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Gülin SÜLEYMANLAR

COMPETITION BETWEEN ORIGINATORS AND GENERIC PRODUCERS IN THE EUROPEAN UNION PHARMACEUTICAL SECTOR

Joint Master's Programme European Studies Master Thesis

Antalya / Hamburg, 2014

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Competition Between Originators and Generic Producers in the European Union Pharmaceutical Sector

Onay : Yukarıdaki imzaların, adı geçen öğretim üyelerine ait olduğunu onaylarım.

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LIST OF ABBREVIATIONS

EC: European Community

EEA: European Economic Area

EFPIA: European Federation of Pharmaceutical Industries and Association

EGA: The European Generics Medicines Association

EPA: European Patent Convention

EU: European Union

EUR: Euro

CFI: Court of First Instance

CJEU: Court of Justice of the European Union

GC: General Court

IP: Intellectual Property

IPR: Intellectual Property Right

MUPS: Multiple Unit Pellet System

OFT: Office of Fair Trading

PO: Patent Office

PPI: Proton Pump Inhibitor

PPRS: Pharmaceutical Price Regulation Scheme

R&D: Research and Development

SPC: Supplementary Protection Certificate

TFEU: Treaty on the Functioning of the European Union

UK: The United Kingdom

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SUMMARY

COMPETITION BETWEEN ORIGINATORS AND GENERIC PRODUCERS IN THE EUROPEAN UNION PHARMACEUTICAL SECTOR

The main ground which urged me to decide the topic of this study is the fact that in recent years, the competition between originator companies and generic producers has brought to the top of the EU pharmaceutical sector's agenda. This issue is at the interaction point of competition law and intellectual property law in a highly regulated research based industry. The pharmaceutical sector is not only specifically regulated, but also influenced by the special characteristics of the patent system. Therefore, the useful debates concerning the interface between competition law and intellectual property law and background information on the structure and regulatory issues relating to the EU pharmaceutical sector are given in order to facilitate readers to easily comprehend the core questions.

This thesis study addresses the major developments in the EU which are the reasons why such level of competition attracts high attention. The first one is the Pharmaceutical Sector Inquiry Report of 2009 in which the European Commission identified "defensive patent strategies" as a potential anti-competitive abuse in the sense of Article 102 TFEU. Such strategies include particularly patent filings that may delay the market entry of generic drugs. Yet, the Report refrains from a thorough legal analysis of such behavior. With the objective of clarifying the legal implications of the Sector Inquiry Report, the study analyses the *AstraZeneca* case (including the Commission's decision, the judgment of the General Court, the judgment of CJEU) as a precedent for assessing the anti-competitive character of patent filings under EU competition law. This benchmark case sheds light on the applicable approach within the EU. In this regard, it is revealed that competition law takes a very strict view on the pharmaceutical industry.

ÖZET

AVRUPA BİRLİĞİ BEŞERİ İLAÇ SEKTÖRÜNDE ORİJİNAL İLAÇ ÜRETİCİLERİ ve JENERİK (EŞDEĞER) İLAÇ ÜRETİCİLERİ ARASINDAKİ REKABET

Orijinal ilaç üreticileri ve jenerik ilaç üreticileri arasındaki rekabet koşullarının son dönemde Avrupa Birliği beşeri ilaç sektörünün en önemli hususlarından biri haline gelmesi bu çalışmanın konusunu belirlemede etkili olmuştur. Tez çalışması genel hatlarıyla, inovasyona dayalı ve yoğun bir şekilde regüle edilmiş olan beşeri ilaç sektörü bakımından rekabet hukuku ve fikri mülkiyet hukukunun kesişim noktasını konu edinmektedir. Beşeri ilaç sektörü özel olarak regüle edilmiş olmanın yanında, patent sisteminden kaynaklanan etkileri de barındırmaktadır. Beşeri ilaç sektörünün sahip olduğu özellikli durum nedeniyle, tez çalışmasında esas olarak odaklanılan soruların daha iyi anlaşılması bakımından rekabet hukuku ve fikri mülkiyet hukuku ilişkisi hakkındaki tartışmalar ile Avrupa Birliği beşeri ilaç sektörünün yapısı ve sektöre ilişkin mevzuata yönelik temel bilgiler üzerinde durmanın yararlı olacağı düşünülmüştür.

Tez çalışmasında asıl olarak üzerinde durulan husus, orijinal ilaç üreticileri ve jenerik ilaç üreticileri düzleminde Avrupa Birliği rekabet hukukunda yaşanan önemli gelişmelerdir. Bu kapsamda ilk olarak ele alınan gelişme, Avrupa Birliği Komisyonu'nun "koruyucu patent stratejieri"ni ABİTDA madde 102 çerçevesinde potansiyel bir anti-rekabetçi kötüye kullanma olarak değerlendirdiği 2009 tarihli Beşeri İlaç Sektör Araştırması Raporu'dur. Başta patent başvuruları olmak üzere bu tür stratejiler, jenerik ürünlerin pazara girişine engel olabilmektedir. Buna rağmen, Avrupa Komisyonu'nun anılan Raporu'nda bu tür eylem ve davranışlara ilişkin detaylı bir hukuki değerlendirme yapılmadığı görülmektedir. Sektör Araştırma Raporu'nun hukuki etkilerini açıklığa kavuşturmak amacıyla, Avrupa Birliği rekabet hukuku altında patent başvurularının anti-rekabetçi karakterini ortaya koyan ve bu nedenle çok önemli bir emsal niteliği taşıyan *AstraZeneca* kararı (Avrupa Birliği Komisyonu Kararı, Avrupa Birliği İlk Derece Mahkemesi Kararı, Avrupa Birliği Adalet Divanı Kararı) incelenmiştir. Nirengi noktası olarak anılabilecek bu karar Avrupa Birliği'nde uygulanagelen yaklaşıma ışık tutmaktadır. Bu anlamda *AstraZeneca* kararı, rekabet hukukunun beşeri ilaç endüstrisine ne derece katı yaklaştığını ortaya koymaktadır.

INTRODUCTION

Objective

The pharmaceutical sector in the EU has been at the center of a number of recent controversies from the competition law perspective. One of the controversies stems from the intersection between IPRs and competition rules. Given the nature of pharmaceutical industry which reaps its profits directly from innovation, IPRs constitute a major component of pharmaceutical companies' business. On the other hand, the EU competition law functions and some practices of these companies get caught by the radar of enforcement of competition rules laid down in Treat for the Treaty on the Functioning of the European Union TFEU. At this point, the uncertain boundaries between competition and intellectual property law appear to be explored.

It is observed that the European Commission ("Commission") which is the enforcer of the EU competition rules has put fresh wind in its sails and led to increased enforcement activity aimed at numerous defensive patent strategies (i.e. life cycle management strategies) of pharmaceutical companies. As to the question what actually triggered the new enforcement priorities of the Commission and consequentially of the European Courts, it should be underlined that the *AstraZeneca* case has evidently played a prominent role in this regard. Following the investigation initiated against AstraZeneca by the Commission, the Commission also carried out the pharmaceutical sector inquiry which suggested the necessity to proceed cautiously at the intellectual property and competition intersection. The focal point of this sector inquiry was based on delays in the entry of generics into the market arising from originator companies' patent based strategies. These developments in the recent years confirm that the Commission has notably shifted its competition enforcement priorities in the pharmaceutical sector from parallel trade to generic entry.

In the wake of the shifting trend toward competition between originators and generic producers, the *AstraZeneca* case constitutes a significant asset for now. This case concerning the novel findings of abuse of patent related regulatory procedures reveals a debate on the threshold for intervention to playing field of a dominant originator company, the legitimacy of patent strategies of originator companies in order to enjoy their IPRs for a longer time period. Such concerns generate the following questions: To what extent originator companies are allowed to employ such strategies? Do they use their IPRs in the expense of impeding the market entry of generics? What is the benchmark in order for patent strategy to be qualified as

abuse? To what extent do such practices can be cleared? How far was the enforcement of Article 102 TFEU expanded in the EU pharmaceutical sector by *AstraZeneca* Case? How were the practices of AstraZeneca, which were considered to be the abuse of both patent system and regulatory procedures, assessed by Commission and the EU courts? What is the importance of these novel types of abuses of AstraZeneca in the context of the competition between originator companies and generic companies in the EU pharmaceutical sector?

The purpose of this thesis has been to explore the competition between originators and generic producers in the EU pharmaceutical market from the competition law perspective in the light of the said concerns. The starting point is to address the interface between IPRs and competition law. The conflicting and overlapping aims of such law are elaborated. This serves to constitute a solid ground for a better understanding of the core issues of the thesis. Peculiarities of the EU pharmaceutical industry are discussed in detail in the chapter two. This chapter aims at providing the mechanics and structure of the pharmaceutical industry in order to enable the reader to conceive the underlying legal and regulatory facts of *AstraZeneca* case. The relevant legislation is mentioned under this chapter as well in order to present a background reading. As to the third chapter, the Commission's approach at the Sector Inquiry level is elaborated through the findings of both Preliminary Report and of Final Report. Such findings facilitate to find answers to the abovementioned questions. This chapter is quite important to demonstrate the Commission's focus. Lastly and most importantly, *AstraZeneca* case, on which is put the emphasis, is discussed through focusing on the Commission's decision and the judgments of the GC and the CJEU. Implications of this case are highlighted at the end of the last chapter. If necessary to rephrase, the aim of the thesis is to distinguish what kind of practices of the originator companies in the pharmaceutical sector is benign and what kind of practices of those is considered illicit within the scope of the application of the EU competition law. In addition, the thesis serves for summarizing the current situation and open up certain avenues of reflection for the future in terms of protecting and distributing pharmaceutical specialties in light of competition law.

Method and Delimitations

The main method is conventional legal research and reasoning, even though because this issue is of both great economic importance and legal interest, some non-legal data is also referred in order to explain relevant aspects of the EU pharmaceutical market.

In this thesis, the reader is assumed to have general background knowledge of the fundamentals of the EU law, the EU competition law, basic principles pertaining to IPRs and basic terminology concerning the pharmaceutical sector. Therefore, the general aspects of such bodies of law will not be analyzed. Rather, the analysis will be directed at evaluation of the overlapping fields of patent system and competition law, the use of IPRs by originator pharmaceutical companies, the application of Article 102 TFEU (i.e. abuse of dominance) with a particular focus on *AstraZeneca* case.

This thesis study is also limited to the discussion of competition law issues concerning competition between the originators and generic producers in the pharmaceutical industry.

CHAPTER 1
THE INTERFACE BETWEEN COMPETITION LAW AND INTELLECTUAL PROPERTY RIGHTS

1.1 Overview

It has been acknowledged principle in EU competition law that there is no inherent conflict between competition law intellectual property rights[1]; however, the relationship between IPRs and competition law is a controversial subject. Despite the natural overlap in the aims of two fields of law namely, the enhancement of consumer welfare and promoting innovation, some problems arise as they operate divergently.

Competition law aims to achieve the object of maximizing static and dynamic efficiency[2] by preventing monopolistic output reduction and unlawful restrictions on competition, while IPRs seek to achieve the same end by providing a legal monopoly as an incentive for innovation and for the launch of new and cheaper products into market. Firms do not only compete by price. Innovation is a dynamic and another essential parameter of an open and competitive market that deserves to be protected alongside low prices, high quantities, high product quality and variety.[3] IPRs increase the rate of innovation and this fosters dynamic competition. Practices that are characterized as anti-competitive are those that produce negative impact not only on market prices, but also on innovation, quality, and variety of goods.[4] Restrictions of dynamic competition may have even a much more detrimental effect on economic growth than restrictions on static price competition.[5] Despite the importance of innovation for both bodies of laws, the opposition to monopoly so central to competition law gives rise to problems in the field of IP law where legislator has intentionally

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[1] KJOLBYE, *Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?*, in *World Competition*, 2009, no. 32 (2), 163-188, p. 163.

[2] Commissioner Monti described the Treaty by emphasizing "the fundamental role of the market and of competition in guaranteeing consumer welfare, in encouraging the optimal allocation of resources, and in granting to economic agents the appropriate incentives to pursue productive efficiency, quality, and innovation." *See* MONTI, *Remarks at the 28th Annual Conference on International Antitrust Law and Policy*, New York, European Competition Policy for the 21st Century (20 October 2000), available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/00/389&format=HTML&aged=0&language=EN&guiLanguage=en

[3] *See* European Commission Guidance on the Commission's Enforcement Priorities in Applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, of 27 April 2009, O.J. (C 45) 02

[4] *See* KROES, *European Competition Policy: Delivering Better Markets and Better Choices, Remarks at European Consumer and Competition Day*, London," 15 September 2005, available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/05/512

[5] DREXL, *Anticompetitive Stumbling Stones on the Way to a Cleaner World: Protecting Competition in Innovation without a Market*, in *Journal of Competition Law & Economics*, 2012, no. 8(3), 507-543, p. 511.

created a monopoly to encourage and reward innovation. The grant of an IPR in itself has an exclusionary effect on the market and the behavior of competitors who might be affected in their own R&D activities. Thus, it is very nature of patents to IPRs to cause at least some market foreclosure effect, and actually, the legislature intends to have such an effect. However, IPRs produce overall pro-competitive effects by excluding competition by imitation and, thereby enhancing competition by substitution. The period of proprietary exclusivity that imposes artificial barriers around the creation, protecting it and precluding competitors from taking, adopting or adapting it. Therefore, when viewed from this aspect, IP laws can be deemed as an instrument of correcting market failure.

Hence, whilst the relationship between competition law and IPRs is not perceived as inherently conflictual, and the possible pro-competitive role of IPRs has been recognized, at least for long-term competition, there are still cases where EU competition law will intervene if it is determined that the short-term impact on competition prevails over the long-term efficiencies. The competition law intervention takes place if the patent holder is able to extend his legal monopoly beyond the statutory grant, often to overlap with an economic monopoly, or to pursue aims against the letter and the spirit of the EU competition provisions.

The competition rules are considered to be a second-tier regulation of the exercise of IPRs, providing an external system of regulation that applies to anti-competitive practice not prevented by the internal system of regulation offered by IP legislation.[6] Even though the system of protection of IPRs strikes the balance between the exclusivity conferred upon pioneer inventors[7], and the limits and exceptions in favor of follow-on innovators; the limits of allowed exercise of IPRs are determined not only by the IP law but also by competition law. According to the case law, when certain types of exercise of IPRs are to be found anti-competitive or restrictive of competition, they can be unlawful even if they are entirely lawful under IP law. That is to say that the outer limits of the exclusivity of IPRs are drawn by the prohibition of the competition rules even when the conduct is permitted by IP rules. As such a case that the competition law is used as an external balancing tool arises the concern that the shield granted by IPR has been gradually eroded.[8]

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[6] ANDERMAN and SCHMIDT, *EU Competition Law and Intellectual Property Rights The Regulation of Innovation*, New York: Oxford University Press: 2011, p. 4.

[7] The phrase originally coined by ULLRICH and mentioned by DREXL, *Is there a More Economic Approach to Intellectual Property and Competition Law*, in DREXL, *Research Handbook on Intellectual Property and Competition Law*, Cheltenham, UK and Northampton, MA, USA: Edward Elgar, 2008.

[8] EZRACHI and MAGGIOLINO, *European Competition Law, Compulsory Licensing, and Innovation*, in *Journal of Competition Law & Economics*, 2009, no. 8 (3), 595-614, p. 595.

1.2 European Formula for Intervention

In recent years EU competition law has continued to demonstrate its capacity to regulate the exercise of IPRs. This ongoing widening of the scope of Article 102 TFEU to IPR raises the concern whether this trend could undermine innovation in the long run.[9] Consecutively, the question how EU competition law has been applied to limit the protection awarded to IPR holders is brought up. To some extent, a certain part of the remarkable case law[10] of the CJEU has defeated these concerns by establishing that competition law intervention is limited to exceptional circumstances. Because the notion of exceptional circumstances acts as an important safety valve that stresses the need for proportionality and that restrains the application of competition law[11]. Yet, this does not change the fact that the boundaries of competition law enforcement have been gradually widening[12] and that the threshold for intervention has been lowered[13]. In essence, the developments in case law reveal a move along the intervention spectrum that lowers the protection awarded by IPR, but it does not eliminate the core incentive to innovate.[14] The CJEU has recurrently indicated that the

[9] *Ibid.* p. 599.

[10] In *Magill* and *IMS*, CJEU confirmed that in exceptional circumstances the European Commission has the power to end an abusive refusal to license by imposing a compulsory copyrights license. *IMS Health* established, on the basis of prior case law, that failure to grant a license, even if it is the act of a dominant firm, cannot in itself constitute an abuse of a dominant position. But, in exceptional circumstances, refusal to provide access to a product or service may amount to abuse of a dominant position. Four conditions must be met to find an abuse: the refusal must relate to a product or service indispensable to the exercise of a particular activity on a neighboring market; it excludes competition on a neighboring market; it prevents the emergence of a new product for which there is a potential consumer demand; and refusal is not objectively justified. The same ground applies to refusal to supply raw materials. In *Commercial Solvents*, Commercial Solvents refused to supply raw materials, as it planned to vertically integrate into the downstream market and to make use of all its raw materials internally. The CJEU found that Commercial Solvents abused its dominant position by refusing to supply its customers, thereby effectively excluding them from the market. (See CJEU, 6 April1995, in joined cases C-241-2/91 P and C-242/91 P *Radio Telefis Eireann (Magill) v. Commission*; CJEU, 29 April 2004, in case C-418/01, *IMS Health GmbH* & Co. OHG v NDC Health GmbH & Co. KG; CJEU, 6 March 1974, in joined cases C-6-7/73, *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents v. Commission*)

[11] It should be specified that the notion of exceptional circumstances pertains to the application of Article 102 of the TFEU.

[12] In view of the developments in the case law from Magill to Microsoft (refusal to license essential IP to protect dominant position in downstream market), the widening trend of Article 102 of the TFEU is apparent. In *Microsoft*, GC upheld the Commission's decision to order compulsory access of interface codes protected by IPRs on the basis that Microsoft's refusal impeded technological progress in the sector. In Microsoft, the General Court broadened the concept of "economic indispensability" which is a requirement of compulsory licensing under the "essential facilities doctrine"(See GC, 17 September 2007, in case Case T-201/04, *Microsoft Corp v Commission*)

[13] In *Microsoft*, General Court lowered the threshold for intervention by eroding the condition of elimination of all competition in the secondary market, which constituted part of the conditions in earlier cases. It held that it is not "necessary to demonstrate that all competition on the market would be eliminated. What matters, for the purpose of establishing an infringement of [Article 102 TFEU], is the refusal at issue is liable to, or is likely to, eliminate all effective competition on the market." (See *Microsoft* 2007, para. 563)

[14] EZRACHI and MAGGIOLINO, *European Competition Law, Compulsory Licensing, and Innovation*, in *Journal of Competition Law & Economics*, 2009, no. 8 (3), 595-614, p. 609.

exclusivity effect of IPRs does not of itself constitute an evidence of a dominant market position of their proprietors.[15]

The competition rules do not apply to the exercise of IPRs at random. They apply if the IPR is used as an 'instrument of abuse'[16] or as a means of restricting competition. The paradigm shift led by modernization of competition rules has admittedly created a better base for their application to the exercise of IPRs. The more realistic economic approach was introduced into regulations and guidelines, and the Commission has claimed that it has intended to take a more effect-based approach. However, the Commission has not been completely consistent in its advocacy of an effects-based test. It has expressed that it will not take this approach in cases where conduct seriously restricts competition[17] due to the need to give priority to existing effective competition as the best guarantee of productive and innovative efficiencies in the long term[18].

