

THE ECONOMICS OF THE ANTITRUST REGULATION IN PHARMACEUTICAL SECTOR

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ABSTRACT

The European Court of Justice (ECJ) ruled a decision on September 16, 2008 concerning GlaxoSmithKline's (Glaxo) actions in the Greek market. Lelos case analysed whether Glaxo has infringed article 82 of the Treaty of Rome (Current Article 102 of the Treaty on the Functioning of the European Union) regarding abuse of its dominant position in the market through a refusal to supply. The ECJ decided that there was an abuse of the dominant position, but it indicated a ground-breaking decision by stating that the pharmaceutical companies invest in R&D, this is a sector which is directly related to human health, this is why these in-

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vestments serve to the consumer welfare. Since the protection of the consumer welfare is the responsibility of the court while applying *antitrust* rules, pharmaceutical companies decided to be tolerated more than other companies because by protecting their commercial interests they indeed help to advance the consumer welfare.

The risks that the Lelos decision pose is the increase in prices and effecting consumer welfare in a negative way in the long run by providing too much toleration to the pharmaceutical companies, thus the prices come up to a point where the majority cannot afford it. The appliance of some economic models shows that the consumer welfare is not at risk in the long run due to the market dynamics, but the Court's decision should be supported by some clear restrictions on the comparison amounts invested in R&D and the annual profits of the companies.

JEL Classifications: I19, I31, K10, K21, K41, K42

LOS ASPECTOS ECONOMICOS DE LA REGULACION ANTITRUST EN EL SECTOR FARMACEUTICO

Resumen

El Tribunal de Justicia de la Unión Europea emitió una decisión el pasado 16 de septiembre de 2008 acerca de las acciones de GlaxoSmithKline (Glaxo) en el mercado de Grecia. El caso Lelos analizó si Glaxo infringió el Artículo 82 del Tratado de Roma (actual artículo 102 del Tratado de Funcionamiento de la Unión Europea) acerca del abuso de su posición dominante en el mercado a través de una negativa de suministro. La Corte decidió que había un abuso de su posición dominante, pero en una decisión

heterodoxa estableció que las compañías farmacéuticas invierten en Investigación y Desarrollo y que es un sector directamente relacionado con la salud humana y que por ello estas inversiones sirven al bienestar del consumidor. Dado que la protección del bienestar del consumidor es la responsabilidad del Tribunal al aplicar las normas antitrust, hubo mayor tolerancia con respecto a las compañías farmacéuticas y mucho más que otras compañías ya que las primeras al proteger sus intereses comerciales en realidad ayudan a que progrese el bienestar del consumidor.

El riesgo de la decisión Lelos es el incremento en los precios y que se brinde un bienestar del consumidor de forma negativa en el largo plazo dando demasiado margen de tolerancia a las compañías farmacéuticas; por ende, los precios suben a un punto en que la mayoría no puede costearlos. La aplicación de algunos modelos económicos muestra que el bienestar del consumidor no es un riesgo a largo plazo debido a las dinámicas del mercado, pero la decisión del Tribunal debe ser apoyada mediante algunas restricciones claras sobre las cantidades materia de comparación invertidas en Investigación y Desarrollo y las utilidades anuales de las compañías.

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I. INTRODUCTION OF THE LÉLOS CASE

A. Facts

The events in the Lelos case took place in 2000, in Greece where the medicine prices were the lowest within the Member States. Greek wholesalers were placing exorbitant orders for Glaxo's products with its Greek subsidiary. For three products, one for epilepsy, one for migraines and one for asthma, Glaxo was supplying seven times of the consumers demand in Greece. Nevermore, almost all of these supplies were being exported and this is why the

Greek pharmacies could not even fulfill the demands of the Greek consumers. Because of this reason, Glaxo decided not to supply for nine weeks, these three products to pharmacies, but let them know about this suspense so that they can take stocks for the actual consumer demand. After this suspense, Glaxo decreased the amount of supply to the annual consumption level of the Greek consumers with a little extra as a safety margin¹.

Many Greek wholesalers complained before the Hellenic Competition Commission (hereinafter referred as HCC) in 2001. They claimed that Glaxo held a dominant position on the market for each of the three medicines and that limiting supplies of the three medicines, is the abuse of that dominant position. They simultaneously opened civil proceedings before the Greek courts asking for the supply of additional quantities of products from Glaxo supported with the damages².

“On 3 August 2001, the HCC ordered Glaxo to supply the three medicines to Greek wholesalers in *unlimited quantities*. The order came as a surprise, as never before had a competition authority ordered the supply of *unlimited quantities*, not even from a public utility company. On 6 August 2001, Glaxo closed for the summer holidays. When it re-opened on August 27, it found vast orders for the three products awaiting it. Wholesalers who had been in the habit of ordering 300 units were now asking for 40,000 units. Total orders booked on that *one day* amounted to several times the total amount of the products supplied by Glaxo to all Greek purchasers in the previous year. Glaxo began to execute the orders, dispatching the earliest first. Its entire stock was cleaned out in 24 hours.”³ Glaxo notified the Greek authorities about its inabi-

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1. Judgment of the Court *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEE Farmakeftikon Proionton*, formerly *Glaxowellcome AEE*, C 468/06 to C 478/06, para. 1-27.
 2. FORRESTER, IAN, who led the Glaxo's legal team of experts in *Lelos* case, from http://www.whitecase.com/talking_11182008/, (Downloaded on 27 June, 2010).
 3. FORRESTER.

lity to supply unlimited quantities. Then, on 27 November 2001, the authority decided that Glaxo should supply just the needs of the national Greek market and plus 25% as a safety margin⁴.

The hereinabove referred situation, can be commented as a different abuse. The refusal to supply by Glaxo could have been commented as a abuse of the dominant position in the sense of the article 82, but it is also known that Glaxo has let the market now about the shortage before this refusal so that they guaranteed in a way that the Greek consumers of these drugs did not suffer from the decision of Glaxo. The Greek authorities' decision for being supplied by unlimited quantities has effected the Greek consumers in a worse way, and did cause harm because since all the drugs were exported by trusting that Glaxo was obliged to supply the new quantities soon, some wholesalers risked not to supply pharmacies with these drugs for a long time. The wholesalers were not aiming to harm the consumers, they were expecting new products from Glaxo but the excessive consumption of the product did not allow Glaxo to keep the national need in the Greek market. So, in a way, Greek authorities abused their dominant position and harmed the Greek consumers, in the specific market for the relevant 3 types of drugs.

After these important events, the HCC received written submissions between January and May 2002. In 2003, the HCC applied before the ECJ by asking if Glaxo's refusal to supply unlimited quantities is an abuse of dominant position, in the application the Case-53/03 Syfait was referred. The Court refused the answer the Syfait case in 2005 since the latter was not a court or a tribunal. Nevermore most of the questions from Syfait were parallel to Lelos case and answered in this case⁵.

