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José Rivas (Master Supervisor)

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Summary

Thesis presented by Teresa Lorca Morales for the Degree of Master of Arts in European Advanced Interdisciplinary Studies. Master Supervisor: José Rivas.

INTRODUCTION

The competition policy is the mean for the correct assignment of resources between enterprises and consumers. It promotes the economic growth and enhances consumer welfare by avoiding situations which can affect negatively the product/service quality, increase the prices or reduce the level of innovation.[1]

The promotion of innovation is one of the main objectives of the competition policy. The competitive concerns are especially important in the technologic-based industries, where the main factor of growth and economic success is the innovation, as result of the R&D processes. The innovation policy, like an instrument of economic development, is capital and not only the European Authorities but also the American Government have realised this. Recently, the US Congress has recognized the necessity to reform its innovation policy, and the European Commission is also aware about the need of an innovation friendly approach in all the European legislation, as it was proposed in the framework of the Lisbon Agenda.[2]

The European Commission knows the impact of the competition law in the innovation race among companies, especially between the *high-tech* based companies. Normally, these types of companies have high fixed costs in order to pursue R&D projects, which will permit the launch of successful innovative products. The *high-tech* companies usually carry out concentration operations, with the purpose to reduce the risk and innovation time, to reach new markets, benefit and exploit from other companies Intellectual Property rights and cover high pipeline costs. However, "a*lthough these transactions may be pro-competitive, they may also raise antitrust concerns and may therefore fall under competition rules".*[3]

It is likely that the concentration operations, and among them, the mergers, in the *high-tech* industry, fall within the scope of competition law. Because of this, it is necessary to adopt a dynamic competition practice, which is coherent with the industry reality. In the other case, the companies could not find incentives to pursue innovation activities, and the final result could be a challenge to the international industry competitiveness and to the consumer welfare. This consumer welfare danger is much higher in sensible sectors, like the pharmaceutical one, where there is the risk that consumer do not benefit from new, more efficient, safer and cheaper drugs for the diseases treatment.

Competition in innovative sectors has characteristics not found in the traditional industries. Are the standard competition procedures valid in the assessment of potentially anti-competitive concentration in the innovative sector? "*The question of appropriateness arises because competition in these industries displays features that are radically different from those encountered in traditional sectors of the economy.*"[4]

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[1] Frederic Jenny, "Razón de ser del Derecho de la competencia y misiones encomendadas a sus autoridades" Ekonomiaz: Revista vasca de economía, ISSN 0213-3865, Nº. 61, 2006, p. 40-55.

[2] Gómez-Acebo & Pombo and Ablondi, Foster, Sobin & Davidow, "Impact of EU Competition Legislation on Innovation."

[3] Ibid.

[4] David Encaoua and Abraham Hollander, Competition policy and innovation, Oxford Review of Economic Policy vol. 18, nº1.

In the European context, the Commission is taking a further step for an innovation approach in the Merger Control, studying not only competition *in the market* but also *for the market*. Competition *in the market* approach takes into account the existing products and considers the R&D efforts only like a part of the product market. Competition *for the market* assessment considers the R&D efforts like a separate market from the existing products. This approach is called "*Innovation Market",* and supposes that the projects for the development of new products/services are analysed as a different market. It has its origin in the American legislation.[5]

This paper will be focused in the Merger Control, where the "*Innovation Market"* appraisal is normally applied. When the antitrust authorities exam a merger between *high tech* companies, they must predict the future competition not only in products, but also the future competition in the research projects, and it is here where the analysis of the "*Innovation Market"* is especially relevant.[6]

Nevertheless, the application of the "*Innovation Market"* in the Merger Control, involves some difficulties. Firstly, concentration in product supply side is assumed to be negative for the consumers, but in the case of "*Innovation Market",* there is no proof that links concentration in research with less innovation output. Concentration in R&D projects could lead to more or less innovation results, depending on the case. Secondly, any anti-competitive reduction in the research competition, could suppose an increase in prices, decrease in diversity of products, less quality of the final product and less innovation.[7]

Competition authorities consider that only in some cases "*Innovation Markets*" are truly pertinent (as in the case of *high-tech* markets, where there are rapid changes and growth, due to significant innovation). Among them we can also find the pharmaceutical sector. Actually, the ethical drug sector offers more guarantees in the application of "*Innovation Market"* because, due to the testing process, (which is public and highly regulated), it is easier to discover the future overlaps between the pipelines than in other industries, where sometimes the projects are secret or hidden by the companies.[8][9] In the field of Merger Control between pharmaceutical companies, the American and European Authorities have developed consolidated practices, where the "*Innovation Market"* assessment is always included.

The objective of this paper is to expose the pertinence of the application of the "*Innovation Market"* in the framework of pharmaceutical mergers. Moreover, this thesis will discuss how the American Federal Trade Commission and the European Commission apply the "*Innovation Market"* analysis, through three different Merger Cases between pharmaceutical undertakings. The reason to choose these three particular cases is because they show how the European and American Authorities valued in a very different way the "*Innovation Markets*" and, consequently, the outcomes of their final decisions are the complete opposite.

The study is organized as follows:

1. Section 1 discusses the Merger Control in *high tech* markets dilemma, that means, the problems encountered by concentration operations between *high-tech* companies,

2. Section 2 provides an overview for a better understanding of the "*Innovation Market"* analysis,

[5] Gómez-Acebo & Pombo , op. cit. note 2.

[6] Directorate for Financial, Fiscal and Enterprise Affairs Competition Committee Merger Review in Emerging High Innovation Markets. Organisation for Economic Co-operation and Development 24-Jan-2003.

[7] Thomas C. Lawton, European Industrial Policy and Competitivenness-Concepts and Instruments, Edited by Thomas C. Lawton, Ed MacMillan business. Chapter 2: "Fostering invention and innovation: Europe's collaborative R&TD initiatives", p. 23-44.

[8] Lexicon http://www.ephmra.org/PDF/Lexicon%20Final%20Jan%2005.pdf 03.04.07.

[9] Directorate for Financial, Fiscal and Enterprise Affairs Competition Committee Merger Review in Emerging High Innovation Markets, op. cit. note 6.

3. Section 3 touches the legal basis for the application of the "*Innovation Market"* assessment in the Merger Control in the European Union,

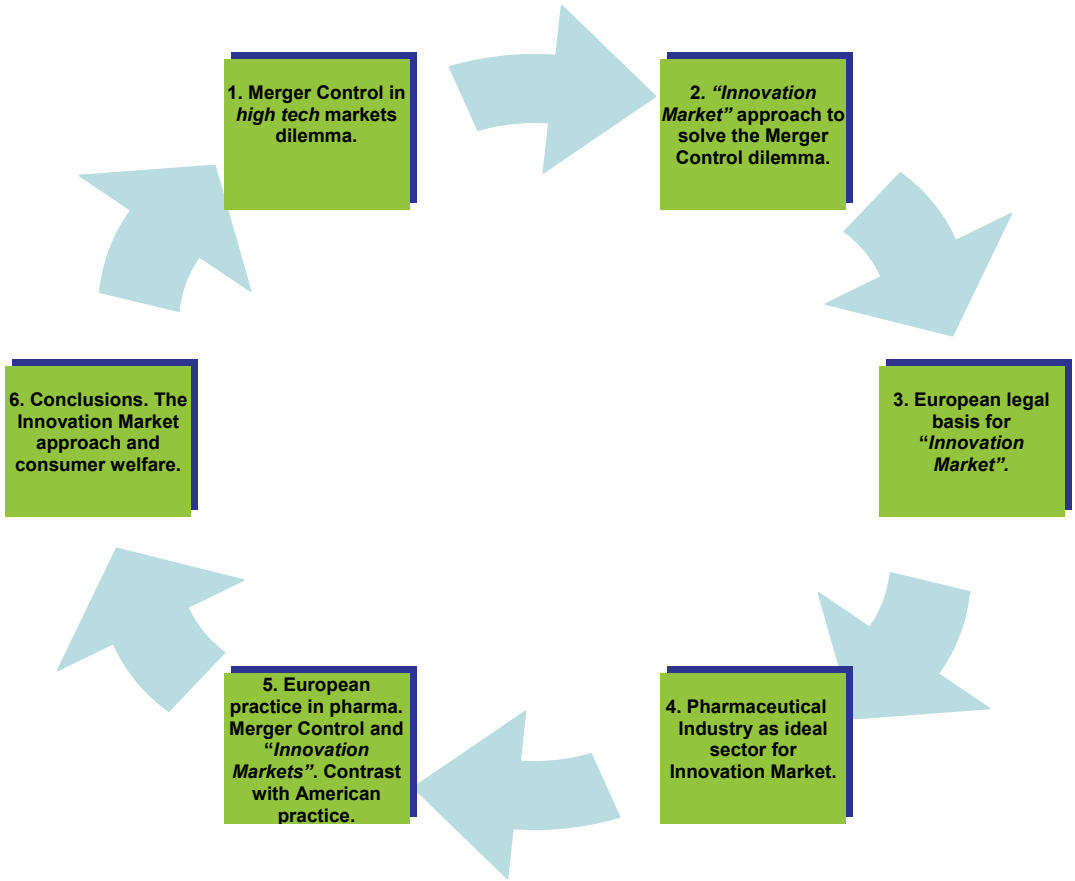
4. Section 4 deals with the pharmaceutical industry, a *high-tech* based sector, and examines its suitability for the application of "*Innovation Market"* assessment,

5. Section 5 assesses the European Practice in the control of concentrations between pharmaceutical firms and how the European authorities have used the "*Innovation Market"* appraisal in three concrete Merger Cases. This practice will be compared and contrasted with the American point of view in the same Merger Cases,

6. Section 6 points out the main conclusions.

The implementation and correct application of *"Innovation Market"* assessment is not in vain, because an erroneous appraisal of this criterion would lead to a reduction in the R&D output, a reduction in innovation, and in the pharmaceutical case, this lessening would mean the privation for consumers of more effective and safer medicaments to combat important diseases. Thus, the role of *"Innovation Market"* in the consumer welfare is more than obvious.

THESIS STRUCTURE



1. MERGER CONTROL IN HIGH TECH-MARKETS DILEMMA

1.1. Reference to Competition Policy in *high tech* markets

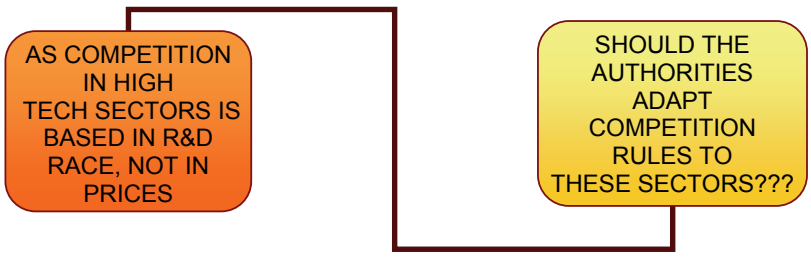
"Competition policy prohibits and combats anti-competitive practices that hurt customers and competitors. Hereby, competition policy allows the most efficient undertakings to flourish, and promotes the flow of capital and labor between sectors based on maximizing returns on investment. This facilitates structural adjustment and rationalization of the European economy by means of the market mechanism".[10]

The existence of competition policy is capital to regulate the market correctly and to promote the consumer welfare. Furthermore, the specific characteristics of some markets, may affect the competition analysis. This is the case of *high-tech* markets, where the competition is focused in the R&D race. Because of this, in concentration operations between *high-tech* companies, the problem which arises is the need of competition control of R&D pipelines. As specialists in the field pointed out: "*The fact that antitrust authorities attempt to regulate innovation is perhaps the most important development in competition law this decade*".[11]

Some of the main characteristics of the *high-tech* markets are their strong dependency from R&D, significant economies of scale, high entry barriers (for example heavy fixed costs), Intellectual Property rights dependency, high level of technical complexity and fast technological change.[12] Should in these cases, the authorities enter to assess the future development of competition in the research projects, with the risky cost of uncertainty? Alternatively, should the competition policy let the market-forces actuate by themselves in the research race, with the expectation that concentration in pipelines would lead to positive output in innovation? Or, should the Authorities build a middle ground between the two precedent positions, maintaining predictability and transparency?[13]

When competition authorities are investigating an antitrust case in the field of *high-tech* companies, the analysis should be tailored to the specific situation in which it is applied. In the next point, we will study how the Merger review has been adapted to innovative environments, following the trend of adapting antitrust practices to market structures.[14]

MAIN CONCLUSION



[10] Thomas C. Lawton., op. cit. note 7, Chapter 3: "EU Competition Rules: promoting and policing the Internal Market" written by Steven McGuire, p. 72-91.

[11] Lawrence B. Landman, Innovation and the Structure of Competition, 81 J. Pat. & Trademark off. soc'y 728, 729 (1999).

[12] Directorate for Financial, Fiscal and Enterprise Affairs Competition Committee Merger Review in Emerging High Innovation Markets, op. cit. note 6.

[13] Glader, Marcus, Innovation market and Competition analysis. EU Competition Law and US Antitrust Law. New Horizons in Competition Law and Economics, 2006, Chapter 1.

[14] Ibid.

1.2. The complexity of Merger review in *high tech* markets

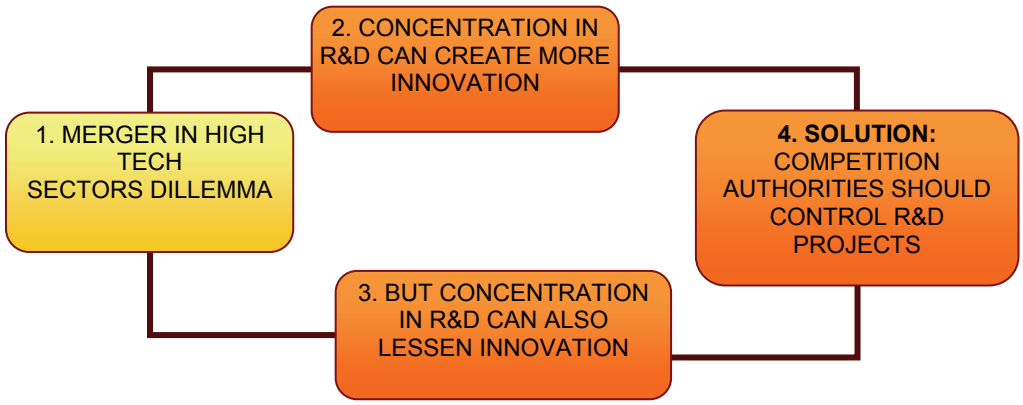
The antitrust authorities' objective is to determine which merger, if consummated, could create the market circumstances that would allow to the resulting firm to raise prices or collude with other companies in the same market. The growth in prices is directly related with reduction in consumer welfare. In an increasingly technologic-based society, not only prices affect consumers, but also innovation can enhance enormously the welfare. The competition officials have agreed that customisation is needed in the Merger Control of *high-tech* sectors. For example, to define the market, the SSNIP test (small but significant non transitory increases in prices) could not give much help in *high-tech* sectors, as consumers would be more concerned about product efficiency or innovative characteristics, than about prices.

Mergers in high innovative markets can originate efficiencies and benefits to consumers, but they also can be the mean to exclude a competitor in R&D projects, through the purchase of the rival in R&D. Experts in the field have stated that, if a number of mergers have optimistic effects, *"there are at least as many instances where the effect is negative"*.[15]

If two competitors in R&D merge, this concentration has the potential effect of reducing the motivation to be the first to market a given product.[16] However, the merger may also promote the efficiency of research programmes, as consequence of the combination of different approaches for the same pipeline. After the counterbalance of the two possible effects, if the first predominates, then, we might anticipate that anti-competitive concerns rise. In the opposite situation, if the merger has for major effect the spillover in R&D, the concentration should be approved by the competition authorities.[17] Hence, the analysis of the research efforts and their substitutes is capital to detect competition problems in merging-innovative companies[18].

"The complexity of mergers in high innovation sectors may require rethinking of the merger review process, increasing sector specific expertise in competition authorities, and taking pro-active steps to prepare for mergers in high innovation markets."[19]

MAIN CONCLUSION



[15] Michael E. D. Koenig, Elizabeth M. Mezick, Impact of mergers & acquisitions on research productivity within the pharmaceutical industry. Jointly published by Akadémiai Kiadó, Budapest Scientometrics, and Kluwer Academic Publishers, Dordrecht Vol. 59, No. 1 (2004) 157.16.

[16] Marcus Glader, op. cit. note 13.

[17] Patricia M. Danzon et al., Mergers and acquisitions in the pharmaceutical and biotech industries, (National Bureau of Econ. Research Working Paper 10536, June 2004), available at http://www.nber.org/papers/w10536.pdf. 09.04.07.

[18] Directorate for Financial, Fiscal and Enterprise Affairs Competition Committee Merger Review in Emerging High Innovation Markets, op. cit. note 6.

[19] Ibid.