The case law of the CJEU has clearly highlighted that mere exercise of an IPR cannot itself constitute an abuse of a dominant position within the meaning of Article 102 TFEU, and even in market dominance, the exercise of an IPR can be classified as abusive only under strictly defined conditions.

1.3 Intersection of Both Body Laws at Dynamic Markets

Dynamic markets are fast-growing markets that consist of high-tech markets and pharmaceutical market.[19] There is a fierce competition to develop and launch technically advanced products or next generation of an existing product subsequent to significant investment in R&D, and IPRs are essential to commercial strategy and success. As to another feature of dynamic markets, companies try to stifle and manipulate the markets to increase their exploits and obtain monopoly rents.

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[15] *See* e.g. STRAUS, *Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?*, in *Journal of European Competition Law & Practice*, 2010, no.1 (3), 189-201, p. 194, or NISSEN, VAN DE WALLE GHELCKE and VILARASAU, *Chapter 15: Competition Law in the Pharmaceutical Sector* , in SHORTHOSE, *Guide to EU Pharmaceutical Regulatory Law*, The Netherlands: Wolters Kluwer, 2011, 503-531, p.518

[16] *See* e.g. CJEU, 13 February 1979, in case 85/76, *Hoffmann-La Roche & Co AG v Commission*, para 16.

[17] European Commission Communication OF 24 February 2009 on the Guidance on the Commission's Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, paras 19-20

[18] European Commission, Directorate General for Competition, *Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses*, December 2005, para. 91, available at http://ec.europa.eu/comm/competition/antitrust/art82/discpaper2005.pdf

[19] GALLOWAY, *Driving Innovation: A Case for Targeted Competition Policy in Dynamic Markets*, in *World Competition*, 2011, no 34(1), 73-96, p.75

Dynamic markets set a clear example of this interface between competition law and intellectual property law. The application of competition law in cases where IPRs, especially patents, is often controversial[20]; however, it should be determined considering the natural scope of IPR. Controversial conduct in the pharmaceutical and high-tech markets shows that competition law intervention can be tailored to protect competitive intensity while respecting the extent of existing IPRs. At this point, it should be referred to former EU Commissioner Mario Monti's statements. "Competition is a necessary stimulus for innovation. IPR law and competition law have a complementary role to play in promoting innovation to the benefit of consumers" and, thus, it is significant to understand "how to marry the innovation bride and the competition groom".[21]

Characteristics of high-tech and pharmaceutical markets are considerably different but share key traits including strong competition on non-price factors, often requiring ongoing investment in R&D to further promote the product or better satisfy consumer needs. These markets undergo faster technological change with shorter product life cycles than other markets. R&D investments, with high fixed costs, which amount a relatively high percentage of turn-over in dynamic markets[22], is thus vital to continued success. Accordingly, IP such as patents a know-how are significant in making the products following this costly R&D process commercially viable. Several dynamic markets are highly regulated to protect consumer interests outside of competition law, particularly the EU pharmaceutical market. While these markets have intricate market conditions, it is apparent that they do not enjoy any general exemption from the application of competition law. This feature of these markets raises concerns that imposing a strong and effective competition policy into already difficult market conditions may deter innovation. Therefore, it can be argued that there is a lack of tolerance for technical and legalistic limits on the powers of Article 102 TFEU.[23] However, when viewed from another aspect, competition law intervention complements the IPR and market

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[20] See *Ibid.*; MCMOHAN, *Interoperability: "Indispensability" and "Special Responsibility" in High Technology Markets*, in *Tulane Journal of Technology and Intellectual Property*, 2007, no. 9, p.123; and AITMAN and JONES, *Competition and Copyright Owner Lost Control?*, in *European Intellectual Property Review*, 2004, p.137

[21] MONTI, Commissioner for Competition Policy, *The New EU Policy on Technology Transfer Agreements*, SPEECH/04/19, Ecole des Mines, Paris, 16 January 2004.

[22] As an example of R&D investments in the pharmaceutical sector, large originator companies spent an average of 17 % of turnover on R&D between 2000 and 2007, and smaller biopharmaceutical companies spent almost 40% of turnover on R&D during the same period. *See* European Commission, *Final Report of Pharmaceutical Sector Inquiry*, 8 July 2009, paras. 72 and 56, respectively.

[23] KALLAUGHER, *Pharmaceutical Sector Inquiry Competition Law Issues*, 2009, p.5 (PowerPoint presentation), available at http://www.ucl.ac.uk/laws/ibil/docs/ibil_21jan09_kallaugher_pp.pdf

regulation regimes in a positive manner, precluding the manipulation of those regimes contrary to set objectives and limiting conduct that harms consumer welfare.[24]

[24] GALLOWAY, *Driving Innovation: A Case for Targeted Competition Policy in Dynamic Markets*, in *World Competition*, 2011, no. 34(1), 73-96, p.77

CHAPTER 2
THE PHARMACEUTICAL INDUSTRY IN THE EU

2.1 Overview of the Unique Nature of the EU Pharmaceutical Industry

The production and the distribution of medicinal product[25] differs the pharmaceutical sectors from any other sectors.[26] The EU pharmaceutical market is a complex market characterized by a number of potential market failures such as under-investment for particular disease, free-riding behavior concerning the use of the R&D, and information asymmetry between professionals and clients on various levels. Regarding the extent and depth of its failure to meet the criteria for a perfect market, the pharmaceutical market is unique. The pharmaceutical market is heavily regulated[27] both on the supply and demand side, and it is a market to which the ordinary rules of competition cannot easily be applied.[28]

In the sense of being highly regulated market, there are two main differences of pharmaceutical market from 'normal market', namely:[29] (i) The price of prescription medicines tends to be regulated. This is due to the fact that pharmaceutical companies encounter with the Government as a single monopsony buyer or payer. This regulation implies that companies cannot freely set prices over time even if it is otherwise profitable to do so. Besides, companies are usually free to decrease prices when facing fiercer competition. (ii) These markets are characterized by an unusual structure whereby the final consumer (patient) differs from the decision maker (doctor) and generally from the payer (national insurance service or private health insurance). Due to this unique structure, there is usually limited price sensitivity on the part of the decision maker. The pharmaceutical sector as the paradigm of an industry where the factors having a decisive impact are beyond the control of the undertakings involved that is to say, 'normal competition' is substantially precluded due

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[25] A *medicinal product* is defined in Council Directive No. 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use as follows: "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings: or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis." *Substance* is defined as any human, animal vegetable, or chemical matter, irrespective of origin.

[26] European Commission, *The Single Market Review: Subseries I: Impact on Manufacturing, Vol.2: Pharmaceutical Products*, in European Commission, *The Pharmaceutical Sector in the EU*, 1997, p.99.

[27] Regulation of pharmaceutical markets still takes place considerably at the national rather than EU level.

[28] HANCHER, *The European Pharmaceutical Market: Problems of Partial Harmonisation,* in *European Law Review*, 1990, no. 15(1), 9-33, p.9.

[29] WESTIN, *Defining relevant market in the pharmaceutical sector in the light of the Losec case- just how different is the pharmaceutical market?,* in *European Competition Law Review, 2011,* no. 32 (2), 57-62, p. 57.

to the measures such as price controls in the Member States.[30] In other words, the pharmaceutical market in the EU is not a free market because of the continuing government controls in most countries. It is argued that these factors not only make the EU pharmaceutical sector unique, but also require a new approach that is specific to this sector.[31] However, this is easier to be said than done. The authors who support the latter approach rely on the fact that the undertakings in pharmaceutical sector do not have freedom to determine the price of the products.

Three reasons for the state-controlled prices can be counted. Initially, if patients had to fully bear their prices, many would force to make a choice between financial ruin or health injuries. As the second reason, pharmaceuticals protected by patents allow the patent holder to impose monopoly prices in the absence of government intervention. Last but not least, in the absence of publicly mandated sickness insurance and income-based insurance subsidies, only rich patients would be able to purchase all drugs and poor patients would be unable to buy most of them. These reasons apparently show the market failure: Without government subsidy of demand through insurance schemes, pharmaceutical companies would not invest in R&D for the medicines that a majority of patients were not able to bear the cost.[32]

Although a single market in pharmaceuticals is generally considered desirable, national regulation of pharmaceuticals is a reality, which is here to stay[33] and it is even argued that where a market is characterized by heavy investment prior to product launch on the market, coupled with customers with the different demand features, market segregation and with price segregation, can be actually be beneficial.[34]

Eventually, the present nature of the "Single Market in Pharmaceuticals" remains far from completed.[35] In other words, price harmonization is still only partial. This so-called "partial harmonization"[36] exists considering the harmonization of marketing authorization procedures and other licenses, and the indirect harmonization of price controls measures; the elimination of national measures of control of public expenditures that create obstacles to free

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[30] FERNANDEZ VICIEN, *Why Parallel Imports of Pharmaceuticals Should be Forbidden,* in *European Competition Law Review,* 1996, no. 17(4) 219-225, p. 223.
[31] *Ibid.* at 219.
[32] JUNOD, *An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in GlaxoWellcome,* in *World Competition*, 2007, no. 30(2), 291-306, p. 304.
[33] Pricing and reimbursement of medicines fall within the competence of Member States.
[34] BOER, EDMONDS, GLYNN and OGLIALORO, *Economic Aspects of the Single Market in Pharmaceuticals*, in *European Competition Law Review*, 1999, no. 12(3), 256-264, p. 256.
[35] *See* HANCHER, *The European Pharmaceutical Market: Problems of Partial Harmonisation,* in *European Law Review,* 1990, no. 15(1), 9-33, p.10.
[36] This term is taken from an article by HANCHER, *The European Pharmaceutical Market: Problems of Partial Harmonisation,* in *European Law Review,* 1990, no. 15(1), 9-33, p.11.

movement of pharmaceuticals; and the harmonization of national patent systems[37] where the degree of protection was not considered adequate to the logic of the single market. At the end of the day, the national price regulation schemes still divide the single market.[38] National price control mechanisms create the observable price gaps existing for same drug in different countries, although it is even argued that price discrimination strategies applied by pharmaceutical companies also seem to play a role in this respect.[39] Furthermore, the distribution system for pharmaceutical products diverges across the EU Member States.[40] Thus, it is acknowledged that there is a continuing lack of a single pharmaceuticals market.[41]

To sum up, the relevant factors distinguishing pharmaceuticals from traditional sectors: an industry protected by patents, a research-intensive industry, a highly regulated industry, peculiar structure of supply and demand-side, and a competitive industry.

2.1.1 Major Issue: R&D

One of the distinctive features of the pharmaceutical industry is its high reliance on innovation for the development of new products. According to the European Commission's 2010 scorecard of worldwide corporate investment in R&D[42], the pharmaceutical sector is the top global investor in R&D and has the highest R&D intensity ratios of all sectors. According to data of European Federation of Pharmaceutical Industries and Associations (EFPIA), in

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[37] It should be stated that the regulations related to Unitary Patent protection entered into force on 20 January 2013. However, they will only apply from 1 January 2014 or the date of entry into force of the Agreement on a Unified Patent Court, whichever is the later. Therefore, in the near future with the launch of 'unitary patent', the most important step will be taken in the course of realizing the single market in pharmaceuticals. *See* e.g. European Patent Office, *Unitary Patent* available at http://www.epo.org/law-practice/unitary/unitary-patent.html ; NEEDLE, *A New European Patents Regime* on *Mondaq*, 29 January 2013, available at http://www.mondaq.com/x/218512/Patent/A+New+European+Patents+Regime; After 40 years of false starts, a European Patent with Unitary Effect (the UP) and a Unitary Patent Court (the UPC) is expected in the near future. The pharmaceutical industry strongly supports a unitary patent and court although, the UP and UPC will not launch in all EU Member States initially (Italy and Spain are yet to join) and with legal uncertainities that may see an incremental engagement of pharmaceutical industry with the UP/UPC. EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *Considering the Impact: A European Patent with Unitary Effect and Unitary Patent Court*, 2012, available at http://www.efpia.eu/blogs/considering-impact-european-patent-unitary-effect-and-unitary-patent-court

[38] HANCHER, *The European Community Dimension: Coordinating Divergence, The Politics of Pharmaceuticals in the European Union*, in MOSSIALOS, MRAZEK, and WALLEY, *Regulating Pharmaceuticals in the Europe: Striving for Efficiency, Equity and Quality*, Berkshire: Open University Press, 2004, 55-79, p.65.

[39] DESOGUS, *Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade*, Bologna: Intersentia Uitgevers, 2011, p. 41.

[40] *See* HANCHER, *The European Pharmaceutical Market: Problems of Partial Harmonisation*, in *European Law Review*, 1990, no. 15(1), 9-33, p.11.

[41] *See* PERMANAND, and ALTENSTETTER, *The Politics of Pharmaceuticals in the European Union*, in MOSSIALOS, MRAZEK, and WALLEY, *Regulating Pharmaceuticals in the Europe: Striving for Efficiency, Equity and Quality*, Berkshire: Open University Press, 2004, 38-54, p. 51.

[42] European Commission, *The 2010 Industrial R&D Investment Scoreboard*, available at http://iri.jrc.es/research/docs/2010/SB_2010_BXL_17-11-2010.pdf.

2011 the industry invested € 27.5 billion in R&D in Europe[43], and the average total R&D cost per new medicine is estimated as €1,059 million[44]. Pharmaceutical companies face an extremely costly and protracted process in presenting any new product to the market. It is significant to launch the medicinal product on the markets of large industrialized countries as promptly as possible, because such an investment can be financed only if the company is able to generate the sufficient cash-flow during the period of patent protection. The profitability of products and the regular renewal of portfolios of patents on new medicinal products are decisive factors of the survival of large pharmaceutical companies.[45]

With regard to the cash flow of a pharmaceutical company, while for most corporations in other sectors, R&D spending does not depend upon internal cash-flows; pharmaceutical R&D is almost entirely internally generated. That is to say that profits earned by a pharmaceutical company through the commercialization of its products are the source of funds, which supports those investments.[46] So, lower profits would yield lower financial resources available for R&D. As the Commission set forth[47], 90% of R&D is internally-generated, and that should be seen as ability that should be preserved because of the risks inherent in such high investments. Furthermore, the R&D costs constitute a high entry barrier to the market. Indeed, it is difficult to replace the firms if they disappeared from the market and this fact results in fewer new products being developed in the future by fewer firms left in the market.

Only a small fraction of the products in which is invested can manage to enter the market[48] that is to say that chances of extracting a substance with therapeutic value are relatively low. This means that every attempt to develop a new medicine cannot turn out to be a commercial success.

The process of launching a new medicine into the market takes an average 10-13 years. While 5000 molecules are tested at first step, 200 of them enter into preclinical testing, 10 of them pass clinical development stage, and only 1 is approved by regulatory authorities

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[43] EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *Research and Innovation*, 2012, available at http://www.efpia.eu/topic-list/17

[44] *See* DI MASI, HANSEN and GRABOWSKI, *The Price of Innovation: New Estimates of Drug Development Costs*, in *Journal of Health Economics*, 2003, no.22, 151-185.

[45] FERNANDEZ VICIEN, *Why Parallel Imports of Pharmaceuticals Should be Forbidden*, in *European Competition Law Review*, 1996, no.17 (4), 219-225, p. 221.

[46] DESOGUS, *Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade*, Bologna: Intersentia Uitgevers, 2011, p. 258.

[47] European Commission Communication to the Council and the European Parliament on the Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community, COM (93) 718 final of 2 March 1994, p.5

[48] *See e.g.* DI MASSI, HANSEN and GRABOWSKI, *The Price of Innovation: New Estimates of Drug Development Costs*, in *Journal of Health Economics*, 2003, no.22, 151-185.

and come onto the market where only 3 out of 10 medicines recouping R&D costs prior to patent expiry and intense generic competition.[49] As the European Council also acknowledged, "[s]ome conditions occur so infrequently that the cost of developing and bringing to the market a medicinal product to diagnose, prevent or treat the condition would not be recovered by the expected sales of the medicinal product […] it is therefore necessary to stimulate the research, development and bringing to the market of appropriate medications by the pharmaceutical industry."[50]

2.1.2 Price Controls and Purchase Arrangements

The prices are not determined under normal market conditions. While pharmaceutical companies, aiming at obtaining the highest price which each national market can bear, price their products differently in line with variations in the ability to pay; governments use their authoritative power to moderate pharmaceutical prices according to cost containment objectives and public health goals. The current absence of price competition has given rise most Member States to impose some form of price or profit control and/or to restrict the number of products, which qualify for reimbursement from public funds. This can be clarified by the fact that the public or social insurance funds bear considerable part of the cost of pharmaceuticals and health authorities thus have a legitimate interest in containing spending in this field as well as gaining good value for money.[51] The interplay between the private and public interest results in drug prices. The method of balancing the opposing interests differs from country to country, depending on the health care system; on budget constraints; on the industrial policy pursued; on the type of regulatory tool used to moderate drug prices such as profit cap, price controls, reference pricing[52], substitution policy, reimbursement policy; on the health status of the citizens; on medical culture; on the type of medicine. The regulatory

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[49] EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *The Pharmaceutical Industry in Figures*, Edition 2012, EFPIA Publication, p. 6, available at http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA_Figures_2012_Final-20120622-003-EN-v1.pdf

[50] Council Regulation No. 141/2000 of 16 December 1999 on Orphan Medicinal Products

[51] *See* FERNANDEZ VICIEN, *Why Parallel Imports of Pharmaceuticals Should be Forbidden,* in *European Competition Law Review,* 1996, no. 17(4) 219-225, p. 219.

[52] 'Reference pricing' indicates any mechanism of reimbursement used by national health authorities or insurances, which determines maximum reimbursement price of a drug with reference to the price of a cheaper substitute present in the market. Particularly, under a reference pricing system, products are classified in sub-groups with similar therapeutic effects; a maximum reimbursement price is set for all the products belonging to the subgroups; pharmaceutical companies are free to price their products but if they exceed the reference price, the difference is paid by the patient. A reference price system was introduced by Germany in 1989. Afterwards, other Member States adopted this policy: the Netherlands (1991), Sweden (1993), Denmark (1993), Italy (1996) and Spain (2000). In UK there has been a form of implicit reference pricing for a long time. *See* DANZON, *Reference Pricing: Theory and Evidence*, in LOPEZ-CASASNOVAS and JÖNSSON, *The Economics of Reference Pricing and Pharmaceutical Policy,* 2011, 86-126.

differences exhibit the dissimilar relations between government and industry in different Member States, which stem from each country's regulatory tradition.

