zeneca's brief of alleged infringement of Article 82 EC. Available at <http://www.astrazeneca.com/sites/7/imagebank/typearticleparam511187/astrazeneca-ec-omeprazole-investigation-brief.pdf>. Visited on the 23rd of April 2006.

¹²⁵ Case T-111/96 *ITT Promedia NV v Commission of the European Communities*, [1998] ECR II-2937, para. 60.

I find that as the fully owned subsidiary of AZ had turned to court to assert its position regarding the relevant date for calculating the SPC, AZ's conduct should escape Article 82 EC under the *ITT Promedia* judgment. The general principle of law – the ability to assert one's rights through the courts – outweighs Article 82 EC, even if in the end it turns out that the position of the claimant was incorrect.

I see no reason why now, as it has turned out that the patent protection granted for the drug “Losec” had actually expired and AZ was in possession of certificates which were wrongly issued, AZ should be held liable under Article 82 EC. The generic producers could turn to other available legal remedies *e.g.* sue AZ or the respective state authority for damages (the unearned profit) that the unlawfully extended SPC-s allegedly caused them.

Applying Article 82 EC to AZ would mean that a situation AZ was in 1993-1994, would be assessed *ex tunc* having regard the *ex nunc* interpretation of the ECJ. In essence, the interpretation of the ECJ from the end of 2003 would have retroactive effect to hold AZ liable under Article 82 EC. Though Article 82 EC is not a provision of criminal law *strictu sensu* where the principle *nullum crimen, nulla poena sine praevia lege poenali* applies, I still find that the legal uncertainty caused by the authorities should not be used against AZ.

AZ could not have been sure of the right conduct *i.e.* what the right date was for calculating the duration of the supplementary protection. The information AZ submitted could not be “misleading” because legislation was unclear – as the ECJ noted in *Hässle AB v Ratiopharm GmbH*, the regulation in question did not specify which the relevant marketing authorization was. This is a question that the Commission and other EC institutions should have addressed when they adopted the regulation in question.

I find that giving the alleged “misleading” information was at the time in 1993 and 1994 an objectively justified conduct which should rebut the Commission's claims of infringement under Article 82 EC.

4.2.2.3 Blocking Entry to Other Firms

Commission claims that AZ abused its dominant position through the introduction of the MUPS formulation and through the withdrawal of “Losec” capsules in some markets “with the intent of blocking or delaying entry by generic firms and parallel traders”. Against this background, it is interesting to note that in 2004 the Canadian competition authority refused to pursue a complaint about “evergreening” practices. The Canadian Competition Bureau said that the regulatory framework already contained specific provisions designed to balance the competing interests of patentees and generic manufacturers and that additional competition intervention was not warranted.¹²⁶

Pharmaceutical companies may decide to withdraw marketing authorizations in a variety of circumstances. For example, the company may have developed an improved version of the drug or the product may be subject to pharmaco-vigilance issues. Indeed, there is no legal obligation to maintain the authorization indefinitely. The AZ decision raises the question of whether the competition authorities should intervene in this way in an industry which is already heavily regulated and which, furthermore, is not fully harmonized across the EU.¹²⁷

In the Decision, the Commission looks very favorably at parallel imports for medicinal products and claims that AZ abused its dominant position *inter*

¹²⁶ Lawrance, S. and Treacy, P. The Commission's AstraZeneca Decision: Delaying Generic Entry is an Abuse of a Dominant Position. *Journal of Intellectual Property Law & Practice* 2005 vol 1 no 1 pages 7-9. Available at <http://jiplp.oxfordjournals.org/cgi/content/full/1/1/7>. Visited on the 23rd of April 2006.

¹²⁷ *Id.*

alia by preventing access for parallel imported products.¹²⁸ In that context, a brief summary of the *Syfait* case is in order.