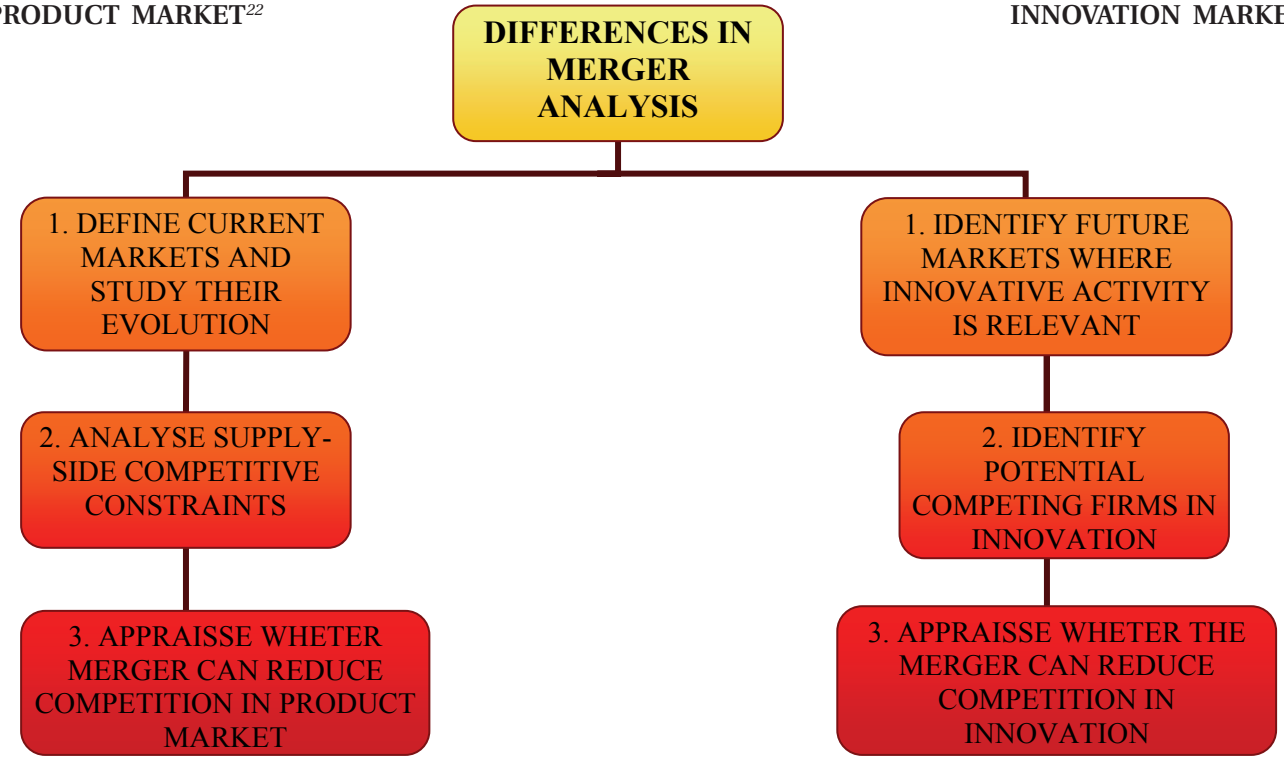
2. INNOVATION MARKET APPROACH (ANALYSIS OF COMPETITION IN R&D AS A SEPARATE MARKET)

To solve the problem of the merger dilemma in *high-tech* sectors, the US competition authorities introduced in 1995 the "*Innovation Market*" analysis in the Antitrust Guidelines for the Licensing of Intellectual Property (IP Guidelines).[20] The *"Innovation Market"* approach supposes the identification of R&D pipelines (directed to a particular new or improved goods or processes), and their close substitutes in the industry.

The objective of the "*Innovation Market"* approach in the Merger Control is to fill the gaps of the traditional merger study, which normally is focused only on competition in the product market. This analysis answers the needed for a tailored competition examination of *high-innovative* sectors, whose characteristics we have mentioned above. In a fast-moving technological world, where many sectors are based in innovation, more than in product prices, the "*Innovation Market"* analysis provides the basis for a correct Merger Control and addresses the present economic environment.

In the traditional Merger Control, competition authorities studied the relevant market, by dividing it into geographic and product market and not paying attention to the future products under development. The fact of maintaining that static Merger Control analysis in dynamic sectors of the economy, where innovation is a capital part, may rise prices in the future products. Moreover, it may delay the launch of products and consequently may negatively affect consumer welfare.[21]

PRODUCT MARKET[22]



INNOVATION MARKET

[20] As described in the 1995 United States Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property.

[21] Directorate for Financial, Fiscal and Enterprise Affairs Competition Committee Merger Review in Emerging High Innovation Markets, op. cit. note 6.

[22] Diagram based on: Marcus Glader, op. cit. note 13, "New horizons in Competition Law and Economy" 2006, p. 208.

The "*Innovation Market"* analysis focuses on the competitive significance of a merger's outcome on innovation, preventing negative effects in the R&D market. This criterion is defined in the IP Guidelines as follows: *"the research and development directed to particular new or improved goods or processes, and the close substitutes for that research and development."*[23] "*Innovation Market"* is neither a product, nor a technology market. *"In an innovation market no one buys or sells anything; rather, one prepares to sell innovative products at some future time".*[24] The "*Innovation Market"* concept tries to recognize mergers that could lessen competition in one market that will exist in the future, but that does not exist yet.[25]

The IP guidelines also define close substitutes like "*research and development efforts, technologies, and goods that significantly constrain the exercise of market power with respect to the relevant research and development, for example by limiting the ability and incentive of a hypothetical monopolist to retard the pace of research and development."* Consequently, the R&D efforts can compete not only with other research pipelines, but also with existing products/services already marketed.[26] To establish the substitutes in R&D projects, the SSNIP test is applied, but customized, requesting if a *"hypothetical monopolist would impose at least a small but significant and non transitory reduction in research and development effort."*[27] R&D pipelines are studied like a separate market by the antitrust authorities and, if the concentration can damage the mentioned "*Innovation Market"*, with the consequent reduction in the innovation efforts, the proposed operation will be censured.

The advantages of the "*Innovation Market"* have been exposed. However, there are also disadvantages from its application. Economic commentators, robustly disagree on the role of *"Innovation Market"* in the Merger analysis.[28] This sceptical stance is based on two points:

I. The difficulty of dealing with Research programmes:

   Some economists argue that "*Innovation Market"* is a risky play where the competition authorities try to guess the future behaviour of the merged companies in the instable field of R&D. Actually, the "*Innovation Market"* approach supposes the acknowledgment that undertakings are not only competing in price, but also in technological development. But innovation analysis is much more problematic that price analysis: how do you establish whether a merger can lessen innovation?[29] Moreover, R&D pipelines are usually hidden or protected like secrets by the undertakings, and frequently, it is difficult to find out the significant projects to include in the *"Innovation Market"*. Since R&D is normally secretive, it is difficult to delineate correctly the *"Innovation Market"*.

II. The lack of causal relation between more competition and more innovation:

   "Economic theory and empirical investigations have not established a relationship between innovation and competition"[30].

[23] Dror. Ben-Asher, "In need of treatment? Merger Control, Pharmaceutical Innovation and Cosumer Welfare", LL.B., M.Juris.* The Journal of Legal Medicine, 21, 271–349, C 2000.

[24] Ronald W. Davis, "Innovation Markets and Merger Enforcement: Current Practice in Perspective", 71 Antitrust L.J. 677, 679 (2003).

[25] Kristen Riemenschneider, New Economy 2006, "Antitrust Review of Merger Analysis Using Innovation Markets", p. 7.

[26] Ibid., p. 11.

[27] Ibid.

[28] Ibid., p. 2.

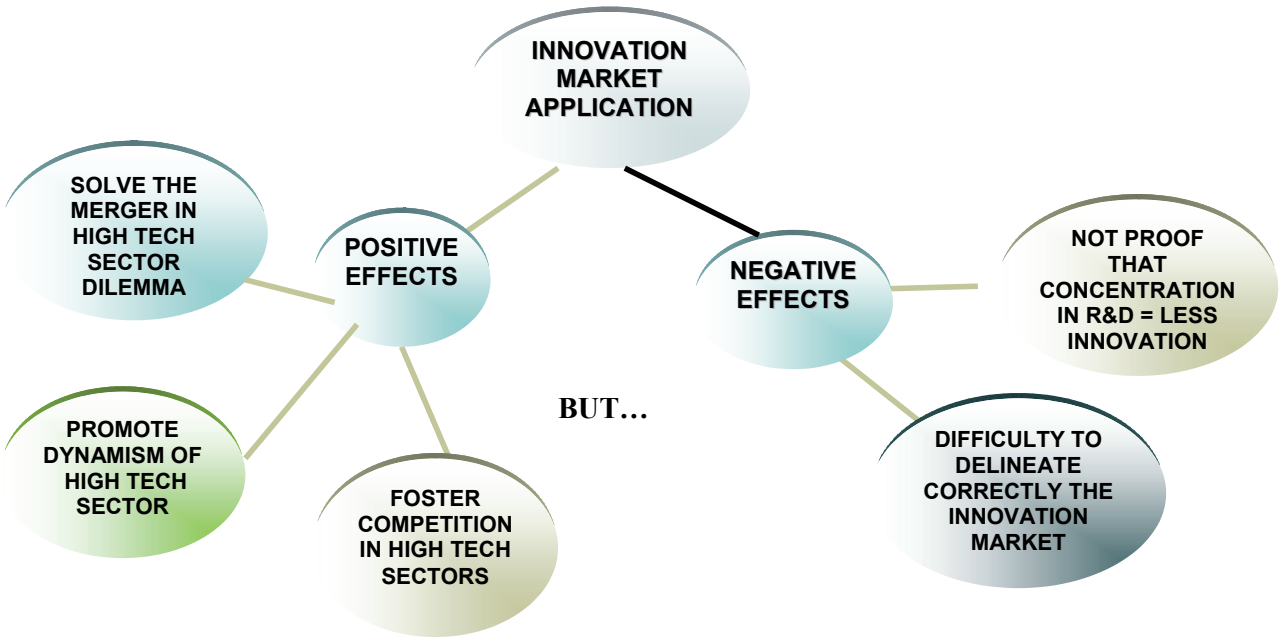
[29] Ibid., p.12.

[30] Federal Trade Commission, "Anticipating the 21ST Century: Competition Policy in the new high-tech global market place", Ch. 7, at 16 (1996), available at http://www.ftc.gov/opp/global/report/gc_v1.pdf.

In the same way that concentration in product supply is assumed to be negative, concentration in R&D efforts has not been proved to reduce R&D output. The equilibrium in the innovation race has not been determined and the use (or abuse) of the *"Innovation Market"* analysis could potentially imply over enforcement.

Even though, several observers have emphasized that concentration in *high-tech* sectors is pro-competitive and that antitrust should not intervene in this type of transaction. Among them, it is possible to underline Schumpeter, who always defended that innovation is promoted when one firm possesses all the creation powers and can make use of this position proficiently.[31] Consequently, if there are less firms carrying out R&D, there will be more R&D output and more innovation. The theoretical basis for those commentators is that more R&D paths for the same project would suppose less efficiency, because more resources will be employed for the same objective. This increase in costs will reverberate negatively in the consumer welfare, because prices will be higher. This argument has for conclusion that concentration in *high-tech* sectors is pro-competitive and, consequently, the introduction of the "*Innovation Market*" analysis would harm the positive effect of collusion (diminish duplicative efforts, reduce costs or industry "synergies").

MAIN CONCLUSION



[31] Kristen Riemenschneider, op.cit. note 25.

3. LEGAL BASIS FOR INNOVATION MARKET IN THE EUROPEAN UNION

We have studied above that *"Innovation Market"* is an American concept introduced in 1995 through the Antitrust Guidelines for the Licensing of Intellectual Property. But, how do the European authorities deal with this concept? The explicit recognition of the *"Innovation Market"* in the European legislation is very recent, starting in 2001. Nowadays, the European legal basis for the introduction of *"Innovation Market"* in the Merger Control praxis is spread among different legal texts (policy documents and regulations) which have progressively elaborated a market definition including R&D examination and its impact in the competition analysis.

The present section tries to study chronologically the European competition legislation, applicable in the Merger Control Procedure, which has introduced the notion of *"Innovation Market"* in the European *"legal praxis"*. We will expose an overview of the main contributions of each of these documents in the configuration of the mentioned concept and, at the end of this section, all different inputs for the building of the *"Innovation Market"* concept in Europe will be summarized.

Through these pieces of legislation and guidelines,[32] antitrust law has been moved from a static to a dynamic approach, where the authorities will be also concerned if a merger transaction can reduce competition in the *future*.[33]

3.1. Commission notice on the definition of the relevant market (1997)

The definition of relevant market is of vital importance in the Merger Control, because the impact of this type of concentration is based on how we delineate this concept. In the current text, the Commission does not mention the *"future markets"* and follows the path built by its previous assessments. However, the definition of the relevant market is the first step for the construction of the "*Innovation Market"* concept, and the logical origin of the analysis at the present time.

The second epigraph of this Notice states that "*Market Definition is a tool to identify and define the boundaries of competition between firms"*. The two basic principles to establish the relevant market are: the demand-side substitutability and the supply-side substitutability.[34]

The Notice 97/C372/03 defends that the relevant market study should be divided into two different parameters: relevant product[35] and relevant geographic market.[36] Consequently, the relevant market has to be understood like the combination of both concepts.[37] Once the market has been delimited, it is possible to

[32] From a practical point of view, competition is one area where not only legal documents are important, but also GUIDELINES, have become frequently used by European (also American) authorities to influence the legal practice, to guide the policy, and set principles for the industry, the market and the courts. Despite the fact that the guidelines are not binding on the courts, their influence among lawyers and judges have grown, and they are generally accepted (also cited) in the tribunals.

[33] Marcus Glader, op. cit. note 13, p. 62.

[34] Commission Notice on the Definition of relevant market for the purposes of Community Competition law (97/CF 372/03), paragraph 15-23.

[35] Ibid., paragraph 7: 'Relevant product markets` are defined as follows: "A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use".

[36] Ibid., paragraph 7: 'Relevant geographic markets` are defined as follows: "The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas".

[37] Ibid., paragraph 9.

calculate markets share for suppliers, based on their relevant product sales in the relevant area.[38] The market share will provide useful information about the market power of the undertakings.

In the framework of Merger Control, the objective of this Notice is to prevent the creation of a dominant position, which can impede normal competition in the common market.[39] Aditionally, in section number four, the relevant market particularities in pharmaceutical mergers will be studied.

3.2. Guidelines on horizontal cooperation (2001)

The Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements, (2001/C 3/02) *set out the principles for the assessment of horizontal cooperation agreements under Article 81 of the Treaty.* [40]

Mergers are within the scope of the Guidelines, because they are horizontal agreements, between two companies which operate *at the same level in the market,* and in most of the cases, competitors.[41]

The Guidelines on Horizontal Cooperation introduce, for the very first time in the European legislation, the concept of "*Innovation Market".* Moreover, the guidelines, make a difference between "existing markets" (which include not only product markets but also technology markets) and "competition in innovation" or (R&D efforts). From paragraph 43 to 52 there is a further explanation of those different arenas:

1. Existing markets, which are divided into:

   • Product markets, integrated not only by products already marketed, but also R&D projects, which are devoted to improve slightly existing product. In product innovation markets, where R&D is directed towards improvements or variations of particular products, the Commission will look for alternatives technologies to which consumer can turn in the case of price increase.[42]

   • Technology markets, formed by Intellectual Properties which are sold independently from the products concerned, and its substitutes.[43]

2. Competition in Innovation/Innovation market, which are R&D efforts related to completely new products, and, therefore, create their own new market.[44] "*In this respect, two scenarios can be distinguished, depending on the nature of the innovative process":*[45]

   • In the case that the R&D efforts can be identified (as in the case of pharmaceutical industry), the competition authorities will seek competing R&D poles, or close substitutes, taking into account "*the nature, scope and size of possible other R & D efforts, their access to financial and human resources,*

[38] Ibid., paragraph 53.

[39] Ibid., paragraph 10.

[40] Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements (2001/C 3/02) paragraph 1.

[41] Ibid.

[42] Ibid.

[43] Ibid., paragraph 47 (b): Technology market: "R & D cooperation may not only concern products but also technology. When rights to intellectual property are marketed separately from the products concerned to which they relate, the relevant technology market has to be defined as well. Technology markets consist of the intellectual property that is licensed and its close substitutes, i.e. other technologies which customers could use as a substitute."

[44] Edurne Navarro, Andrés Font, Jaime Folguera, Juan Briones. "Merger Control in the EU", Oxford University Press 2002, p. 136.

[45] Op. cit. note 40, paragraph 50.

know-how/patents …".[46] The Commission will analyse *"if after the agreement, there will be a sufficient number of R & D poles left".*[47]

- In the case that innovative process is not clearly structured and transparent to identify credible competing R&D projects, the competition authorities will not assess its impact in the future market.[48]

Finally, the guidelines consider that an agreement which eliminates competition on innovation would violate article 81.1 of the Treaty and would not be within the exemption scope of article 81.3. Consequently, in paragraph 71, the Commission reflects its approach concerning innovation in the competition race, thereby reaching a formalization of its former practice:[49]

> "*71 Where as a consequence of a R & D agreement an undertaking is dominant or becoming dominant either on an existing markets or with respect to innovation, such an agreement which produces anti-competitive effects in the meaning of Article 81 can in principle not be exempted. For innovation this is the case, for example, if the agreement combines the only two existing poles of research.*"

3.3. The EC Merger Regulation and Guidelines (2004)

The Council Regulation No 139/2004 of 20 January 2004 on control of concentrations between undertakings (the EC Merger Regulation), set the rules for the control of horizontal mergers.

For the object of our study, it is important to underline art. 2.b, which makes a call for an innovation friendly environment when it provides that, in the appraisal of concentrations, *the Commission shall take into account:" […] the development of technical and economic progress provided that it is to consumers' advantage and does not form an obstacle to competition."*

After the publication of the Merger Regulation, the Commission issued the Guidelines to provide a methodological framework in which the Commission would appraise concentrations between competitors in the market. [50]

The Horizontal Merger Guidelines divide the Commission appraisal of mergers into two different steps:

1. Definition of the relevant market, where there is a general reference to the Commission Notice on the definition of relevant market.

2. The competitive assessment, where the Guidelines are much more focused.[51]

The "innovation friendly approach" of the Commission appears several times through the Guidelines:

[46] Op. cit. note 40, paragraph 51.