Different states have different rationales behind their national health policies and different means of their realization.[53] Governments have also put in place different measures to reduce or contain expenditure. For example, external reference pricing (in which the price is set on the basis of the prices in other Member States) takes place in Denmark, the Netherlands, Ireland, Italy, Greece, and Portugal; internal reference pricing (where the price or reimbursement of a product is based on prices of products considered to be essentially similar) is also employed in the Netherlands, Germany, Belgium, Italy and Greece.[54]

In line with this, national rules on pricing of medicines, and on the amounts reimbursed by national social security systems considerably differ.[55] The prices set by the manufacturers of medicines can be regulated in two different manners on the supply side. The first one, which is called direct price setting, is simply to impose a price at which the medicine can be sold. Different methods exist which vary from regulations unilaterally made by the public authority in charge[56] to negotiations between the industry and the health authorities.[57] The second way of regulating the price of the medicines is an indirect price setting. Some regulatory systems do not set the price of certain drugs; however, the health authorities reimburse only a fixed amount in order to control public expenditure.[58]

Pharmaceutical pricing policy should also be assessed in the light of the effectiveness of the patent system.[59] The value of a patent should be ascertained by what the market would be willing to pay for the medicines, which is pricing policies unavoidably bring down the value of patents.

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

[54] REY and VENIT, *Parallel trade and pharmaceuticals: a policy in search of itself*, in *European Law Review 2004*, 29(2), 153-177, p. 160.

[55] *See* OECD, *Pharmaceutical Pricing Policies in a Global Market, Report of OECD Health Policy Studies*, Paris, 24 September 2008.

[56] This mechanism is adopted, for example, by Italy for "old" products, Ireland and the Netherlands. *See* KAVANOS, *Overview of Pharmaceutical Pricing and Reimbursement Regulation in Europe*, LSE Health Working Paper, 2001, p.3, table 1, available at: http://www.eco.uc3m.es/servicios/sesam/actividades/jornada_legislacion/DOC%209%20EMEARoadMap.pdf

[57] The negotiations method is in place, for example, in Denmark, France and Italy (but only for new and innovative products).

[58] NAZZINI, *Parallel Trade in the Pharmaceutical Market Current Trends and Future Solutions*, in *World Competition*, 2003, no. 26(1), 53-74, p. 58.

[59] FINK, *International Price Discrimination and Market Segmentation for Patented Pharmaceuticals in the EU. A Social Welfare Analysis- A Comment*, in GOVAERE and ULLRICH, *Intellectual Property, Public Policy and International Trade*, College of Europe Series No 6, Brussels: P.I.E. Peter Lang, 2007, p.171.

2.1.3 Conflicting Interests in the Pharmaceutical Sector

While originator firms are in a struggle for longer patent exclusivity, the Commission and national competition authorities incline to prioritize compliance with the EU competition rules over IPR. Although the general aspects of this debate are mentioned in the first chapter, issues specific to the pharmaceutical sector related to this debate are elaborated in this part.

2.1.3.1 The Industry's Need for Intellectual Property Exclusivity

The industry claims that the patent system balances interests of an inventor with the broader interests of society at large, because it is an instrument for an inventor to eliminate free-riders and for the society to increase its knowledge base. Considering high investment and risk required to develop new medicine, patents[60] are vital to the research-based pharmaceutical industry.

In addition to the issues mentioned under the title of "Major Issue: R&D", instead of full lifespan of a patent which is averagely 20 years, because patent applications normally are filed early in the research phase, medicines can only enjoy effective protection roughly from 8 to 10 years due to long clinical testing, registration process and market access delays. Even though most profits from a branded medicine are made during the first five to eight years of market exclusivity, this short period of legal protection may reduce originator firms' possibilities of receiving an adequate yield from their investments. Since the EU has to some extent realized this matter and introduced SPC that extends the protection up to 5 years[61] and thereby ensuring a maximum of 15 years market exclusivity for a new medical product[62].

The threat of generics is another reason why originator companies need longer exclusivity. It is technically easy to copy an innovative small molecule product, and a regulatory approval is not difficult to be obtained because there is an already existing market. Therefore, it can be claimed that market entry cost of generics is considerably small compared to originator products, and that generic entry rapidly and irrevocably takes market share and lowers the price of the patented product.[63]

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[60] "Patents do not award a legal monopoly over the treatment of a specific disease, but only over a specific product or process. Hence, there is often some potential for strong competition between products in a therapeutic class." HARACOGLOU, *Competition Law and Patents A Follow-on Innovation Perspective in the Biopharmaceutical Industry*, Edward Elgar: Cheltanham, UK; Northampton, MA, USA, 2009, p. 120.

[61] Article 13(2) of European Parliament and Council Regulation No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products

[62] *Ibid.* Preamble 9

[63] EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *Intellectual Property and Pharmaceuticals*, 2008, available at http://www.efpia.eu/intellectual-property-and-pharmaceuticals-june-2008

In short, it is apparent that IP exclusivity is pivotal in order for companies to be incentivized in pursuing innovation. Even the EU legislator has supported this idea by emphasizing that in the absence of an effective IPR enforcement, innovation and creativity are discouraged and level of investment decreases.[64]

2.1.3.2 The EU Competition Rules

The European Commission has claimed that while Europe was once known as the 'world's pharmacy', today this has declined to about three out of ten.[65] It is alleged that Europe is losing competitive ground not only vis-à-vis the United States, but also vis-à-vis China, India and Singapore. At this point, it should be questioned that what type of competition would be for the benefit of consumers.[66] Considering the unique nature of the pharmaceutical industry, it can be claimed that the Commission should apply competition rules in a different manner that differentiate from the way they are applied to other sectors.

This suggestion appears to be accepted by the Commission which refused to apply the general rule on compulsory licensing as established in *Magill*[67] to the pharmaceutical sector in its *Lederle-Praxis Biologicals* decision[68]. According to the Commission decision in *Lederle-Praxis Biologicals*, " *[…] at the current stage of Competition law, it is highly doubtful whether one could impose an obligation upon a dominant firm remedy to ensure the maintenance of effective competition in the national markets, to share its intellectual property rights with third parties to allow them to develop, produce and market the same products […] which the alleged dominant firm is also seeking to develop, produce and market. This was judged to be all the more precarious in sectors such as the vaccine sector where R&D requires high investment. Even a simple refusal to supply could not be considered as an abuse as Lederle was not an existing customer that had found itself in a situation of factual dependence*."[69]

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[64] European Commission Decision No. 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights, Recital 3, OJ L 195/16-25.
[65] *See* European Commission, *Public-Private Research Initiative to boost the competitiveness of Europe's pharmaceutical industry*, Press Release No. IP/08/662 of 30 April 2008.
[66] HUNTER, *The Pharmaceutical Sector in the European Union: Intellectual Property Rights, Parallel Trade and Community Competition Law*, Stockholm: Juristförlaget, 2001, p. 5.
[67] CJEU, 6 April 1995, in joined cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission.*
[68] European Commission Decision No. 94/770/EC of 6 October 1994in case IV/34.776- *Pasteur Merieux-Merck*
[69] HUNTER, *The Pharmaceutical Sector in the European Union: Intellectual Property Rights, Parallel Trade and Community Competition Law*, Stockholm: Juristförlaget, 2001, p. 15.

However, based on the Commission's decision in the cases such as *Bayer (Adalat)*[70], *GlaxoSmithKlein Spain*[71], *GlaxoSmithKlein Syfait*[72], and *Sot. Lelos kai Sia (Syfait II)*[73] where the Commission encouraged parallel trade to the detriment of originator companies, it is not adequate to say that Commission is consistent in its prior view. Such an inconsistency together with other market distorting factors seems to offer a potential justification for the industry to engage in defensive strategies.[74]

2.2 The Parameters for Competition in the EU Pharmaceutical Market

The EU pharmaceutical market is characterized by three kinds of competition. They are counted as therapeutic competition, generic[75] competition and intra-brand competition. Considering the scope and the subject of the thesis, before the generic competition will be assessed, therapeutic and intra-brand competition will be briefly mentioned.

Therapeutic competition is tantamount to competition between originator companies namely competition between new, patented, innovative products. Research-based pharmaceutical companies compete to develop new medicines that are superior to existing or coming medicines developed by their competitors and they endeavor to convince the relevant national 'payers' to pay for or reimburse a considerable part of the price for these medicines. Therapeutic competition is considered to be relatively benign in the sense that EU competition law generally promotes joint R&D, licensing, co-marketing and co-distribution arrangements as long as the positive effects of cooperation outweigh any negative effect on

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[70] GC, 26 October 2006, in case T-41/96 *Bayer AG v Commission (*hereinafter, GC's *Bayer* ruling*)*; CJEU, 6 January 2004, in joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure v Commission (hereinafter, Bayer* appeal).

[71] GC, 27 September 2006, in case T-168/01 *GlaxoSmithKlein Services Unlimited v Commission* (hereinafter, GC's *GSK Spain* ruling*)*; CJEU, 6 October 2009, in joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKlein Services v Commission (*hereinafter, *GSK Spain* appeal).

[72] CJEU, 31 May 2005, in case C-53/03, *Reference for a preliminary ruling from the Epitropi Antagonismou in Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKlein plc and Others (*hereinafter, *Syfait*)

[73] CJEU, 16 September 2008, in joined cases C-468/06-C-478/06, *Sotiris Lelos kai Sia EE and Others v. GlaxoSmithKlein AEVE Farmakeftikon Proionton (*hereinafter, *Sot. Lelos kai Sia)*

[74] HUNTER, *The Pharmaceutical Sector in the European Union: Intellectual Property Rights, Parallel Trade and Community Competition Law*, Stockholm: Juristförlaget, 2001, p. 15.

[75] A generic medicinal product is defined under Article 10 2(b) of European Parliament and Council Directive No. 2001/83/EC of 6 November 2001 (as amended) as: "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate reference medicinal product has been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixture of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance; unless they differ significantly in properties with regard to safety and/or efficacy [...] The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form."

competition.[76] The monopsonistic[77] power of many governments is also deemed to be useful to protect dominant companies from claims of abusive conduct by some authors.[78]

The competition between originator companies and parallel importers is referred to as intra-brand competition. It takes the form of parallel imports of cheaper products from low-priced Member States into higher-priced markets. In other words it is the competition between manufacturers and parallel importers, which derives from the price differences between Member States. Therapeutic competition and intra-brand competition differentiate from generic competition in terms of their effective period because generic competition comes into play after the expiration of the patent.

As to the generic competition, this type of competition is progressively promoted at the EU and national levels, even though this research-based industry is also shielded from generic competition by a variety of legal and regulatory means aiming at providing incentive for R&D by conferring innovative products a de facto market exclusivity at least for a limited period of time. Although according to the Commission Communication, it is estimated that prices for generics that are bio-equivalent to its formerly patented medicine are on average 25% lower than prices of original products; it is even claimed that a launch of a generic on the market has led to considerable fall in price that even amounts up to 80% when both patent and regulatory data protection periods have expired[79]. The demand for generic medicines has expanded.[80] The EGA asserts that generic medicines account for 50% of dispensed medicines and 18% of pharmaceutical expenditure in the EU.[81] Although the market shares of generics vary significantly from one Member State to another[82], manufacturers of generics play a

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[76] HANCHER, *The EU Pharmaceuticals Market: Parameters and Pathways*, in MOSSIALOS, PERMANAND, BAETEN and HERVEY, *Health Systems Governance in Europe the Role of European Union Law and Policy*, Cambridge: Cambridge University Press, 2010, 635-682, p. 640.

[77] Monopsony is defined as the existence of only one buyer in a market, forcing sellers to accept a lower price than the socially optimal price. *See* http://financial-dictionary.thefreedictionary.com/monopsonist

[78] *See e.g.* HANCHER, *The EU Pharmaceuticals Market: Parameters and Pathways*, in MOSSIALOS, PERMANAND, BAETEN and HERVEY, *Health Systems Governance in Europe the Role of European Union Law and Policy*, Cambridge: Cambridge University Press, 2010, 635-682, p. 640.

[79] *Ibid.* p.641.

[80] According to a report of British OFT on the United Kingdom's PPRS published in mid-2007, approximately 83% of prescribed medicines in the UK is generic prescribing compared to only 51% in 1994. *See* Office of Fair Trading, *The Pharmaceutical Price Regulation Scheme. An OFT Market Study*, Office of Fair Trading: London, 2007a.

[81] EUROPEAN GENERICS MEDICINES (EGA), *EGA Fact Sheet on Generic Medicines*, p.1 available at *http://www.egagenerics.com/images/EGA_factsheet_09.pdf*

[82] For example, while the market share of generics is 61% in Poland, it is 7.2% in Spain. It appears that market shares of generics tend to be higher in new EU Member States, which is mostly because of the historically low levels of intellectual property protection in those Member States. *See* EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *The Pharmaceutical Industry in Figures*, Edition 2009, EFPIA Publication, p. 17, available at *http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA%20in%20Figures%202009-20080612-009-EN-v1%20(1)_0.pdf*

significant role on the EU pharmaceutical market. Therefore, originator companies have repeatedly attempted to prevent or delay registration and marketing of generic copies of their pioneer products. As discussed in greater detail below, the application of 102 TFEU, which prohibits abuse of a dominant position, is increasingly becoming of greater importance in determining the legality of certain strategies pertaining to pharmaceutical industry to delay or deter generic competition. Besides of its implications on competition and innovation, generic competition is also seen as a cornerstone of the EU healthcare policy.[83]

2.3 Legal Tools for Protecting Intellectual Property for Pharmaceuticals

In the field of pharmaceuticals in the EU, patents, SPCs and regulatory market and data protection are the principal legal tools which provide a period of exclusivity or protection against imitation.

2.3.1 Patent Protection and the Supplementary Protection Certificate Regime

Although the patent system is not entirely harmonized within the EU so far[84], it can be assumed that the patent systems of the Member States are roughly similar due to the fact that TRIPS Agreement has a harmonizing impact and that Member States are parties to the European Patent Convention. Thus, according this legislation, the period of protection is 20 years starting from the filing date of the patent application.[85] During that period, the patent holder has an exclusive right to prevent third parties from making, using, selling, importing or stocking the patented product that falls within the scope of the patent. When a patent for a medicine is filed, preclinical and clinical testing (safety and efficacy testing) commence in order to obtain marketing authorization. However, as a result of strict premarketing regulation, obtaining the necessary authorization takes a long time that can last between 6-12 years.[86] Therefore, the medicine is protected by patent considerably less than 20 years after first marketing. That is to say that, 'effective patent protection' can be enjoyed much shorter than 20 years.

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[83] Every year, generic medicines bring savings of € 35 billion to the EU 27, and generic medicines provide equal access and affordable frontline treatments for over 500 million European citizens. *See* EUROPEAN GENERICS MEDICINES (EGA), *EGA Fact Sheet on Generic Medicines,* p.1 available at *http://www.egagenerics.com/images/EGA_factsheet_09.pdf*

[84] However, with the entry into force of long awaited 'Unitary Patent Protection' in January 2014, the uniform protection of patents will be provided at last.

[85] *See* Article 63 of the European Patent Convention (EPC)

[86] HANCHER, *The EU Pharmaceuticals Market: Parameters and Pathways*, in MOSSIALOS, PERMANAND, BAETEN and HERVEY, *Health Systems Governance in Europe the Role of European Union Law and Policy*, Cambridge: Cambridge University Press, 2010, 635-682, p. 647.

In response to this insufficiency of an effective patent protection which penalizes pharmaceutical research, the EU introduced SPC by adopting the Regulation 1768/92[87] which was abrogated by Regulation 469/2009[88] (hereinafter called as SPC Regulation). With this regime, the term of a patent for medicinal product or process has been extended in order to compensate the patent holder for the lost period of monopoly caused by the need to obtain a marketing authorization. The SPC Regulation provides that SPC can be granted if there is a basic patent in force for the product in a states covered by the EEA Agreement, the product has not already been subject to such a certificate, and there is a valid authorization to place the product on the market. A SPC takes effect at the end of the lawful term of the basic patent and last for a period equaling to the period of time that has elapsed between the date on which the basic patent was applied for and the date when the product covered by the patent was first authorized to be put on the market. This extension provided by the SPC regulation is up to 5 years. However, the patentee cannot enjoy more than 15 years of combined patent and SPC exclusivity from the first authorization.

An application for an SPC needs a standard form to be completed and submitted to the national patent office together with certain supporting documents. Both the first authorization date[89] has to be provided to the patent office in the Member State in which the application is to be made. Then the patent offices process the application, and in so doing many of them conducted in due diligence. However, the patent office rely on the information that pharmaceutical companies provide in their application; that is to say that the enforcement of these public procedures do not require patent offices to implement discretionary powers.

2.3.2 Data Exclusivity and Marketing Exclusivity

Additional market protection for the originator product may be provided by data exclusivity that precludes authorities from accepting an application for a marketing authorization based on bioequivalence during a defined period. Therefore, it is accepted as a form of exclusive right enforced through the marketing authorization procedure. As to the

[87] Council Regulation No. 1768/92/EEC of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

[88] European Parliament and Council Regulation No. 469/2009 of 6 May 2009 concerning supplementary protection certificate for medicinal products.

[89] The meaning of 'the first authorization date' had been unclear until it was clarified in a 2003 judgment of the CJEU (CJEU, 11 December 2003, in case C-127/00 *Hassle AB v Ratiopharm GmbH*). The common interpretation was the date when the national authority granted the marketing authorization. The alternative interpretation was the date when all administrative steps had been completed and the marketing authorization actually became effective, which was the date when the national government approved the price of the product.

legislation in this field, Directive 2004/27/EC[90] brought a number of significant amendments to the provisions governing data exclusivity in Directive 2001/83/EC[91].

Data exclusivity is to some extent intricate in the context of 'abridged application'[92] procedure for marketing a generic medicine. As a matter of principle, the regulatory authorities can only process a generic application after defined period of time following the granting of the first marketing authorization of the originator or innovative medicine. Therefore, data exclusivity prevents authorities for a reasonable period of time from using or relying on the originator's registration or the data submitted by the innovator for the benefit of third parties intending to market a copy of the product without producing their own data. Subsequent to the expiration of the period of data exclusivity, the originator's data can be relied upon as a reference by the authorities in order to give market approval of copy products. Thus the need for the second application to repeat pre-clinical tests and clinical trials, which has already been conducted by the originator is obviated. However, this does not give the generic manufacturer access to the originator's research data[93].

Generic manufacturers are prevented from referring to the results of preclinical tests and clinical trials of the originator's product until 8 years have elapsed from the date of authorization. In some Member States, the data exclusivity period has been extended by 2 years, while it has been reduced by two in others. Besides, 'marketing exclusivity' has been introduced to preclude the marketing of a generic medicine during the 2 years following the data exclusivity period.

The period of marketing exclusivity expires in parallel with the data exclusivity but it is effective for 10 years. That is to say that at the end of data exclusivity, an additional 2-year market exclusivity come into effect. The two-year additional market exclusivity period can be extended by one year, if, during the period of eight-year data exclusivity, the originator company obtains an authorization for one or more new therapeutic indications, which are held to lead an important clinical advantage compared to existing therapies. Together with this

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[90] European Parliament and Council Directive No 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use

[91] Council Directive No. 2001/83/EC of 6 November 2001 on the Community Code Relating to Medicinal Product for Human Use.