Until November 2000, GSK met in full the orders which it received in Greece for “Imigran”, “Lamictal” and “Serevent” from pharmaceutical wholesalers. A substantial proportion of those orders were then exported by the wholesalers to other Member States of the European Union where the prices were much higher.¹²⁹

From early November 2000, however, GSK stopped meeting orders from pharmaceutical wholesalers and stated instead that it would supply hospitals and pharmacies directly. It alleged that the export of the relevant products by wholesalers was leading to significant shortages on the Greek market. It subsequently reinstated supplies to wholesalers, but still refused to meet their orders in full.¹³⁰

That refusal formed the subject of proceedings before the Greek Competition Commission as a result both of complaints brought by the pharmaceutical wholesalers and of several applications made by GSK for the negative clearance of its distribution policy. Following hearings at which the interested parties set out their positions orally and answered questions put to them, the Competition Commission determined, by a decision of 22 January 2003, to suspend the case before it and to refer various questions to the ECJ.¹³¹

AG Jacobs found in his opinion that a dominant pharmaceutical undertaking which restricts the supply of its products does not necessarily abuse its

¹²⁸ See Decision, paras 139-142.

¹²⁹ Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE*, opinion of AG Jacobs delivered on the 28th of October 2004, [2005] ECR-I 4609, para 5.

¹³⁰ *Id.* para. 6.

¹³¹ *Id.* para. 7-9.

dominant position within the meaning of Article 82 EC merely because of its intention thereby to limit parallel trade.¹³²

He concluded that “a restriction of supply by a dominant pharmaceutical undertaking in order to limit parallel trade is capable of justification as a reasonable and proportionate measure in defense of that undertaking's commercial interests. Such a restriction does not protect price disparities which are of the undertaking's own making, nor does it directly impede trade, which is rather blocked by public service obligations imposed by the Member States. To require the undertaking to supply all export orders placed with it would in many cases impose a disproportionate burden given the moral and legal obligations on it to maintain supplies in all Member States. Given the specific economic characteristics of the pharmaceutical industry, a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate. Moreover, it cannot be assumed that parallel trade would in fact benefit either the ultimate consumers of pharmaceutical products or the Member States, as primary purchasers of such products.”¹³³

Unfortunately the ECJ found that it has no jurisdiction to answer the questions referred by the Greek Competition Commission by decision of 22 January 2003 and did not deal with the issue of interpreting Article 82 EC.¹³⁴

It seems to me that with respect to impeding parallel trade, AZ can put forth the same arguments as did GSK in the *Syfait* case – the conduct of AZ, even if found as an abuse under Article 82 EC, is objectively justified against parallel importers in defense of AZ's commercial interests.

¹³² *Id.* para. 69.

¹³³ *Id.* para. 100.

¹³⁴ Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AVEE* [2005] ECR I-4609.

Furthermore, I am of the opinion that the objective justification holds also to introduction of the MUPS formulation and withdrawal of “Losec” capsules, which allegedly had the effect of blocking or delaying entry by generic firms. As the Commission acknowledges, changes were made to Directive 2001/83/EC,¹³⁵ to make it impossible to repeat this specific conduct by other undertakings.

The Commission institutions consider access to generic medicines as one of the objectives of Community pharmaceutical legislation and policy.¹³⁶ The Commission does not contend in the *AstraZeneca* case that the purpose of the marketing authorization is to facilitate entry of generic products but that, in the specific circumstances of the case, the surrender of the market authorization may be an element of the abuse.¹³⁷

I find that it is only natural that undertakings which see an opportunity to protect their commercial interests and maximize profit, would use such an opportunity. Even though dominant undertakings have a “special responsibility”, I am of the opinion that it should not go as far as to help the competitors of the undertaking in a situation where the competitors’ interests are infringed not by the dominant undertaking, but the fact that Commission officials neglected to see future problems with the adopted regulation.

To me, the explanation of AZ that MUPS formulation offers significant benefits over capsules for certain categories of patients seems perfectly plausible. However, there is also much weight in the Commission’s argument in the Decision that AZ’s behavior did not – at least at the relevant point in time – constitute standard industry practice.¹³⁸

¹³⁵ See FN 12.

¹³⁶ See Decision, para 113.

¹³⁷ *Id.*, para. 842.

¹³⁸ *Id.* paras 821-829.

There is no legal obligation to maintain the authorization indefinitely. I find that that the obligation to maintain authorization could not arise from Article 82 EC merely because there are competitors who would need the authorization of the dominant undertaking to enter the market more quickly. This is all the more true if in fact the generic competitors could have relied on published literature to secure their own marketing authorizations, as AZ claims.