[47] Ibid.

[48] Op. cit. note 40, paragraph 52.

[49] Op. cit. note 40, paragraph 71.

[50] Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings Official Journal C 031 , 05/02/2004, p. 5 – 18.

[51] Ibid., paragraph 10.

Firstly, paragraph 8, considers that increased market power, (a capital concept for the Commission to prevent a dominant position[52]), is also the ability of one or more firms to, profitably, diminish innovation and deprive customer of its benefits.

Secondly, paragraph 38, states that mergers between firms in innovation-based markets, can raise serious competition concerns with respect to their pipeline projects, but also can promote competitiveness among the other companies driving them to innovate in the market.

Thirdly, in paragraph 71, the Commission mentions different barriers to entry into the market and, among them, *"technical advantages, such as preferential access to essential facilities, natural resources (90), innovation and R & D(91), or intellectual property rights(92), which make it difficult for any firm to compete successfully. For instance, in certain industries, it might be difficult to obtain essential input materials, or patents might protect products or processes. Other factors such as economies of scale and scope, distribution and sales networks (93), access to important technologies, may also constitute barriers to entry."*

Finally, according to paragraph 76, when the Commission investigates a proposed transaction, it will counteract the anti-competitive effects with the efficiencies brought about by a merger: "*like the development of technical and economic progress or new or improved products or services, resulting from efficiency gains in the sphere of R & D and innovation.*"[53] In addition, the Guidelines point out that the efficiencies must be timely, in order to be considered as a counteracting factor.[54]

3.4. Technology Transfer Block Exemption And Guidelines (2004)

In the Commission Regulation No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements (TTBER) the application of article 81 to the technology transfer agreements between undertakings that fulfill determined requisites is excluded. The sense of this Block exemption is that such agreements, for the licensing of technology, will usually improve economic efficiency and will be pro-competitive as they can reduce duplication of research and development, strengthen the incentive for the initial research and development, spur incremental innovation, facilitate diffusion and generate product market competition.[55]

Like article 2 of TTBER indicates, the technology transfer agreements between two undertakings, which allow *the production of contract products,* will be outside of the scope of Article 81(1).[56] For the applicability of this exemption, two important limitations appear:

1. If the agreement is between competing undertakings, the combined market share of the parties cannot exceed 20 % on the affected relevant technology and product market. Between not competing undertakings, the limitation raise to 30% of the market share.[57]

2. If the agreement does not contain any of the hardcore restraints, listed in article 3, for competing and no competing undertakings.[58]

[52] Ibid., paragraph 4.

[53] Ibid., paragraphs 80 – 81.

[54] Ibid., paragraph 83.

[55] Commission Regulation (EC) No 772/2004 of 27 April 2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements, paragraph 5.

[56] Ibid., art 2.

[57] Ibid,. art 3.

[58] Marcus Glader, op. cit. note 13, p. 82-83.

On the other hand, the TTBER Guidelines *provide guidance on the application of the TTBER, as well as on the application of Article 81 to technology transfer agreements that fall outside the scope of the TTBER.* [59]

The most important part of the guidelines, for the object of our research, is the definitive step to distinguish between product market, technologic market and "*Innovation Market*":

- Product market: this field is defined like *"relevant goods and service markets in both their geographic and product dimension."*[60]

- Technology market: the guidelines identify this market as the *"licensed technology and its substitutes"*[61] (i.e. other technologies which are regarded by the licensees as "interchangeable with" or "substitutable for" the licensed technology, by reason of the technologies' characteristics, their royalties and their intended use). The Commission will use the same method as in the product market to identify the technology market: defining alternative technologies to which consumer could switch in the case of a change in prices. The technological market share will be calculated by reference to the royalties or licence payments generated.[62]

- "*Innovation Markets*": here, the Commission will deal with neither existing products, nor technology markets, but potential competition in absolutely new products race. *"In a limited number of cases, however, it may be useful and necessary to also define innovation markets. This is particularly the case where the agreement affects innovation aiming at creating new products and where it is possible at an early stage to identify research and development poles (22). In such cases it can be analysed whether after the agreement there will be a sufficient number of competing research and development poles left for effective competition in innovation to be maintained."*[63]

MAIN CONCLUSION

POLICY DEVELOPMENT	CONTRIBUTION FOR THE DEFINITION OF INNOVATION MARKET
Notice on the definition of the relevant market	Division between product/geographic market
Guidelines on the applicability of Article 81 of the EC Treaty to horizontal cooperation agreements	1. Definition of *"Innovation Market"* and distinguish from product market and technology market
The EC Merger Regulation and Guidelines	1. Merger between firms in innovation-based markets, can raise serious competition concerns
	2. In a transaction, the Commission will counteract the anti-competitive effects with the efficiencies in R & D and innovation
	3. Consideration of IPRs handling like entry barriers
Technology Transfer Block Exemption and Guidelines	1. Confirmation of 3 different markets: product, technology and innovation

[59] Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C 101/02) paragraph 2.

[60] Ibid., paragraph 20.

[61] Ibid.

[62] Ibid., paragraph 22, Edurne Navarro op. cit. note 44, p. 136.

[63] Op. cit. note 60, paragraph 25.

4. PHARMACEUTICAL SECTOR AND INNOVATION MARKET

For a better understanding of the pharmaceutical industry like the "ideal" framework for the *"Innovation Market*" appraisal, it is important to study deeply the characteristic of the industry, paying special attention to the R&D importance in the sector.

4.1. Overview and trends of the sector: (The nature of competition between pharmaceutical firms)

The pharmaceutical sector is devoted to the development of ethical drugs for human consumption, including new chemical medicaments and bio-technology. [64]

The pharmaceutical industry provides the means to improve the human health, launching products to treat all types of diseases. In this point the industry differs from other economic sectors because it has an enormous repercussion in the consumer welfare. The logic consequence of this fact is the public interest implication in the drug industry, which provides more effective, innovative and safer treatments.[65] This involvement of the public sector supposes a heavy regulation of the pharmaceutical sector at national level, which implies the segmentation of the market.

The capital importance of the pharmaceutical sector and its influence in the European-International arena is motivated by the economic power of this industry: new drugs are extremely profitable and this sector provides relevant benefits at employment level. "*Over 500.000 people are directly employed in the EU pharmaceutical industry (EPFIA 2002), with many more jobs indirectly generated*".[66]

The drug development process is very complicated and risky, with a high failure rate. Actually, for 10.000 medicaments patented, only 10 will be launched into the market. The research process for a drug is lengthy (between 10 to 20 years) and is divided into a number of phases called Clinical Trials, where the medicament is successively tested in order to assure its effectiveness. Other characteristic of the sector is the dependency from Intellectual Property Rights, like patents, which protect drug innovation. The fixed costs of the incumbents in this sector are very high, because the drug research process is prolonged, difficult and extremely expensive. Research investments are vital in the industry. All these factors cause that the entry barriers of the sector are high.[67]

The innovation in the ethical drug sector is the principal competitive variable. Actually, the innovation factor supposes better, more effective and less expensive drugs. The launching of an innovative drug leads to higher profits for the undertaking and this stimulates the competition in the innovation race. A less effective medicament or with more side effects, would see reduced its market share and profits. Therefore, the

[64] Charles River Associates, Innovation of the Pharmaceutical Sector: a study undertaken for the European Commission, 8th November 2004, p. 283: "But excludes medical devices that may substitute for pharmaceutical product".

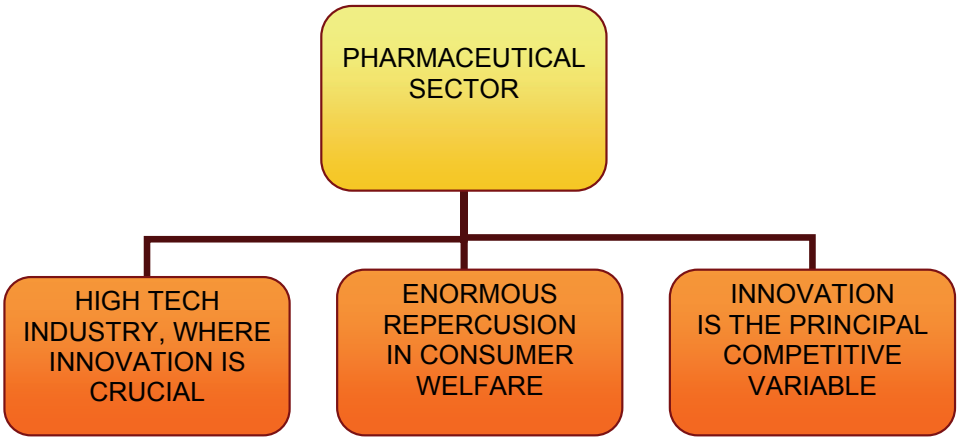
[65] Ibid. p. 284.

[66] Elias Mossialos, Monique Mrazek and Tom Walley, "Regulating pharmaceuticals in Europe: striving for efficiency, equity and quality." World health on behalf of the European Observatory on Health Systems and Policies 2004, Chapter 2 "The politics of pharmaceuticals in the European Union" by Govin Permanand and Christa Altenstetter.

[67] Marcus Glader, op. cit. note 13.

pharmaceutical industry is a very dynamic market, where the incumbents can obtain a leadership position depending on its capacity to innovate.[68]

MAIN CONCLUSION



4.2. R&D and Innovation in the industry

As we have underlined in the previous section, one of the main characteristics of the pharmaceutical industry is the vital importance of innovation in this *high-tech* sector. In this section, we will expose the situation of R&D in the ethical drug companies and the perspectives for the future. This point of view will help us to understand the pertinence of applying *"Innovation Market"* analysis in the concentration operations, within this innovation-based industry.

Innovation can be defined as *"technological progress that leads to the creation of an entirely new product or a reduction in the cost of producing or an increase in the therapeutic value of an existing product"*.[69]

In the last years, from 1999 to 2003, the European and American Regulatory Authorities in the pharmaceutical sector (European Agency for the Evaluation of Medicinal Products, EMEA, and US Food and Drug Administration, FDA) have registered a noticeable reduction in the number of applications for marketing authorisations of pharmaceutical products (reduction in more than 30%). The translation of this number is a great drop in the number of new pharmaceutical products, which means, the decrease of innovation in the pharmaceutical sector. A downward trend in R&D output is obvious.

How can we explain this downward trend in innovation? The first conclusion that can be reached is that increase in the R&D costs supposes, like logical consequence, a decrease in the incentive to innovate.[70] Some factors are the cause of this opposite trend between innovation and R&D expenditures:

1. During the last decade, there have been evidences that prove rising costs of the medicament projects, especially because the number of trials needed to launch a new drug has grown over the last ten years and because the R&D is becoming more focused in complex drug areas, which are also more costly.

[68] Ibid.

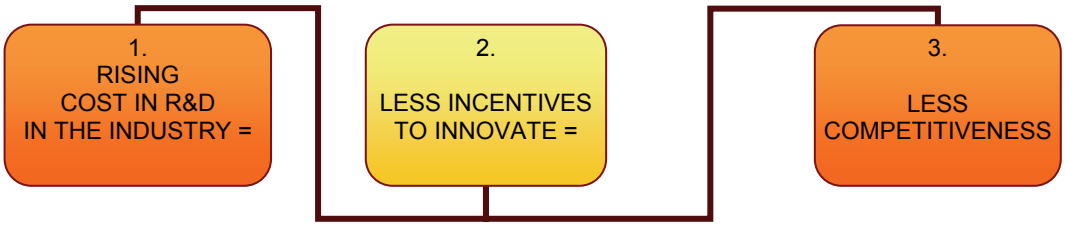
[69] Charles River Associates, op. cit. note 65, p. 4.

[70] Ibid.

2. Some regulatory factors have reduced during the last decade the returns in R&D, and therefore, the incentives to innovate. Two examples of these regulatory factors are the authorization for parallel trade and the growth of generic drugs, both of them promoted by the different Governments.

Moreover, the "Global Competitiveness in Pharmaceuticals" Report (2000, commissioned by the Directorate-General for Enterprise) pointed out that Europe is lagging behind US in terms of competitiveness in the pharmacy sector. The report considers that the main reason for this decrease is the lack of capacity of Europe to promote and develop more innovation in pharmaceuticals, due to the high costs and complexity of the innovative process.[71]

MAIN CONCLUSION



4.3. Merger motives and effects within the pharmaceutical industry

In the previous section, we have observed that during the last decade, in the pharmaceutical sector, there was a downward trend in innovation. At present, the phenomenon of mergers between pharmaceutical undertakings will be pointed out. Is the objective to catch up the loss of innovation the main reason to merge? In the case of an affirmative answer, should the antitrust authorities be tolerant with this type of pro-innovation concentrations? The present section will try to provide an answer to all these questions.

Since the 1990s, a significant number of pharmaceutical companies have merged and contributed to the consolidation of the sector *(See Annexe)*. This merger wave has supposed a challenge for the antitrust authorities, who must prevent anti-competitive effects from this concentration process in a fast-moving and innovation-based sector.[72]

The principal objective of the undertakings in the pharmaceutical sector is to be more efficient and competitive and to gain profits. In fact, mergers between pharmaceutical companies may generate considerable efficiencies, as follows:

- Exploitation of economies of scale,
- Reduction of expenditures (cut in transaction costs included),
- Sharing of know-how and Intellectual Property rights,
- Diminishing of risk,
- Faster technological growth.[73]

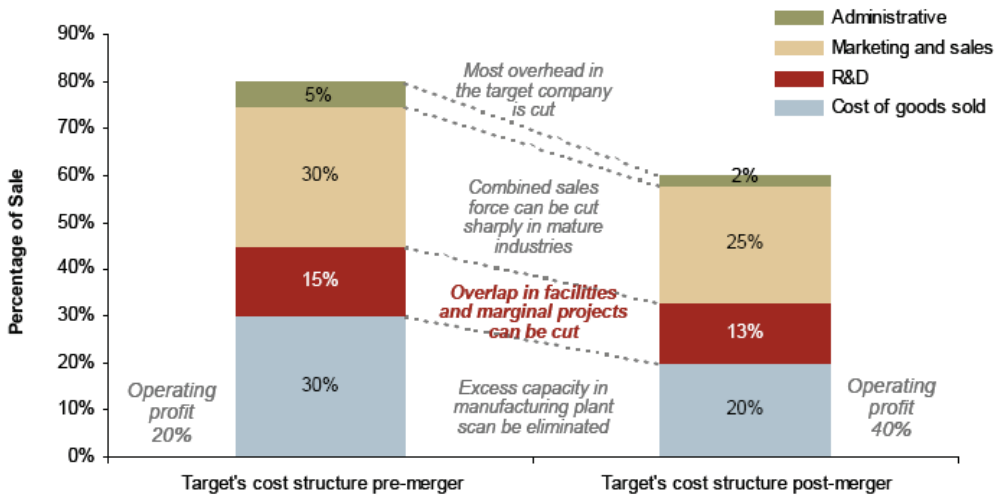
[71] Elias Mossialos, op. cit. note 68.

[72] Dror. Ben-Asher, op. cit. note 23, p. 1; Charles River Associates, op. cit. note 65, p. 104.

[73] Directorate for Financial, Fiscal and Enterprise Affairs Committee, "Merger Review in Emerging High Innovation Markets", Organisation for Economic Co-operation and Development, January 2003, p. 20.

The following figure shows the efficiencies created from pharmaceutical mergers:

Figure 51: Merger efficiencies in horizontal pharmaceutical mergers



Source: Ravenscraft and Long (2000), p. 313.

The above figure[74] illustrates that the major efficiencies come from the results of economies of scale, like the elimination of *excess capacity in manufacturing plants* and the *combination of sales force*. Consequently, one of the main reasons for the merger waves in the pharmaceutical sector is the exploitation of economies of scale.

Like the figure shows, elimination of overlapping projects would lead to cost savings of only 2%. Accordingly, the reduction in cost of R&D does not seem to be the main reason for the undertaking to merge. However, this concentration process can reduce by 12% the costs of research and development.[75]

Despite the fact that costs cut in R&D is not the main force to merge, this type of operation has an important impact in the research level. It is possible to divide the merger effects in R&D in short and in long term effects:

- In short term, there are several factors which suggest negative post-merger effects in the number and quality of pipelines after the merger, within the pharmaceutical sector.[76]

- The results in long term are more difficult to predict, but also it is possible to find some positive facts in the long-run activity of the merged companies:

    1. The removal of marginal pipelines can originate a quality selection among research projects. This trend reflects more efficiency because of the elimination of pre-merger duplication of efforts.

[74] Charles River Associates, op. cit. note 65, p. 107.

[75] Ibid.

[76] Dror. Ben-Asher, op. cit. note 23. This author enumerates the factors as follows: 'Due to the desire of costs reduction, several R&D facilities (laboratories, personal) are generally closed or fired after the merger. The wish of reducing the overlapping programmes in R&D supposes the reduction in the number of pipelines, especially those considered "marginal". Merged pharmaceutical companies have very high R&D expenditures, but this spending is the lowest in the sector as a percentage of their potential. The crash between two different cultures of business can damage the research projects and could originate the lost of brilliant researchers'.

2. The mixture of scientists from the merged companies can lead to positive results in the long term, in the sense of knowledge contribution.