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4. Judgment of the Court *Sot. Lelos kai Sia EE v. GlaxoSmithKline AEVE Farmakeftikon Proionton*, formerly *Glaxowellcome AEVE*, C 468/06 to C 478/06, para: 13-18.
 5. Judgment *Lelos*, para. 22-23.

“In October 2004, Advocate General (AG) Jacobs of the ECJ delivered an Opinion, endorsing most of the arguments made by Glaxo. He agreed that because of the specific characteristics of the European prescription medicines market (notably that prices were set by the state), Glaxo could not be said to have abused its dominant position and that the parallel trade of medicines does not necessarily result in either any substantial benefits for the ultimate consumers of pharmaceutical products, or contribute to the creation of a European common market in prescription medicines⁶.”

The ECJ never proceeded to issue a final judgment on the merits of the case, because the HCC was not a court. In 2006, the Lelos case was returned to the ECJ, by the reference from the Greek civil courts hearing the same questions. The background of the Syfait and Léllos cases was therefore identical⁷.

B. Court’s reasoning

The Greek wholesalers, supported by the European Commission responded that parallel trade has benefits for the consumers in Member States and that suppliers are free to decide whether or not to supply at a low price in a certain market or to place on the market their products in higher priced countries and delay bringing them on the market in lower priced countries. Advocate General Colomer, who delivered his Opinion in April 2008, broadly supported their position, holding that none of the grounds relied on by Glaxo were adequate to justify not delivering supplies⁸.

There are both national and supra-national jurisdictions in European Union. “Most European countries have not had a proper

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competition laws until very recently, and such national laws are to a large extent reproducing the same features as the laws introduced by the Treaty of Rome and its successive modifications.⁹ In the *Lelos* case, the national jurisdiction created a problem for the appliance of the article 82, since it prohibits the refusal to supply and the Greek jurisdiction wanted a supply of unlimited quantities.

The ECJ pointed out that parallel trade of medicines from a Member State where the prices are low to other Member States where the prices are higher open up an alternative source of supply to buyers of the medicines in the relevant countries. So, Glaxo's argument that the parallel exports are of only minimal benefit to the final consumers collapses.

After this, the ECJ analyzed the possible effect of State regulation of the prices of prescription medicines on the assessment of whether Glaxo's alleged refusal to supply constituted an abuse. The Court observed that the control exercised by Member States over the prices and the reimbursement levels of prescription medicines does not entirely remove those products from the law of supply and demand. Therefore, the degree of the price regulation in the -prescription medicines- sector could not preclude the Community rules on competition from applying. However, the ECJ acknowledged that, in the case of Member States with a system of price regulation, governmental price regulation is one of the factors liable to create opportunities for parallel trade¹⁰.

In the similar *United Brands* case, the ECJ stated that a dominant's firm has no right to refusal to supply for a long-standing customer unless he orders in an ordinary way¹¹.

9. MOTTA, MASSIMO, *Competition policy theory and practice*, Cambridge University Press, p. 9.

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11. TU THANH NGUYEN, TIMO MINNSEN, and XAVIER GROUSSOT, *The Rule of Reason under Article 82 EC After *Sot Lelos kai Sia**, p. 9.

Moreover, the ECJ did not share the opinion of the Commission which had argued that although every company is free to place its products on a lower-price market or not, once the product is sold in such a market, the company has to accept parallel exports. The ECJ stated that in order to defend its own commercial interests, it cannot be the case that the only choice left for a pharmaceuticals company in a dominant position is not to sell its products at all in a Member State where the prices of prescription medicines are set at a low level¹².

The ECJ commented that even if a pharmaceutical company has the dominant position in the market it still has to take proportionate steps to protect its own commercial interests. So, it would be unfair to push this company by the HCC to supply unlimited quantities. ECJ also ruled that the pharmaceutical company, Glaxo can limit its supplies due to the national need of supply and demand of the wholesalers¹³.

The most interesting part of the Lelos case is the clearly shown tolerance for the Glaxo in a way of using the up-limit flexibility of commenting the article 82. The ECJ declared that Glaxo was tolerated because it is a pharmaceutical company and pharmaceutical sector has a specific importance for the society. This specific importance shall bring them the advantage of benefiting from *antitrust* policies, so that their interests can also be known as the interests of the society in a less material sense. In other words; EC guideline for the article 82 states that the main point of preventing the abuse of the dominant position is for protecting consumers from harm, which is also named as the “effect-based” approach. Nevermore, this “consumer harm” has never been explained clearly, and on the contrary, the Lelos case decision states

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that a pharmaceutical company's commercial interests better be protected because they invest their money to R&D departments of theirs and this serves directly to society's benefit, so it's not harmful but beneficial for "consumer welfare". Neither the Commission nor the ECJ defined properly "consumer harm" or "consumer welfare". As a matter of fact in this master thesis, the question to be answered shall be; whether this tolerance of *antitrust* policies for pharmaceuticals might result badly for consumers and in order to answer this question the main method shall be enlightening the definitions of these key concepts by using former decisions as a reference point.

This application first of all risks making Glaxo a monopoly since it has a huge competition advantage –being allowed to the abuse of dominance for its commercial interest officially by ECJ itself–. As an economic fact that if it became a monopoly company would end up with higher prices for consumer it cannot easily be named as a consumer benefit in an effect-based approach.

If there was a chance to choose for consumers; is it better to have same drugs for a reasonable price for a short time, or to have better drugs on an often developed market with very high prices? Here an economic analysis is needed to compare the benefit of the consumers in both cases. The needed elements for these analysis are, the price of the drugs and the benefit of the each consumer, the number of consumers who could not reach the drug because of high prices, the number of consumers who does not care about the money when it comes to drugs, and than calculate the total number to see the social welfare result. Unfortunately, pharmaceutical sector is very hard to analyze in this way since the price of health cannot be calculated even approximately since the analyzed "newly invented drugs" are too much hypothetical.

Another important element is that; if Glaxo was not tolerated and there were new entrances to the market; maybe these new

drugs shall also be invented but it would take more time since one company, in our example Glaxo, would not have such a large R&D department. Then it is very hard to compare, whether it is better to have the new drug at a cheaper price but 10 years later or at a high price but now. Can we tell that it is better to have the drugs 10 years later by ignoring the ill consumers who could have benefited and maybe even saved from death within those 10 years? This question is to be answered in Section II, through economic analysis.

1. ANALYSIS OF THE ARTICLE 82 THROUGH THE CASE

“EC competition law is not always disciplined in application, nor adequately informed by economics, especially in relation to the analysis of abuse of dominance”¹⁴ article 82 of the Treaty regulates the measures on the concept “abuse of dominance” as follows;

Article 82¹⁵

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

14. VICKERS, Competition Policy and Property Rights, Department of Economics Discussion Paper Series No. 436, p. 24.

15. <http://eur-lex.europa.eu> (Downloaded on 17.06.2010).

according to commercial usage, have no connection with the subject of such contracts.