4.2.2.4 Assessment of R&D

It is noteworthy that in assessing the *AstraZeneca* case, the Commission does not attribute almost any importance to R&D. The Commission finds that in dynamic markets, such as the pharmaceutical sector, where innovation plays an important role, dominance cannot be limited to situations where the dominant company would simply refrain from investing in R&D. In such markets, a dominant company has to invest regularly if it wants to preserve its position. The mere fact that a company invests in promotion and R&D does not by itself rule out dominance.¹³⁹

I find that this short assessment by the Commission is short-sighted. It is true that investment in R&D is a necessity for pharmaceutical undertakings. However, I the Commission must have taken into account the size of the R&D investments and the likelihood that these investments pay off. As stated above, on average, out of every 10,000 substances synthesised in laboratories, only one or two will successfully pass all the stages to become marketable medicines and for every ten drugs that came to market, only three cover the average development costs.

¹³⁹ *Id.* para. 514.

Essentially, AZ is being punished for having invested in R&D, taken the risks, developed a new drug and (against all odds) gained unusually high profit from it. If the Decision shall stand, it is bound to have a cooling effect on R&D for the pharmaceutical undertakings.

The Commission's policy on promoting access to generic producers to cut down prices for pharmaceutical products does not in the long run benefit the industry. If the Community Courts find that AZ had a special responsibility to help generic producers, it is likely that in the future (due to likely cuts in R&D costs) there are less drugs that could be generically produced, parallel imported or used to cure patients.

The added risk of being liable under Article 82 EC could mean that the companies would lose incentive for innovation, which would not benefit neither the generic producers, parallel importers nor the customers.

4.2.2.5 Assessment of the Role of National Authorities

The price of medicinal products is negotiated with national governments. The Commission finds however, that AZ arguments about buyer power constituting an element conducive to lack of dominance are exaggerated. The health system may negotiate a price for a medicine, but it cannot normally determine the quantity of the medicine that will be bought, as the decision is mainly taken by a third party (normally the prescribing doctors and, to a limited extent, the final consumer). Within the EEA measures are taken to encourage doctors to prescribe more cost-effective medicines but their effects are often limited.¹⁴⁰ In any event the fact that a dominant undertaking may make more limited use of price as a parameter of

¹⁴⁰ *Id.* para. 558.

competition does not mean that it may not behave to some extent independently of its competitors.¹⁴¹

I don't agree with the Commission. Though it is true that price is not the only relevant factor on the market, it is still the most important factor. Pharmaceutical undertakings must be able to regain their investments in R&D. Since only three drugs out of ten cover their development costs, it is obvious that contrary to the claims of the Commission, the national authorities must have substantial buyer-power. What is more, the Commission does not deny that national authorities have adopted a policy to reduce expenses on health care.¹⁴² How can the national authorities not have buyer power if they can effectively enact cost-saving measures?

Moreover, due to public-service obligations, the pharmaceutical undertakings can not freely determine the quantity of products to place on the market. As evidenced by the *Syfait* and *Adalat* cases, pharmaceutical undertakings could suffer substantial loss due to parallel imports.

4.2.3 Summary of the *AstraZeneca* case

I find that the Commission could have interpreted Article 82 EC too broadly and defined the relevant market too narrowly. As both the PPI-s and H2 blockers are used to cure the same disease, it seems to me that there must be some interchangeability between those products *i.e.* they must be on the same relevant market.

It is true that any dominant undertaking has a special responsibility to maintain effective competition, but this does not mean that an allegedly dominant undertaking must facilitate access to the market for generic

¹⁴¹ *Id.* para. 561.

¹⁴² *Id.* para. 70.

producers. An undertaking which asserts its alleged rights through courts can not in my mind be held liable under Article 82 EC.

I find that the statements of AZ regarding the relevant date for SPCs were not misleading at the relevant time since the regulation was not sufficiently clear as to what should be considered as the relevant date. The introduction of MUPS capsules should also be seen as a justified business conduct. The “special responsibility” of AZ did not extend to providing help for generic competitors to enter the market, especially if they could do that (as AZ alleges) irrespective of the conduct of AZ.