3. Increased internal funds may originate more cash flow available for the development of new R&D projects.

4. Consolidation of the pharmaceutical industry can encourage the innovation competition. Stronger pharmaceutical firms will increase the strength of the "patent race" in the sector.[77]

But this long-term picture is incomplete. There are also several negative effects in the post-merger performance. Firstly, if the merged firms get key Intellectual Property rights for the development of R&D projects, this can foreclose the market to the other competitors. Secondly, the new company can also have the trend to give up overlapping R&D projects. Thirdly and, as consequence of the previous effect, the removal of one independent R&D line could have anticompetitive results and delay the launch of innovative drugs.[78] Moreover, several economics studies (SHLEIFER & VISHNY, 1990; MITCHELL & LEHN, 1990) show that the working together of two or more pharmaceutical companies does not produce a better result than the addition of their individual effects, so there is no synergy or improved efficiency from merged pharmaceutical undertakings.[79] Finally, a strong consolidation of the merged firms in specific R&D fields could cause the reduction in the competitor's efforts to innovate, in the concrete field.

All these negative consequences can damage the consumers/patients. Therefore it is defended that not only the legal competition rules, but also the practices carried out by the competition authorities must be aware about these concerns. The long-term positive effects can often outweigh the negative effects, but this trend is far away from becoming a rule. The solution found by the antitrust agencies is to permit mergers between pharmaceutical companies with the introduction of remedies, such as divestitures of R&D projects to approved firms.[80]

Therefore, through this reasoning, a link has been found between concentration and a risk of reduction in pharmaceutical innovation. It has been studied that the R&D costs reductions are very likely in the post merger arena and, this rationalisation, could lead to a negative effect in the innovation and also eventual welfare damage.[81] Consecuently, it is strongly recommended that the antitrust agencies survey R&D pipelines, in order to avoid lessening in innovative performance.[82]

As we saw in the previous section, the competitiveness in the pharmaceutical sector is based on innovation. Because of this, not only the antitrust authorities, but also the industry should agree on implementing the "*Innovation Market"*. The pharmaceutical sector must avoid any lessening in innovation, in order to promote the competitiveness of the whole industry. Consequently, the ethical drugs companies should also consent a Merger Control which pays attention to the level of innovation and to the promotion of competition and this also in innovative projects under development.

[77] Ibid.
[78] Ibid.
[79] Ibid.
[80] Charles River Associates, op. cit. note 65, p. 118-120.
[81] Dror. Ben-Asher, op. cit. note 23, p. 323.
[82] Ibid.

MAIN CONCLUSION

PHARMACEUTICAL MERGER SYLLOGISM

LESS INNOVATION=LESS COMPETITIVENESS IN THE SECTOR
MERGER OPERATIONS=RISK LESS INNOVATION
MERGER OPERATIONS=RISK LESS COMPETITIVENESS IN THE SECTOR

LESS INNOVATION=LESS CONSUMER WELFARE
MERGER OPERATION=RISK OF LESS INNOVATION
MERGER OPERATIONS=RISK OF LESS CONSUMER WELFARE

POSSIBLE SOLUTION OF SYLLOGISM: EXAM OF R&D PROJECTS BY ANTITRUST AUTHORITIES= TO AVOID RISK OF LESS CONSUMER WELFARE AND PROMOTE COMPETITIVENESS

4.4. Pharmaceutical Merger Control like an ideal target for *"Innovation Market"* practice

In the previous section we have concluded that when two (or more) pharmaceutical companies merge, a drop off in innovation is likely, and because of this, the competition authorities must be aware in the Merger Control appraisal about the R&D projects of each undertaking. This is exactly what "*Innovation Market"* is about (*see above*: "*The innovation market approach supposes the identification of R&D pipeline, directed to particular new or improved goods or processes, and their close substitutes among the industry"*).

In this **key section** we will deal with the Merger Control in the Pharmaceutical industry like a perfect target for the application of "*Innovation Market",* revising all the arguments to reach this conclusion. The identification of the pipelines from merging undertakings and the verification that, after the concentration, there will be enough number of R&D efforts, is the path to prevent the damage in the level of innovation in the concentration operations.

1) Firstly, we saw that the main pillar for the *"Innovation Market"* approach was its **application to innovation-based sectors,** and as one specialist in the pharmaceutical sector defended: *"Innovation is the name of the game. The significance of innovation as a source of competition in the pharmaceutical sector suggests that merger analysis in that sector should focus not only on existing product market but also on competition over research and development".*[83]

2) The *"Innovation Market"* is the answer for the Pharmaceutical Merger Syllogism (*see above*). Because of the narrow link between innovation/competitiveness, it is important to foster R&D output for

[83] Dror. Ben-Asher, op. cit. note 23, p. 273.

the **promotion of competitiveness**. Moreover, it has been exposed that mergers can originate less innovation in the long term, with the consequent damage in **consumer welfare**, and "*Innovation Market"* assessment would avoid that.

3) As it was exposed, one of the main critics to the "*Innovation Market"* analysis is the lack of proven link between concentration in R&D and challenge to innovation.[84] Nevertheless, this limitation does not prevent the use of "*Innovation Market"* in the pharmaceutical sector. The availability of data, regulation of clinical trials and registration of patens make possible to predict, without uncertainty, the post-merger behaviour. [85]

4) Other critic to the application of "*Innovation Market"* analysis is the lack of certitude to identify the pipelines. However, this situation does not exist in this sector, dominated by high regulation, public control and publicity. The lengthy and expensive process to create a new drug supposes a series of tests, called Clinical trials, which are public and heavily regulated. Because of this special need, the pharmaceutical sector can not rapidly create a new product, or hide a new project, like in other technology-based sectors. This fact would permit to the antitrust authorities to identify the R&D projects and to detect possible overlaps through the industry, like the "*Innovation Market"* criterion defends. Clinical Trials are divided into three phases:

   - Phase I of the human clinical trials is the first exercise to experiment a medicament on a small number of healthy patients. Phase I is intended to provide that the drug is relatively secure and to estimate the adequate dose-range and treatment.[86] The probability that one medicament in Phase I will be launched on the market is only between 10 and 15%, and the average time to reach the market is 8.5 years.

   - Phase II is where trials are carried out on patients with the specific disease, to prove the efficacy of the drug. This phase is focused in the definitive dose definition, the application areas, the side effects and safety. For drugs that reach Phase II, the percentage of success increases to 30 percent. It takes about 6 years for medicaments in this phase to reach the market.

   - Phase III supposes much larger and expensive studies, which normally involve more than 3000 patients. The main objective of this phase is to create a definitive confirmation of safety and efficacy of the drug. The success of the third phase is acknowledged to be more than 50%.[87] It takes an average of 4 years for a medicament in Phase III to be marketed.[88]

[84] Ibid.

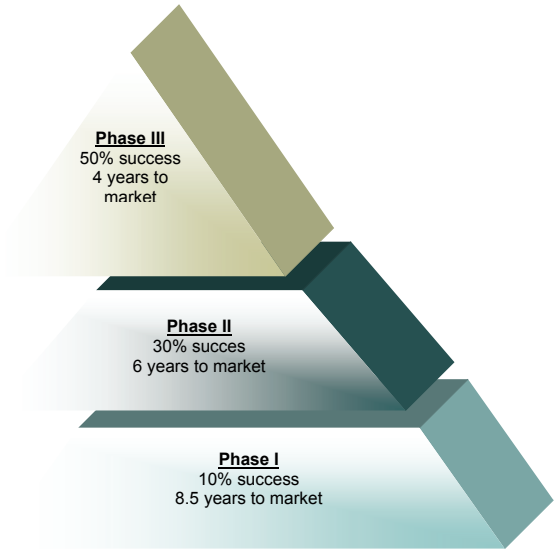
[85] Ibid.

[86] Rosa M. Abrantes-Metz, Christopher P. Adams and Albert D. Metz, The antitrust Source: "Empirical facts and Innovation Markets: Analysis of the Pharmaceutical Industry", www.antitrustsource.com, 12.04.07.

[87] Commission Decision, Case No IV/M. 737-Ciba-Beigy/Sandoz; Dror. Ben-Asher, op. cit. note 23.

[88] Rosa M. Abrantes-Metz, Christopher P. Adams and Albert D. Metz, op. cit. note 87.

Clinical Trials in Pharmaceutical



So, in the case of pharmaceutical industry, it is very easy to guess the future overlaps in concentration operations, looking at the clinical trials of each undertaking. Moreover, like Gotts and Rapp defend "*proper enforcement involving future goods can only happen when the good is far enough in the development process to allow it to be identified as source o potential competition, along with its close substitutes, in a forecast relevant good market*".[89] Because of this, we can conclude that only drugs under Phases II or III of Clinical trials are enough developed and foreseeable to be assessed by the competition authorities. Only drugs in the second and third step of the drug development can be surely identified and the possible overlaps in R&D pipelines established.

MAIN CONCLUSION

WHY PHARMACEUTICAL INDUSTRY IS THE PERFECT TARGET FOR INNOVATION MARKET ANALYSIS?	
INNOVATION MARKET FEATURES	**PHARMACEUTICAL INDUSTRY FEATURES**
SUITABLE FOR HIGH-TECH SECTORS	HIGH-TECH SECTOR
PROMOTES INNOVATION	INNOVATION=MORE COMPETITIVENESS
	INNOVATION= MORE CONSUMER WELFARE
IT IS DIFFICULT TO DEAL WITH R&D	R&D PUBLIC AND REGULATED, EASY TO IDENTIFY
NOT ECONOMIC LINK BETWEEN LESS R&D AND LESS INNOVATION	PREDICTABLE DAMAGE IN INNOVATION

So, once the pharmaceutical sector syllogism and the need of the "*Innovation Market*" analysis presented, the next logical question is whether the concept is effectively applied in practice. Does the application of "*Innovation Market*" work?

[89] Ilene Knable Gotts & Richard T. Rapp, "Antitrust Treatment of Mergers Involving Future Goods", Antitrust, Fall 2004, p. 100.

5. ANALYSIS IN PRACTICE. HOW EUROPEAN COMMISSION IS APPLYING "INNOVATION MARKET"? CONTRAST WITH THE AMERICAN PRACTICE

5.1. The five steps to analyse an *"Innovation Market"* [90]

When the antitrust authorities, not only European, but also American, are involved in a Merger Control case, the appraisal of "*Innovation Markets*" in the pharmaceutical sector responds to a consolidated practice that could be divided in five steps:

5.1.1. Product market

The first step in the Merger analysis is identifying possible R&D overlaps between the merged companies. The antitrust agencies will explore alternative R&D projects among the industry and its degree of substitutability. This assignment will not be difficult because the different drug classifications and patent registration of the medicaments under development provide enough and accessible information.

The competition authorities must take into account that the more developed the drug in the Clinical Trial process is, the higher the chances to be marketed. Entry barriers in those R&D projects also must be determined for a correct assessment. The property of Intellectual rights, patents and know-how by the merged incumbents can be seen like entry barriers.

5.1.2. Geographic market

Once the first step is analysed, the competition authorities will scrutinize the geographic market. This market should be an area of homogenous competing conditions. It is presumed by the authorities that, in the pharmaceutical sector, the "*Innovation Market*" is a world-wide geographic market.

5.1.3. Anti-competitive evaluation

In the anti-competitive effects assessment of the merger, the first step is to measure the post-merger increase in R&D concentration, looking at the number of competitors and the intensity of competition (the feasibility of new incumbents' entry is also examined).

The second step is to asses the negative effects of this concentration in innovation and consumer welfare (for example: delay/elimination medicament's launch, product quality and efficacy, side effects, level of prices…).

[90] Dror. Ben-Asher, op. cit. note 23, p. 324-330.

5.1.4. R&D Efficiencies

Competition authorities will study the positive effects of the merger on innovation. One of the most important benefits of this type of concentration, in the ethical drug sector, is the elimination of superfluous or redundant R&D pipelines. If these efficiencies can counterbalance the anti-competitive effects of the merger, no remedies will be imposed.

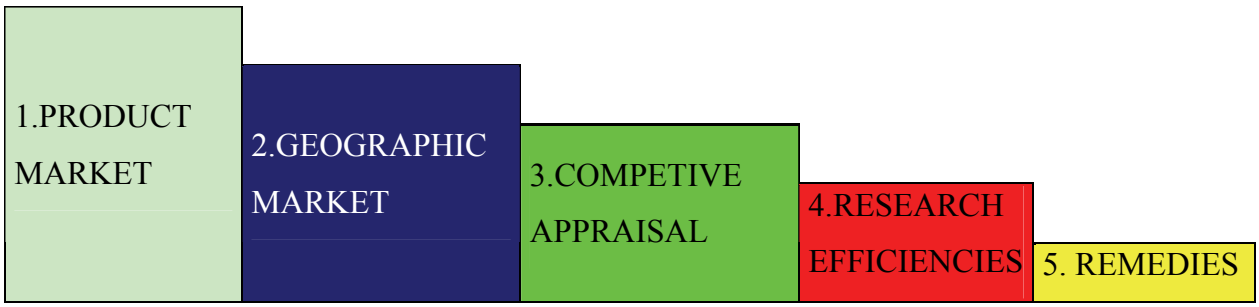
5.1.5. Remedies

When the merger has potential anti-competitive effects, remedies are required. The competition authorities impose two types of remedies in this field:

- Licenses, which allow the merged firm to continue one of its R&D pipelines but also force it to offer the Intellectual Property rights and patents needed to the other firm, to pursue the pipeline. This remedy tries to promote the innovation race by increasing the number of researchers.

- Divestitures, which forces the merged undertaking to give up one R&D project that will be pursued by other approved company. This remedy is the solution when the merged company has not incentives to continue one determined pipeline.

THE FIVE STEPS IN THE INNOVATION MARKET PRACTICE



5.2. European consolidated practice in the Pharmaceutical Merger Control. The introduction of *"Innovation Market"* appraisal

In the previous section, the five steps for the appraisal of the *"Innovation Market"* have been established. In the present section, we will deal with the European Commission practice to define the relevant product market (step nº1) and the relevant geographic market (step nº2) in the field of pharmaceutical mergers. Both concepts (product and geographic market) constitute the relevant market, and suppose the pillar for the Merger assessment in the pharmaceutical sector. It is through the Commission practice, that the "*Innovation Market"* concept has been introduced in Europe, subsequently confirmed by its incorporation in the legislation. The examination of this consolidated practice will permit us to understand better the practical cases exposed afterwards.

5.2.1. Relevant product market

As it was exposed above, the *Commission Notice 97/C372/03 on the definition of the relevant market* defines the relevant product market as follows *"all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use*".

The European Commission, trough different decisions[91], has divided the relevant product market in pharmaceuticals into three brands:

a. Medicines/Pharmaceutical specialities,
b. Active substances,
c. Future markets.

a. Medicines/Pharmaceutical specialities

The European Commission has classified the different pharmaceutical specialties by reference to the "ATC" (Anatomical Therapeutic Classification), which was devised by EphMRA (European Pharmaceutical Marketing Research Association).[92] The World Health Organization defines the ATC like *"*an *international standard for drug utilization studies"*.[93]

In this classification, the drugs are divided into 4 different levels, from the most general to the most specific. The third level classifies the medicaments by therapeutic indications (in terms of intended use) and is employed by the Commission as reference to delimitate the market. ATC 3 determines the level of substitutability of the medicaments (for example, if both of them are substitute treatments for the same illness/disease), in the framework of European Merger Control. Usually, this group of products can not be interchanged by drugs from other ATC 3 category.[94]

Nevertheless, ATC 3 is only the starting point when the Commission delimitates the relevant product market. It is easy to guess that ATC 3 is not always suitable to determine the interchangeability of the drugs,

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[91] Commission decisions of 10 June 1991,.Sanofi/Sterling Drug; 29 April 1993 Procordia/Herbamond; 18 April 1994, Rhône-Poulenc/Cooper; 20 June 1993, La Roche/Syntex; 19 September 1994, AHP/Cyanamid; 28. February 1995, Glaxo/Wellcome; 3 April 1995, Behringwerke AG/Armour Pharmaceutical Co.; 22 June 1995, Hoechst/Marion Merrell Dow; 28 September 1995, Upjohn/Pharmacia.

[92] Paper "MERGER CASE STUDY: GLAXO WELLCOME" by Teresa Lorca Morales for the Competition Policy and Market Regulation course of B. Dumont & P. Holmes, College of Europe. April 07, based on World Health Organization, The WHO Collaborating Centre for Drug Statistics Methodology http://www.whocc.no/atcddd/ 14.03.07.: "Its origins are in Oslo in 1969, where was celebrated a symposium "The Consumption of Drugs" where it was accorded the needed of an internationally classification for drug consumption studies. Norwegian researchers developed a system known as the Anatomical Therapeutic Chemical (ATC) classification. In order to measure drug use, it is important to have both a classification system and a unit of measurement. To deal with the objections against traditional units of measurement, a technical unit of measurement called the Defined Daily Dose (DDD) to be used in drug utilisation studies was developed. The Nordic Council on Medicines (NLN) established in 1975, collaborated with Norwegian researchers to further develop the ATC system. The NLN published the Nordic Statistics on Medicines using the ATC methodology for the first time in 1976. In 1996, WHO recognised the need to develop use of the ATC system as an international standard for drug utilization studies. Access to standardised and validated information on drug use is essential to allow audit of patterns of drug utilization, identification of problems, educational or other interventions and monitoring of the outcomes of the interventions."

[93] World Health Organization, The WHO Collaborating Centre for Drug Statistics Methodology http://www.whocc.no/atcddd/.