[92] Article 8(3)(i) of Council Directive No. 2001/83/EC of 6 November 2001 on the Community Code Relating to Medicinal Product for Human Use substantially amended a number of Council Directives and codified them in a single text. Council Directive 65/65 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products, Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products can be given as examples for the amended Council Directives.

[93] Article 10 of Council Directive No. 2001/83/EC of 6 November 2001 on the Community Code Relating to Medicinal Product for Human Use.

additional 1-year, the effective period of market exclusivity can even therefore become 11 years. This is so-called ‘8+2+1’ formula.

Only after the defined period of exclusivity, generic manufacturer are permitted to refer to the originator’s data and file for an abridged license, citing the originators work and having to prove that their product is the same as that of the originator. The costs and complexity coupled with an abridged application for a marketing authorization are considerably lower than those for a full application.

Considering the issue of data exclusivity, it should be recalled that where there is a patent cover in place within a given state, this would in any case obstruct marketing of the product. But the reverse also applies, in that if patent cover has expired or has never existed, there may still be a period of data exclusivity that applies, precluding an abridged application from being filed.

CHAPTER 3
THE EU PHARMACEUTICAL SECTOR INQUIRY

The concern at this chapter is to what extent the AstraZeneca judgment provides a precedent for assessing strategies of pharmaceutical companies identified the EU Pharmaceutical Sector Inquiry Report (hereinafter called as Report) as likely anti-competitive. In this respect, in order to answer this question, the legal basis and the purpose of the Report will be firstly clarified this chapter. Then the strategies for which the *AstraZeneca* judgment proves to be relevant will be identified, and then the findings of the Report will be explained. Lastly, the consequences which the Commission has so far inferred from the EU Pharmaceutical Sector Inquiry (hereinafter called as Report) will be mentioned.

3.1 Legal Basis and Purpose of the EU Pharmaceutical Sector Inquiry

According to Article 17 of Council Regulation 1/2003, the European Commission is entitled to conduct an inquiry into a particular sector of the economy when the circumstances raise the concerns that competition may be restricted or distorted within the common market. On January 16, 2008, the Commission initiated a wide-ranging inquiry into the pharmaceutical sector in response to the perception that competition in the pharmaceutical sector in the EU does not work efficiently. This perception was based on a decline of innovation as measured by the decreasing number of new medicines accessing the market each year[94] and by delayed market entry of generic drugs. In this respect, a wide range of potentially anti-competitive practices were caught by the Commission's radar. Based on such imperfections in the market, the Commission aimed at obtaining a better understanding of competition in the sector and determining whether above-stated two concerns were caused by anti-competitive practices in its Inquiry.

Two proceedings in *AstraZeneca* and *Boehringer* may have triggered the Commission to initiate the Inquiry. The purpose of the Inquiry is solely limited to pure fact finding with respect to the functioning of competition in the pharmaceutical sector. It is not aimed to reach any legal conclusions on infringements.[95] Accordingly, the Report primarily serves to clarify

[94] Considering the statics provided by the industry, there was a decline from 40 new molecules accessing the market per annum in the period from 1995 to 1999 to 27 in the period 2000-2007.

[95] The Commission itself stated that the Report does not have the purpose of providing guidance concerning compatibility of certain practices with competition law. See *European Commission, Final Report of Sector Inquiry into Pharmaceuticals*, 8 July 2009, paras 472, 1088, 1096, available at

the outcomes of the fact-finding mission and classification of specific forms of conduct, which is identified as potentially anti-competitive, without providing guidance for the legal assessment of an individual case.

The sector inquiry closely investigated certain practices by originator companies aimed at delaying the entry into the market of generic medicines. Directorate General for Competition considered whether and, if so, when practices of so-called life-cycle management of original medicines may constitute a breach of the EU competition rules, rather than the mere exercise of rights stemming from the regulatory or intellectual property framework applicable to pharmaceutical products. The inquiry was particularly focused on agreements between pharmaceutical companies such as settlement agreements in patent disputes, and establishing whether companies have created artificial barriers to product entry through misuse of patent rights, vexatious litigation or other means.[96] This latter concern apparently derived from the Commission's investigation into AstraZeneca. In other words, the type of behavior that the Commission had condemned in *AstraZeneca* was also scrutinized within the scope of the sector inquiry.

The sector inquiry served to underline that the Commission's focus has shifted from parallel trade to generic entry. Report did not examine competition among generic companies though. Therefore it can be said that while the sector inquiry indicated a shift in Commission's overall competition enforcement priorities in the pharmaceutical sector towards issues concerning generic entry, this shift already got underway with the Commission's 2005 decision in *AstraZeneca*[97]. Accordingly, this far-reaching Inquiry has moved competition law to the center of generics debate. As discussed, it has also addressed to thorny issues with respect to the intersection of competition and IP law.

3.2 Findings of the Report

On November 28, 2008, the Commission issued a preliminary report of certain facts and initial conclusions from the inquiry. The Preliminary Report suggested that a broad set of practices employed by originator companies to maximize the value of IPRs were problematic under competition law. The Preliminary Report revealed that Article 101 of TFEU and Article

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http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf (hereinafter called as *Final Report*)

[96] *See* European Commission, *Commission launches sector inquiry into pharmaceuticals with unannounced inspections*, Press Release No. IP/08/49 of 16 January 2008

[97] European Commission Decision of 15 June 2005, 2006/857/EC in case No. COMP/37.507/F3 –*AstraZeneca* (hereinafter called as *AstraZeneca Decision*)

102 of TFEU were conceived as appropriate instruments for addressing at least some of the patent imperfections. The Preliminary Report defines these practices as a "tool-box" of instruments used by originators to delay the market entry of generics. This perception adopted in the Preliminary Report concerned competition lawyer because many of such practices would only turn into a problem in exceptional circumstances. Likewise, the suggestion that practices that are prevalent in all high-tech sectors not just in the pharmaceutical sector were inconsistent with competition rules worried IP experts. In view of these criticisms, it would be better off espousing a position that was not only compatible with existing law, but that was not chilling the innovation that IPRs were designed to boost. Accordingly, the release of the Preliminary Report elicited heavy criticism from pharmaceutical industry.

Subsequent to the preliminary report[98], on July 8, 2009 the Final report was published. Compared to the preliminary report, the Commission substantially toned down through revising its emotive and accusatory tone. While "in the preliminary report, patent portfolio, litigation, settlements, regulatory communications and patented second generation products are all marked out as potentially guilty of an overcharge of EUR 3 Billion to European health systems by blocking cheaper generics"[99], in the final report, the Commission took a more balanced and cautious approach. Accordingly the Commission expressed that the terms including "tool-box"[100], "patent thickets", "patent clusters", "secondary", "divisional patents" and "defensive patents" which were viewed as having a derogatory connotation under the Preliminary Report were not in themselves considered as illegal, and would only lead to infringements in exceptional circumstances.[101]

As discussed, the Inquiry initiated with a focus on commercial practices of firms raising delays of market entry of generics and the Preliminary Report reflected this concern. However, as the investigation evolved and the Commission received extra input from industry in response to the Preliminary Report, it became clear that the regulatory system was the predominant problem rather than companies' commercial practices. To this end, the Commission did not narrow down its conclusion on the competition law issues, and it proposed an institutional flexibility that is to say that the unusual complexness of the

[98] *See* European Commission, *Pharmaceutical Sector Inquiry Preliminary Report*, 28 November 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

[99] *Final Report*, supra note 95, paras 1607-1612. *See* also BATCHELOR, *EC tones down its final report into the pharma sector, but ramps up enforcement activity*, in *European Competition Law Review*, 2010, 31(1), 16-20, p.16.

[100] This terminology was firstly adopted in the preliminary report.

[101] *Final Report*, supra note 95, para. 1568.

pharmaceutical industry was recognized by suggesting a wide range of policy recommendations.

3.3 Investigated Practices

Indeed, behaviors subject to investigation can be mainly categorized as follows: patent strategies, patent litigation, and patent settlements. The Commission examined these practices in two different groups. The first focus (i.e. originator product versus generic product) concentrated on strategies that are designed to reduce price competition by artificially delaying market entry of generic products. The second focus (i.e. competition between originator companies) concerns strategies directed toward other companies. Given the topic of this thesis which is limited to competition between originators and generic producers; investigated practices in relation to competition between originators will not be elaborated.

3.3.1 Patent Strategies

The abuses identified in *AstraZeneca* fall within the scope of this group of strategies which amounts to delaying the entry of generic products into the market. AstraZeneca is significant for the assessment of patent-filing strategies. In *AstraZeneca,* the Commission had accused AstraZeneca of abusing its dominant position by misusing the current regulatory framework to delay generic entry. While recognizing that "single acts including the launch, withdrawal or requests for deregistration of a pharmaceutical product would not normally be regarded as an abuse,"[102] the Commission set that AstraZeneca had engaged in abusive conduct by pursuing a broad, coordinated strategy for the purpose of excluding generics.

According the Commission, patent strategies that are aimed at blocking the entry of generic products into the market constitute a predominant part of life-cycle management of the patent portfolios of pharmaceutical companies, a practice that has the intention to "obtain the most efficient, broadest and longest possible patent protection for this product and variations thereof."[103] Most significantly, pharmaceutical companies endeavor to thrive this aim by applying for a number of "secondary patents" covering products and processes generated in later R&D stages (such as dosage forms, processes, and pharmaceutical formulations), perhaps even after launch of the product[104], in addition to the original patent in order to effectively prolong the exclusivity beyond the expiry of the protection period of the

[102] *AstraZeneca Decision*, supra note 97, para. 793.
[103] *Final Report*, supra note 95, para. 473.
[104] *Ibid*, para. 138.

original patent[105]. If this occurs towards the end of the expiration date of the original patent - a strategy generally termed as "evergreening of patents"[106] - this will lessen originators' vulnerability to challenges by generic companies to the validity of key patents. Besides, the Commission pointed out that pharmaceutical companies file patent for many forms of incremental innovation, thereby creating "patent clusters"[107] enclosing the original patent. Whereas such a strategy is not at all deemed as illegitimate from a patent law perspective, it causes problems for the market entry of generics to the extent that, in consideration of the solely incremental nature of the invention, such "secondary patents" may be more prone to invalidation and thereby raising the uncertainty over the timing of market entry of generics [108] In the Final Report, the Commission established that such "secondary patenting" strategies are applied by originators with apparent intention of blocking generics[109] by increasing legal uncertainty. [110] According to the Commission, originator companies even consciously use weak patents as a means of blocking generics.[111]

In view of such findings, the major concern is under which conditions such patent strategies are no longer to be deemed to be legitimate and enter the ambit of competition law liability. Even though the Commission was not in an attempt to give guidance for the application of competition law in individual cases[112], it address to a standard for distinguishing legal and illegal strategies: "*While [such a strategy], during the period of exclusivity, is generally in line with the underlying objectives of patent systems, it may in certain cases only be aimed at excluding competition and not at safeguarding a viable commercial development of own innovation covered by the clusters.*"[113]

Accordingly, the Commission put forth that if the applicant has not any intention to develop its innovation; this is assessed as the indication of 100 % anticompetitive intent which gives rise to competition law concerns. Differing from the approached adopted in the Preliminary Report, the Commission pointed out that filing for numerous patents on an invention is regular practice and is not inherently problematic. Competition law concerns are most possibly reveal when the originator files for patents with the intention to exclude competitors such as where it files for a patent, however it does not use the patent and refuses

[105] *Final Report*, supra note 95, para. 476 *et seq*.
[106] *Ibid.* para. 476
[107] *Ibid.*
[108] *Final Report*, supra note 95, para. 494.
[109] *Final Report*, supra note 95, para.494.
[110] *Final Report*, supra note 95, para.525-27.
[111] *Final Report*, supra note 95, para.503-05.
[112] *Final Report*, supra note 95, para. 472.
[113] *Final Report*, supra note 95, para. 523.

requests to license the patent.[114] This approach is more limited and in parallel with existing law.[115]

3.3.2 Patent Litigation

It needs to be highlighted that enforcing patent rights is a fundamental right which is not put into question by the Inquiry. However, the Inquiry exhibited that litigation can also be used as an efficient way of creating barriers against competitors, particularly against smaller competitors. Originator companies may sometimes pursue patent litigation as a signal to deter generic entrants in order to shield their market from generic entry. In the Preliminary Report, the Commission claimed the fact that originator firms resorting patent litigation against generics could be deemed as an anticompetitive behavior. Unsurprisingly, this innuendo elicited criticism because patent litigation could only give rise to anticompetitive conduct in exceptional circumstances under current established case law. If a company is at dominant position, such litigation could be challenged as abusive under Article 102 of TFEU. *ITT Promedia* can be referred as the most striking example in this respect. This judgment brought a standard that requires the claim must be "manifestly unfounded" and it must be brought for the purpose of eliminating competition.[116]

The Final Report acknowledged that a company is entitled to enforce its patent rights, even if this constitutes obstacle against generic companies. It stated that "[e]nforcing patent rights is legitimate and constitutes a fundamental right guaranteed by the European Convention on Human Rights."[117]

3.3.3 Patent Settlements

The approach to patent settlements did not considerably differ in the Final Report compared to the Preliminary Report. The Final Report revealed that competition law concerns are possibly appear in relation to agreements designed to keep competitors out of the market, particularly patent settlement agreements that block generic entry by means of value transfer from originator company to generic company.[118]

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[114] *Final Report*, supra note 95, para. 1571.
[115] HULL, *The Application of EU Competition Law In The Pharmaceutical Sector*, in *Journal of European Competition Law & Practice*, 2010, no.1(5), 429-437,p. 431.
[116] CJEU, 17 July 1998, in case T-111/ 96, *ITT Promedia NV v Commission*, para. 55-56.
[117] *Final Report*, supra note 95, para. 548.
[118] *Ibid.* para. 1573

As a general principle, settlements not imposing restrictions on the generic company that go beyond the term of the patent should benefit from the presumption that patents must be valid. To this end, it would be inconsistent with this general rule to suggest that patent settlements, in particular those involving a reverse payment, are generally problematic under the competition rules. Besides, there may be entirely a justified rationale behind these payments.

It became apparent within the Inquiry that the most relevant factors which originator companies consider before entering into a settlement agreement are the strength of their position in the patent litigation, their chances of getting an interim injunction to obstruct the sale of the generic product and the importance of the product in question and its market size. From the generic companies' point of view, the most significant factor when deciding whether to settle is the cost of litigation. In this respect, it is evident that the generic companies do not benefit from any revenues during that period of time, if they do not launch the product at risk.[119] For example, in the EU, an originator companies may stand to monetarily lose even if it eventually wins the patent litigation since it may not be able to recoup its loss of sales incurred during the period between the launch of the generic and the judgment from a generic company. [120] Accordingly, an originator company may choose to pay the generic to stay off the market until the final judgment is rendered. The recent trend shows that originator companies acquire stakes in generic companies.

3.4 Implications and Policy Recommendations

Strikingly, that the Commission did not tend to provide any guidance on the competition law analysis of the numerous practices scrutinized within the framework of the Inquiry caused a disappointment.[121] This approach of developing law through individual cases is deemed as a problem because companies are left confronting with an undesirable level of legal uncertainty with respect to practices that are not only prevalent in the sector, but should not lead to competition concerns. Case law is not considered to be a substitute for guidelines in providing an ideal legal framework for evaluating the numerous practices in question since phases of litigation could take years for an issue and it arises in *ad hoc* fashion. Meanwhile, companies have been left guessing with respect to whether a given practice is acceptable, and

[119] SCHICHELS and SULE, *The Pharmaceutical Sector Inquiry and Its Impact on Competition Law Enforcement*, in *Journal of European Competition Law & Practice*, 2010, no.1(2),93-111, p. 99.
[120] HULL, *The Application of EU Competition Law In The Pharmaceutical Sector*, in *Journal of European Competition Law & Practice*, 2010, no. 1(5), 429-437, p. 432.
[121] *Ibid.* p. 432

the Inquiry was considered to be resulted in general demonization of the pharmaceutical industry[122]. Conclusively, this is not seen as constructive and could slow down innovation.

Since the Inquiry did not generate a satisfactory output in respect of pharmaceutical companies, the announcement that"[the f]irst enforcement action is already under way" was the most appealing part of the Final Report.[123] This expression clearly proves the Commission's intention to intensify its scrutiny of the pharmaceutical sector under competition law. In other words, while the Commission stated that the Report does not seek to identify unlawful conducts of individual companies, certainly the information obtained in the course of the Inquiry is used by the Commission to initiate investigations under Article 101 TFEU and Article 102 TFEU in areas identified as troublesome.

As a matter of fact, the Commission successively carried out several inspections and started several inspections and other scrutinies in this regard such as monitoring of patent settlements (commencement date 12 January 2010, publish date of the report 6 July 2011), closing of the investigation into Boehringer which is related to an allegation on misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease drugs (closing date of the investigation, 6 July 2011), investigation into Les Laboratoires Servier and a number of generic pharmaceutical companies (commencement date of the investigation, 8 July 2009, on the very same day of publish date of the Final Report), surprise inspections in France (in the premises of Mylan, Novartis, Ranbaxy, Ratiopharm, Sandoz, Sanofi-Aventis and Teva which concerns delays in the launch of generic drugs), investigation into Lundbeck concerning unilateral behavior and agreements entered into by Lundbeck which may hinder the entry of generic versions of the anti-depressant drug citalopram into markets in the EEA (commencement date of the investigation, 7 January 2010), closing of antitrust investigation into AstraZeneca and Nycomed (closing date of the investigation, 6 July 2011), investigation into Cephalon and Teva concerning patent settlement agreements (commencement date of the investigation, 28 April 2011),

[122] TUOMINEN, *Patenting Strategies of the EU Pharmaceutical Industry: Regular Business Practice or Abuse of Dominance*, in *World Competition* 35, no. 1 (2012), 27-54, p. 54.
[123] BATCHELOR, *EC tones down its final report into the pharma sector, but ramps up enforcement activity*, in *European Competition Law Review*, 2010, 31 (1), 16-20, p. 20, *See also* European Commission, *Commission confirms surprise inspections in the pharmaceutical sector*, MEMO/09/435 of 6 October 2009, available at: http://europa.eu/rapid/press-release_MEMO-09-435_en.htm

investigation into Johnson & Johnson and Novartis concerning agreements which may hinder the market entry of generic versions of Fentanyl in the Netherlands.[124]

As discussed, the Commission suggested that a variety of practices of originator companies raised delays in generic entry; however, deficiencies in the regulatory framework were seen as a major factor. Likewise, in the release of the Final Report Commissioner Neelie Kroes stressed the need for more competition and less "red tape". To that end, the Report brought a number of concrete policy recommendations intended to get rid of red tape: (i) single Community patent litigation system in Europe, legal certainty through avoiding of multiple rulings, (ii) high quality standard in granting patent, expedited procedures, (iii) keeping third party submission at minimum level and transparent in order to prevent delays in market authorization approvals, (iv) expedited approval procedures for generics.

[124] *See* KAR and MCGRATH, *EU scrutiny of the pharmaceutical sector since the European Commission's sector inquiry*, in *Linklaters Newsletter*, May 2012.