If the Commission’s Decision would not be annulled, it would discourage the pharmaceutical undertakings to use their patents and other legal means to protect their R&D investments. This would limit production, markets and technical development to the prejudice of consumers.

Conclusion

The pharmaceutical industry is very specific, which sets it apart from all other industries engaged in the production of readily traded goods. The pharmaceutical undertakings can not freely set the prices for their products and once a drug has been marketed, are under an obligation to supply all Member States and parts of all Member States. This makes it all the more difficult for pharmaceutical undertakings to recover the “sunk” R&D costs on medicinal products.

Since prices for medicines are determined by national public authorities, there can be no single market in medicinal products in the EU. A single price for pharmaceuticals in the EU would in any case not be economically feasible, having regard the huge regulatory and price differences in Member States which would force the pharmaceutical undertakings to limit their production and sell only to high-priced countries. Surely, protection of health is more important than forcing a single market for medicines.

Clearly, as there can be no single market for pharmaceuticals, the market definition under Article 82 EC must be determined along national lines. The market definition under Article 82 EC must take into account all possible substitutes on the supply side, demand side and potential competition. It should not be allowed for the Commission to define the relevant market very narrowly, just to make Article 82 EC applicable in a particular case. I am of the opinion that this could have happened in the *AstraZeneca* case. Still, this question is ultimately for the Community Courts to decide.

The Commission finds that “where a certain exclusionary conduct is clearly not competition on the merits, in particular conduct which clearly creates no efficiencies and which only raises obstacles to residual competition, such conduct is presumed to be an abuse.” I find that in the *AstraZeneca* case, the Commission is too short-sighted in finding that the conduct of AZ was an abuse of its alleged dominant position. Pharmaceutical undertakings, which

make about 17% of the total EU business R&D expenditure,¹⁴³ create efficiencies (new drugs to cure illnesses) and compete on the merits (regaining R&D investment is also part of competition on the merits in the pharmaceutical industry). The conduct of AZ was in my assessment legitimate and objectively justified.

Both the interests of the original producers and generic producers are regulated in detail by Community legislation. AZ should not suffer the consequences under Article 82 EC merely because the Commission and the Parliament overlooked the likely implications of the unclear legislation. Pharmaceutical undertakings should be able to defend their business interests using all available legal methods. The generic producers could similarly use all available legal methods to regain their allegedly unearned profit due to the AZ's unlawful SPC's.

Even though dominant undertakings have a special responsibility, I deem that this responsibility does not go as far as to be active and help competitors. If AZ had valid reasons for deregistering its products and for introducing new products, these legitimate business decisions can not be deemed as an abuse under Article 82 EC merely because it would have been easier for generic producers to compete with AZ, if AZ had not taken those decisions. This would hold all the more if in fact the generic producers could have entered the market irrespective of the AZ's conduct.

The *AstraZeneca* case is the first case applying Article 82 EC by the Commission to pharmaceutical undertakings. In light of the recently published Discussion Paper and the opinion of AG Jacobs in *Syfait*, the outcome of this case will decide what the limits of Article 82 EC for pharmaceutical undertakings are.

If the Decision is upheld by the courts, it could be a serious disincentive for pharmaceutical undertakings to innovate and cause many uncertainties,

¹⁴³ See FN 10.

which in the long run would not benefit neither generic producers nor consumers.

Bibliography

Commission Decisions

1. 85/609/EEC: Commission Decision of 14 December 1985 relating to a proceeding under Article 86 [now Article 82] of the EEC Treaty (IV/30.698 - *ECS/AKZO*), ([1985] OJ L 374/1);
2. 87/409/EEC: Commission Decision of 13 July 1987 relating to a proceeding under Article 85 [now Article 81] of the EEC Treaty (IV/31.741 - *Sandoz*), ([1987] OJ L 222/28);
3. Case no IV/M072 - *Sanofi/Sterling Drug*. Decision from the 10 June 1991 pursuant to Article 4 of Council Regulation No 4064/89. Available at http://www.eu.int/comm/competition/mergers/cases/decisions/m72_en.pdf. Visited on the 21st of April 2006;
4. Case no IV/M.1286 - *Johnson & Johnson/Depuy*. Decision from the 28 October 1998 pursuant to Article 4 of Council Regulation No 4064/89. 36. Available at http://europa.eu.int/comm/competition/mergers/cases/decisions/m1286_en.pdf. Visited on the 23rd of April 2006;
5. Commission Decision from the 15 April 2005 Relating to a Proceeding Under Article 82 of the EC Treaty and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 *AstraZeneca*). Available at http://ec.europa.eu/comm/competition/antitrust/cases/decisions/37507/prov_version.pdf. Visited on the 13th of May 2006.