The Commission's Guideline Paper on Article 82 is mostly based on presumptions *au lieu de* clear legal norms; it can also be criticized to use a complete economic approach even in some concepts where legal reasoning was needed¹⁶.

In the 1970's and early 1980's, the ECJ's definition for a dominant position as in article 82, was whether the undertaking has ability to act independently, but currently when searching the occurrence of the dominant position it is necessary to point out the ability of the dominant undertaking in the market to profitably raise prices in the relevant market.¹⁷ As the dominant firms have more effect in the market they also suffer from more strict competition rules in order to protect the competition itself¹⁸.

The ECJ decisions concerning the article 82 tolerate pharmaceutical sector also in Syfait case by stating that the situations in both cases can be named as "abuse of dominance" and these tolerances can also be demanded by other sectors and the Lelos case can cause a short-cut on the defensive arguments of companies who clearly breach article 82 in the future. *Antitrust* Policies first aim to protect the competition and then the consumers and in article 82 it is clearly stated that this abuse can effect the trade between States. In Lelos case, the parallel trade has taken a hit by Glaxo and the Commission decided that, on the contrary of the article 82, even if the trade between the Member States is infringed, the consumer welfare is the one thing that worths protecting.

16. LANG, Article 82EC – The Problems and The Solution, *Nota Di Lavoro* 65.2009, p. 8.

17. JONES, SUFRIN, *EC Competition Law, text, cases and materials*, Oxford Press, p. 292.

18. KARAKURT, ALPER, *Ekonomik ve Hukuki Açıkdan Piyasa Kapama Etkisi*, p. 32.

The ECJ main reasoning was how the R&D investments in pharmaceutical sector are important for the consumer welfare since it is directly related to human health. Nevermore, most of the big companies in many different sectors invest in R&D and they come up with also new invention which are very beneficial for the consumers welfare. Thus, while abusing the dominant position, many sectors can legitimize their act by claiming that they are doing this for increasing the commercial interest which would be invested in R&D departments. It is not hard to foresee that there is a high risk that this decision can sabotage the primarily reasons for having a common competition policy and to protect the consumer welfare.

“Since the objective of competition policy is not to protect competitors but to protect competition and increase welfare, economic analysis suggests to undertake the following four-step approach in order to find whether a firm has engaged in abusive practices: first, find whether the firm is dominant, that is whether it has considerable market power; second, identify whether the practice does indeed have possible anticompetitive effects, including the formulation of a coherent hypothesis about the strategy of the firm; third, analyze possible pro-competitive efficiency effects of the practice at hand; fourth, balance the anti-and pro-competitive effects, that is carry out an assessment of the net effects on consumer welfare¹⁹”.

It is stated very often that the debate about the reform, or “modernization”, of article 82 centres on widely accepted idea that an effects-based analysis of article 82 concerned only with consumer welfare should be adopted²⁰.

The meaning of article 82 is commented differently with many experts, the difference in comments also caused by the different

19. MOTTA, p. 42.

20. JONES, SUFRIN, p. 311.

translation of this article. Looking at the meaning in French and German texts, the abuse of the dominant position can only be understood as exploitive abuse instead of exclusive abuse²¹.

The Guideline Paper states that article 82 shall be commented on a more effects-based approach rather than a form-based approach²². This can also be said as the ECJ has to spend more time on discovering the economic effects of a case, which would be time consuming, hypothetical and subjective and there will always be a risk to either see long term effects and ignore the short term ones or vice versa, or even if both are very well analyzed how can they be compared and chosen one over the other. The form-based approach can also be criticized as not being fair for individual cases nevermore it provides a short-cut to the decisions while effect-based approach risks wrong analysis and unfair decisions.

There is an example case like *Lelos*, which is called *Glaxo Dual Pricing* case where “Glaxo sold its medicines to Spanish wholesalers at prices differentiated according to where the medicine would be consumed”²³.

The ECJ not only made an exception in this case, for commenting article 82 and tolerating, it also took a step forward from the protection and encouraging of the parallel trade for medicines by many jurisprudence of the European Courts’ which aimed to protect the *antitrust* rules and of course the basic principle of free movement of goods.

Moreover, national price measures vary in the twenty-five member European Union and include measures that set the maximum sales price that can be charged to the final consumer or the

21. JONES, SUFRIN, p. 316.

22. LANG, Article 82EC . The Problems and The Solution, *Nota Di Lavoro* 65.2009, p. 31.

23. BRUCE LYONS (edited by), Patrick Rey and James S. Venit, *Cases in European Competition Policy, The Economic Analysis*, Cambridge, *Parallel Trade of Prescription Medicines the Glaxo Dual Pricing case*, p. 268.

reimbursement price, which in effect normally determines the maximum price charged. Although some Member States such as the United Kingdom do not regulate prices, but profits instead, price regulation, often extending to intermediate levels of trade, is the rule in the majority of the Member States.²⁴ Since the abuse of dominance is directly related with the profits, the UK application can be more useful in a case like *Lelos*, where the court ruled that the profits, not the whole turnover, shall be invested in R&D.

2. CRITIQUES ON THE SIMILAR JUDGMENTS

“The Court’s decision is ground-breaking. It placed the consumer welfare at the heart of its analysis in this decision under article 82, such as it was made before for articles 81(1) and 81(3) in the *Glaxo Dual Pricing Case*.²⁵ In *Lelos* case, even there had been a slight limiting of market integration, the protection of the consumer welfare was stated as the highest priority²⁶.

It is known that the Commission has a long-standing commitment for the protection of the parallel trade in medicines as a means of enhancing the single market²⁷ “The legitimacy of Commission’s use of parallel trade to achieve a single market for pharmaceutical products and more pronouncedly in the Advocate General’s opinion in the *Syfait* case, which went further in arguing both that pharmaceutical companies had a legitimate invest in impeding parallel trade and that parallel trade might not be welfare enhancing²⁸”.

“Indeed, the EU case law has so far disregarded the actual effects of the allegedly abusive practices, the Commission does

24. LYONS, p. 268, fn.2.

25. LYONS, p. 272.

26. NGUYEN, p. 16.

27. LYONS, p. 270.

28. LYONS, p. 270.

not need to prove that exclusionary effects have indeed taken place, nor does it need to show that consumers have been hurt, the mere possibility that they could distort competition being enough for a finding of infringement of article 82 of the Treaty²⁹.”

In Glaxo-Wellcome case, it was argued that Commission’s policy of encouraging parallel trade in prescription medicines have not protected consumer welfare, and it was harmful, thus challenging on economic grounds the foundations of the Commission’s approach to parallel trade and market integration. In support of its arguments, GW introduced two economic studies, one on the need for a new approach to parallel imports and the other on the adverse effects of parallel imports on consumer welfare. An additional study refining these two initial studies was introduced during the course of the Commission’s proceeding³⁰. Commission also examined consumer welfare in this decision but in a different way, it found out that there are similar products who were still in R&D, which could be substitutes of Glaxo’s product, so that the opting out of Glaxo’s medicine would not effect consumers negatively³¹.