CHAPTER 4
ASTRAZENECA CASE

4.1 Background

Competition law did not display a prominent role in relationship between originator companies and generic companies till the investigation conducted against AstraZeneca. The Commission did not publish any decisions concentrated on the competition law implications of efforts by pharmaceutical companies to delay the market entry of generics with the notable exception of its *AstraZeneca* decision[125] in which the Commission established that AstraZeneca had abused its dominant position by pursuing certain practices intended for keeping generics off the market. Not to mention the fact that this decision induced the Inquiry which signaled that it may have triggered other investigations. However, none of such proceedings have until now led to an extensive competition law analysis of the practices investigated in the Reports. Therefore, *AstraZeneca* case is the only really instructive precedent on the application of Article 102 TFEU to practices used by originator companies in order to extend the life cycle of their products. The Commission's decision was upheld by the GC and the CJEU. The *AstraZeneca* judgment[126] can exactly be deemed a landmark decision assessing patent filings under competition law since abuse of patent system was a novel type of infringement of Article 102 TFEU.

The AstraZeneca case is one of the most protracted enforcement proceedings in EU competition law history, a fact which may show the unprecedented and the controversial types of abuse identified, as well as the complexity of the underlying circumstances. The time line of the case lasting for twenty years is as follows:

- 1993-2000: the period of the alleged abusive activity
- 1999: complaints by generic companies to the Commission
- 2000: the Commission's dawn raid into AstraZeneca
- 2005: the Commission's decision to impose EUR 60 million on AstraZeneca
- 2010: the GC's decision largely upholding the Commission's decision (but fine reduced to EUR 52.5 million)
- May 2012: Advocate-General's Opinion

[125] *AstraZeneca Decision*, supra note 97.
[126] GC, 1 July 2010, in case T-321/05, *AstraZeneca v. Commission* (hereinafter *AstraZeneca judgment before the GC*).

- December 2012: final judgment from CJEU

This case attracts high attention for various reasons. For the first time, a pharmaceutical company was fined for an abuse of market dominance. For the first time, European Institutions had to analyze the relevant markets in the area of pharmaceuticals outside the area of merger control. For the first time, the question whether strategic use of procedures before patent offices could be considered a breach of competition law provisions was asked.

In 2005 The Commission imposed EUR 60 million fine on AstraZeneca for abuse of its market dominance on a number of European national markets for oral prescription proton pump inhibitors (PPIs), by preventing competitors from marketing its generics and restricting parallel imports. The main PPI is Losec which is a very successful and profitable anti-ulcer medicine. Two types of abuses were identified:

(i) The first abuse was a pattern of deliberate misrepresentations that AstraZeneca made to obtain SPC providing an additional protection for Losec which went beyond the original patent protection. Such misrepresentations covered that made to patent agents, patent offices in Germany, Belgium, Denmark, Norway, the Netherlands, the United Kingdom and national courts of Germany and Norway with the aim of restricting competition from generic products and parallel imports,

(ii) The second abuse referred to operating a strategy pursuant to which it selectively replaced its Losec MUPS capsules[127] with Losec tablets, selectively withdrew Losec capsules, and selectively requested the deregistration of its market authorization for Losec capsules in Denmark, Norway and Sweden combined with the aim of restricting competition from generic companies and parallel importers, which were thereby impeded from relying on AstraZeneca's marketing authorization for the capsules to capable of accessing market for their own products.

On 1 July 2010, the GC has largely confirmed the Commission's findings against AstraZeneca for abuse of its dominant position by misusing of the patent and regulatory systems but reduced the EUR 60 million fine to EUR 52.5 million. As to parallel imports, the GC found that the Commission failed to prove that parallel imports had effectively been prevented in Denmark and Norway.

[127] Losec MUPS tablets have certain advantages over the original capsules formulation. (i.e. they can be dispersed in water, are more easily taken by older patients, and does not include gelatine intolerant patients.

On 6 December 2012, the long-awaited judgment of the CJEU was published. In its judgment, the CJEU upheld the judgment of the GC and also rejected two cross-appeals brought by the Commission and the EFPIA. Despite not changing the result of the case (or the EUR 52.5 million fine on AstraZeneca), the judgment[128] covers some interesting statements of law which may have wider implications beyond the pharmaceutical sector.

4.2 The Commission's Decision

4.2.1 Market Definition

The Commission Decision is interesting, not only because it introduced two novel types of abuse to the open-ended list laid down in Article 102 TFEU, but also because the Commission was called to define the relevant market under Article 102 TFEU in the pharmaceutical sector for the first time. However, considering the scope of the thesis concentrated on new kinds of abuse, an in-depth analysis is not taken place in this section.

The relevant market comprises national markets for PPIs sold in prescription which are used for gastro-intestinal acid related disease (such as ulcers) and in which AstraZeneca was the leading player through Losec. AstraZeneca was the pioneer of the PPIs and held the key technology protecting the active ingredient omeprazole. The Commission excluded from the market definition other drugs used for the treatment of same disease, such as H2 blockers. The Commission reached a conclusion that a PPI market was established in the seven EEA markets concerned (Belgium, Denmark, Germany, the Netherlands, Norway, Sweden and the UK) for the period between 1993 and 2000. The Commission found that throughout the relevant period in the countries concerned the prior generation of anti-ulcer products (H2 blockers) did not exercise a substantial competitive constraint on the PPIs. During the 1990s, there was an apparent one-side substitution pattern whereby PPIs gradually replaced H2 blockers with respect to all acid-related disease and conditions. The facts and figures pertaining to those years became fundamental for product market definitions. Over this period of time, it was proven that PPIs were most cost effective than H2 blockers. Reaching this conclusion, the Commission took into consideration the specific characteristics of the pharmaceutical sector, such as the regulatory context including price regulation. The Commission set that pharmaceutical companies offering therapeutically superior products to the authorities were generally able to get higher reimbursement prices than those established

[128] CJEU, 6 December 2012, in case C-457/10 P *AstraZeneca v Commission* (hereinafter *AstraZeneca judgment before the CJEU).*

for prior generations of less effective drugs. In parallel with this, PPIs were deemed to be therapeutically superior to H2 blockers and to other drugs used for the treatment of acid-related conditions[129], doctors who are the main determinant of demand in markets for prescription drugs[130] considered that PPIs constituted the most effective and appropriate remedy. Given the suggested facts above, the Commission found that because an innovative and better product (e.g. PPIs) progressively over time captured a considerable market share from the incumbent product (e.g. H2 blockers), the innovative product must have had in a separate product market throughout the relevant period.

Assessing competition constraints in relation to the therapeutic use, the Commission took into account of the relevant products' characteristics and modes of action, non-price factors concerning the competition in pharmaceutical prescription markets as well as the impact of certain actual events on the market ("natural events" such as the lack of impact on prices of and demand for PPIs following the entry of cheaper H2 blockers). As a consequence, the Commission's analysis on the relevant product market that PPIs and H2 blockers constitute separate product markets elicited some criticisms as well.[131] This gave a signal of moving away from market definitions based on a broad assessment of therapeutic substitutability towards a more refined approach that takes into consideration a number of factors, including individual molecules, formulation, and means of administration.

4.2.2 Market Dominance

The Decision established that AstraZeneca held a dominant position on the PPI market in Belgium, the Netherlands, Norway, Sweden (1993-2000), Denmark and the UK (1993-1999) and Germany (1993-1997). The Commission based its findings on a number of factors including (i) AstraZeneca's high market shares in the narrowly defined PPI market, (ii) the relevance of price as a competition parameter in the pharmaceutical sector, (iii) the absence of buyer power despite the presence of monopsony buyers, (iv) certain non-price factors as competition parameters in the pharmaceutical sector such as AstraZeneca's alleged technology and regulatory rights blocking the potential entrants and restricting existing competitors, (v) the advantages with respect to incumbency in the pharmaceutical sector.

[129] *AstraZeneca Decision*, supra note 97, para. 382.
[130] *AstraZeneca Decision*, supra note 97, para. 115.
[131] *See*, e.g., MURPHY, *Abuse of regulatory procedures*, in *European Competition Law Review*, 2009, 30(5), 223-229, p.225

The first mover in a pharmaceutical market can generally obtain and maintain higher prices than later entrants to the market. Indeed AstraZeneca, as the first mover into the PPI market, could generally obtain and maintain higher prices than later entrants into the PPI market. The ability to sustain a higher price constitutes evidence of market power since it shows the company's bargaining power vis-à-vis national health authority or the ability (to the extent that a company can freely set its prices) to charge a price premium above the reimbursement level.

Reaching the conclusion that monopsony buyers (i.e. national health systems) did not apply substantial pressure on price of product, the Commission also observed that bargaining power of monopsony buyers was significantly reduced vis-à-vis companies offering genuinely innovative new products (such as Losec) in addition the monopsony buyers were not in a position to control market entry.

4.2.3 Abuse of Dominant Position

4.2.3.1 First Abuse: Misuse of the Patent System

The Commission alleged that, as mentioned above, AstraZeneca abused its dominant position in six countries: Belgium (1993-2000), Denmark (1993-1999), Germany (1993-1997), the Netherlands (1993-2000), Norway (1994-2000), and the UK (1993-1999).[132] The Commission contended that AstraZeneca's misrepresentations in its SPC applications in each of these countries consisted in providing the national POs and courts with incorrect date and failing to be transparent with regard to calculating the period of time for supplementary protection. According to the Commission, this amounted to that AstraZeneca obtained SPCs for Losec for a longer period than AstraZeneca was entitled to. [133]

By the time, AstraZeneca made the SPC Applications, there was a lack of clarity in the wording of the regulation as far as the meaning of, "first authorization to place […] on the market" contained in Article 19 (1) of the SPC Regulation referred under Section 2.3.1. National patent offices had not a common understanding on the interpretation of the relevant regulation. While some took the date to refer solely to the first grant of a marketing authorization in the EU / EEA which corresponded to technical authorization, some took the later date on which a price or reimbursement level was agreed with the respective national authority, since this was also a precondition to commercialization which amounted to effective marketing authorization date. Indeed, this position clearly revealed that there was a

[132] *AstraZeneca Decision*, supra note 97, para. 773.
[133] *Ibid.*

need for a certainty surrounding the meaning of first authorization date. Hence, the matter was brought before CJEU for a preliminary ruling. In 2000, the CJEU put forth that the SPC Regulation was not clear, and set that the technical authorization date (i.e. the grant of the first authorization) was the relevant date in *Hässle AB Ratiopharm GmbH* judgment[134]. Accordingly AstraZeneca made use of this preliminary ruling by contending that this obscurity was implicitly acknowledged by the CJEU which ruled on this matter. In other words, AstraZeneca tried to justify the difference in its interpretation of the first authorization date as the effective marketing authorization date.

The Commission described the SPC abuse as a "single and continuous abuse"; however it identified two different stages[135]. The Commission asserted that the first stage of the abuse was AstraZeneca's transmission of "highly misleading" instructions to its patent agents. The Commission did not claim that AstraZeneca's instructions were wrong only because they were based on the effective marketing authorization date rather than the technical authorization date. That is to say that the Decision raised no objections to AstraZeneca's incorrect interpretation. Besides, the Commission did not challenge AstraZeneca's good faith in relation to its effective marketing date interpretation. The Commission's claim was that AstraZeneca abusively conducted as by the time it applied to the national Patent Offices ("**POs**") for an SPC for Losec, AstraZeneca did not proactively inform the national POs of the basis upon which AstraZeneca determined its legal entitlement to obtain a SPC for Losec. Accordingly, the Commission found AstraZeneca guilty, not of having deliberately misinterpreted the meaning of the relevant provision in SPC Regulation, but of having set up a "pattern of misleading representation to patent agents, POs and national courts as part of its overall SPC strategy."[136]

The Commission stated the second stage of the abuse comprised of numerous "misleading representations" made by AstraZeneca in reply to queries from POs and within the scope of certain proceedings brought before national courts by generic companies. Especially, the Commission asserted that, AstraZeneca had no longer any reasonable ground for depending on its interpretation of the effective marketing date; since AstraZeneca should have been aware of that it was mistaken in its interpretation. The Commission rejected AstraZeneca's argument that the first technical authorization date for Losec in the EU at that time was unclear, and it had thus decided to continue relying on the effective marketing date.

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[134] CJEU, 11 December 2003, in case C-127/00, *Hässle AB Ratiopharm GmbH*.
[135] *AstraZeneca Decision*, supra note 97, paras 628-629.
[136] *AstraZeneca Decision*, supra note 97, para. 666.

The Commission inferred that "the purpose underlying AstraZeneca's strategy for omeprazole was to strengthen its position on the market by delaying the entry of generic versions of omeprazole and to create [an] extra hurdle for generic firms."[137]

According to the Commission's findings, AstraZeneca's "consistent and linear course of conduct" put its competitors into a position to bring lengthy and costly litigation to invalidate AstraZeneca's SPCs. In some countries, AstraZeneca was able to file lawsuits concerning patent infringement against generic companies by invoking the SPCs it had gained through misleading representations. Moreover, AstraZeneca's conduct resulted in uncertainty, delays and disruption of generic companies' preparations for market entry.

The Decision found that the special responsibility of a company holding dominant position also covers the use of public procedures and regulations. The use of such procedures and regulations might be abusive in specific circumstances where a dominant undertaking has a clear intent to foreclose competition, especially where the authorities or bodies applying such procedures have little or no discretion. In the existing case, such a regulatory context existed because the POs generally accepted the data submitted by the SPC applications at face value. In addition, limited information on applications for and grants of SPCs was available for the access of competitors.

The Commission alleged that the acquisition of a right might constitute an abuse. Therefore, behavior in the process leading up to the acquisition of a right was also considered as an abuse. Given that AstraZeneca's initial misleading representations were before the grant of the rights in question, the finding of an abuse cannot affect the subject-matter of the said rights.

The Commission found that there was no reason to limit the applicability of competition law to circumstances where such conduct does not violate other laws and where there are no other remedies. In parallel with this conclusion, a behavior may also lead to liability under other laws regardless of any anti-competitive effects it may have. In addition, the scope of remedies under patent laws in the *AstraZeneca* case was very limited. The only sanction under patent law would be the annulment of the SPCs. As to failed attempts to obtain SPCs through misleading information, no sanctions would be imposed.[138]

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[137] *AstraZeneca Decision*, supra note 97, para. 677.

[138] FAGERLUND and RASMUSSEN, *AstraZeneca: the first abuse case in the pharmaceutical sector*, in *Competition Policy Newsletter*, 2005, no. 3, 54-56, p. 55.

Those findings raised some questions such as: (i) What is the relevance of a bona fide and reasonably held interpretation of an EU Regulation when a dominant company applies to an authority to gain extra patent protection? (ii) What is the degree to which practical implementation is required in order for a conduct to be "capable of having the effect of restricting competition" for the purpose of Article 102 TFEU? (iii) When can the acquisition of an IPR be abusive?[139]

In this respect, the Decision elicited some criticisms. These critics base on the following arguments: (i) The concept of abuse is an objective concept and implies no intention to cause harm.[140] (ii) Actual effect need not to be shown if the conduct is "capable" of having the effect of restricting competition[141]. (iii) Accordingly, a sole intention fraudulently to gain a patent or SPC (even if that intention is exhibited in certain conduct) cannot inherently equal to an abuse. (iv) A mere application for a patent or SPC (even if fraudently made) cannot correspond to an abuse. (v) The grant of a patent or SPC (i.e. acquisition of a patent or SPC) cannot be considered to be an abuse until the patent or SPC comes into force (i.e. is at least capable of immediate enforcement)[142]. (vi) An abuse may only and in very limited circumstances exist where the fraudently obtained patent is enforced, and accordingly the acquisition and enforcement of the patent must be made subjectively as part of a strategy to eliminate competition, and objectively, lack any reasonable foundation[143]. As a result of these arguments, it was concluded that the Commission's approach was contrary to the goals of the Treaty in promoting innovation and competitiveness within the EU.

4.2.3.2 Second Abuse: Misuse of Procedures Relating to the Marketing of the Pharmaceutical Products

In brief and as mentioned above, the Commission's allegation comprised of selective deregistration of the marketing authorization for Losec capsules in Denmark, Norway and Sweden where it ceased marketing Losec capsules on these markets and launched Losec MUPS tablets instead. This abuse can be also described as misusing the rules and procedures (specifically the rules concerning abridged procedure as laid down in Article 4 of Directive

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[139] *See*, e.g., MURPHY, *Abuse of Regulatory Procedures-the AstraZeneca Case: Part 2*, in *European Competition Law Review*, 2009, no 30(6), 289-300, p. 290.
[140] *See*, e.g., CJEU, 13 February 1979, in case 85/76, *Hoffman-La Roche & Co AG v Commission*, para. 91; and CJEU, 12 December 2000, in case T-128/98, *Aeroports de Paris v Commission*, paras 172-173.
[141] *See*, e.g., CJEU, 30 September 2003, in case T-203/01, *Michelin v Commission*, paras 239-241.
[142] *See*, e.g., CJEU, 10 July 1990, in case T-51/89, *Tetra Pak v Commission*, paras 23-24.
[143] *See*, e.g., CJEU, 17 July 1998, in case T-111/96, *ITT Promedia v Commission*, paras 55, 61.

65/65[144]) applied by national regulatory authorities which allow reliance by new entrants and parallel importers on the pharmacological and toxicological tests and clinical trials which such authorities used to grant the marketing authorization of an original product and which are onerous and costly. The relevant legislation at time necessitated, in order to benefit from the abridged procedure for obtaining a market authorization or an import license, that the reference product was authorized in the Community and that the reference product was put into market in the Member States where the application was referred.[145] Therefore, the Commission acted with a view that generic firms would be unable to take advantage of the abridged procedure because they were unable to rely on the scientific data that have been generated by the marketing authorization holder of the reference product. The Commission contended that AstraZeneca took advantage of the loopholes in the legislation. It was maintained that AstraZeneca operated a strategy which was called "Losec Post Patent Strategy" the intent of which was to minimize the impact on AstraZeneca of its patent / SPC expiry for omeprazole[146]. The Commission maintained that this strategy covered a number of actions with the intention of preventing or at least delaying generic market entry and stopping parallel trade.[147] The Commission also alleged that the requests for deregistration of the marketing authorization were geographically selective and were implemented in countries where AstraZeneca thought that it was likely to be successful as it proved to be, considering the way in which national authorities interpreted the legal provisions.[148] This allegation was reinforced by the fact that this strategy was not put in other countries that is to say that even after the launch of Losec MUPS tablets, the Losec capsules continued to be marketed.[149] Besides, it was noted that AstraZeneca's conduct was not a standard type of industry practice at the relevant period of time.[150] The Commission set that AstraZeneca's conduct could not be objectively justified. It gave an example that AstraZeneca's requests for deregistration were not related to public health considerations.

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[144] Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products. (As amended by Council Directives 1975, 1983/570, 1987/21, 1989/341, 1993/39, 2001/83 and 2004/27)

[145] This abuse is not possible to be replicated due the amendment of Council Directive 2001/83 (whose Article 10, before the amendments, was substantively identical to Article 4 of Council Directive 65/65) by Council Directive 2004/ 27. According the new formulation, it is no longer required that a market reference authorization is effective in the Member States or in the Member State where the generic producer wishes to penetrate.

[146] Omeprazole is the active ingredient in Losec.

[147] *AstraZeneca Decision*, supra note 97, paras 788-789.