[94] Guidelines on the assessment of horizontal mergers under the Council Regulation on the control of concentrations between undertakings 2004/C 31/03, paragraph 28: "Products may be differentiated within a relevant market such that some products are closer substitutes than others. The higher the degree of substitutability between the merging firms' products, the more likely it is that the merging firms will raise prices significantly. For example, a merger between two producers offering products which a substantial number of customers regard as their first and second choices could generate a significant price increase. Thus, the fact that rivalry between the parties has been an important source of competition on the market may be a central factor in the analysis. High pre-merger margins may also make significant price increases more likely. The merging firms' incentive to raise prices is more likely to be constrained when rival firms produce close substitutes to the products of the merging firms than when they offer less close substitutes. It is therefore less likely that a merger will significantly impede effective competition, in particular through the creation or strengthening of a dominant position, when there is a high degree of substitutability between the products of the merging firms and those supplied by rival producers."

and sometimes may be too broad and sometimes too narrow.[95] The European competition Authority has considered in several decisions that other levels of the classification (ATC 2/ATC 4, based in pharmacological standards and application formula respectively)[96] could be taken also into account. Furthermore, other factors are also relevant to distinguish the medicaments (prescription needed or not, drug reimbursed or not…).[97]

b. Active substances

"*Active substances are produced from chemical and biological product*". The mix of active substances can be used to create a pharmaceutical product *(in-house purposes)*, but they also can be traded independently *("There are markets for active substances to the extent that such substances are the object for transactions between a producer and a buyer of these substances*")[98]. The Commission considers that active substances, previous to the market for medicaments, are a *separate and specific* market.

c. Future products/Innovation markets

The Commission, even before the introduction of "*Innovation Market*" concept by the Guidelines on Horizontal Cooperation (2001), has set up the analysis of the R&D efforts in the Merger Control practice, within the pharmaceutical sector. In this way, the European Authority began in the early 90's to assess, like a separate and independent market, the R&D pipelines.[99]

In the R&D efforts, the Commission, through its consolidated practice, distinguishes between:

1. R&D poles that are intended to replace existing medicaments. In this case, the projects will be integrated in the respective ATC category,[100]

2. R&D poles that are intended to create a completely new drug; they will be classified following only their own characteristics and indications to be applied. They will be included in the *Future/Innovation markets.*[101]

5.2.2. Relevant geographic market

'Relevant geographic markets' are defined as follows*: 'The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogeneous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas."* [102]

[95] Garrigues Abogados, Law firm 2006, "Market Definition Report in Pharmaceutical Industry".

[96] European Commission, Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraph 23 and s.

[97] Ibid.

[98] European Commission, Case No IV/M 1835 Monsanto/Pharmacia & Upjohn.

[99] Edurne Navarro, op. cit. note 44.

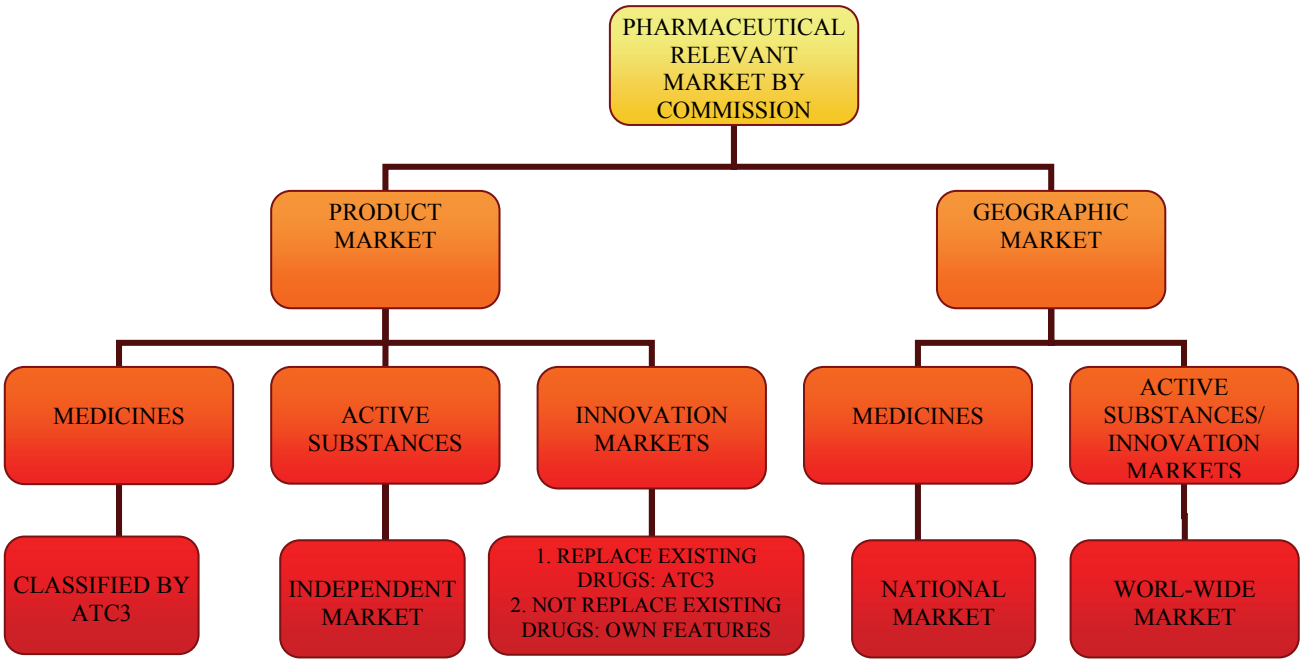
[100] European Commission, Case No Comp/M. 2517 Bristol-Myers Squibb/Duppont, Case No Comp/M. 2312 Abbot/Basf, Case No Comp./M. 1878-Pfizer/Warner-Lambert, Monsanto/Pharmacia & Upjohn.

[101] European Commission, Case No IV/M. 1397-Sanofi/Synthelabo.

[102] Commission Notice on the Definition of relevant market for the purposes of Community Competition law (97/CF 372/03).

Pharmaceutical policy is primarily regulated at national level by each Member State, like pricing, R&D promotion and reimbursement level. However, some aspects have been harmonized at European level.[103] The main consequence of this double regulation dimension, in the object of our study, is the fragmentation of the market, which supposes that the relevant geographic market, in the Merger Control, will be restricted to national level, because of the national price systems. Nevertheless, that delimitation only touches the medicines/pharmaceutical specialties. In the case of active substances and "*Innovation Market",* the antitrust authorities consider that the relevant geographic market is worldwide, because the pharmaceutical undertakings compete at international level.

MAIN CONCLUSION



5.3. Cases studies

In the current sub-section, the assessment of *"Innovation Market"* in three different Merger Cases between pharmaceutical companies, by the European Commission and the Federal Trade Commission, will be studied. The three particular cases chosen for analysis in this Master thesis are those where the European and the American Authorities have reached different final decisions by using the *"Innovation Market"* criterion. At the end of each Case Study, the advantages and disadvantages of the American and European approaches respecting the *future markets* will be evaluated.

[103] Elias Mossialos, Monique Mrazek and Tom Walley, op. cit. note 68, Chapter 1: "Regulating pharmaceuticals in Europe: an overview".

5.3.1. Glaxo-Wellcome[104]

Facts

In 1995 Glaxo, a UK-based pharmaceutical company, launched a public bid of Wellcome, another British drug company. The result of that merger was the largest pharmaceutical company at that moment, where a merger wave was taking place and would last until the end of the nineties.[105] Glaxo-Wellcome turned into a manufacturer of many blockbuster medicaments for several diseases like cancer, HIV, central nervous system disorders, cardiovascular diseases migraine, herpes, allergy, etc.

In 2000, a new merger in the firm took place, this time with SmithKline Beecham. The new merged company Glaxo SmithKline was the leading ethical drug company world-wide.[106]

European Commission Approach

Warning: In 1995, when the merger between Glaxo and Wellcome took place, the Merger Regulation in force was the Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings. The articles that will be mentioned correspond to that Regulation, nowadays revoked by Council regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings.

The European Commission, after receiving the notification of the merger on 30th January 1995, started the appraisal of the concentration. The two necessary prerequisites for the Commission assessment were fulfilled: Community dimension[107] and concentration,[108] in the sense of article 3.1 Merger regulation.[109]

A. STEP 1: RELEVANT PRODUCT MARKET APPRAISAL

The European competition Authority found 3 different brands where both companies were active and where there was the possibility for the creation of a dominant position.[110]

1. Antiemetics - Antinauseants,[111]

[104] This section is based on the Paper "MERGER CASE STUDY: GLAXO WELLCOME" by Teresa Lorca Morales for the Competition Policy and Market Regulation course of B. Dumont & P. Holmes, College of Europe. April 07.

[105] Marcus Glader, op. cit. note 13, pages 133-134.

[106] The Pharmaceutical Century, "Ten decades of drug discovery", http://pubs.acs.org/journals/pharmcent/company9.html 5.03.07

[107] The merger was within art. 1 Council Regulation 4064/89. The aggregate worldwide turnover of Glaxo and Wellcome was more than 5000 million ECU and the aggregate Community-wide turnover of each company was more than 250 million ECU. The exception of art 1.2 b) did not apply "unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State."

[108] Definition of concentration: art. 1. "A concentration shall be deemed to arise where: (b) one or more persons already controlling at least one undertaking, or one or more undertakings, acquire, whether by purchase of securities or assets, by contract or by any other means, direct or indirect control of the whole or parts of one or more other undertakings." article 3.1 b) of the Merger Regulation.

[109] European Commission, Case No IV/M. 555 Glaxo/ Wellcome, paragraph 4-5.

[110] Ibid., paragraph 10.

[111] Paper "MERGER CASE STUDY: GLAXO WELLCOME" by Teresa Lorca Morales for the Competition Policy and Market Regulation course of B. Dumont & P. Holmes, College of Europe, April 07, Concerning the Antinauseants, "The Commission has analyzed the anti-emetic products in the market, which can not be only included in the A3F category (from the ATC classification), but also can be substituted by the A4A products (information provided by important pharmaceutical undertakings). To analyse the competition problems that could arise in this sector, the Commission focuses firstly in the market share of both companies and secondly in the blockbuster products of each firm in the area. The Wellcome's market share of anti-emitics in Europe is low, but in Denmark, the share increases substantially. Also in Denmark, Glaxo has an important market share. With respect to the blockbuster products in this sector, the Wellcome's most sold medicament "Valoid" is being selling outside of the EEA, and the Glaxo's main medicine Zovran is used in the hospital framework, and does not overlap with "Valoid" which is used in the hospital environment. Taking into account these considerations, despite the high market share of both companies in Denmark, their Antinauseant drugs did not overlap (in both ATC categories, A4A and A3F). The Commission concluded that there are not

2. Systemic Antibiotics[112] and
3. Anti-migraine treatments

In only one of the three brands, anti-migraine treatments, competition concerns in *"Innovation Markets"* arose. This group will be spotlighted in the competition analysis of the case. (*For the other brands, Antinauseants/Systemic Antibiotic, see footnotes 112/113).*

B. STEP 2: GEOGRAPHIC MARKET

As in previous decisions, the Commission considered that the geographic market for existing medicaments was fundamentally national, due the fact that "*the sale of medicines is influenced by the administrative or purchasing policies adopted in Member States by national health services. […] Pharmaceutical prices may differ from one Member State to another. In addition there exists widespread different branding and sizing strategies and distribution systems, which further indicate national market characteristics."*[113]

In the case of R&D projects ("*Innovation Market*"), the geographic competition was much wider, and the companies would compete at European or even world-wide level.[114]

C. STEP 3&4: COMPETITIVE ASSESTEMENT & EFFICIENCIES

In the case of anti-migraine treatments, Glaxo and Wellcome marketed both products for migraine attacks and also both companies had under development R&D projects for this disease.

A further description about this market is needed:

- Glaxo marketed a product**,** Imigran, an injectable and expensive drug for the migraine attacks, launched in 1991, with a very high market share in the European Union among the anti-migraine products.[115]

- Wellcome commercialized an oral anti-migraine product (Migril)**,** at a reasonable price, off-patented, and with very low market shares in all the European Union. The Commission underlined, because of all these characteristics, that Migril and Imigran did not belong to the same market.[116]

- Both companies were developing respectively two pipelines for the migraine treatment. In particular, Wellcome's pipeline was in Phase III of Clinical Trials, expected to be launched into the market in 1997, and likely to be an oral substitute of Imigran.[117]

competition problems arising between Glaxo and Wellcome in this area."

[112] Paper "MERGER CASE STUDY: GLAXO WELLCOME" by Teresa Lorca Morales for the Competition Policy and Market Regulation course of B. Dumont & P. Holmes, College of Europe. April 07, Concerning the Antibiotics "In this field, the Commission concluded that there are not overlaps between the Glaxo and Wellcome products, regarding the third level of ATC classification. The non overlapping is demonstrated like follows: On one hand, the Wellcome's antibiotic market, is divided in systematic antibacterial and topical antibacterial, both of them off-patent and sold without prescription. On the other hand, the Glaxo's antibiotic market is focused on cephalosporins, which are injectables and normally sold in hospitals. The market share of both companies in a lax product market definition of antibiotics is less than 10% in almost all the countries of the EU. The companies would not overlap even in the case of a more restrictive relevant market approach. These data confirm that competitions questions do not arise in this type of drug".

[113] European Commission, Case No IV/M. 555 Glaxo/ Wellcome, paragraphs 15-18.

[114] Ibid.

[115] Ibid., paragraphs 14 and 23.

[116] Ibid., paragraph 27.

[117] Ibid., paragraph 28.

As Migril was not a substitute of Imigran, no competition concerns raised between the existing medicaments. The situation was different in the "*Innovation Market"*, because Wellcome's project for migraine attacks could become a substitute of Imigran.

In that situation, the Commission estimated that, nevertheless, the transaction would not reduce the competition in the future market of anti-migraine treatment. The main reason to defend the compatibility of the merger with the Common Market was the existence of pharmaceutical companies developing the same type of compound that Wellcome's pipeline.[118] In this framework, the Commission stated that the merger would not have a negative impact on competition.[119]

D. STEP 5: FINAL DECISION. REMEDIES

The Glaxo-Wellcome merger was declared, at the end of Phase I, compatible with the common market (in application of article 6.1.b Merger Regulation).[120] No conditions neither obligations were imposed.[121]

Federal Trade Commission Approach

A. STEP 1: RELEVANT PRODUCT MARKET APPRAISAL

In the present case, the Federal Trade Commission made a distinction between the injectable and non-injectable treatments for the migraine attacks. It was argued that both means of administration of the drug were no substitutes, and each category created an independent market.[122]

As we saw in the European decision, Glaxo had a blockbuster in the market, Imigran, an expensive injectable drug for migraines, which had also important market shares in United States.

The FTC identified like *"Innovation relevant markets"* two pipelines from both companies with the same components (*5HT sub1D agonists)*[123] for the creation of an oral drug for migraine treatment. In the case that those medicaments reached the market, they would be the only competitors of Glaxo's blockbuster, Imigran.

B. STEP 2: RELEVANT GEOGRAPHIC MARKET APPRAISAL

As in other decisions, the FTC considered that the geographic area, to analyze the merger's effects in R&D, was the United States. The main reason for this geographic limitation was that both projects were under the Food and Drug Administration ("FDA") approval.[124] This Agency controls the medicines market within the United States.

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[118] Ibid., paragraph 31.

[119] Marcus Glader, op. cit. note 13.

[120] Article 6.1.b Merger Regulation: "The Commission shall examine the notification as soon as it is received. […] (b) Where it finds that the concentration notified, although falling within the scope of this Regulation, does not raise serious doubts as to its compatibility with the common market, it shall decide not to oppose it and shall declare that it is compatible with the common market."

[121] European Commission, Case No IV/M. 555 Glaxo/ Wellcome, paragraph 34.

[122] Marcus Glader, op. cit. note 13, p.133.

[123] "A class of drugs known to act on the receptors in the human body that are responsible for migraine attacks" .

[124] Marcus Glader, op. cit. note 13, p.133.

C. STEP 3&4: COMPETITIVE ASSESTEMENT & EFFICIENCIES

The FTC considered that the market in anti-migraine treatment was highly concentrated and with heavy entry barriers.

The concentration in the migraine treatment was proved because Glaxo and Wellcome were the only undertakings who had best performed in the R&D race for the creation of non-injectable drugs for migraine attack, using 5HT compounds. The FTC took into consideration the lengthy and very expensive process to develop this type of drug, which originated heavy entry barriers.

The FTC underlined that the merger would eliminate R&D competition between the merging undertakings in oral drugs for migraine, because, as consequence of the concentration operation, it would create a monopoly in the mentioned field. Furthermore, it was considered the likely post-merger elimination of one project between the two Glaxo and Wellcome pipelines.

D. STEP 5: FINAL DECISION. REMEDIES

As consequence of the facts exposed above, the FTC concluded that the merger would lessen competition in R&D market ("*Innovation Market*"), with the consequent damage in consumer welfare[125].

It was imposed to Glaxo the divestiture of the Intellectual Property rights of Welcome's pipeline for the migraine attacks to an approved company. It was also demanded to Glaxo technical assistance for that acquirer. The objective of these remedies was the creation of a "viable competitor" to substitute the competition vanished in the concentration operation.[126]

MAIN CONCLUSION

INNOVATION MARKET APPRAISAL	**EUROPEAN APPROACH**	**AMERICAN APPROACH**
STEP 1: RELEVANT PRODUCT	Anti-migraine drugs	R&D Anti-migraine **oral** drugs
STEP 2: RELEVANT GEOGRAPHIC	**European/World-wide**	**American/World-wide**

[125] Glaxo, FTC File No 951-0054, 60 Fed. Reg. 16,139 (Mar. 29, 1995).

[126] Marcus Glader, op. cit. note 13, p.134.

STEPS 3&4: COMPETITION ANALYSIS & EFFICIENCIES	**NO** dominant position in the market of anti-migraine drugs	High concentration in the market+Heavy barriers to entry=Creation of **dominant position**
STEP 5: REMEDIES	**NO** conditions, neither **remedies** were imposed	**Disvestiture** of Wellcome's IPs project and compulsory **technical assistance.**

Advantages and Disadvantages of the American/European Approaches

In the present case there were considerable divergences between the European Commission and the Federal trade Commission decisions, when they were dealing with the same merger operation.