“It is important to notice that this concept of welfare completely overlooks the issue of income distribution among consumers and producers. This is not because economists think it is an irrelevant issue, but rather because it is a different issue. The welfare measure is a summarizing measure of how efficient a given industry is as a whole and does not address the question of how equal or unequal income is distributed, which can be dealt with by other measures. Note also that the rationale for not considering distributional issues is that in principle it is possible to operate redistribution schemes such that consumers and producers are

29. MOTTA, MASSIMO, *Michelin II – The treatment of rebates*, (edited by) LYONS, p.28.

30. LYONS, p. 271.

31. HATIPOĞLU, CUMHU, *İlac Sektöründeki Rekabet Hukuku Uygulamalarında AR-GE/izin surecindeki ilaclar, Rekabet Kurumu Tez Serisi No:92*, p. 36.

both either better off or worse off. Imagine for instance a situation where, as a result of a change in the economy, welfare increases as the net effect of an increase in consumer surplus and a decrease in producer surplus. In theory, it is possible to redistribute gains from consumers to producers in such a way that both groups are at least as well off as they were before the changes took place³².”

It can be claimed that abusive behaviour consists mainly of exclusionary practices due to the decision Hoffman-La Roche. A possible exception is price discrimination across member states, which occupies a special place in view of the economic integration, objective of the European Union. The list of possible abuses is not exhaustive and it is included just to give possible examples. In general, article 82 is related to exploitative behaviour and such exclusionary practices as predatory pricing or refusal to supply³³.

“Commission disputed there was a direct link between parallel trade and any negative effect on R&D and disputed the magnitude of whatever indirect effect there was. It also rejected GW’s argument that parallel trade has a disruptive effect on distribution and that benefited consumers. The Commission argued instead that no direct link had been established between parallel trade and a decrease in R&D, that parallel trade benefited consumers by ensuring a second source of supply and that the consumers benefited from parallel trade under the various national reimbursement systems, some of which were structured to encourage parallel trade³⁴.”

On October 2006, CFI forced the commission also to re-examine the findings in the Dual-Pricing Case and the key issue of this examination will be to decide whether the additional profit gained by Glaxo through infringing article 81 can advance consumer

32. MOTTA, p.18.

33. MOTTA, p. 34.

34. CFI Judgment in Case, T-168/01, GlaxoSmithKline v. Commission, para. 155-184.

welfare by increasing the investments in R&D. Before this re-examination took place, the ECJ decision on *Lelos*, opened the path to legitimize the pharmaceutical's abusive acts by giving them the reasoning of "increasing investments in R&D", thus advancing the consumer welfare.

The Court rejected the Commission's traditional, doctrinal stance that any measures restricting parallel trade must be automatically condemned as inimical to the single market. As a matter of fact, the Court replaced this per se approach with a rule of reason designed to examine the actual effects of parallel trade on consumer welfare in the relevant economic context³⁵.

The Court expressly referred to a consumer welfare standard when it further noted that, given the legal and economic context in which the notified agreement operated, it was possible that wholesalers' may benefit in terms of price which parallel trade may entail, in which case the advantage will not be passed on to final consumers³⁶.

In order to apply this rule of reason, the market environment should be taken into consideration, when the subject is the prescription medicines; there are particular regulations that determine this industry.

"The Commission had itself concluded inter alia that: the pharmaceutical industry is characterized by intense competition in R&D and it mainly relies on its own profits to finance its investment in R&D. Member States differ significantly as to per capita income and wealth and health care systems with a positive link between healthcare expenditure and income. It might be extremely difficult to establish a single price for the Community as low prices which benefit immediate healthcare budgetary objecti-

35. LYONS, p. 274.

36. LYONS, p. 274.

ves would provoke a steady diminution of R&D investment, whereas high prices would reduce access to consumers and payers in those countries where high prices could not be afforded and pharmaceutical companies charge different prices to take account of the different ability to pay³⁷.”

The *Lelos* case is a very important European Court of Justice (hereinafter referred as ECJ) decision since it rules to tolerate the limitation of supply by the pharmaceutical companies even if it is against parallel trade since these companies have a critical position in society and need to protect their commercial interests in order to invest in R&D departments.

Bearing in mind that ECJ's decision was based on the article 82, the discussion papers of the commission and different ideas on the subject shall be reported.

Commissions discussion papers state that the main argument in application of article 82 is not causing consumer harm. The paper also indicates that refusal to supply can cause competitive problems and it defines this refusal as an abuse of dominant position under the specific conditions named in the article.

All these conditions existed on *Lelos* case when Glaxo refused to supply so the only argument that could be used to match the ECJ's decision in this paper is the “consumer harm” part. The paragraph 87 of the discussion paper states that if the company proves that the non-competitive acts were resulting in favor of the consumers, nevertheless these proofs have to be analysed well such as in *Lelos* case, it shall be analysed whether the extreme power of Glaxo can harm the customers in the long run.

In order to fulfill the third condition the dominant company needs to show that efficiencies brought about by the conduct concerned outweigh the likely negative effects on competition and

37. LYONS, p. 277.

therewith the likely harm to consumers that the conduct might otherwise have. “This will be the case when the Commission on the basis of sufficient evidence is in a position to conclude that the efficiencies generated by the conduct are likely to enhance the ability and incentive of the dominant company to act pro-competitively for the benefit of consumers³⁸.”

“The Discussion Paper, while adopting a general effects-based approach still maintained some form-based elements in the shape of rules and presumptions. Many respondents to the Discussion Paper were critical of this and considered too much form-based analysis lingered on”³⁹.

Many writers discuss that the *Lelos* case will cause uncertainty since it is not easy to set ground rules while creating exceptions to the legal articles. One of the supportive ideas for ECJ’s decision would be find in an article which was written before the final decision on the case such that “the attention of competition authorities which intervene into the fierce competition between the pharmaceutical industry and inter alia parallel traders should not merely focus on the understandable public wish to achieve the cheapest possible access to pharmaceuticals throughout the entire EU. In order to meet utilitarian goals and to enhance the further development of ‘high tech’ drugs, it is also necessary to acknowledge and respect that the development of pharmaceuticals towards market approval is usually extremely risky and expensive and that it is therefore equally important that the original innovators can recoup (or even profit from) their immense R & D investments on reasonable terms”⁴⁰.

38. DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses, Brussels 2005.

39. JONES, SUFRIN, p. 331.

40. NGUYEN, pp. 20-21.

The main problem to be solved in this case is how to decide whether the consumer has an advantage or disadvantage in the long run, so it is essential to define consumer welfare in the sense it is used in the Discussion Paper on Article 82. The EC Commission does not refer to ‘consumer’ in the sense of final-user which is the usual understanding of the term in consumer law casts further doubt on its genuineness⁴¹. Ms. Akman argues that the Commission has to clear this uncertainty and she proposes a test such as that; is the harm shall be borne on the “consumer welfare” then the ground rule shall be to analyze whether the harm in the competition resulted in as harm to the consumers. For example in *Lelos* case, the consumers were not supplied with crucial medicines because of Glaxo’s refusal to supply so this can be a case where a consumer welfare test would result as a “harm to the consumer welfare” while the ECJ taught of it as beneficial for the consumers in the long run.

Most of the doctrines point out that it is very obscure to decide on the effects of a competitive abuse. It is generally accepted that the many of the national courts across Europe have limited capacity when it comes to the analysis and deliberation of complex economic concepts and the assessment of ‘consumer harm’. Given this, a rule based approach, formalistic in nature, is both easier to apply and to predict. By contrast, an effect based approach, requires courts to grapple with complex economic concepts and large quantities of empirical evidence in order to establish the ‘true’ impact of an undertaking’s conduct⁴². It is easy to foresee that the effect based approach shall lead to many different solutions thus, it will result with opposite decisions in very similar

41. AKMAN, PINAR, ‘Consumer Welfare’ and Article 82EC: Practice and Rhetoric, July 2008, p.5, <http://www.ssrn.com> (Downloaded on 20.06.2010).

42. EZRACHI, ARIEL, The European Commission Guidance on Article 82 EC –The Way in which Institutional Realities Limit the Potential for Reform, p. 27.

cases with the breaches of same articles so it will most probably cause a big confusion which would be very risky in *antitrust* law since the fines are extremely high so the rules should be very clear.

Although the views on important issues in *antitrust* policy may differ sharply, the most basic questions are answered by some core beliefs such as; a remedy requiring frequent and detailed assessments of specific business decisions may be infeasible, the more open-ended the enquiry into consumer effects, the greater the incidence of false positives, errors are inevitable in attempts to assess the effects of particular conduct, especially when such effects are in the future, and whether particular conduct benefits or harms consumers over the long term may be difficult to determine⁴³. As a matter of fact; the answers given by the ECJ under the *Lelos* case falls under the definition of these “hard to determine” issues.

There are many questions arising from the effect-based approach, but the most relative one the *Lelos* case shall be “if the competitors are shown to be excluded by the conduct, should it be assumed that consumers are thereby harmed as a result? This is one of the most contentious issues of all and goes back to the reason for protecting the competitive structure by prohibiting exclusionary abuses. If the *antitrust* rules really do only protect competition as a means of protecting consumers, then exclusion which does not harm consumers should be permitted. Much of the criticism of the previous decisional practice of the Commission centers around the tendency to assume detrimental effects on consumers from the exclusion of competitors⁴⁴.

43. WERDEN, G.J., ‘Competition Policy on Exclusionary Conduct, Towards an Effects-based Analysis (2006), *European Competition Journal* 53, 54-55.

44. JONES, SUFRIN, p. 331.

II. ECONOMIC ANALYSIS ON GLAXO'S SITUATION ON A CONSUMER WELFARE APPROACH

The ECJ decision was aiming to protect the consumer welfare, since it foresees that the Glaxo's financial interest would become consumers' interest through investing in R&D. It is known that the pharmaceutical sector relies on R&D work and on patents, and in order to have a patent before the others the R&D investments are seen as a high profit increaser by the companies of this sector. Nevertheless, is there a risk that the tolerated large scale pharmaceutical firms would become so powerful that the rivals would go off the market and the incentives to invest in R&D for the large scale companies would decrease since they would not be in need to rush to get new patents.

Glaxo is the number 2 of the international pharmaceutical sector. It has a turnover around 24,3 billion dollars. It has been established in 116 countries and its R&D budget is about 3,5 billion dollars⁴⁵.

In 1992 there had been a long discussion on the Senate floor in US concerning the effects of the *antitrust* policies applied to the pharmaceutical sectors on consumer welfare. Some senators believed that too much profit and too much monopoly power of certain pharmaceutical companies would effect consumer welfare negatively by causing high drug prices and by reducing the incentives to invest in R&D and some senators were arguing that even though there are risk of high prices the effects of the new invented drugs would be beneficial for consumer welfare.

Senator Pryor was believing that the pharmaceutical companies have too much monopoly power and this could harm the consumer welfare by imposing very high prices. So he was aiming to tolerate the sector less⁴⁶.

45. *Affaire GlaxoSmithKline*, p. 4.

46. VISCUSI, HARRINGTON, VERNON, *Economics of Regulation and Antitrust*, the MIT Press. 895.

“Senator Bradley had made a clear point on the subject by these words;
“*Certainly, lower prices will help consumers to be able to afford prescription drugs. But the question is, what are they going to be able to buy?*”⁴⁷

Bradley’s words show that he was believing that tolerating the pharmaceutical sector creates higher incentives to invest in R&D and thus, high priced better drugs makes consumer welfare better off.

Senator Hatch ended this discussion by a motto which explains also the ideal solution to the R&D tolerations for pharmaceutical sector;

“The public receives the best of both worlds- cheaper drugs today and better drugs tomorrow⁴⁸.”

Hereinbelow some economic models are applied to the relevant case in order to show, how becoming an oligopoly, in other words the number of rivals would effect the incentives to invest in R&D, what regulatory precautions could be implied by calculating the value of statistical life, how the R&D investments are threatened by becoming a monopoly and finally by implying HHI, whether Glaxo could have been commented as a market leader based on the information on 2008 in pharmaceutical market.

A. R&D Rivalry Model

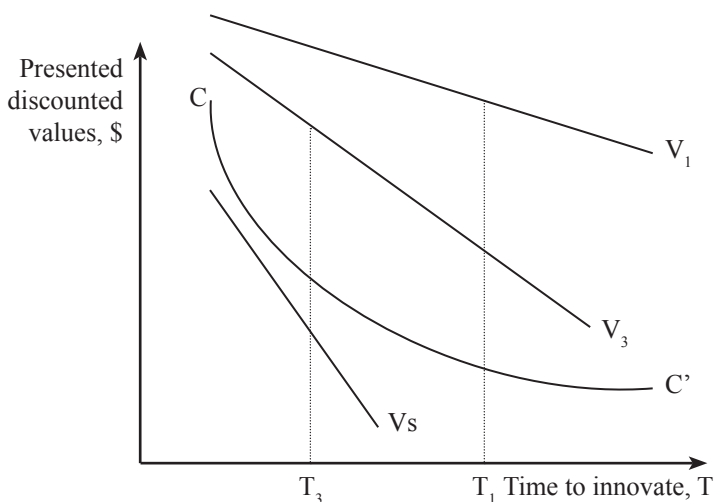
“F.M. Schere and D. Ross have presented an instructive model of R&D rivalry in their book, *Industrial Market Structure and Economic Performance*. Their model is useful in illuminating the conflicting incentives that market structure provides for innovation: (1) more rivals tend to stimulate more rapid innovation in order to

47. Viscusi, p. 895.

48. VISCUSI, p. 894.

be first with a new product and benefits from the disproportionate rewards of being first, and (2) more rivals split the potential benefits into more parts, making each firm's share less...⁴⁹

"The model seeks to show what factors lead to the firm's choice of the number of years from beginning R&D to the market introduction of the product. It should be noted that it is incorrect to equate a shorter time necessarily with "socially preferred." While we often seem to identify higher rates of innovation as necessarily "good", it is of course possible for innovation to take place too rapidly⁵⁰."