[148] *AstraZeneca Decision*, supra note 97, paras 789.

[149] *AstraZeneca Decision*, supra note 97, paras 805.

[150] *AstraZeneca Decision*, supra note 97, paras 791.

In the light of these findings, thus AstraZeneca's conduct constituted an abuse of a dominant position. Nevertheless, it should be noted that while reaching the conclusion stated above, the Commission recognized that (i) "single acts involving launch, withdrawal or requests for deregistration of a pharmaceutical product would not normally be considered as an abuse"[151]; (ii) "the launch of a new formulation of Losec MUPS and/or withdrawal of Losec capsules would not as such constitute an abuse"[152]; (iii) "AstraZeneca's interpretation of Community pharmaceutical law (in particular Council Directive 65/65/EEC) and AstraZeneca and AstraZeneca's interpretation of "national rules on parallel trade licenses in the light of Articles 28,28, 29 of the Treaty"[153]; (iv) "Directive 65/65/EEC does not oblige the holder of a marketing authorization to maintain it"[154]; (v) Generics and parallel importers were not dependent on the existence of a marketing authorization to compete with the holder of a former marketing authorization in the supply of the same or significantly similar products[155]; (vi) it was not the function of marketing authorizations to ease market entry of generic products[156].

Some authors have argued that the Commission should have abstained from imposing fines on AstraZeneca, or at least that it should have imposed a lower fine, bearing in mind that the novelty of the abuse and the fact that at the time the legislation was ambiguous.[157] These authors argued that AstraZeneca pursued its own commercial strategy employing the instruments at its disposal, which should not be considered contrary to Article 102 TFEU.[158] The same group of commentators have also concerned that the Decision may result in putting dominant companies under a positive obligation to actively maintain their rights, whether exclusive or non-exclusive, they have obtained to commercialize their products, if the maintenance of those rights would facilitate others to compete with dominant companies.[159] In other words, it can be said that decisions regarding whether a marketing authorization should be withdrawn are the commercial prerogative of every pharmaceutical firm, and "no

[151] *AstraZeneca Decision*, supra note 97, paras 792.
[152] *AstraZeneca Decision*, supra note 97, paras 793.
[153] *AstraZeneca Decision*, supra note 97, paras 820.
[154] *AstraZeneca Decision*, supra note 97, paras 832.
[155] *AstraZeneca Decision*, supra note 97, paras 820.
[156] *AstraZeneca Decision*, supra note 97, paras 842.
[157] *See*, e.g., MANELY and WRAY, *New pitfall for the pharmaceutical industry*, in *Journal of Intellectual Property Law and Practice*, 2006, no 1 (4), 266-271, p. 266, 269 and 271; LAWRANCE and TREACY, *The Commission's AstraZeneca decision: Delaying generic entry is an abuse of dominant position*, in *Journal of Intellectual Property Law and Practice*, 2005, no 1(1), p.7.
[158] MANELY and WRAY, *New pitfall for the pharmaceutical industry*, in *Journal of Intellectual Property Law and Practice*, 2006, no 1(4), 266-271, p. 266, 268 and 269.
[159] MURPHY, *Abuse of regulatory procedures- the AstraZeneca Case: Part 3*, in *European Competition Law Review*, 2009, no. 30(7), 314-323,p.225

proprietary company is legally obliged to keep a marketing authorization in place, and there are valid commercial reasons why it may wish to withdraw it."[160] On the other hand, according to the commentators having tendency to the Commission's approach, dominant firms have a special responsibility to use specific entitlements, whether the private or public, in a reasonable manner with respect to market access for other parties.[161] Pursuant to this approach, it is contended that although the principle of commercial freedom which amounts to that all undertakings must in principle be able to pursue the commercial strategy that better fits to their business, this principle is not absolute and it cannot be employed for threatening the competitive process.[162]

4.3 The General Court's Judgment

4.3.1 Market Definition and Dominance

The GC upheld the Commission's finding that the relevant product market for Losec (i.e. AstraZeneca's product) consisted solely of PPIs, and did not includes H2 blockers. In excluding H2 blockers from the relevant market, the Commission established that they did not exercise significant competitive constraints over Losec and other PPIs. This finding was arisen out of therapeutic differences between the products, the steady increase of PPIs sales at the expense of H2 blockers, price factor, and natural events.

First, as to the therapeutic properties of the products, the GC upheld the Commission's finding that PPIs and H2 blockers have differentiated therapeutic usages. Apart from some overlapping assessments, the GC resolved that PPIS were generally prescribed to treat severe cases, whereas H2 blockers were generally prescribed for mild treatments.

Second, the GC examined the evidence proving that PPIs sales continually increased in the course of the relevant period, at the expense of H2 blockers, which decreased or remained stable. Especially, the GC analyzed AstraZeneca's argument that inertia of doctors to prescribe H2 blockers was indicative of that H2 blockers exert significant constraint over PPIs. In this respect, the GC upheld the Commission's position that the existence of such inertia did not amount to a concrete indication, or even create a presumption, that H2 blockers exerted a significant competitive constraint. Further, the GC resolved that AstraZeneca did

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[160] MANELY and WRAY, *New pitfall for the pharmaceutical industry*, in *Journal of Intellectual Property Law and Practice*, 2006, no.1(4), 266-271, p. 271.
[161] *See*, e.g. FAGERLUND and RASMUSSEN, *AstraZeneca: the first abuse case in the pharmaceutical sector*, in *Competition Policy NewsLetter*, 2005, no. 3, 54-56, p. 56.
[162] NEGRINOTTI, *Abuse of regulatory procedures in the intellectual property context: the AstraZeneca case*, in *European Competition Law Review*, 2008, no. 29 (8), 446-459, p. 456.

not show any evidence that the quality of the H2 blockers increased the level of inertia thereby creating a competitive constraint. Instead, the GC held that considering the repositioning of H2 blockers to milder cases, the trend of asymmetrical substitution pointed out that H2 blockers did not exercise any considerable competitive constraint.

Third, the GC examined the Commission's reliance on price differences of the products as an indication that they constitute separate markets. Especially, the GC declined that AstraZeneca's arguments that as prices were highly regulated, price was irrelevant and held instead that the prices established by the authorities pointed out the relative therapeutic value of the products. In addition, owing to the complexity and ambiguity of the necessary analysis, the GC also declined AstraZeneca's objections that the Commission should have considered the products' prices in light of the duration of treatment and should have taken into consideration volume-based market share figures instead of value-based market share figures.

Finally, the GC analyzed evidence from natural events including the entry of a competing PPI, a generic H2 blocker, and a generic version of Losec into market in order to identify the effect of such event on the sales, pricing, and promotion levels of the products. Based on this evidence, the GC held that entry of the competing PPI and generic versions of Losec (i.e. omeprazole) had a considerable impact on the levels of sales of Losec. On the contrary, the entry of the generic H2 blockers had negligible impact on the sales level, and had no impact on the pricing or promotion levels of Losec. Thus, the GC found that Commission's finding that such natural events shows that H2 blockers are not in the relevant market.

The GC, while acknowledging that the Commission exercises a margin of discretion in making such an analysis, made an excessively detailed examination of the evidence before upholding the Commission's finding. Further, the GC's may well embolden the Commission to pursue narrow market definitions for medicines, in particular, when a new medicine represents a clear improvement over existing medicines.

As to the dominance of AstraZeneca, the Commission had revealed that a number of factors pointing out AstraZeneca's dominance in this market. Especially, it had a patent for the active ingredient in Losec, which was the first and the most expensive PPI, and had very high market shares (always over 50 per cent and often over 80 percent) in the relevant countries (i.e. Belgium, the Netherlands, Sweden, Denmark, the UK and Germany) at time of the alleged abuse. The GC upheld these findings, by reference to AstraZeneca's market share

and the price levels that it had been able to sustain for Losec. The GC also confirmed that the relevance of AstraZeneca's IPRs, its "first-mover advantage" and its financial strength. Also the GC approved that AstraZeneca was able to obtain higher prices or reimbursement levels than those for other suppliers' PPIs and AstraZeneca's dominance was not defeated by the buyer power national health services. Subsequently, the GC rose that AstraZeneca was not appreciably constrained by its competitors, customers and suppliers. At this point, it should be reminded that holding an IP, in itself, does not prove market dominance. [163]

4.3.2 Abuse of Dominant Position

4.3.2.1 First Abuse: Misuse of the Patent System

On the first abuse with regard to the extension of patent rights (i.e. SPC), the GC upheld that the Commission's finding that AstraZeneca abused its dominant position by supplying misleading information to national POs. In its appeal, AstraZeneca had argued that the Commission had both erred in defining the standard for the abuse and failed to prove sufficient facts for an abuse. The Court set the legal standard of abuse by resolving that the submission of misleading information to public authorities that is liable to lead them to grant an exclusive right to which the company is not entitled constitutes a practice falling outside the scope of competition on the merits and, thus, runs afoul of the competition rules.[164] This finding is far-reaching in several aspects: first, it emphasized that even acts before an authority may be considered conduct that falls within the scope of application of competition law. In doing so, the GC declined the potential counterarguments according to which, to have an effect on competition, the right holder must use the patent in the market, perhaps most importantly by refusing to license the right to a potential competitor. According the GC, merely patent filing in itself was considered as a potential abuse having exclusionary effect, and the IPR was alleged to have the exclusionary effect on the market. This immediate market effect was explicitly acknowledged by the GC: "*When granted by a public authority, an intellectual property right is normally assumed to be a valid and an undertaking's ownership of that right is assumed to be lawful. The mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since regulations require them to respect that exclusive right."*[165] The GC continued that arguing otherwise would make application

[163] This has been recognized by the European Courts for a long time. *See,* e.g. CJEU, 6 April 1995, in joined cases C-241/91 P and C-242/91 P, *RTE and ITP v Commission ("Magill")*, para. 46 ("*So far as dominant position is concerned, it is to be remembered at the outset that mere ownership of an intellectual property right cannot confer such a position.*")
[164] *AstraZeneca* judgment before the GC, supra note 126, paras 295, 613.
[165] *AstraZeneca* judgment before the GC, supra note 126, paras 362.

Article 102 TFEU conditional on an infringement of an existing IPR by competitors.[166] Likewise, the GC did not admit the availability of remedies except for competition law, in particular the possibility of competitors to file a patent suit for invalidation of patents, as a counterargument with respect to Article 102 TFEU.

Nevertheless, the GC expressed that patent fraud by itself did not form a constraint of competition. Rather, the GC emphasized that an assessment *in concreto* was required, and that the assessment "*may vary according to the specific circumstances of each case*".[167] Accordingly, The GC addressed the concrete situation of the patent offices in relation to the application for SPCs. The GC adopted that "*in this respect, as the Commission asserts, the limited discretion of public authorities or the absence of any obligation on their part to verify the accuracy or veracity of the information provided may be relevant factors to be taken into consideration for the purposes of determining whether the practice in question is liable to raise regulatory obstacles to competition."*[168] As the transitional rules of the SPC Regulation[169] did not leave the patent authorities any room for discretion to grant or not to grant the SPCs, such test referred above was apparently met. Furthermore, the patent authorities were not a duty to verify the dates of the grant of the first marketing authorization within the EU as delivered by an SPC applicant.

It should also be noted that the GC adhered to the traditional concept of abuse which amounts to an objective concept.[170] Pursuant this approach, the GC highlighted that it was not required to establish a deliberate intent to deceive the patent office. Nevertheless, where there is a proof indicating a specific intent, this can be taken into consideration for affirming an abusive conduct.[171] The GC resolved that it did not matter the fact that the behavior did not actually produce the desired effects, that is to say that AstraZeneca did not achieve to obtain SPCs granting protection beyond the original patent. The GC continued that it was sufficient that AstraZeneca's conduct was very likely to give rise to the issuance of the SPCs and that, if the SPCs had been issued, they would have resulted in significant anti-competitive effects.

While reaching a conclusion that there was a plenty of evidence indicating that AstraZeneca had misled the patent offices, the GC found that AstraZeneca could not

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[166] *Ibid.*
[167] *AstraZeneca* judgment before the GC, supra note 126, para. 357.
[168] *Ibid.*
[169] Article 19 SPC Regulation
[170] Ast*raZeneca* judgment before the GC, supra note 126, paras 352 and 359.
[171] *AstraZeneca* judgment before the GC, supra note 126, para. 459.

reasonably be unaware that its conduct was misleading.[172] It also put forth that the reasonableness of AstraZeneca's interpretation of the relevant regulation was not at stake; rather, the problem was that it failed to be transparent with the patent offices about its interpretation.

The analysis of the GC involves unsettling features that could give rise much second-guessing among corporate counsels in the scope of their dealings with patent authorities and other regulatory agencies. Particularly, the GC's finding manifested the inclination to set a low threshold for a finding that a dominant firm supplied misleading information. In other words, it did not need to establish the company's intention to deceive the patent office, or that its behavior had anticompetitive effects. Instead, it sufficed to reveal that the company should have reasonably been aware that its behavior would likely mislead the patent authority and that the behavior was capable of having anticompetitive effects. Likewise, the GC reiterated the established principle of EU competition law that an abuse does not require elimination all competition.[173] In its finding, the GC accepted substantive patent law as a non-rebuttable presumption for the appropriate balancing of the interest in promoting innovation through patent law and the interest in controlling prices by allowing generic products to enter the market.[174] Subsequently, the GC reached a conclusion that an extension of the period for protection based on deceptive conduct of an applicant whom is entitled to such extension even reduces the applicant's incentives for innovation because such conduct would strengthen market power of the applicant without being forced to invest in R&D for new medicines as an alternative, pro-innovation and pro-competitive strategy.[175] Accordingly, the GC considered expiry of the patent as a part of the pro-innovation design of patent law.

While the GC highlighted that the issue of whether the information is misleading must be assessed on the basis of the specific circumstances of each individual case, an uncertainty surrounds the meaning of misleading. Thus, some commentators points out this ambiguity which would make the dominant companies to consider whether the failure to proactively disclose these weakness is misleading, whether it is required to show that the patent authority would not issue the patent if it was aware of the issue, whether it is sufficient to establish that patent office would be unlikely to issue the patent, and whether the likelihood that the patent authority would normally find and investigate such a weakness in the course of its review of a

[172] *AstraZeneca* judgment before the GC, supra note 126, para. 493.
[173] *AstraZeneca* judgment before the GC, supra note 126, para. 364 *et seq*.
[174] *AstraZeneca* judgment before the GC, supra note 126, para. 367.
[175] *AstraZeneca* judgment before the GC, supra note 126, para. 367.

patent makes any difference.[176] They also add that narrow interpretation of the concept of "misleading" is critical and this would have a chilling effect on innovation. According to such critics, an undesirable level of uncertainty arises from the imposition an ill-defined duty of proactive transparency on dominant undertakings, and the injection of such uncertainty may undermine the value of IPRs and dilute the pro-competitive incentives they are created to foster.

4.3.2.2 Second Abuse: Misuse of Procedures Relating to the Marketing of the Pharmaceutical Products

As to the second abuse concerning selective withdrawal and deregistration of Losec capsules, it is very significant to note the reasons for which the GC held that even the use of legally available procedures can give rise to an infringement of competition law. The GC made a distinction between what is legal under the relevant pharmaceutical legislation and what is to considered illicit conduct under competition law: "*Furthermore, the fact, relied on by the applicants, that AZ was entitled to request the withdrawal of its marketing authorizations for Losec capsules in no way causes that conduct to escape the prohibition laid down in Article [102 TFEU]. As the Commission observes, the illegality of abusive conduct under Article [102 TFEU] is unrelated to its compliance or non-compliance with other legal rules. It must be observed, in this respect, that in the majority of cases, abuses of dominant positions consist of behavior which is otherwise lawful under branches of law other than competition law."*[177] Thus, legality of the behavior under the relevant pharmaceutical legislation, in itself, does not automatically preserve AstraZeneca's behavior from competition law liability. The GC relied on its precedents which set that EU competition law imposes on a dominant company a "*special responsibility not impair, by using methods other than those which come within the scope of competition on the merits, genuine undistorted competition in the common market*".[178] The GC distinguished use of regulatory procedures from competition on merits "*in such a way as to prevent or make difficult the entry of competitors on the market, in the absence of grounds relating to the defense of the legitimate interests of an undertaking engaged in competition on merits or in the absence of objective justification".*[179] According to the GC's findings, there are two necessary points: firstly, in the

[176] *See e.g.* HULL, *The Application of EU Competition Law in the Pharmaceutical Sector*, in *Journal of European Competition Law & Practice*, 2011, no. 2 (5), 480-488, p. 485.
[177] *AstraZeneca* judgment before the GC, supra note 126, para. 677.
[178] *AstraZeneca* judgment before the GC, supra note 126, para. 671.
[179] *AstraZeneca* judgment before the GC, supra note 126, para. 672.

respect of market foreclosure, the behavior has to produce anti-competitive effect; and secondly, the behavior must not be objectively justified.

As to the test for identifying the nature of the behavior as anti-competitive, three aspects of *AstraZeneca* should be underlined. First of all, the GC declined AstraZeneca's defense to apply the "essential facilities"[180] principle.[181] In this respect, the GC indicated that since this principle had been developed in the scope of exclusive rights (*i.e.* refusals to license) and the AstraZeneca's exclusive right to make use of the data on its tests and clinical trials had expired, no such rights were no longer accorded to AstraZeneca,[182] having regard the fact that the respective legislation (i.e. Directive 65/65) clearly allowed generic producers for relying on such data after the expiry of the exclusivity period in the framework of the abridged procedure, AstraZeneca could not rely on any property rights in the data.[183] The GC implicitly distinguished *AstraZeneca* from one of the most important judgment concerning essential facilities standard, *Microsoft* which presented a case on refusal to provide access to information as trade secrets, by addressing that AstraZeneca's allegedly abusive behavior was "*not a refusal to give access to the results of the pharmaceutical and toxicological tests and clinical trials contained in the file, since AZ cannot, in any event, use its alleged property right to prevent the national authorities from relying on the data in question in the abridged procedure."*[184]

Secondly, regarding the standard to be applied, the GC needed an indication that the registration gave rise to regulatory barriers against the market entry of generic products and against parallel imports of such products.[185] Hence, the GC reaffirmed the concept of "abuse" as an objective one by establishing that Article 102 TFEU did not require a "malevolent" or "intentional" foreclosure strategy.[186] Nonetheless, the GC mentioned that there was sufficient evidence indicating that AstraZeneca was "*aware of the utility that the deregistration of the*

[180] The essential facilities doctrine imposes on owners of essential facilities a duty to deal with competitors. The doctrine was first developed in the United States. Under EU law, the development of the essential facilities doctrine has been based on Article 102 TFEU. This provision prohibits abuses of dominant position within the common market. A refusal to deal can indeed constitute an abuse of dominant position under Article 102 TFEU. The most-known judgments are those in CJEU, 6 April 1995, in joined cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission*; CJEU, 26 November 1998, in case C-7/97, *Oscar Bronner*; CJEU, 29 April 2004, in case C-418/01 *IMS Health;* CJEU, 17 September 2007, in case T-201/04 *Microsoft v Commission.*
[181] *AstraZeneca* judgment before the GC, supra note 126, para. 678-682.
[182] *AstraZeneca* judgment before the GC, supra note 126, para. 680.
[183] *AstraZeneca* judgment before the GC, supra note 126, para. 681.
[184] *AstraZeneca* judgment before the GC, supra note 126, para. 682.
[185] *AstraZeneca* judgment before the GC, supra note 126, paras 608 and 814.
[186] *AstraZeneca* judgment before the GC, supra note 126, para. 813.