The most important difference in the relevant product assessment was the division between oral and injectable form of migraine treatment. In medicament's field, it is crucial to delimitate the relevant product market and, also the substitutability of the drugs is the essential start point to define the market. The European Commission did not assess correctly the market, when it considered both means of administration as interchangeable. Moreover, the European Authority did not observe the creation of a monopoly in the oral drugs for the migraine treatment. It has been studied that one important reason to merge is "monopoly motive"[127], that means, the aspiration to accomplish or strengthen a situation of monopoly. As the Financial Times editorial noted *"Companies rarely hesitate to buy patents, people or technologies that might challenge their markets—even if this damages the long-term health of research."*[128]

Despite the strong position of Imigran in the market, the Commission considered that Merger Control is about the post-merger effects, and not an evaluation of the pre-merger situation.[129] The European Commission did not see, that the developed pipelines of both companies in the migraine headaches attacks, were quasi a duopoly in the sector, and after the merger, would be a monopoly.

The FTC, contrarily, considered the *"Innovation Market"* – the R&D project for an oral drug against migraine- the basis to challenge the merger. The high concentration of that market and entry barriers were studied carefully and concluded that Glaxo-Wellcome would have the incentive to give up one of the two projects. This reduction in the number of R&D tracks could delay the launch of the drug into the market, lessen the level of innovation, decrease the quality of the final product, and obviously, rise prices.[130]

To end up, it is important underlining the complete success of the compulsory divestiture of Wellcome's pipeline by the FTC, when in only 15 months, Zeneca, the approved acquirer, obtained the approval of the medicament by the FDA.[131]

[127] Terminology used by Scherer and Ross, Dror. Ben-Asher, op. cit. note 23.

[128] Dror. Ben-Asher, op. cit. note 23, p. 318.

[129] European Commission, Case No IV/M. 555 Glaxo/ Wellcome, paragraph 24.

[130] Kristen Riemenschneider, op. cit. note 25.

[131] Marcus Glader, op. cit. note 13, p. 134.

5.3.2. Pharmacia-Upjohn

Facts

On August 1995 Pharmacia AB, Stockholm (Pharmacia) and The Upjohn Company, USA (Upjohn) announced a "merger of equals". The resulted company, called Pharmacia & Upjohn, created "the world's ninth-largest drug maker" at that time[132] with annual sales of $7 billion.[133]

European Commission Approach

Warning: In 1995, when the merger between Pharmacia and Upjohn took place, the Merger Regulation in force was the Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings. The articles that will be mentioned correspond to that Regulation, nowadays revoked by Council regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings.

On 28 August 1995 Upjohn Co. and the Swedish pharmaceutical manufacturer, Pharmacia AB, announced to the Commission the merger, following article 4 of Council Regulation 4064/89.[134] The merged company had around 2,5% of pharmaceutical sales in Europe.[135]

The Upjohn and Pharmacia merger was a concentration in the sense of art 3.1.b) Merger Regulation."[136] The merger had Community dimension, within the scope art 3 Council Regulation 4064/89.[137]

A. STEP 1: RELEVANT PRODUCT MARKET APPRAISAL

Here, the Commission, like in precedent cases, divided the product market into pharmaceutics preparations[138] and future products/R&D pipelines. (*To obtain more information about Commission's appraisal in pharmaceutical preparations, see footnote 139*).

With respect to the *"Innovation Markets"*, the Commission found two different projects where the companies could overlap:

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[132] New York Times,
http://query.nytimes.com/gst/fullpage.html?res=9D07E7D81639F931A35752C1A963958260 06.04.07

[133] European Commission, Case No IV/M.631-Upjohn/Pharmacia, paragraph 2.

[134] Article 4 "Prior notification of concentrations:
1. Concentrations with a Community dimension as referred to by this Regulation shall be notified to the Commission not more than one week after the conclusion of the agreement, or the announcement of the public bid, or the acquisition of a controlling interest. That week shall begin when the first of those events occurs.
2. A concentration which consists of a merger within the meaning of Article 3 (1) (a) or in the acquisition of joint control within the meaning of Article 3 (1) (b) shall be notified jointly by the parties to the merger or by those acquiring joint control as the case may be.[…] ").

[135] European Commission, Case No IV/M.631-Upjohn/Pharmacia, paragraph 2.

[136] Art 3: "1. A concentration shall be deemed to arise where: (b) - one or more undertakings, acquire, whether by purchase of securities or assets, by contract or by any other means, direct or indirect control of the whole or parts of one or more other undertakings"; European Commission, Case No IV/M.631-Upjohn/Pharmacia, paragraph 4.

[137] Because the combined worldwide turnover of both undertakings was more than 5000 million ECU and the aggregate Community-wide turnover of each party involved was also more than 250 million ECU. The case did not fall in the exception of art 1.2 b) "unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State. "

[138] European Commission, Case No IV/M.631-Upjohn/Pharmacia, paragraphs from 17 to 24, Concerning pharmaceutics preparations, the merger created overlapping in 14 different drugs, grouped following ATC classification, third level. Product market, positive factors for further market entries and no plenty substitutability between the Upjohn and Pharmacia drugs.

- Cancer/solid tumors treatment; where both companies were developing a pipeline in this field, concerning the same class of compounds.

- Parkinson's treatment; where Upjohn and Pharmacia had both projects for Parkinson's disease.

B. STEP 2: RELEVANT GEOGRAPHIC MARKET APPRAISAL

Due to the degree of decentralization of Health Policy in the European Union (where each Member State has the power to fix pharmaceutical prices and the grade of reimbursement by the public system), the Commission considered as relevant geographic market for pharmaceutical products, the national market.[139]

In R&D projects, for the development of new drugs, the market was defined at world wide level.[140]

C. STEP 3&4: COMPETITIVE ASSESTEMENT & EFFICIENCIES

For the purposes of this thesis, only the *"Innovation Market"* competition appraisal will be object of further explanation. (*For the Commission assessment of pharmaceutical preparations see footnote 139*).[141]

- Cancer/solid tumors treatment

Upjohn was developing a product (CPT-11) in Phase III, expected to be launched in three years (1998).[142] The drug belonged to other company, the Japanese Yakult Honsha, which had licensed to Upjohn the component in America and Australia, and to Rhône-Poulenc Rorer in Europe.[143]

Pharmacia had a trial in Phase III, whose launch was predicted in six years (2001). The geographic market of the product (9AC) was the EEA. There were at least three competing projects, which would reach the market in one or two years (1996-7).[144]

The Commission also found that it was not clear whether the different compounds developed for each undertaking (CPT-11 and 9AC) belonged to the same ATC group and would consequently be substitutes.[145]

Like a consequence to the facts exposed above, the Commission concluded that there was no geographic overlap and very uncertain product overlap**.** Following this logical path, the European Competition Authority decided that the merger operation would not originate a dominant position in the market of solid tumor's treatment.

[139] Ibid., paragraph 14.

[140] Ibid., paragraph 15.

[141] European Commission Case No IV/M.631-Upjohn/Pharmacia: Concerning pharmaceutical products, the combined share of all these products in each Member States was below 35%, and effective competition in the respective markets was demonstrated, stated the Commission. Only two products among them had higher shares: Cytostatic antibiotics in Austria (68.8%) and Plain corticosteroids in Sweden (55.5%). The Commission concluded that "both cases do not pose any competitive problems with respect to market domination created by this operation" and based its decision in several factors like the existence of important competitors in the field.

[142] Ibid., paragraph 26.

[143] Ibid., paragraph 28.

[144] Ibid., paragraph 27.

[145] Ibid., paragraph 16-24.

- Parkinson's treatment

  Both companies developed R&D activities for the Parkinson disease in Phase III, expected to be launched in two years (1997).[146]

  The Commission found 12 competing products under development in this field and at least five EU competitors' products, already marketed, belonged to the corresponding third level of ATC (Roche, Merck, Sandoz, Britannia/Orion, Astra Medica).[147]

  For the former reasons, within the Parkinson treatment, the Commission defended: *"the notified operation will create or increase a dominant position neither on the respective R+D/compound market nor for future developments*".[148]

D. STEP 5: FINAL DECISION.REMEDIES

The Commission cleared the merger, and declared that the concentration operation between the companies was compatible with the Common Market, within its powers of decision, established in art 8.2.[149] The clearance was adopted in application of article 6.1.b).[150] Neither conditions, nor obligations were imposed by the Competition Authority.[151]

Federal Trade Commission Approach

A. STEP 1: RELEVANT PRODUCT MARKET

Within the future market approach, the American Antitrust Authority was concerned about the anticompetitive effects of the merger in the R&D for the colorectal cancer treatment.

The FTC underlined the overlapping R&D projects for Upjohn and Pharmacia in this type of cancer. Actually, both firms were among a few undertakings in advanced stages of development of the component *topoisomerase I inhibitors,* for the colorectal cancer disease.[152]

B. STEP 2: RELEVANT GEOGRAPHIC MARKET APPRAISAL

In the case of the R&D project for the treatment of colorectal tumor, the Federal Trade Commission, considered United States like the geographic relevant market.

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[146] Ibid., paragraph 30.

[147] Ibid., paragraph 31.

[148] Ibid., paragraph 32.

[149] Article 8.2 Merger Regulation: "Where the Commission finds that, following modification by the undertakings concerned if necessary, a notified concentration fulfils the criterion laid down in Article 2 (2) and, in the cases referred to in Article 2(4), the criteria laid down in Article 85(3) of the Treaty, it shall issue a decision declaring the concentration compatible with the common market".

[150] " The Commission shall examine the notification as soon as it is received.
(a) Where it concludes that the concentration notified does not fall within the scope of this Regulation, it shall record that finding by means of a decision.
(b) Where it finds that the concentration notified, although falling within the scope of this Regulation, does not raise serious doubts as to its compatibility with the common market, it shall decide not to oppose it and shall declare that it is compatible with the common market."

[151] Art 8.2, Merger Regulation: "It may attach to its decision conditions and obligations intended to ensure that the undertakings concerned comply with the commitments they have entered into vis-à-vis the Commission with a view to rendering the concentration compatible with the common market. The decision declaring the concentration compatible with the common market shall also cover restrictions directly related and necessary to the implementation of the concentration."

[152] Federal Trade Commission Trade, news release, October 27, 1995, FTC Settlement In Upjohn/Pharmacia Merger To Preserve Competition For Colorectal Cancer Drug, http://www.ftc.gov/opa/1995/10/upjm.shtm

C. STEP 3&4: COMPETITIVE ASSESTEMENT & EFFICIENCIES

In the framework of colorectal cancer treatment:

- Upjohn had a pipeline product "CPT-11," expected to reach the market (and FDA approval) in a short period.
- Pharmacia's *topoisomerase I inhibitors* project, (9-AC) was predicted to wait more years before being launched.

In any case, only few competitors at worldwide level were found in the field of *topoisomerase I inhibitors*. In this framework, there are high entry barriers, because the timing for the development of similar projects is lengthy and the scientific procedure is complicated. The FTC concluded that in such circumstances, it was not likely that other companies created a competition environment in the *topoisomerase I market*.

D. STEP 5: FINAL DECISION. REMEDIES

The FTC alleged that the merger would damage R&D competition and violate the American antitrust law. The concentration operation would impede the development of one of the two companies' pipelines in the field of colorectal cancer disease. It was also stressed the high incentive to give up the Pharmacia project, with the consequent reduction in the number of *topoisomerase I inhibitors* pipelines. Consequently, the concentration would decrease price competition between the two future products.

The final decision of FTC was the clearance of the merger conditioned to the divestiture of Pharmacia's pipeline (9-AC) to an approved buyer. The American Authority considered this measure necessary to maintain the R&D race in the colorectal cancer treatment. The FTC also required from the merged company to provide technical assistance to the approved acquirer, in order to develop the 9-AC Pharmacia's project.

MAIN CONCLUSION

INNOVATION MARKET APPRAISAL	EUROPEAN APPROACH	AMERICAN APPROACH
STEP 1: RELEVANT PRODUCT	1. Solid Tumor Treatment 2. Parkinson's Treatment	Colorectal Cancer Treatment
STEP 2: RELEVANT GEOGRAPHIC	**World wide**	**American**

STEPS 3&4: COMPETITION ANALYSIS & EFFICIENCIES	**NO** creation of dominant position	Highly concentrated market +Important entry barriers= **DOMINANT** position of merged company in the *Innovation market*
STEP 5: REMEDIES	**Nor remedies** neither conditions were imposed to clear the merger	**Compulsory divestiture** Pharmacia's pipeline+ Compulsory **technical assistance** to the approved acquirer

Advantages and Disadvantages of the American/European Approaches

On one hand, the Commission decision did not condition the clearance to the divestiture of any product. The European Authority considered that the merger was indispensable because the size of the merging companies (middle-size) impeded the development of costly pharmaceutical products.[153] *"Therefore it is likely that the notified operation will actually create a joint critical mass allowing the merged entity via pooled skills and resources to be a competitive player on the worldwide R&D markets of developing and inventing active compounds and resulting pharmaceutical products."*[154] Curiously, in the Commission's reasoning, this argument was not used to measure the competing firms in the market.

It is important to point out that the main difference between the American and European outcome was the delimitation of the R&D market in the case of cancer treatment projects. While the European Commission considered like "*Innovation Market*" the pipeline for the treatment of cancer, the FTC reduced the scope of that relevant market to the colorectal cancer. In addition, the FTC stressed that colorectal cancer is the "*second most common form of cancer and, for those patients whose cancer recurs, only 15 percent survive.*"[155] No drug for this disease existed at this time.[156] The product at issue, *topoisomerase I inhibitors*, could increase the survival rate of colorectal cancer patients. The capital importance of that drug was evident and the competition concerns were directly linked with the consumer welfare.[157]

On the other hand, the FTC believed in the anticompetitive effects of the merger in the colorectal cancer treatment. The American Authority pointed out the heavy entry barriers in the sector, especially considering the length and complexity of the clinical trials, circumstance that impeded an easy entry into the market and a fast product's development. Because of this, the Federal Trade Commission demanded the settlement of an agreement from both companies that would keep competition in the *topoisomerase I inhibitors*, by avoiding the interruption of either of the two-research project.[158]

[153] Ibid.

[154] European Commission, Case No IV/M.631-Upjohn/Pharmacia, paragraph 25.

[155] Federal Trade Commission Trade, News Release October 27, 1995, FTC Settlement In Upjohn/Pharmacia Merger To Preserve Competition For Colorectal Cancer Drug, http://www.ftc.gov/opa/1995/10/upjm.shtm

[156] Marcus Glader, op. cit. note 13, p. 139.

[157] Ibid.

[158] Federal Trade Commission Trade, News Release October 27, 1995, FTC Settlement In Upjohn/Pharmacia Merger To Preserve Competition For Colorectal Cancer Drug, http://www.ftc.gov/opa/1995/10/upjm.shtm.

5.3.3. Ciba-Geigy / Sandoz

Facts

In March 1996, Ciba-Geigy AG (Ciba) and Sandoz AG (Sandoz), both companies based in Basel, Switzerland, and manufactures of biological and chemical products in the health, agricultural and industrial chemical sectors,[159] expressed their desire to merge and create a new company called Novartis. It was supposed to become the world's second-largest pharmaceutical company, only after Glaxo Wellcome (United Kingdom) in the drug-industry arena.[160]

The resultant incumbent from the merger, Novartis, a giant in the drug arena, would reach a 5% in the worldwide pharmaceutical sales and would be mainly active in fields like cardiovascular diseases, hormonal diseases, dermatology, cancer, asthma, immunology and diseases of the central nervous system.[161] The new entity would manage assets over $80 billion of value.[162]

European Commission Approach

Warning: In 1996, when the merger between Ciba and Sandoz took place, the Merger Regulation in force was the Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings. The articles that will be mentioned correspond to that Regulation, nowadays revoked by Council regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings.

On 27 March 1996 Ciba-Geigy AG and Sandoz AG notified to the Commission the merger, in order to create a new enterprise (Novartis), in the sense of article 4 of Council Regulation 4064/89.[163]

The Commission found serious concerns about merger's compatibility with the Single Market.[164] The European Authority, after having examined the Community dimension of the merger[165], and that the operation was a concentration within the meaning of art 3.1.a of the Merger Regulation,[166] it initiated the appraisal of the operation.

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[159] Commission Decision, Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraphs 5 and 6.

[160] Ciba-Sandoz merger gets FTC's go-ahead - Ciba-Geigy AG, Sandoz AG, BBI Newsletter, Jan, 1997, http://www.findarticles.com/p/articles/mi_m3570/is_n1_v20/ai_19137536 08.04.07.

[161] Commission Decision, Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraphs 52 and 53.

[162] Ciba-Geigy Ltd 123 FTC 842, Docket no C-3725 (1997) Complaint, paragraph 8.

[163] "Prior notification of concentrations:
1. Concentrations with a Community dimension as referred to by this Regulation shall be notified to the Commission not more than one week after the conclusion of the agreement, or the announcement of the public bid, or the acquisition of a controlling interest. That week shall begin when the first of those events occurs.
2. A concentration which consists of a merger within the meaning of Article 3 (1) (a) or in the acquisition of joint control within the meaning of Article 3 (1) (b) shall be notified jointly by the parties to the merger or by those acquiring joint control as the case may be.[…]".

[164] Commission Decision, Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraph 3.

[165] The Community dimension, was proved by the combined worldwide turnover, higher than 5000 million ECU, and the aggregate Community-wide turnover of each party involved is also more than 250 million ECU. Article 1 Council Regulation (EEC) No 4064/89. Does not apply art 1.2 b) "unless each of the undertakings concerned achieves more than two-thirds of its aggregate Community-wide turnover within one and the same Member State."