"Clearly the implication is that it costs more to shorten the time to innovation, there are several reasons for this. First, costly errors can be made when development steps are taken concurrently instead of waiting for the information early experiments supply. Secondly, parallel experimental approaches may be ne-

49. VISCUSI, p. 95.

50. VISCUSI, p. 95.

cessary to hedge against uncertainty. Third, there are diminishing returns in the application of additional scientific and engineering manpower to a given technical project⁵¹.”

“It assumed that firms choose the time to innovation T , in order to maximize the present discounted value of their profits. Hence the next step is to introduce the function V , which represents how the present value of net revenues varies with T . It is simply that value of T that is associated with the largest vertical difference between the present values of R&D costs. This is also found by locating the value of T where the slope of V_1 equals the slope of CC' . The optimal T is shown as T_1 . The reduced expected appropriability of net revenues by the firm can lead to a situation in which the innovation is simply unprofitable- with a zero rate of innovation. Such a case is shown by the function V_5 , which corresponds to five rivals. Presumably five rivals is too many and would result in too much imitation for R&D to be undertaken at all. The relative payoff for a low T is greater than the case of monopoly. Furthermore, in some cases the pioneer firm is even relatively better off because of brand loyalty developed during the early years. This makes it possible to keep a proportionately greater share of the market than its imitators. For example, brand loyalty may make it possible for the pioneer to keep half the market, with each imitator getting one-fourth⁵².”

So one may claim that, even if the rivals of Glaxo produces a drug with the same effects, the relevant rival also has to convince the doctors, the insurance companies and hospitals that their product is as good as Glaxo's and thus there will be an increased marketing cost for the rival firm. When a doctor prescribes a medicine, he is not effected by its price, so even if there is a very close substitute, the willingness-to-pay in pharmaceutical market

51. VISCUSI, p. 96.

52. VISCUSI, p. 98.

usually is not related to the consumers' choices.⁵³ The ECJ decision on *Lelos* case tolerated the big pharmaceutical companies but it can be said that the pharmaceutical sector in itself also tolerated the large scale companies, both because of the effect and deals on the brand name and for the fact that once a patent is acquired it is easier to innovate that idea by the patent-holder itself.

Therefore the model that is described points clearly to the influence of market structure on innovation. This simple model of R&D rivalry illustrated how increasing the number of rivals can have two opposing effects on the speed of innovation. The key point of the model is that no simple relationship between the number of rivals and the rates of innovation exists a larger number of rivals does not always produce better results for society⁵⁴.

B. Other economic theorems

In order to create a formula for the consumer welfare, an individuals benefit from the pharmaceutical sector should have been calculated but when it comes to value of life there are no accurate economic analysis tools. There are certain applications of economic tools in labor law and in insurance law based on the potential life that a person could lead. However, some drugs are efficient for increasing life quality not directly they propose a longer life, but they ease the life of the disease person in a way that could not be defined by calculations. This is why the following economic theorems that base on the risk calculation could not be used for indicating the optimum consumer welfare when it comes to evaluate the benefits of the invention of a new drug through highly invested R&D work.

53. HATİPOĞLU, p. 4.

54. VISCUSI, p. 99.

1. Policy Evaluation Principles

The main matter of concern is society's total willingness-to-pay for avoiding small probabilities of death or adverse health effects⁵⁵. The ECJ decision risks that the consumer bare high drug prices because of the toleration on pharmaceutical companies to protect their financial interests, is can be commented as the potential increase in the consumer welfare by the invention of a new drug and the willingness-to-pay might increase for this new, more efficient drug. By this economic approach, his willingness to pay is converted into a value of life.

“What it is meant by the value-of-life terminology is the value that you would be willing to pay to prevent a statistical death. This amount is straightforward to calculate. To calculate this magnitude, one simply divides your willingness-to-pay response by the level of the risk that you are reducing, or

$$\text{Value of Statistical life} = \text{Willingness-to-pay} / \text{Size of reduction}$$

This equation gives the amount you would be willing to pay per unit of mortality risk. For the specific values given in the example we considered, the value-of-statistical-life number can be calculated as

$$\text{Value of Statistical life} = \text{Willingness-to-pay} / (1/10000)^{56}$$

As a matter of fact, using drugs do not only help the consumers to live longer but they increase the quality of life, since the value of the high quality and low quality life would differ, and could not be calculated easily, this model is hard to apply to the results of the Lelos case.

55. VISCUSI, p. 717.

56. VISCUSI, p. 717.

2. Value of Risks to Life for Regulatory Policies

“It is useful to examine the government policies that have actually been pursued in the social regulation area to see the extent to which they conform with an appropriate value of statistical life. While agencies diligently value life following norms, the amounts that are actually spent to reduce risks to life are often quite different and may bear little relationship to these benefit values. It is not necessary to pinpoint the exact value of statistical life that is appropriate for any government policy⁵⁷.”

The problem for the consumers who might be affected by the *Lelos* case is again not about the value of the life but the problem to be analyzed is what the quality of that life is? This could also have been solved by some regulatory policies by the government, which foresees a certain amount of government support when it comes to certain, “essential” drugs. Essential drug: a painkiller drug can be very useful but not essential for a consumer A who suffers from a chronic headache so he can choose not to buy the newly produced stronger product, but for other diseases, such as the consumer B who suffers from cancer, the stronger product can be the only way to continue a normal life, so the profit favoring application might hurt this consumer B more than the consumer A. Then there can be a consumer discrimination, and government can favor some types of diseases, such as insurance companies who impose different payments for different consumers, higher payments for more serious diseases, etc.

3. Monopoly Risk concerning R&D

The ECJ Judgment only risks one point, which is not putting any sanctions for not investing in R&D. So the ECJ could have gua-

57. *VISCUSI*, p. 731.

rantee the consumer's welfare by imposing a simple sanctions, such as asking for annual reports from Glaxo for, for example the following 5 years, and if the reports prove that the profits which are gained by the Court's tolerance are invested in R&D, then it should be ok but if they were not equal then Glaxo could have paid a remedy.

The simple calculation should be like that;

Glaxo's annual profit (GAP)

Glaxo's R&D Investment (GRDI)

$$\frac{\text{GAP}(t) - \text{GAP}(t-1)}{\text{GAP}(t-1) \text{ GRDI}(t-1)} = \text{GRDI}(t) - \text{GRDI}(t-1)$$

By putting x instead of GRDI (t) the next year's R&D investment requirement could also be calculated.