Legislative Acts

1. Agreement on Trade Related Intellectual Property Rights, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994;

2. Commission Communication on the Single Market in Pharmaceuticals, Brussels, 25 November 1998, COM(98) 588 final. Available at http://europa.eu.int/comm/enterprise/library/lib-regulation/doc/com-98-588_en.pdf. Visited on the 11th of April 2006;
3. Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, ([1997] OJ C 372);
4. Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions: “A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action,” Brussels, 1 June 2003, COM(2003) 383 final. Available at http://mednet3.who.int/prioritymeds/report/append/22c_apx.pdf. Visited on the 11th of April 2006;
5. Consolidated Version of the Treaty Establishing the European Community, ([2002] OJ C 325/33);
6. Council Regulation (EEC) No 1768/92 of 18 June 1992 Concerning the Creation of a Supplementary Protection Certificate for Medicinal Products, ([1992] OJ L 182/1);
7. Council Directive 89/105/EEC of 21 December 1988 Relating to the Transparency of Measures Regulating the Prices of Medicinal Products for Human Use and their Inclusion in the Scope of National Health Insurance Systems, ([1989] OJ L 40/8);
8. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Veterinary Medicinal Products, ([2001] OJ L 311/1);
9. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, ([2001] OJ L 311/67);

10. 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, ([2004] OJ L 136/34);
11. European Commission Directorate General for Competition, "DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses." Available at <http://europa.eu.int/comm/competition/antitrust/others/discpaper2005.pdf>. Visited on the 11th of April 2006;
12. Note on the Citation of Articles of the Treaties in the Publications of the Court of Justice and the Court of First Instance, ([1999] OJ C 246/1).

Literature

1. Astra Zeneca's brief of alleged infringement of Article 82 EC. Available at <http://www.astrazeneca.com/sites/7/imagebank/typearticleparam511187/astrazeneca-ec-omeprazole-investigation-brief.pdf>. Visited on the 23rd of April 2006;
2. Commission's press release IP/05/737. Available at <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/737&type=HTML&aged=0&language=EN&guiLanguage=en>. Visited on the 23rd of April 2006;
3. Danzon, P. M., Price Discrimination for Pharmaceuticals: Welfare Effects in the US and the EU. *International Journal of the Economics of Business*, November 1997, no 4, page 307;
4. Danzon, P. M., *The Pharmaceutical Industry*, The Wharton School – University of Pennsylvania, 1999. Available at <http://hc.wharton.upenn.edu/danzon/PDF%20FILES/5880book.pdf>. Visited on the 12th of April 2006;

5. Dullec, U. and Kercshbamer, R., Where are the Problems with Credence Goods? January 2000. Can be downloaded from <http://ideas.repec.org/p/ecm/wc2000/1441.html>. Visited on the 12th of April 2006;
6. EFPIA paper “Article 82 EC: Can It Be Applied to Control Sales by Pharmaceutical Manufacturers to Wholesalers?” Available at http://www.efpia.org/6_publ/Article82ECNov04.pdf. Visited on the 11th of April 2006;
7. EFPIA paper “The Pharmaceutical Industry in Figures, 2005 update.” Available at http://www.efpia.org/6_publ/infigures2005.pdf. Visited on the 11th of April 2006;
8. Eilmansberger, T., How to Distinguish Good From Bad Competition Under Article 82 EC: In Search of Clearer and More Coherent Standards for Anti-Competitive Abuses, Common Market Law Review No 42, February 2005;
9. Engle-Warnick, J. and Ruffle, B. J., Buyer Countervailing Power versus Monopoly Power: Evidence from Experimental Posted-Offer Markets, April 2002. Available at <http://www.econ.bgu.ac.il/papers/154.pdf>. Visited on the 23rd of April 2006;
10. Gambardella, A. *et alia*, Global Competitiveness in Pharmaceuticals, A European Perspective, November 2000. Report prepared for the Enterprise Directorate-General of the European Commission. Available at http://europa.eu.int/comm/enterprise/library/enterprise-papers/pdf/enterprise_paper_01_2001.pdf. Visited on the 11th of April 2006;
11. Glover, G. J., Competition in the Pharmaceutical Marketplace, March 19, 2002. Available at <http://www.ftc.gov/opp/intellect/020319gregoryjglover.pdf>. Visited on the 12th of April 2006;
12. Korah, V., EC Competition Law, Hart Publishing Limited, 2001;