[166] Art 3.1.a) Merger Regulation: "A concentration shall be deemed to arise where: (b) - one or more undertakings, acquire, whether by purchase of securities or assets, by contract or by any other means, direct or indirect control of the whole or parts of one or more other undertakings."

A. STEP 1: RELEVANT PRODUCT MARKET APPRAISAL

The Commission divided the relevant market in four different brands, where both industries were active: health-care products (or pharmaceutical products), plant protection, animal health products and seeds.[167]

For the object of our study, we will be focused only in the field of pharmaceutical products. In this framework, the Commission subdivided the market (as its usual practice) between medicines,[168] actives substances[169] and future markets. Again, precisions only about the *future market* examination by the Commission will be done in this essay. (*For medicines and active substances, see footnotes 169-170*)

The Commission identified as research activities, where the companies could overlap, the *HS-TK gene therapy* for the treatment of brain tumors and other tumors.[170]

The Commission admitted, in the merger in question, that there was a need of deep analysis of the research project of both parties in *HS-TK gene therapy*, for the treatment of brain tumors, to avoid the creation of a dominant position in that field.

B. STEP 2: RELEVANT GEOGRAPHIC MARKET APPRAISAL

As in the product market, here the Commission also made a distinction between medicines,[171] active substances[172] and future markets.

In the case of "*Innovation Markets*" the market was divided into two geographic areas: the United States and Europe. The reason defended by the Commission to maintain this division was that patents were granted independently in both territories.[173]

C. STEP 3&4: COMPETITIVE ASSESTEMENT & EFFICIENCIES

It is important to point out that Ciba-Geigy was the largest shareholder of Chiron, an American-based pharmaceutical company, which developed research work in *HS-TK gene therapy* at the preclinical stage. Moreover, Sandoz had an important ownership percentage of GTI, other drug company from US, which had developed gene therapy at phase II/III.[174]

[167] Commission Decision, Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraph 10.

[168] In the Ciba-Sandoz case, 3 different overlapping products (already marketed) were identified using the ATC: Rauwolfia and beta blockers, calcitonins and muscle relaxants. In the merger appraisal, the Commission opined that the concentration did not create a dominant position in neither of these areas.

[169] Following the information provided for both companies, their respective shares in the market of the active substances were marginal. The merger, so, would not create a dominant position in this arena.

[170] Commission Decision Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraph 45: "HS-TK gene therapy is , according to the parties , a process of suicide gene therapy in which an enzyme gene is fed through a vector system into diseased cells. A prod rug is then administered which is activated by the enzyme gene. Prod rug means a drug pre-stage which, in conjunction with the enzyme gene, has the effect of killing the cell. In this way, the diseased cells are killed off".

[171] The relevant market was national. Despite the European efforts for harmonization, the sale of pharmaceutical products is influenced by national policies through their health systems.

[172] Following previous decisions, the Commission considered that the geographic market for active substances was world-wide. The absent of barriers for the mutual recognition of substances licenses at global level, corroborated this fact.

[173] Commission Decision Case No IV/M. 737-Ciba-Beigy/Sandoz, paragraph 51.

[174] Ibid., paragraph 96-97.

These agreements permitted the parties to have exclusive access to patent rights in the gene therapy for tumors treatment. Those patents, broadly defined (especially in the case of Chiron), could impede the entry of other undertakings in the R&D market for this type of disease. "*Where a merger leads to the holding of such a combination of patents, market foreclosure can result*".[175]

According to the Commission, this situation would lead to a dominant post-merger position **only in the concurrence of three circumstances:**

1) Gene therapy was proved successful,
2) Gene therapy was the only viable research project with the desiderated therapeutic results, and
3) The patents were granted (because in that moment the parties had only submitted the applications).

The European Authority studied the likelihood of each circumstance:

1) In the first point, the Commission argued the lack of certainty to prove the future success of the gene therapy,
2) Secondly, it was defended the possibility that competing firms would find a circumventing way to solve the possibility of patent block,
3) Thirdly, it was concluded that the granting of broadly defined patents was plausible and could constitute an obstacle to incumbents in the R&D market. However, only this argument was not sufficient for the Commission to create the presumption of a dominant position.[176]

As only one of the three conditions was probable, the Commission did not consider that the merger could originate a dominant position in gene therapy.

D. STEP 5: FINAL DECISION. REMEDIES

Finally, the Commission did not consider that the merger would damage the competition in future markets. The European Authority only requested to Novartis a statement in order to guarantee that Chiron would grant licenses of their tumor therapy patents to the intereseted firms at European or national level. This obligation would apply for 10 years.[177]

Federal Trade Commission Approach

In the present case, the Federal Trade Commission started the proceeding against the merger between Ciba and Sandoz to create Novartis, because it considered that the concentration would be against the public interest. The Commission started the reasoning with the presumption of a violation of Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act.

[175] Ibid., paragraph 99.

[176] Ibid., paragraph 101- 105.

[177] Ibid., paragraph 107: "Both undertakings hereby make the following binding influence which it has as result of its holding in Chiron Corporation, Emeryville, California, United States of America and through the Board Members appointed by it in such a way as to ensure that the Chiron subsidiary Viagene issues to interested firms on the terms and conditions customary in trade and industry non-exclusive licences for each European patent and national patents derived therefrom that are based on the international patent application Nos WO 89/09271 and WO 90/07936 for HSTK (Herpes simplex Thymidine Kinase) gene therapy for tumors. […]".

A. STEP 1: RELEVANT PRODUCT MARKET APPRAISAL

The FTC divided the relevant market in three parts:

1. Gene therapy,[178]
2. Corn herbicides,
3. Flea control products.

As the corn herbicides and the flea control products are out of the scope of the pharmaceutical products, our analysis will be focused exclusively on **gene therapy**.

Like no gene therapy product had been previously accepted by the FDA, gene therapy was an *"Innovation Market"*, a R&D pipeline, under clinical trials.

The gene therapy market was divided by the FTC in four different brands: *"including research, development, manufacture and sale of:*

(a) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer;
(b) HSV-tk gene therapy for the treatment of graft versus host disease;
(c) gene therapy for the treatment of hemophilia; and
(d) chemoresistance gene therapy."[179]

B. STEP 2: RELEVANT GEOGRAPHIC MARKET APPRAISAL

The American Antitrust Authority considered the US as the relevant geographic market. The main reason to reach this conclusion was defended as follows: in the United States there are two Agencies: the Food and Drug Administration ("FDA") and the Environmental Protection Agency ("EPA"), which rule regulations to control the drug market in United States and impede the entry of other products which do not meet their requirements.[180] This situation created a barrier to entry in the American drug market for foreign companies and thus segmenting the geographic market.

C. STEP 3&4: COMPETITIVE ASSESTEMENT & EFFICIENCIES

The general evaluation by the FTC of the gene therapy showed a high concentration market. Only a few companies were developing this type of treatment, and among them only Ciba, Chiron and Sandoz handled the patents and know-how which permitted the research, manufacture and commercialization of the gene therapy products. These companies were already involved in different stages of the gene therapy pipeline, Sandoz in phase III and Chiron in preclinical stage. The result of all these circumstances was that Ciba/Chiron and Sandoz were leaders in the gene therapy development[181].

[178] Ciba-Geigy Ltd 123 FTC 842, Docket no C-3725 (1997), Complaint, paragraph 9: "Gene therapy is a therapeutic intervention in humans based on modification of the genetic material of living cells. Cells may be modified ex vivo for subsequent administration or altered in vivo bygene therapy products given directly to the patient".

[179] Ibid.

[180] Ibid., paragraph 13.

[181] Ibid., paragraphs 14 and 15.

Moreover, the entry into the gene market supposed a great effort in several aspects. The FTC provided an overview of these barriers:

- Economic barrier: enter into the market requires an important investment and high expenditures,
- Clinical barrier: lengthy clinical testing process, lasting at least 10 or 12 years,
- Regulatory barrier: approval of each clinical phase by the FDA is needed,
- Technical barrier: high degree of expertise is required in the gene therapy field,
- Patent barrier: the company must be the owner of patent rights and intellectual properties over several inputs in gene therapy to complete successfully R&D projects in this field.[182]

Finally, **the FTC concluded that the merger could create a monopoly in the gene therapy.** [183] Concretely, in the gene therapy, the merger would:

1. Reduce the competition in the R&D race,
2. Create a dominant position of the merged incumbents in the market,
3. Reinforce the barriers to entry in the market due to the high concentration of patents portfolio in the new merged company,
4. Decrease the incentive to license intellectual rights by the merged undertaking to other companies.[184]

D. STEP 5: FINAL DECISION. REMEDIES

The FTC concluded in the Complaint report "*The merger, if consummated, would constitute a violation of Section 5 of the FTC Act, 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. § 18."*[185]

The remedies imposed by the American Authority involved several requirements for the merged company, Novartis, in the gene therapy R&D:

- Firstly, the merged company was demanded to grant licences of technologies needed for the general development of gene therapy ("Anderson *ex vivo* patent" and patents for cytokines) to any other requesting company. These licences had to be granted in a non-exclusive regimen.[186]

- Secondly, the FTC required to Novartis to grant the license of Intellectual rights in certain fields (*"HSV-tk" gene therapy for the treatment of cancer and gene therapy for the treatment of hemophilia*)[187]

[182] Ibid., paragraph 26.

[183] The FTC argued that despite the existence of other potential competitors in the gene therapy, they did not have the patent rights for their commercialization, and the merged firm could be the exclusive ownership, FTC News Release: December 17, 1996 . FTC Accord in Ciba Giegy/Sandoz Merger to Prevent Slowdown in Gene Therapy Development & Preserve Competition in Corn Herbicides, Flea-Control Markets http://www.ftc.gov/opa/1996/12/ciba.shtm 14.04.07

[184] Ciba-Geigy Ltd 123 FTC 842, Docket no C-3725 (1997) Complaint, paragraph 31.

[185] Ibid., paragraph 33.

[186] Ibid.

[187] Marcus Glader, op. cit. note 13, p. 154 : "In the "HSV-tk" gene therapy for the treatment of cancer and for the treatment of graft versus host disease, it was demanded to the merger company to grant a world wide patent (in a non-exclusive regimen) to Rhône-Poulenc Rorer, or another approved pharmaceutical company. to make, use and sell HSV-tk. The main objective for the HSV-tk License is to guarantee the development of HSVtk gene therapy research and later approval by the FDA and sale in the American market. This remedy, argues the FTC, is the path to avoid a disruption in the post-merger gene competition. In the gene therapy for the treatment of hemophilia; Novartis was required to make available its exclusive intellectual property right for the Factor VIII gene to

to the company Rhône-Poulenc Rorer Inc. Through this remedy, the FTC tried to preserve Rhône-Poulenc in a competitive situation regarding the powerful new merged company.[188]

MAIN CONCLUSION

INNOVATION MARKET APPRAISAL	EUROPEAN APPROACH	AMERICAN APPROACH
STEP 1: RELEVANT PRODUCT	HS-TK gene therapy for the treatment of brain tumors	General gene therapy + 4 brands
STEP 2: RELEVANT GEOGRAPHIC	**European**	**American**
STEPS 3&4: COMPETITION ANALYSIS & EFFICIENCIES	**NO** dominant position in the market of the gene therapy	Highly concentrated market +Important entry barriers= **DOMINANT** position of Novartis in the market
STEP 5: REMEDIES	**A statement** in order to guarantee the issue by Chiron of non exclusive licenses at European or national level	1. **Compulsory licenses** of Intellectual rights in some gene therapy specified fields to Rhône-Poulenc 2. **Compulsory licences** of technologies needed for the general development of gene therapy

Advantages and Disadvantages of the American/European Approaches

In this merger case study, the *"Innovation Market"* was underlined by the American and European Authorities, when they identified the R&D pipelines, their competitive or anti-competitive effects and remedies, involving the research projects.[189]

It was proved that gene therapy treatments would offer substantial improvements in the fight against cancer before the year 2000. Gene therapy research pursued fatal diseases treatment. This was the case of several types of cancer where no previous treatment had demonstrated to be effective, like for example brain cancer, disease where the gene therapy could be the only cure expectancy for the patients.[190]

It was also vital to predict the economic benefits of these gene projects, in the case of a successful launching into the market. Like the FTC reflected, the sales of gene therapy, while at that time the product was not sold on the market, would reach $45 billion by 2010. More concretely, in oncology, it was projected that sales

other companies or to endow Rhône-Poulenc Rorer a sublicense; In the chemoresistance gene therapy. Novartis was banned to acquire new intellectual rights for the development, use and commercialization of this treatment."

[188] FTC News Release: December 17, 1996 . FTC Accord in Ciba Giegy/Sandoz Merger to Prevent Slowdown in Gene Therapy Development & Preserve Competition in Corn Herbicides, Flea-Control Markets http://www.ftc.gov/opa/1996/12/ciba.shtm 14.04.07

[189] Ibid.

[190] Ibid.

of gene therapy for cancer treatment would exceed $600 million by 2002. It is important to point out the possible benefits because at that moment, there were no economic substitutes for genetic therapy.[191]

Before the merger, Ciba and Sandoz had the Intellectual property rights, patents and know-how needed to complete the gene pipeline independently. Previously to 1997, the merged parties were competitors, both of them with an important range of patents and IPs in the gene therapy. In that time, they could license those patents to other undertaking, obtaining benefices or rights like counterpart. But, after the merger, they would not have incentives to license intellectual rights, and this situation could easily block the R&D gene therapy by other companies, unable to develop the treatment without the required patents.[192] Because of this, the merger could eliminate the competition between them in the future market. Once the different pipelines were merged, the innovation race could be over. The competition in *"Innovation Market"* would be in danger.

The FTC found, in consequence, a highly concentrated market in this field and the risk of creation of a dominant position by the merging undertakings, which controlled capital patents in the different gene therapy brands.[193]

The FTC expected to protect price competition and the research in this field through the requirement of granting several licenses to other companies. The different licenses that the FTC obliged to grant to Roner were the mean to maintain a second firm in the market able to compete (handling the necessary IPs) in equal conditions with the giant "Novartis".

However, the European Commission considered that the potential overlap between both companies in gene therapy was only focused in the gene therapy for cancer treatment. Within cancer field, the European Authority did not find evidences for a future dominant position. The Commission did not take into account that competition in the general gene therapy research could be reduced (also blocked) because of the combination of patents that the merging incumbents handled.[194]

[191] Ciba-Geigy Ltd 123 FTC 842, Docket no C-3725 (1997) Complaint, paragraph 10.

[192] Marcus Glader, op. cit. note 13, p.154.

[193] Ciba-Geigy Ltd 123 FTC 842, Docket no C-3725 (1997) Complaint, paragraph 16-20:
"(a) herpes simplex virus-thymidine kinase ("HSV-tk") gene therapy for the treatment of cancer; The research market in this field is also strongly concentrated and only Sandoz and Chiron controlled the intellectual properties and know-how to develop gene therapy against cancer. This patent exclusivity constituted an entry barrier in the gene therapy for the cancer, excluding other companies in the race for the development of this technology.
(b) HSV-tk gene therapy for the treatment of graft versus host disease
Also here only Sandoz and Chiron leaded the R&D market because the exclusive control of patents and know-how..
(c) gene therapy for the treatment of hemophilia;
Chiron and Sandoz controlled in a duopoly regimen critical intellectual property portfolios in the gene hemophilia treatment. These two pharmaceutical companies were also leaders in the mentioned pipeline
(d) chemoresistance gene therapy
The R&D market for the treatment of chemoresistance belonged to few pharmaceutical companies, standing out Chiron and Sandoz like leading developers and controllers of capital intellectual rights, like patents."

[194] Marcus Glader, op. cit. note 13, p.154.

6. CONCLUSIONS

This paper has followed a logical path from the *high-tech* sectors Merger Dilemma to three concrete cases of Merger Control in the Pharmaceutical sector through the decisions of the European and American Authorities.

The different sections of this thesis have not only shown, but also proved, the necessity of the implementation of "*Innovation Market*" assessment in the Merger Control, concretely with respect to concentration operation between pharmaceutical companies. In spite of the uncertainties that the analysis of R&D projects supposes and the lack of proved links between reduction in the number of R&D pipelines and lessening in innovation, the positive factors in the application of this approach counterbalance the negative ones. To expose clearly the conclusions reached, different paragraphs will explain the basis to defend each conclusion. The conclusions chain is in order from the most general outcome to the most specific, and each one is the consequence of the previous.

Conclusion 1: "*Innovation market"* to solve *high-tech* markets Merger Dilemma

We have studied in section 1.2 that mergers between *high-tech* undertakings have their own features. On one hand, concentration between *high-techs* can lead to foster the innovation but also can lessen the R&D output. We have called these diverging outcomes in innovation "the Merger in *high-tech* sectors dilemma". The post-merger results in terms of innovation can thus be positive or negative.

When a merger involves the development of new products, which may became in the future a part of the relevant product market, the simple study of current/product markets, does not answer the reality of the concentration. The *"Innovation Market*" approach was created to avoid the gaps in the traditional Merger Control, when innovation-based companies are involved. The *"Innovation Market"* supposes the analysis of the merging companies R&D projects to avoid that the concentration reduces the innovation level.

Competition law must be applied customized to the situation that is engaged. The mere study of the current product markets in the traditional industries is inappropriate for the innovation-based sectors.

Conclusion 2: *"Innovation Market"* to foster innovation

In Section 2, it has been exposed, that "*Innovation Market"* analysis is appropriate to avoid lessening in innovation within *high-tech* companies' concentration operations. The control of research pipelines among the merged companies is the only way to guarantee competition in sectors characterised by fast technological advance.[195]

The main reason to maintain several R&D competing programmes is that they can increase chances to obtain a future product market.[196] An anti-competitive reduction in the number of independent R&D tracks may suppose the reduction in the level of innovation, and consequently the delay of the product launching into the market. *"Innovation Market"* is about preventing the reduction of competition in the future.