Viscusi states that it turns out that only three out of ten drugs that are marketed cover their total costs. Including their share of failures. Therefore, a firm must maintain a large enough R&D budget to ensure that it will have at least the minimal number of successes necessary to maintain financial viability. The large scale pharmaceutical companies, are in need of a new and successful drug submission to the market in every 2 or 3 years in order to keep their financial position⁵⁸.

C. HHI Index

Herfindahl-Hirsch index

The Herfindahl- Hirsch index (HHI) shows that relation between firms, industry and competition within the industry. The market shares are expressed with fractions. The Herfindahl- Hirsch index

58. HATIPOGLU, p. 9.

is varying between 0 and 1,0 and HHI shows that very small firm whereas 1,0 as HHI a single monopolistic producer. The following formula shows how to calculate HHI of the firms.

$$H = \sum_{i=1}^N S_i^2$$

where s_i is the market share of firm i in the market, and N is the number of firms.

Top 20 Pharmaceutical Companies				
	Firms Name	Revenue in Million⁵⁹	Market Share*	s_i^2
1	Pfizer	\$44,424	11.47%	0.01
2	GlaxoSmithKline	\$38,501	9.94%	0.01
3	Sanofi-Aventis	\$38,452	9.93%	0.01
4	AstraZeneca	\$28,713	7.41%	0.01
5	Merck	\$26,532	6.85%	0.00
6	Novartis	\$25,477	6.58%	0.00
7	Johnson & Johnson	\$24,866	6.42%	0.00
8	Roche	\$21,998	5.68%	0.00
9	Eli Lilly & Co.	\$17,638	4.55%	0.00
10	Wyeth	\$17,179	4.43%	0.00
11	Bristol-Myers Squibb	\$15,622	4.03%	0.00
12	Abbott Laboratories	\$14,632	3.78%	0.00
13	Schering-Plough	\$12,773	3.30%	0.00
14	Bayer Schering	\$12,294	3.17%	0.00

(Continúa)

59. www.contractpharma.com (downloaded on 03.08.2010).

(Continuación)

15	Boehringer Ingelheim	\$11,103	2.87%	0.00
16	Takeda	\$10,626	2.74%	0.00
17	Astellas	\$8,530	2.20%	0.00
18	Daiichi-Sankyo	\$7,382	1.91%	0.00
19	Eisai	\$6,250	1.61%	0.00
20	UCB Group	\$4,370	1.13%	0.00
			HHI	0.07

- calculated due to given revenues of 20 companies.

The calculations based on the given revenue table of top 20 pharmaceutical companies prove two points.

First of all, by a given share of 9,9% Glaxo is definitely one of the market leaders, in other words it does had a dominant position in the market on 2008, the year of the ECJ's decision. This proves that the acts held by Glaxo could be named as the abuse of the dominant position under the article 82.

Secondly, by implication of HHI to the market share of the pharmaceutical companies, the HHI is calculated as 0,07, which shows that there is no monopolistic behaviour in the market. This outcome is important because by the economic analysis, it was stated that one of the biggest risks for the consumer welfare would occur if Glaxo could act as a monopolist. This could have result in very high prices and low incentives to invest in R&D. HHI shows that, even if the pharmaceutical companies to benefit from the tolerance of the ECJ and use this decision in their favor to increase their commercial interests, still they will have high incentives to invest in R&D because they have very close and many rivals.

III. ENLIGHTENING THE AMBIGUOUS CONCEPTS

A. What the Lelos Case Might Bring?

The economic analysis which have been applied so far to the pharmaceutical sectors' R&D investments compared to the economic analysis of the value of life proves that the ECJ's decision to tolerate Glaxo for its own commercial interests is a very reasonable argument. Hence, there is one risk which is whether the profit of Glaxo will be invested in which ratio to the R&D department. So far, it has been explained how the decision which favors commercial interests of the Glaxo can effect the consumers in a negative way but it is also explained how important the R&D investments in this sector are, so the final question to be how the Commission can set control over the investment R&D / profit ratio of the Glaxo.

The differences between the prices would effect the consumers affording power for sure, nevermore as the economic analysis proves the fact that different price regulations are necessary for the pharmaceutical companies in order to increase the R&D investments. When it comes to important diseases and relatively high priced products, regulations can both increase the affordability of the drugs for the consumers. It will also help the pharmaceutical company to earn enough money to invest in the R&D departments. This could be a solution which takes to burden of affordability off from the shoulders of the consumers and also helps to protect the consumer welfare.

The economic analysis tools can help to answer many questions; for example it helps to determine whether the private or the public sector should undertake the project.⁶⁰ The reaction of the

60. BELLI, ANDERSON, BARNUM, DIXON, *Economic Analysis of Investment Operations*, The World Bank Washington, DC, p. 3.

private sector in the absence of the government project weighs heavily in the consideration of the with and without the project comparison. In some cases the private sector would have stepped in and undertaken the project anyway⁶¹.

There is also a risk that the high toleration might result as turning the large scale pharmaceuticals companies to act as monopolists restricting the parallel trade. “Considering the extreme case of a monopolist serving two countries where market conditions would lead to different prices. If the firm must adopt a uniform price, it can in fact choose between two strategies: supplying both countries at some intermediate price or withdrawing from the low-price country. Withdrawing may take several forms in practice. It may, for example, consist in delaying the introduction of a new product. And supplying consumers from the other country at the same high price as before. Adopting the latter policy is particularly likely when the price differential is large, since supplying both markets would then involve a substantial loss of profitability in high-price country. Whenever the firm chooses to withdraw from the low-price market, no consumer benefits from the imposition of uniform prices: consumers from the high-price country are offered the same price as before, while in the other country consumers have less choice than before and thus again incur a loss of surplus. Interpreting the lack of access to a product as a prohibitive price for the product, imposing price uniformity then leads in fact to even wider price dispersion, since prices that were previously set at affordable levels jump to unreasonable ones⁶².”

“Some consumers may be willing to pay more in exchange for higher quality, while other consumers may prefer a low-price, low quality product. Similarly, some consumers may be willing to trade

61. BELLI-ANDERSON, p. 19.

62. LYONS, p. 279.

off higher prices against higher levels of R&D and the corresponding promise of better products for the future. R&D is a key factor and some governments appear willing to accept higher prices in order to give higher incentives for R&D, so as to improve the development of new drugs. To the extent that the governments cannot directly compensate pharmaceutical companies for the additional R&D efforts that they may require-and these compensations are subject to serious limitations, imposing uniform prices also imposes a uniformity of incentives to R&D and may thus generate inefficiencies and adverse effects on consumer surplus.”⁶³ Each Member States’ national health authorities face a trade-off between budget concerns, either for setting low reimbursement prices and the development of new treatments that will contribute to improve health conditions in the future, or for accepting higher prices. Parallel trade may effect all countries with its adverse effects. Since countries are obliged to obey restrictions on parallel trade and contribution to R&D, preventing the invention of a new drug effects also the other countries⁶⁴.