Losec capsule marketing authorization might have the purposes of raising barriers to entry a regulatory nature".[187]

With respect to the concrete effects on the market, the GC abstained from requiring the Commission to precisely assess the delay of the market entry of generic products led by the deregistration. Rather, it was considered sufficient that the deregistration caused the unavailability of the abridged procedure.[188] Further, in the GC's view, given that alternative routes seemed to be less favorable and more burdensome and costly than abridged procedure, the availability of such alternative routes for obtaining the marketing authorization did not suffice to remove the abusive nature of the conduct of an undertaking in a dominant position where that conduct, considered objectively, has the sole objective of making the abridged procedure unavailable and accordingly, of keeping generic producers away from the market for as long as possible and increasing their costs in overwhelming barriers to market entry.[189] The GC, in this respect, also reinforced its argument by referring to the internal strategy documents of AstraZeneca that manifested a plan to impede generic entrants.

Lastly, *AstraZeneca* case also presents an issue of causation, because it was possible for AstraZeneca to rely on formulation patents and SPCs in Denmark, Norway and Sweden for blocking market entry of generics. In this respect, the GC declined the argument according to which alternative regulatory and judicial tools rendered the deregistration of Losec capsules non-abusive by simply pointing out that the deregistration "*was in any event such as to restrict competition".*[190] Such defense may seem problematic within the context of the legal concept of causation. According to the GC, the alternative routes for market entry of generics would have the effect of slowing the market access. Nevertheless, it should be also noted that those other tools would not have provided AstraZeneca with absolute legal certainty that generic products would effectively be prevented from entering the market.[191]

Furthermore, the GC held that a dominant undertaking's pursuit of a strategy "*whose object is to minimize erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process".*[192] It continued by pointing out a significant condition that such strategy must involve only practices "*coming*

[187] *AstraZeneca* judgment before the GC, supra note 126, para. 814.
[188] *AstraZeneca* judgment before the GC, supra note 126, para. 831.
[189] *AstraZeneca* judgment before the GC, supra note 126, para. 829.
[190] *AstraZeneca* judgment before the GC, supra note 126, para. 836.
[191] DREXL, *AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?,* in *Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02,* p.11
[192] *AstraZeneca* judgment before the GC, supra note 126, para. 804.

within the scope of competition on merits, which is such as to benefit consumers".[193] But, in this respect, it has to be addressed that while condemning the AstraZeneca's conduct, the GC did not require proving consumer harm in addition foreclosure effect. However, such requirement had been previously stipulated by the former CFI in the *GlaxoSmithKlein*[194] case for the application of ex-Article 81 (Article 101 TFEU). Nevertheless, it was then rejected by the CFI in its appeal.[195] The GC, in its *AstraZeneca* judgment, seems to have pursued this approach without any discussion.[196]

The GC also referred the issue of justification several times. Basically, the GC clarified that AstraZeneca was not able to rely on its legitimate commercial interests in protecting its investments in the production of data on which generic producers rely when they apply for marketing authorization.[197] In parallel with the reasoning concerning the first abuse, the GC takes a legislative decision on the data exclusivity term under Directive 65/65 as the reference point for accepting a pro-competitive justification. Therefore, the GC asserted that after the expiry of this exclusivity period, the AstraZeneca's justification claim for delaying the market entry of generics in the light of its own incentives to innovate became baseless.[198]

In addition, the GC claimed that AstraZeneca had not adduced evidence indicating that deregistration was necessary or useful to the introduction of the new form of Losec (i.e. a legitimate business rationale for deregistering Losec capsules). Having regard to the level of safety of drugs evidenced after several years of marketing, the GC was not convinced that the deregistrations were necessary for the purpose of avoiding a considerable burden arising from the pharmacovigilance obligations of the holder of the marketing authorization.[199] Particularly, the AstraZeneca's conduct was deemed as inconsistent, and short of business rationale because it had not deregistered Losec capsules in Germany where the pharmacovigilance obligations were strictest.[200]

The GC overturned the Commission's finding of abuse in relation to the impact of the behavior at stake on parallel importers. Particularly, at the time of AstraZeneca's behavior it

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[193] *Ibid.*
[194] CFI's GSK Spain ruling, n. 71
[195] GSK Spain appeal, n. 71, para. 63.
[196] Furthermore, it should be noted that the GC for purposes of applying ex-article 82 EC, declined the consumer-harm approach, even before the CJEU *GlaxoSmithKlein* decision, in its *Microsoft* judgment. *See*, CJEU, 17 September 2007, in case T-201/04 *Microsoft v Commission*, para. 664.
[197] *AstraZeneca* judgment before the GC, supra note 128, para. 681.
[198] *AstraZeneca* judgment before the GC, supra note 128, paras 674 *et seq*. and 812.
[199] *AstraZeneca* judgment before the GC, supra note 128, para. 689 *et seq*.
[200] *AstraZeneca* judgment before the GC, supra note 128, para. 689 *et seq*.

was vague whether an import license could legally be withdrawn or refused on the basis that there was no reference authorization in force for the product in the destination country. In this respect, the GC stated that the Commission had not produced sufficient evidences that the authorities in Denmark and Norway were indeed likely to withdraw competitors' import licenses following AstraZeneca's deregistration of its marketing authorizations. Accordingly, although AstraZeneca's strategy in its entirety could be considered to have had anti-competitive object, the Commission had not adduce evidence thereby not showing the requisite standard that AstraZeneca's behavior was capable of restricting parallel imports into Denmark or Norway. Based on this finding, the GC reduced AstraZeneca's fine from EUR 60 million to EUR 52.5 million.

According to the opposing views[201], the GC's decision entirely suggested a narrow interpretation of the concepts of "competition on merits" and "objective justification" and this would put dominant undertakings relying heavily on IPRs and regulatory strategies at a considerably disadvantaged position. Pursuant to these views, such companies would be confronted with a high level of uncertainty regarding which IPRs and regulatory practices are permissible. By way of analogy, if a company creates a number of patents around the original patent for the purposes of preventing companies from entering the market on the basis of a product, this could supposedly be challenged as an exclusionary IP strategy that is not competition on merits. Further, it is argued that this narrow interpretation which is likely to lead to uncertainty would urge the companies to reconsider what is generally accepted to be normal competitive behavior in industries where IP is a core asset and/or that are highly regulated.

4.4 The Court of the European Union's Judgment

4.4.1 Market Definition and Dominance

The CJEU upheld the market definition suggested by the Commission, and accepted by the GC, where the market was limited to PPIs, a new category for treatments for hyperacidity. AstraZeneca had argued that Losec, which was the pioneer of PPI, was in competition with other drugs to treat hyperacidity, particularly an older kind of drug H2 blockers. The CJEU upheld the GC's approach according to which this was a market having asymmetrical substitutability (i.e. the treatment of more severe symptoms involved replacing H2 blockers by PPIs which were a more powerful medicine. Nevertheless, the competitive

[201] *See e.g.* HULL, *The Application of EU Competition Law in the Pharmaceutical Sector*", in *Journal of European Competition Law & Practice*, 2011, no. 2(5), 480-488, p. 486.

constraints exercised by the two products groups were not reciprocal in that PPIs exercised a constraint on H2 blockers but not vice versa) and which PPIs were in a distinct. The most striking findings of the CJEU can be identified as follows.

First, the CJEU argued that the relevant market must be set for the entire period of abuse.[202] It is not sufficient for the Commission to determine the market only at the end of the abuse period. The CJEU assessed the evidence employed by the GC's and upheld the GC's approach. However, such principle will be evolving and of ongoing relevance to prospective dominance cases in the pharmaceutical sector.

AstraZeneca claimed in its appeal before the CJEU that the GC had erred in law by failing to properly analyze the relevance of the gradual nature of the increase in the use of PPIs at the expense of H2 blockers as well as the inertia of doctors prescribing PPIs, and had thus not taken into consideration the substantial competitive constraint on H2 blockers. In return, the CJEU upheld the GC's findings that the gradual nature of the increase in sales of a new drug was owing to prescriber inertia namely, doctors did not promptly start prescribing a new medicine until information concerning its properties and particularly potential side-effects had been disseminated.[203] The CJEU found that the slow increase in sales of the new medicine was not indicative of the significant restraint of the existing product on the new product.[204] The CJEU also continued that prescriber inertia boosted the market position of the first marketed product on the market (such as Losec which was the first product of PPIs) since it had already created a solid brand image and reputation, meanwhile doctors would hesitate to prescribe other PPIs newly entering into the market owing to inertia.[205]

The CJEU also pointed out the potential relevance of price competition in terms of competitive constraint. The judgment does not directly address AstraZeneca's argument that the GC had erred in applying the legal standard when stating that the determination of cost-effectiveness was likely to be complicated and thus the GC would not reversed the Commission's decision since it had not been demonstrated that the Commission had made a manifest error in its evaluation. The CJEU declined this argument by stating that the GC's assessment that H2 blockers did not exert a significant competitive restraint on PPIs in terms of price constraint was founded on various elements and that even if it erred in one, this would not affect the bottom-line. The CJEU particularly stated the GC's comments that (i)

[202] *AstraZeneca* judgment before the CJEU, supra note 128, para. 37.
[203] *AstraZeneca* judgment before the CJEU, supra note 128, para. 47.
[204] *AstraZeneca* judgment before the CJEU, supra note 128, para. 48.
[205] *AstraZeneca* judgment before the CJEU, supra note 128, para. 50.

doctors and patients had limited sensitivity to prices and (ii) the regulatory systems in force in the relevant Member States were not designed in such a way as to enable the prices of H2 blockers to exercise downward price pressure on PPIs.[206] It also noted that having regard to the fact that the the therapeutic superiority of PPIs were heavily determined by doctors and patients, price pressures would, under any circumstances, not have eliminate the fact that H2 blockers were not able to exercise significant competitive constraint over PPIs.[207]

As to an issue addressed by EFPIA, the CJEU also deemed the role of the state as monopsonist purchaser. The CJEU considered that the GC's assessment in relation to the state's role (which elicited EFPIA's critics) was "*particularly detailed*".[208] The CJEU affirmed the GC's finding that, even though the price and reimbursement level are set by public authorities, the capability of a pharmaceutical company to obtain a higher price/reimbursement level varies on the basis of the added and innovative value of the product. Therefore AstraZeneca, whose product's (i.e. Losec) therapeutic efficiency was much higher than the H2 blockers, obtained a higher price.[209] The CJEU also mentioned the advantage of "*first-mover status*" for the pioneer products in a new group of drugs which they tend to take advantage of high reimbursement levels (despite health authorities' efforts to decrease health expenditure) and they also enjoy a position that enables the firm to set its price at a high level without having to concern about patients and doctors switching to less costly drugs.[210]

Lastly, the CJEU held that it is acceptable to show regard to IPRs for finding dominance. Nonetheless, in line with the GC's finding, the CJEU held that the sole existence of IPRs does not confer a position of dominance but rather it constitutes one of the components that can be taken into consideration. In fact, the existence and use of IPRs were "*only one of the various factors on which the Commission based the finding in this case that AZ held a dominant position*".[211] Such approach did not, in all circumstances, tantamount to that "*companies introducing innovative products on the market should refrain from acquiring a comprehensive portfolio of intellectual property rights or from enforcing those rights*." [212]

[206] *AstraZeneca* judgment before the CJEU, supra note 128, para. 57.
[207] *AstraZeneca* judgment before the CJEU, supra note 128, para. 58.
[208] *AstraZeneca* judgment before the CJEU, supra note 128, para. 178.
[209] *AstraZeneca* judgment before the CJEU, supra note 128, para. 179.
[210] *AstraZeneca* judgment before the CJEU, supra note 128, para. 180.
[211] *AstraZeneca* judgment before the CJEU, supra note 128, para. 187.
[212] *AstraZeneca* judgment before the CJEU, supra note 128, para. 188.

As a result, the CJEU reiterated that a finding that a dominant company "*is not in itself a criticism of the undertaking concerned*".[213]

To sum up, the CJEU's market definition assessment suggests that therapeutic considerations constitute the benchmark to pharmaceutical market definition. Nevertheless, it can be inferred that in future, the increased efforts of health authorities to cut healthcare expenditure and to ensure cost effectiveness may have more of an influence on market definition, and price factors may become more of an issue in the analysis.

4.4.2 Abuse of Dominant Position

4.4.2.1 First Abuse: Misuse of the Patent System

In its appeal, AstraZeneca claimed that the GC had taken a legally flawed approach to "*competition on the merits*" when holding that AstraZeneca's non-disclosure to the public authorities of its interpretation of the law in relation to the reference date (i.e. first authorization date) on which it based its SPC applications did not fall within the scope of competition on the merits. AstraZeneca argued that the GC erred in assessing its conduct as an abuse. That is to say that AstraZeneca claimed that its conduct cannot be deemed as abusive based on the mere fact that a dominant company seeks a right without disclosing the elements on which it bases its opinion. Accordingly, AstraZeneca brought a counterclaim according to which "*a lack of transparency*" rather than deliberate fraud or deceit could not be sufficient for there to be an abuse and that to accept such a position is likely to impede and delay applications for IPRs in Europe. However, the CJEU rejected AstraZeneca's arguments.

The CJEU, at the outset, referred to its established precedents, namely that an undertaking in a dominant position is under a special responsibility and that it is abusive for such an undertaking to strengthen its position by using means other than those which fall within the scope of "*competition on the merits*".[214] The CJEU then went through the facts with a rather harsh tone.[215] The CJEU listed a series of misrepresentations by AstraZeneca between 1993 and 2000. The CJEU found that AstraZeneca was aware of what it was doing was not right. However, although AstraZeneca could not "*reasonably be unaware*" of the outcomes of its actions, it carried on "*over the long term*".[216] The CJEU stated that

[213] *Ibid.*
[214] *AstraZeneca* judgment before the CJEU, supra note 128, paras 74-75.
[215] *AstraZeneca* judgment before the CJEU, supra note 128, paras 78-92.
[216] *AstraZeneca* judgment before the CJEU, supra note 128, paras 79,81, 84.

AstraZeneca's internal documents were also indicative of AstraZeneca's awareness of the consequences of its conduct.[217]

The CJEU reached a conclusion that "*AZ's consistent and linear conduct*", which was specified as "*highly misleading representations and by a manifest lack of transparency*" and "*by which AZ deliberately attempted to mislead the patent offices and judicial authorities in order to keep for as long as possible its monopoly on the PPI market*" did not amount to competition on the merits.[218]

The CJEU held that the burden was on AstraZeneca to disclose to the patent authorities all relevant information to allow them to decide which authorizations to accept. According to the CJEU, if AstraZeneca had an alternative interpretation which it considered was reasonable and was likely to be followed both by the national courts and by the CJEU, it was supposed to disclose its interpretation to the authorities.[219]

The CJEU put forth that AstraZeneca's recourse to highly misleading misrepresentations for the purpose of leading public offices into error was obviously inconsistent with competition on the merits or with a dominant company's special responsibility.[220]

Lastly, the CJEU presented some elucidation to the pharmaceutical sector.[221] It pointed out that it cannot be inferred from the GC judgment that any patent application which is rejected based on the fact that it does not meet the requirements for patentability automatically leads to liability under Article 102 TFEU.[222] Given the context of the CJEU's overall findings, i.e. the fact that AstraZeneca's behavior was "*highly misleading*" and the CJEU's rather offensive description of AstraZeneca's behavior, it is apparent that the *AstraZeneca* precedent suggests much narrower scope. The CJEU mentioned that representations designed to obtain exclusive rights illicitly constitute an abuse only if it is demonstrated that the representations indeed enable the authorities to grant the exclusive right.[223] Therefore, in the countries where the misleading representations led AstraZeneca to gain illicit SPCs, this gave rise to a significant foreclosure effect after the expiry of the

[217] *AstraZeneca* judgment before the CJEU, supra note 128, paras 79,88, 90.
[218] *AstraZeneca* judgment before the CJEU, supra note 128, para. 93.
[219] *AstraZeneca* judgment before the CJEU, supra note 128, para. 95.
[220] *AstraZeneca* judgment before the CJEU, supra note 128, para. 98.
[221] *AstraZeneca* judgment before the CJEU, supra note 128, para. 99.
[222] *Ibid.*
[223] *AstraZeneca* judgment before the CJEU, supra note 128, para. 106.

original patents and also affected potential competition even before patent expiry.[224] Further, given that the representations were possibly result in the granting of illicit SPCs, in particular as AstraZeneca's behavior was part of an overall exclusionary strategy; the fact that the misrepresentations did not enable AstraZeneca to obtain SPCs in certain countries did not change the finding of abuse.[225]

The CJEU brought to a conclusion that whereas the acts of an undertaking in a position cannot be deemed as abusive in the absence of any anti-competitive effect on the market, such an effect does not necessarily have to be actualized, and it is sufficient to show that there is a potential anti-competitive effect.[226]

4.4.2.2 Second Abuse: Misuse of Procedures Relating to the Marketing of the Pharmaceutical Products

AstraZeneca brought an argument that the GC misconstrued the concept of "*competition on the merits*" and that GC condemned the mere exercise of a right to withdraw a marketing authorization conferred by EU law. According to AstraZeneca, the existence of a marketing authorization imposes strict pharmacovigilence obligations which may constitute a basis for justification with respect to the withdrawal of its marketing authorization in certain countries.

The CJEU rejected AstraZeneca's arguments and affirmed the GC's finding according to which the deregistration by AstraZeneca of its marketing authorization for Losec could be abusive, particularly because in the wake of the withdrawal, generic applicants were impeded from relying upon test data used in the original patent in their simplified application.