13. Lawrance, S. and Treacy, P., The Commission's AstraZeneca Decision: Delaying Generic Entry is an Abuse of a Dominant Position, *Journal of Intellectual Property Law & Practice* 2005 vol 1 no 1. Available at <http://jiplp.oxfordjournals.org/cgi/content/full/1/1/7>. Visited on the 23rd of April 2006;
14. Lawrance, S., Treacy, P., *Legal Uncertainties Leave Pharma Companies in Limbo*, *Managing Intellectual Property*, London, September 2005;
15. Rousseva, E., *Modernizing by Eradicating: How Commission's New Approach to Article 81 EC Dispenses With the Need to Apply Article 82 EC to Vertical Restraints*, *Common Market Law Review*; June 2005 no 42;
16. Schmalensee, R., *Output and Welfare Implications of Monopolistic Third-Degree Price Discrimination*, *Massachusetts Institute of Technology*, 1980. Available to be downloaded from <https://dspace.mit.edu/handle/1721.1/1956>. Visited on the 13th of April 2006;
17. *Simmons & Simmons newsletter of June 2005, Decision of the European Commission in COMP/37.507*. Available at <http://www.simmons-simmons.com/docs/ecjuly.pdf>. Visited on the 23rd of April 2006.

Table of Cases

1. Case 48/69 *Imperial Chemical Industries Ltd. v Commission of the European Communities*, [1972] ECR 619;
2. Case 6/72 *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities*, [1973] ECR 215;
3. Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, [1978] ECR 207;
4. Case 85/76 *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, [1979] ECR 461;
5. Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 3461;
6. Case 41/83 *Italian Republic v Commission of the European Communities*, [1985] ECR 873;
7. Case 170/83 *Hydrotherm Gerätebau GmbH v Compact del Dott. Ing. Mario Andreoli & C. Sas*, [1984] ECR 2999;
8. Cases C-159/91 and C-160/91 *Christian Poucet v Assurances Générales de France and Caisse Mutuelle Régionale du Languedoc-Roussillon*, [1993] ECR I- 637;
9. Case C-73/95 *P Viho Europe BV v Commission of the European Communities*, [1996] ECR I-5457;
10. Case T-234/95 *DSG Dradenauer Stahlgesellschaft mbH v Commission of the European Communities*, [2000] ECR II-2603;
11. Case T-111/96 *ITT Promedia NV v Commission of the European Communities*, [1998] ECR II-2937;

12. Case T-62/98 *Volkswagen AG v Commission of the European Communities*, [2000] ECR II-2707;
13. Case T-66/99 *Minoan Lines SA v Commission of the European Communities*, [2003] ECR II-5515;
14. Case T-319/99 *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental v. Commission of the European Communities*, [2003] ECR II-357;
15. Case C-127/00 *Hässle AB v Ratiopharm GmbH*, [2003] ECR I-14781;
16. Cases C-2/01 P and C-3/01 P *Commission of the European Communities v. Bayer AG (Adalat)*, [2004] ECR I-23;
17. Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE*, [2005] ECR-I 4609;
18. Case C-205/03 P *Federación Nacional de Empresas de Instrumentación Científica, Médica, Técnica y Dental v. Commission of the European Communities* - notification of application, ([2003] OJ C 184/19) and opinion of AG Maduro delivered on the 10th of November 2005, n.y.r.;
19. Case T-321/05 - notification of action brought by AstraZeneca on the 25th of August 2005, ([2005] OJ C 271/24).