“The Commission and the European Courts have a long history of protecting if not promoting parallel trade as a tool for market integration. This led to a per se approach with the result that any restriction on parallel imports was automatically blacklisted as a restriction by object, unlikely ever to be exempted from legal prohibition under article 81 (3). In Contrast, The Court of First Instance departed from the per se approach. It placed consumers rather than any other overriding principle, at the centre of the objectives of *antitrust* rules, thus any application of these *antitrust* rules must be driven by the impact on consumers of the practices under review. It did not constitute by object since prices were anyway regulated,

63. LYONS, p. 281.

64. LYONS, p. 281.

and while the CFI followed the Commission's decision in deciding that Glaxo's provisions had a restrictive effect on competition, it also criticised the Commission's lack of analysis of the economic reality of the markets, as well as the lack of attention paid to the economic facts and reasoning presented by the parties.

Creating new drugs, and investing in R&D incentives are definitely increased when it is highly profitable, this is why this responsibility is given to the private sector, but since health services are one of the basic components of the social welfare, the negative effects which might have arise from the abuse of the dominant position by pharmaceutical sector should be erased by governmental support by further regulations afford of the drugs by the consumers. The costs and benefits of the government-provided goods or services should then be compared with the costs and benefits of having the private sector provide the same goods and services.⁶⁵ "The decision to involve the government in a particular project is ultimately a matter of policy. The role of economic analysis is to guide decision makers by pinpointing the distribution of costs and benefits among the various stakeholders⁶⁶."

"The dominant firm's choice of strategic variable could affect the rival's perception of post-entry profitability in a number of ways. In particular, it could influence; the incumbent's costs, as with R&D and market demand conditions."⁶⁷ Bearing in mind that an active *antitrust* policy without clear objectives like to promote efficiency and competition, can be a major source of social risk and wasted resources⁶⁸.

In other words, when pharmaceutical companies invest in R&D, they can create new drugs which would be very profitable in a fi-

65. BELLI-ANDERSON, p. 20.

66. BELLI-ANDERSON, p. 21.

67. VICKERS, HAY, *The Economics of Market Dominance*, p. 15.

68. SCHMALENSSEE, RICHARD, *Standards for Dominant Firm Conduct*, p. 83.

nancial way for the producers and in a life quality increasing way for the final consumers. In pharmaceutical sector, an innovation is very important to protect through patent and it also gives the owner of the patent a high competitive advantage, but in the end it is used for the consumer welfare since the patents increase the incentives to invest in R&D. The only bad effect of the patents is on rivals. The more new patents a firm holds, the harder for its rivals to compete with it. This is how, tolerating large scale firms might have caused the destroy of the smaller rivals and increase in the prices but the HHI index shows that the market has no incentive to become a monopoly, and rests as a competitive market.

“Competition stimulates innovations, but so does the expectation of being able to appropriate investment in R&D through market profits. To show the importance of market power as an incentives to innovate, but assume that when there is competition no firm can appropriate the innovation, if one firm adopts the technology all other firms are able to produce at the same cost as well, perhaps because there is no patent protecting the innovation firm, or perhaps because of policies which oblige firms to give away their technology to rivals. In this case no firm has an incentive to innovate; diffusion of the technology prevents an innovator from benefiting from it, since after an innovation all firms would charge $p=c$ and make zero profit. If the fixed cost from innovation could never be recovered and no innovation will arise from competition. Market power effects directly the innovation incentives of the firms⁶⁹.”

B. Conclusion

In 2008, ECJ ruled a decision on the article 82 which tolerated the pharmaceutical company, Glaxo by stating that it has a right

69. MOTTA, p. 58.

to protect its own commercial interests by refusing to supply, in other words, by infringing the article 82. ECJ also decided that the company could not be obliged to supply unlimited quantities, and showed that the article 82 prohibits the refusal to supply but “supply” should be commented as the appropriate and proportionate amount, it cannot be excessive as the HCC ordered in *Lelos* case. The ECJ ruled that the refusal to supply by a dominant undertaking falls indeed ambit of article 82 but it should be examined if the undertaking has objective reasons for this refusal⁷⁰.

The decision of the *Lelos* case also specified how the R&D investments are necessary for the consumer welfare. Since this concept is not a clear legal norm, it has been criticized a lot, but what the court had in mind was that; pharmaceutical companies serve directly for public health and they invest their profits in R&D. So if the R&D investments get larger due to higher profits, the consumers will benefit from better drugs.

The consumer welfare will rest as a “open” concept for a little longer but since the competition policies aim to protect this concept through the ECJ judgments, there might be a way to better protect this mal-defined concept by imposing some more restrictions to the newly opened gate through *Lelos* case. The Court could have tolerated Glaxo by stating that they should show some reports in the following years which prove that the increased amount of profit due to the infringement of the article 82 is invested back into the R&D department.

To reach the utilitarian goals and to enhance the further R&D of innovative drugs, it is also required to acknowledge and respect that the development in this sector towards market approval is highly risky and expensive and therefore equally important that the original innovators can profit from their heavy R&D inves-

70. SAMARA, European *Antitrust* Review 2010, Greece.

tments on reasonable terms.⁷¹ Unfortunately, it is very hard to clear all the ambiguities when it comes to pharmaceutical sector *antitrust* policies, this is why the ruling of the Lelos case was seen as a victory by both the pharmaceutical industry and the parallel traders.

By the decision Lelos, the consumer welfare would be increased since they can reach better products hopefully by the expected R&D investments of the pharmaceutical companies and the producer welfare would also be increased since the pharmaceutical companies are given a right to protect their commercial interests even by infringing the EC Treaty.

There is a risk that consumers benefit from the low prices for short terms but then they have to bare the monopoly prices.⁷² The used economic tools showed that Glaxo's tolerated situation is not expected to lead for higher prices for the consumers.

Recent judgments on both national level and the ECJ show that there is a consensus that pharmaceutical companies can legitimate their strategies to restrict the parallel trade as a response to the price differences. Courts recognize that pharmaceutical companies did suffer from parallel trade in some cases and favored them in order to keep their ability to finance the R&D essentials⁷³.

The best solution for the consumer welfare has been exposed by Senator Hatch, in US Senate so this would be a wish which shows the importance of protecting the R&D investments with respect to the consumer welfare;

“The public shall receive the best of both worlds- cheaper drugs today and better drugs tomorrow⁷⁴.”

71. NGUYEN, p. 21.

72. MOTTA, p. 26.

73. HULL, Paralel trade in Pharmaceuticals and EC Competition Law, Life Sciences 2007/08, p. 125.

74. VISCUSI, p. 894.

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