[195] As described in the 1995 United States Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property.

[196] Marcus Glader, op. cit. note 13, p. 193.

Conclusion 3: *"Innovation Market"* to gain consumer welfare

The consumer welfare is the main objective of competition law, which tries to protect consumer against anti-competitive practices. Innovation is an essential mean to achieve consumer welfare and consequently, the antitrust authorities must be concerned about the innovation race. Consumer welfare cannot be limited exclusively to price issues because customers also appreciate the quality, effectiveness or safety of the product. To encourage public welfare in the long run, the promotion of innovation is a key input.

Any anti-competitive reduction in the R&D race could lead to less innovation and, accordingly, that may suppose less competition in a future product market. This would become visible through higher prices, less variety and worse quality in the final product. Therefore, the reduction in the R&D race may affect, in a very negative way the product market competition.[197]

Conclusion 4: *"Innovation Market"* to promote competitiveness

The Organization for Economic Co-operation and Development (OECD) defines competitiveness as "*the ability of companies […] to generate, while being and remaining exposed to international competition, relatively high factor income and factor employment levels on a sustainable basis*".[198] Therefore, it is logical that the companies desire a high level of competitiveness in the sector.

In the *high-tech* sector, the innovation is the main force for the competitiveness. As the Conclusion 3 defended, the "*Innovation Market*" analysis implies more innovation, and as logic consequence, more competitiveness. Therefore, not only the consumers will get benefits from the implementation of *"Innovation Market*" but also the industry in general.

Conclusion 5: The *"Innovation Market"* finds within pharmaceutical industry its perfect framework

The pharmaceutical industry has all the necessary characteristics to become an ideal target for the implementation of *"Innovation Market"*.

As it was explained while discussing the *Pharmaceutical Merger syllogism*, in the concentration operations, *"Innovation Market"* analysis applies to promote not only **competitiveness** in the sector, but also **consumer welfare:**

- In the pharmaceutical industry, **competitiveness** can only be assured if enough efforts are devoted to the innovation race. The innovation in the pharmaceutical sector is the main competitive input and means more benefits for the undertakings.

- More innovation in the sector will provide more effective, cheaper and safer drugs, which will enhance **consumer welfare**. Consumers expect the pharmaceutical industry to deliver safe and effective products at the lowest possible prices. And, like William J. Baer, Director of the FTC's Bureau of

[197] Marcus Glader, op. cit. note 13.

[198] Thomas C. Lawton, op. cit. note 7, p. 1-17.

Competition defended "*This case is about saving lives. Today there are two firms racing to develop new […] therapies to combat deadly diseases. This deal threatened to eliminate that competition. Our order ensures that this sprint to the finish line will continue.*"[199]

It was alleged in section 2 that "*Innovation Market*" analysis has been hardly criticised by the economists, because no link between concentration in R&D and lessening in innovation has been found, and also because it is risky to speculate with the R&D project in Merger Control. Pharmaceutical sector features can offer counter-arguments:

- The special characteristics of this sector, contrasting other *high-tech* industries, permit competition authorities to envisage possible damages to innovation. The uncertainty of the R&D process does not apply to the pharmaceutical sector, where the pipelines are well structured within the Clinical Trial Phases. It is logical to conclude that more advanced is the medicament in the development process (e.g. Phase III) easier it will be to predict the future product market features. *"The more imminent is the future market, the clearer overlap with potential competition doctrines."*[200]

- In addition, the lack of proved link between more concentration in R&D and reduction in the level of innovation was underlined by the economists. The commentators defend, because of this uncertainty, that the authorities must not regulate the level of R&D. However, in the pharmaceutical sector the pipelines are public, available and strongly regulated and, in consequence, is easier to find the link between anti-competitive reduction in the number of R&D projects and drop in innovation.

Conclusion 6: The European and American Agencies must continue to use the *"Innovation Market"* assessment

After all the previous arguments, the logical consequence is that the European Commission and the Federal Trade Commission must persist in the use of *"Innovation Market"*, when they are assessing horizontal mergers in *high-tech* sectors. Moreover, both Agencies should elucidate their respective approaches and remove any uncertainties in the definition of the "*Innovation Market*". The practice in this field must be predictable and must follow a determined path.

In order to reach this mark, the Agencies should re-define "*Innovation Market*" and promulgate new Guidelines that help the implementation of the Innovation market, and develop *a praxis* to define the R&D markets and make clear their position.[201]

Conclusion 7: Europe and American praxis in Merger Control have different approaches

After having examined deeply the European praxis in this framework, it can be concluded that "*Innovation Market*" assessment has a very limited role in the European Merger Control where the R&D pipelines are focussed to new products and the rate of success is absolutely uncertain. Other characteristic of the

[199] Ibid.

[200] Marcus Glader, op. cit. note 13, p.154, 196.

[201] Kristen Riemenschneider, op. cit. note 25, p. 2.

European appraisal is that the antitrust Authority is only taking into consideration projects in Phase III of the Clinical Trials (also Phase II in few cases, where the situation is really clear).[202]

The truth is that, in European Merger practise, unless the parties are currently in a powerful position in the present markets (product market), the Commission is only going to consider as overlapping pipelines, the ones being in advanced development. In this way the European Authority tries to avoid playing the game of guessing the future.[203]

The American approach is broader and it is not limited to the European restrictions. The FTC is taking into account pipelines in early stages of the development process to define the *relevant "Future Market"*. Actually, for the American Authority it is not necessary that the drug is in the stage III of the Clinical Trial to be included in the competition assessment.

Other feature of the American approach, is that the Antitrust Authority is more meticulous when is assessing a merger that can *"restrict substantially competition in R&D "*. The FTC has defined, in a more detailed way, the relevant future markets, reducing their scope, in comparison with the European Authorities.

In any case, it is possible to recognise the difficulty of predicting the success of future product in premature phase of development. In addition, it must be risky to define in a very narrow way the pipelines and their intended use, because of the complicated process to get a medicament, which has important rates of failure and also it is likely to change their properties, use or effectivity.

To sum up, it can be said, that while in the American approach, the "*Innovation Market*" is intended to predict the future product market effects, the European approach, tries to establish the post-merger incentives to reduce R&D projects.[204]

The "*Innovation Market"* analysis is one instrument more in the hands of the Agencies to control the concentration operations. This extra-power is useful to avoid negative post-merger situations, which escape to the traditional merger examination. However, this competence can be dangerous in the case of a very strict application because pro-competitive mergers can be challenged in basis to an incorrect, risky or too much speculative assessment of "*Innovation Markets"*.

[202] Pierre-Karim Lahbabi, DG Comp, Directorate B: Energy, Basic industries, Chemicals and Pharmaceuticals.

[203] Marcus Glader, op. cit. note 13, p. 154, 207.

[204] Marcus Glader, op. cit. note 13, p. 191.

7. ANNEXE

European Commission. Pharmaceutical Merger Notifications Registry. From 1991 to 2006. *Source European Commission, DG Competition.*

Case number	Case name	Notification date	Nace code	Nace description	Decision	Decison date
M.58	BAXTER - NESTLE / SALVIA	04/01/1991	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(a)	06/02/1991
M.72	SANOFI / STERLING DRUGS	03/05/1991	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	10/06/1991
M.323	PROCORDIA / ERBAMONT	24/03/1993	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	29/04/1993
M.285	PASTEUR MERIEUX / MERCK	04/06/1993	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(a)	05/07/1993
M.426	RHONE POULENC / COOPER	11/03/1994	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	18/04/1994
M.457	ROCHE / SYNTEX	16/05/1994	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	20/06/1994
M.480	SANOFI / KODAK	13/07/1994	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	12/08/1994

M.464	BMSC / UPSA	04/08/1994	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	06/09/1994
M.500	AMERIC. HOME PRODUCTS (AHP) / AMERIC. CYANA.	16/08/1994	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	19/09/1994
M.555	GLAXO PLC / WELLCOME PLC	30/01/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	28/02/1995
M.555	GLAXO PLC / WELLCOME PLC	30/01/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 7(2) (N/1)	20/02/1995
M.495	BEHRINGWERKE AG / ARMOUR PHARMA	28/02/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	03/04/1995
M.495	BEHRINGWERKE AG / ARMOUR PHARMA	28/02/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 7(2) (N/1)	22/03/1995
M.572	GEHE / AAH	28/02/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	03/04/1995
M.587	HOECHST AG / MARION MERRELL DOW INC.	17/05/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	22/06/1995
M.632	RHONE-POULENC / FISONS	18/08/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	21/09/1995

M.631	UPJOHN / PHARMACIA	28/08/1995	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	28/09/1995
M.716	GEHE / LLOYDS CHEMISTS	08/02/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical	Art. 7(2) (N/1)	01/03/1996
M.716	GEHE / LLOYDS CHEMISTS	08/02/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 9(4) (N/1)	22/03/1996
M.737	CIBA-GEIGY / SANDOZ	27/03/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(c)	02/05/1996
M.737	CIBA-GEIGY / SANDOZ	27/03/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 7(2) (N/1)	18/04/1996
M.737	CIBA-GEIGY / SANDOZ	27/03/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 8(2) (conditions & obligations)	17/07/1996
M.781	SCHERING / GEHE - JENAPHARM	09/08/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	13/09/1996
M.821	BAXTER / IMMUNO	09/09/1996	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	09/10/1996
M.885	MERCK / RHÔNE-POULENC - MERIAL	02/06/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	02/07/1997

M.885	MERCK / RHÔNE-POULENC - MERIAL	02/06/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 7(2) (N/1)	20/06/1997
M.954	BAIN / HOECHST - DADE BEHRING	31/07/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	02/09/1997
M.954	BAIN / HOECHST - DADE BEHRING	31/07/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical	Art. 7(2) (N/1)	21/08/1997
M.950	HOFFMANN - LA ROCHE / BOEHRINGER MANNHEIM	01/09/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(c)	02/10/1997
M.950	HOFFMANN - LA ROCHE / BOEHRINGER MANNHEIM	01/09/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 7(2) (N/1)	22/09/1997
M.950	HOFFMANN - LA ROCHE / BOEHRINGER MANNHEIM	01/09/1997	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 8(2) (conditions & obligations)	04/02/1998
M.1201	DUPONT / MERCK	25/05/1998	DG.24.04.02	Manufacture of pharmaceutical preparations	Art. 6(1)(b)	23/06/1998
M.1220	ALLIANCE UNICHEM / UNIFARMA	09/06/1998	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 9(4) (N/1)	23/07/1998
M.1229	AMERICAN HOME PRODUCTS / MONSANTO	14/08/1998	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	28/09/1998
M.1366	PARIBAS / CDC / BEAUFOUR	09/11/1998	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(a)	09/12/1998

M.1403	ASTRA / ZENECA	15/01/1999	DG.24.04.02	Manufacture of pharmaceutical preparations	Art. 6(2) (conditions & obligations)	26/02/1999
M.1397	SANOFI / SYNTHELABO	12/02/1999	DG.24.04.02	Manufacture of pharmaceutical preparations	Art. 6(1)(b)	15/03/1999
M.1397	SANOFI / SYNTHELABO	12/02/1999	DG.24.04.02	Manufacture of pharmaceutical preparations	Art. 6(2) (conditions & obligations)	17/05/1999
M.1512	DUPONT / PIONEER HI-BRED INTERNATIONAL	17/05/1999	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	21/06/1999
M.1378	HOECHST / RHÔNE - POULENC	24/06/1999	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	09/08/1999
M.1782	AMERICAN HOME PRODUCTS / WARNER-LAMBERT COMPANY	12/01/2000	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Aborted / withdrawn (N/1)	09/02/2000
M.1835	MONSANTO / PHARMACIA & UPJOHN	16/02/2000	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	30/03/2000
M.1846	GLAXO WELLCOME / SMITHKLINE BEECHAM	20/03/2000	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	08/05/2000
M.1878	PFIZER / WARNER-LAMBERT	31/03/2000	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	22/05/2000
M.2312	ABBOTT / BASF	26/01/2001	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	28/02/2001

M.2419	APAX / SCHERING / METAGEN	04/04/2001	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	14/05/2001
M.2517	BRISTOL MYERS SQUIBB / DU PONT	09/07/2001	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	09/08/2001
M.2922	PFIZER / PHARMACIA	25/10/2002	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 11(N/1)	18/11/2002
M.2922	PFIZER / PHARMACIA	25/10/2002	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical	Art. 6(2) (conditions & obligations)	27/02/2003
M.3015	CREDIT SUISSE / BLACKSTONE / NYCOMED	30/10/2002	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	26/11/2002
M.3323	CARDINAL HEALTH / INTERCARE GROUP	14/11/2003	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	16/12/2003
M.3304	GE / AMERSHAM	08/12/2003	DG.24.04.02	Manufacture of pharmaceutical preparations	Art. 6(1)(b)	21/01/2004
M.3394	JOHNSON & JOHNSON / JOHNSON & JOHNSON MSD EUROPE	27/02/2004	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	29/03/2004
M.3354	SANOFI-SYNTHELABO / AVENTIS	09/03/2004	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(2) (conditions & obligations)	26/04/2004
M.3449	GLAXOSMITHKLINE / SANOFI-SYNTHELABO (ASSETS) (4064)	19/04/2004	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	25/05/2004

M.3497	PFIZER / CAMPTO	25/06/2004	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	29/07/2004
M.3493	YAMANOUCHI / FUJISAWA	14/07/2004	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	18/08/2004
M.3544	BAYER HEALTHCARE / ROCHE (OTC BUSINESS)	29/09/2004	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b) (conditions & obligations)	19/11/2004
M.3755	NORDIC CAPITAL / NYCOMED	14/03/2005	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	19/04/2005
M.3751	NOVARTIS / HEXAL	04/04/2005	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b) (conditions & obligations)	27/05/2005
M.3853	SOLVAY / FOURNIER	13/06/2005	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	18/07/2005
M.3928	TEVA / IVAX	18/10/2005	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	24/11/2005
M.4010	FRESENIUS / HELIOS	03/11/2005	DG.24.04.01	Manufacture of basic pharmaceutical products	Art. 6(1)(b)	08/12/2005
M.4007	RECKITT BENCKISER / BOOTS HEALTHCARE INTERNATIONAL	25/11/2005	DG.24.04.02	Manufacture of pharmaceutical preparations	Art. 6(1)(b)	06/01/2006
M.4049	NOVARTIS / CHIRON	23/12/2005	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	06/02/2006

M.4162	MERCK / SCHERING	16/03/2006	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Aborted / withdrawn (N/1)	27/03/2006
M.4198	BAYER / SCHERING	12/04/2006	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	24/05/2006
M.4210	AGRAVIS RAIFFEISEN / BAYWA / DR GRAUB	18/04/2006	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	19/05/2006
M.4207	CAMPINA / FONTERRA CO-OPERATIVE GROUP / JV	24/04/2006	DG.24.04.01	Manufacture of basic pharmaceutical products	Art. 6(1)(b)	02/06/2006
M.4185	CVCI / AMBER TRUST II / AB SANITAS	16/05/2006	DG.24.04.01	Manufacture of basic pharmaceutical	Art. 6(1)(b)	20/06/2006
M.4402	UCB / SCHWARZ PHARMA	13/10/2006	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	21/11/2006
M.4314	JOHNSON & JOHNSON / PFIZER CONSUMER HEALTHCARE	19/10/2006	DG.24.04.01	Manufacture of basic pharmaceutical products	Art. 6(1)(b) (conditions & obligations)	11/12/2006
M.4418	NYCOMED GROUP / ALTANA PHARMA	08/11/2006	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	13/12/2006
M.4423	MERCK / SERONO	13/11/2006	DG.24.04	Manufacture of pharmaceuticals, medicinal chemicals and botanical products	Art. 6(1)(b)	15/12/2006

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Resumen: Durante los últimos años, se ha producido una oleada de fusiones dentro de la industria farmacéutica. Este sector, a diferencia de otros más tradicionales, se caracteriza por la importancia de la investigación y la tecnología para desarrollar nuevos medicamentos. Dicha característica debe ser tenida en cuenta desde el prisma del derecho de la competencia; así, cuando dos laboratorios farmacéuticos se fusionan, las autoridades Antitrust deberán estudiar, no sólo el mercado relevante del medicamento, sino también los proyectos de investigación farmacéutica, el llamado *mercado del futuro*. Este arriesgado análisis, al que se le ha denominado "*Mercado de la Innovación*", supone un control añadido en manos de los poderes públicos para mantener un nivel óptimo de competencia en I+D, lo cual repercutirá sin duda en el nivel de innovación de la industria farmacéutica y, por ende, en el bienestar de los consumidores.

Palabras clave: Mercado de la Innovación, sector farmacéutico, fusiones, Comisión de Comercio Americana, Comisión Europea, proyecto de investigación, bienestar de los consumidores, I+D, competitividad.

Abstract: During the last years, a wave of mergers in the pharmaceutical sector has taken place, not only at European but also at global level. Within the pharmaceutical sector, (a *high-tech* sector, with important repercussion on consumer welfare), the concentration operations have some features not encountered in traditional sectors and, the main dilemma is the incertitude about the post-merger results, in terms of R&D output. To avoid this anti-competitive lessening in innovation, and consequently, in consumer welfare, a tailored Merger Control in the pharmaceutical field is necessary in order to answer the specific characteristics of the sector. This demand is answered through the "*Innovation Market*" analysis, which studies the merging overlapping pipelines aiming to maintain a level of competition in the R&D market. This is the path to foster the competition in the future product market.

Keywords: Innovation Market, pharmaceutical sector, merger, American Federal Trade Commission, European Commission, pipeline, consumer welfare, R&D, competitiveness.

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