While the CJEU upheld the approach taken by the GC regarding the special responsibility of a dominant company, it argued that a dominant company is not prevented from developing a strategy aimed at preserving the existing level of sales, and that such a strategy to enable it to deal with competition from generic products is lawful and is a constituent of the regular competitive process.[227] Nevertheless, this conduct must not deviate from practices falling within the scope of competition on the merits which have a capacity to provide benefit for consumers.[228]

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[224] *AstraZeneca* judgment before the CJEU, supra note 128, para. 108.
[225] *AstraZeneca* judgment before the CJEU, supra note 128, para. 111.
[226] *AstraZeneca* judgment before the CJEU, supra note 128, para. 112.
[227] *AstraZeneca* judgment before the CJEU, supra note 128, para. 129.
[228] *Ibid.*

The CJEU continued that deregistration, without any objective justification, and after the expiry of the exclusive right to make use of its clinical data, by which AstraZeneca aimed at preventing the market access of generic products and parallel imports, does not amount to competition on the merits.[229] The CJEU noted that since AstraZeneca no longer had the exclusive right on its clinical data, deregistration was not relate, in any way, to the legitimate protection of an investment which fell within the scope of competition on the merits.[230]

Further, the CJEU found that the fact that under EU law (i.e. Directive 65/65), AstraZeneca was entitled to request the withdrawal of its market authorization for Losec capsules, in no way leaves a leeway to circumvent the prohibition laid down in Article 102 TFEU.[231] Conduct can be deemed as abusive under the competition rules irrespective of whether it is in compliance with other legal rules, in particular when these legal rules pursue different objectives to Article 102 TFEU.[232]

The CJEU upheld that a company in dominant position, subject to the special responsibility, cannot take advantage of regulatory procedures in such a way as to prevent or complicate the entry of competitors into the market in the absence of grounds in relation to the defense of the legitimate interests of a company engaged in competition on the merits or in the absence of objective justification.[233] However, this seems quite vague and it may have to be clarified in future cases. Specifically to the pharmaceutical sector, the CJEU also found that whereas theoretically pharmacovigilence obligations could constitute an objective justification, in practice AstraZeneca's conduct had not suggested it.[234]

The CJEU also elucidated that the conduct of deregistration by itself constituted the abuse and that the launch of a new generation Losec constituted only the context within which the deregistration abuse took place.[235]

The CJEU dismissed AstraZeneca's argument that the *IMS Health*[236] case law on compulsory licensing (i.e. a refusal to license an IPR is only considered abusive in exceptional circumstances) should be applied to this case. Because it held that the dominant undertaking's option to deregister a market authorization (for the purposes of preventing or complicating the entry of competitors into the market) is not tantamount to a property right

[229] *AstraZeneca* judgment before the CJEU, supra note 128, para. 130.
[230] *AstraZeneca* judgment before the CJEU, supra note 128, para. 131.
[231] *AstraZeneca* judgment before the CJEU, supra note 128, para. 132.
[232] *AstraZeneca* judgment before the CJEU, supra note 128, paras 132-133.
[233] *AstraZeneca* judgment before the CJEU, supra note 128, paras 134.
[234] *AstraZeneca* judgment before the CJEU, supra note 128, paras 135-136.
[235] *AstraZeneca* judgment before the CJEU, supra note 128, para. 140.
[236] *See* supra note 180.

and thus does not constitute an effective expropriation but a straightforward restriction under EU law.[237] Therefore the CJEU explicitly distinguished this case from a compulsory license, finding that this was in no way an exceptional case and does not justify derogation from Article 102 TFEU.[238]

Ultimately, the CJEU put forth that the deregistration abuse may be relatively wide in ambit, especially because the higher standard for exceptional circumstances does not apply.

4.5 The Implications of the *AstraZeneca* Case

The *AstraZeneca* case, which is was considered as significantly extending the scope of the EU competition law on abuse of dominance, has resulted in uncertainty to all companies that are subject to some form of regulation. Thus, the effects of this judgment resonate beyond the pharmaceutical sector. This is the first case in which abuse of patent and regulatory procedures was held to be an abuse of a dominant position under the EU competition law, and it is confirmed in the CJEU's judgment that it is not sufficient to abide by the rules of a particular regulatory framework. Therefore, it was suggested that both actual and potential competitive impact of a regulatory strategy must also be taken into account. The exploitation of seemingly lawful loopholes, or otherwise gaming the system, can have significant unfavorable consequences, even in the absence of a bad faith intention to exclude competitors. This approach, which sets a low benchmark for competition-law liability in case of such patents filings, imposes a set of onerous but not fully clear obligations on the pharmaceutical industry. Setting a system comprising of more checks and balances to their pharmaceutical companies' internal procedures has become necessary. Strategic corporate decisions should be particularly carefully scrutinized when a product is close to patent expiry.

As discussed, the fact that the relevant ruling, combined with a considerable lack of practical guidance, will offer little area in which companies, particularly those with a dominant position in the market, can act. While the CJEU recognized that it is lawful for companies to adopt competitive strategies, this does not suggest a conventional wisdom and it rather brings an observation in relation to the facts of this specific case. Therefore, there remains some uncertainty as to how the CJEU's judgment will be applied in practice. It is beyond doubt that the effects of this judgment resonate beyond the pharmaceutical sector. The

[237] *AstraZeneca* judgment before the CJEU, supra note 128, para. 149.
[238] *AstraZeneca* judgment before the CJEU, supra note 128, para. 150.

main lesson learnt from this case is to proceed with caution both in the way they manage their IP portfolios and the way in which they engage with regulatory authorities.[239]

This has wide implications for the way dominant companies conduct themselves. Indeed, the low benchmark set by the CJEU may result in that competition law would work as a deterrent to companies from using patent system even for pro-competitive purposes. Therefore, competition-law liability in patent filings cases has to remain as the very rare exception rather than a ground for frequent enforcement action.

Besides, the *AstraZeneca* case's impact has been already absorbed by the pharmaceutical sector in the many years since the Commission's 2005 decision. Nonetheless this judgment is final confirmation of a significant concept- that mere recklessness or sleight of hand in dealing with regulatory bodies may suffice to incur the abuse of dominance. The *AstraZeneca* case has been more influential than the Sector Inquiry and it is also notable that national competition authorities who were emboldened by this judgment have issued decisions similar to the *AstraZeneca* case. As a matter of fact, national competition authorities have already pursued this novel approach while initiating an investigation. In this respect, in the UK, the OFT investigated Reckitt Benckiser in relation to its medicine, Gaviscon and held that the company had abused its dominant position by withdrawing and de-listing Gaviscon Original Liquid from National Health Service's computerized prescribing formulary with the object of restricting pharmacy choice and driving generics out of the market.[240] Likewise, the Italian Competition Authority has found an abuse and imposed a fine on Pfizer on the ground of delays in the market entry of generic products by unduly prolonging patent protection through the use of SPCs.[241] It should also be noted that the Authority's decision was subsequently reversed by the regional administrative court for failure by the Authority to prove sufficient intent. Furthermore, the Authority's decision even went beyond the scope of the CJEU's judgment in qualifying patent related behavior as abusive, thereby suggesting that mere reliance on such patent instruments can constitute an abuse.[242]

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[239] CANA, MEREU and VAN MALDEGEM, *AstraZeneca Loses Appeal at ECJ*, in *Mondaq (Newsletter)*, 25 January, 2013, available at http://www.mondaq.com/x/217344/Patent/AstraZeneca+loses+appeal+at+ECJ

[240] *See*, e.g., NORDLANDER and HARRISON, *Abuse of Regulatory Procedures in the Pharmaceutical Sector- Developments Since the General Court's Judgment in AstraZeneca*, in *Competition Policy International*, July 2012, p.4.

[241] Decision of the Italian Competition Authority of 11 January 2012, Case A431- *Ratiopharm/ Pfizer*, Bulletin No. 26/2011, p.5 (hereinafter called *Pfizer Decision)*

[242] *See*, e.g. DE STEFANO, *Tough Enforcement of Unilateral Conduct at the National Level: Italian Antitrust Authority Sanctions Bayer and Pfizer for Abuse of Dominant Position (aka AstraZeneca Ruling and Essential*

As a result of the *AstraZeneca* case, dominant undertakings are confronted with acute legal risks in this area since it is not possible to mention about a clear line dividing abusive conduct and normal "competition on merits". Such legal risks are particularly acute for a dominant undertaking if it is threatened with new entrants into market and/or if the dominant undertaking is aiming at protecting an asset that is approaching the end of a term of a period of regulatory protection (e.g. where a patent is about to expire.) Therefore, it is also expected to result in more cases of this nature being brought.

Facility Doctrine in Italian Sauce), in *Journal of European Competition Law & Practice,* 2012, no. 3 (4), 396-403, p. 400; GIANNINO, *Beware of competition law! Relying on patents to extend protection for medicines may be competitive*, in *Journal of Intellectual Property Law & Practice,* 2012, no.7(6), 391-391, p. 391; GIANNINO, *Patent procedures misuse and drugs: Italian Competition Authority's Pfizer ruling annulled*, in *Journal of Intellectual Property Law & Practice,* 2013, no. 8 (2), 95-96, p. 95.

CONCLUSION

The central concern with respect to the IP and competition law intersection is whether competition law can prohibit practices that are in compliance with IP law namely whether competition law can be used as a means to control a conduct that is permitted under IP laws, and in favour of immunizing it from liability.[243] Accordingly, because the goal of competition law is to protect competition on merits, it may not strike behavior that is entirely consistent with well-functioning IP regimes, which are intended for fostering innovation. This would true even or particularly for dominant companies. On the other hand, it could be contended that the said position goes too far. Accordingly, some behaviors which are IP-compliant have been held unlawful since it creates barriers against follow-on innovation and therefore is capable not only protecting market power but also of jeopardizing innovation.

The core issue of the thesis is to determine whether the competition rules may be used to place limits on the ability of pharmaceutical companies to exercise and defend their IPRs. In this regard, the AstraZeneca case which is the first and the sole instance in which the Commission and the EU Courts have found abuse of a dominant position in the pharmaceutical sector, has rekindled the debate over the treatment of certain IP and regulatory strategies under the competition law and has encouraged the Commission to challenge a wider range of practices. However, these developments including Sector Inquiry and *AstraZeneca* case over the past years have created uncertainty for companies operating the pharmaceutical than they have provided any meaningful guidance.

Even if alternative legal remedies (e.g. in patent law) may be available to an allegedly excluded firm, the conduct of the course of intellectual property and similar regulatory procedures may constitute abuse. The threshold is set as very low according to which only the capability of having anti-competitive effects is found sufficient for finding breach. Therefore, it is significant for companies to document cautiously any pro-competitive reasons for commercial strategy and to abstain from generating documents wrongly suggesting a strategy of spoiling tactics. *AstraZeneca* case may appear to set a limit on a company's options for managing its IPRs, especially by conceiving them as an "anti-generic weapon"[244]. From

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[243] HARACOGLOU, *Competition Law and Patents A Follow-on Innovation Perspective in the Biopharmaceutical Industry*, Edward Elgar: Cheltanham, UK; Northampton, MA, USA, 2009, p. 116.

[244] This term is quoted from "DIENY, *The Pharmaceutical Industry and Competition Law Between the Present and the Future*, in *European Competition Law Review*, 2007, no. 28(4), 223-232, p. 224."

another perspective, the *AstraZeneca* case does not guide with respect to IP-compliant behavior because it addressed a scenario where incompliance is plain and clear.

Indeed, competition law cannot be applied in a vacuum and it is critical that the policies underlying the IP rules and pharmaceutical regulatory rules that are at the heart of the generics debate should not be undermined. On the other hand, originator companies which can be considered as the engines of market with their valuable input to the market should not be slid into uncertainty in their business activities. As a policy consideration, 'antitrust limitations should be desirable unless they result in a net decrease in innovation'.[245]

The effects of this case may also be felt beyond the pharmaceutical sector. Accordingly, the broad language of the judgment gives rise to implications for not only pharmaceutical companies, but for any company relying on IP and regulatory strategies to protect its market. Pursuant to the rulings, dominant companies have a special responsibility, more particularly an obligation to conduct in a transparent way in their dealings with the authorities.

[245] LAO, *Unilateral Refusals to Sell or License IP and the Antirust Duty to Deal*, in *Cornell Journal of Law & Public Policy*,1999, no.9, p.193.

BIBLIOGRAPHY

All websites last accessed on 14 February 2014

Books

ANDERMAN and SCHMIDT, *EU Competition Law and Intellectual Property Rights The Regulation of Innovation*, New York: Oxford University Press: 2011.

CANA, MEREU and VAN MALDEGEM, *AstraZeneca Loses Appeal at ECJ*, in *Mondaq (Newsletter),* 25 January, 2013, available at http://www.mondaq.com/x/217344/Patent/AstraZeneca+loses+appeal+at+ECJ

DANZON, *Reference Pricing: Theory and Evidence,* in LOPEZ-CASASNOVAS and JÖNSSON, *The Economics of Reference Pricing and Pharmaceutical Policy,* 2011, 86-126.

DESOGUS, *Competition and Innovation in the EU Regulation of Pharmaceuticals: The Case of Parallel Trade*, Bologna: Intersentia Uitgevers, 2011.

FINK, *International Price Discrimination and Market Segmentation for Patented Pharmaceuticals in the EU. A Social Welfare Analysis- A Comment*, in GOVAERE and ULLRICH, *Intellectual Property, Public Policy and International Trade*, College of Europe Series No 6, Brussels: P.I.E. Peter Lang, 2007.

HANCHER, *The European Community Dimension: Coordinating Divergence, The Politics of Pharmaceuticals in the European Union,* in MOSSIALOS, MRAZEK, and WALLEY, *Regulating Pharmaceuticals in the Europe: Striving for Efficiency, Equity and Quality*, Berkshire: Open University Press, 2004, 55-79.

HANCHER, *The EU Pharmaceuticals Market: Parameters and Pathways*, in MOSSIALOS, PERMANAND, BAETEN and HERVEY, *Health Systems Governance in Europe the Role of European Union Law and Policy,* Cambridge: Cambridge University Press, 2010, 635-682.

HARACOGLOU, *Competition Law and Patents A Follow-on Innovation Perspective in the Biopharmaceutical Industry*, Edward Elgar: Cheltanham, UK; Northampton, MA, USA, 2009.

HUNTER, *The Pharmaceutical Sector in the European Union: Intellectual Property Rights, Parallel Trade and Community Competition Law*, Stockholm: Juristförlaget, 2001.

NISSEN, VAN DE WALLE GHELCKE and VILARASAU, *Chapter 15: Competition Law in the Pharmaceutical Sector* , in SHORTHOSE, *Guide to EU Pharmaceutical Regulatory Law,* The Netherlands: Wolters Kluwer, 2011, 503-531.

PERMANAND, and ALTENSTETTER, *The Politics of Pharmaceuticals in the European Union*, in MOSSIALOS, MRAZEK, and WALLEY, *Regulating Pharmaceuticals in the Europe: Striving for Efficiency, Equity and Quality*, Berkshire: Open University Press, 2004, 38-54.

ULLRICH and DREXL, *Is there a More Economic Approach to Intellectual Property and Competition Law*, in DREXL, *Research Handbook on Intellectual Property and Competition Law,* Cheltenham, UK and Northampton, MA, USA: Edward Elgar, 2008.

Articles

AITMAN and JONES, *Competition and Copyright Owner Lost Control?*, in *European Intellectual Property Review,* 2004.

BATCHELOR, *EC tones down its final report into the pharma sector, but ramps up enforcement activity*, in *European Competition Law Review*, 2010, 31(1), 16-20.

BOER, EDMONDS, GLYNN and OGLIALORO, *Economic Aspects of the Single Market in Pharmaceuticals*, in *European Competition Law Review*, 1999, no. 12(3), 256-264.

DE STEFANO, *Tough Enforcement of Unilateral Conduct at the National Level: Italian Antitrust Authority Sanctions Bayer and Pfizer for Abuse of Dominant Position (aka AstraZeneca Ruling and Essential Facility Doctrine in Italian Sauce)*, in *Journal of European Competition Law & Practice*, 2012, no. 3 (4), 396-403.

DIENY, *The Pharmaceutical Industry and Competition Law Between the Present and the Future*, in *European Competition Law Review,* 2007, no. 28(4), 223-232.

DI MASI, HANSEN and GRABOWSKI, *The Price of Innovation: New Estimates of Drug Development Costs*, in *Journal of Health Economics*, 2003, no.22, 151-185.

DREXL, *Anticompetitive Stumbling Stones on the Way to a Cleaner World: Protecting Competition in Innovation without a Market*, in *Journal of Competition Law & Economics*, 2012, no. 8(3), 507-543.

DREXL, *AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law?*, in *Max Planck Institute for Intellectual Property and Competition Law Research Paper* No. 12-02.

EZRACHI and MAGGIOLINO, *European Competition Law, Compulsory Licensing, and Innovation*, in *Journal of Competition Law & Economics,* 2009, no. 8 (3), 595-614.

FAGERLUND and RASMUSSEN, *AstraZeneca: the first abuse case in the pharmaceutical sector*, in *Competition Policy Newsletter, 2*005, no. 3, 54-56.

FERNANDEZ VICIEN, *Why Parallel Imports of Pharmaceuticals Should be Forbidden,* in *European Competition Law Review,* 1996, no. 17(4) 219-225.

GALLOWAY, *Driving Innovation: A Case for Targeted Competition Policy in Dynamic Markets,* in *World Competition,* 2011, no 34(1), 73-96.

GIANNINO, *Beware of competition law! Relying on patents to extend protection for medicines may be competitive*, in *Journal of Intellectual Property Law & Practice,* 2012, no.7(6), 391-391.

GIANNINO, *Patent procedures misuse and drugs: Italian Competition Authority's Pfizer ruling annulled,* in *Journal of Intellectual Property Law & Practice*, 2013, no. 8 (2), 95-96.

HANCHER, *The European Pharmaceutical Market: Problems of Partial Harmonization,* in *European Law Review*, 1990, no. 15(1), 9-33.

HULL, *The Application of EU Competition Law In The Pharmaceutical Sector*, in *Journal of European Competition Law & Practice*, 2010, no.1(5), 429-437.

HULL, *The Application of EU Competition Law in the Pharmaceutical Sector*, in *Journal of European Competition Law & Practice*, 2011, no. 2 (5), 480-488.

JUNOD, *An End to Parallel Imports of Medicines? Comments on the Judgment of the Court of First Instance in GlaxoWellcome,* in *World Competition*, 2007, no. 30(2), 291-306.

KAR and MCGRATH, *EU scrutiny of the pharmaceutical sector since the European Commission's sector inquiry*, in *Linklaters Newsletter*, May 2012.

KAVANOS, *Overview of Pharmaceutical Pricing and Reimbursement Regulation in Europe,* LSE Health Working Paper, 2001, available at http://www.eco.uc3m.es/servicios/sesam/actividades/jornada_legislacion/DOC%209%20EMEARoadMap.pdf

KJOLBYE, *Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?*, in *World Competition,* 2009, no. 32 (2), 163-188.

LAO, *Unilateral Refusals to Sell or License IP and the Antirust Duty to Deal*, in *Cornell Journal of Law & Public Policy,*1999, no.9.

LAWRANCE and TREACY, *The Commission's AstraZeneca decision: Delaying generic entry is an abuse of dominant position*, in *Journal of Intellectual Property Law and Practice*, 2005, no 1(1).

MANELY and WRAY, *New pitfall for the pharmaceutical industry*, in *Journal of Intellectual Property Law and Practice*, 2006, no 1 (4), 266-271.

MCMOHAN, *Interoperability: "Indispensability" and "Special Responsibility"* in *High Technology Markets*, in *Tulane Journal of Technology and Intellectual Property*, 2007, no. 9.

MURPHY, *Abuse of regulatory procedures*, in *European Competition Law Review*, 2009, 30(5), 223-229.

MURPHY, *Abuse of Regulatory Procedures-the AstraZeneca Case: Part 2*, in *European Competition Law Review*, 2009, no 30(6), 289-300.

MURPHY, *Abuse of regulatory procedures- the AstraZeneca Case: Part 3*, in *European Competition Law Review*, 2009, no. 30(7), 314-323.

NAZZINI, *Parallel Trade in the Pharmaceutical Market Current Trends and Future Solutions*, in *World Competition*, 2003, no. 26(1), 53-74.

NEEDLE, *A New European Patents Regime* on *Mondaq*, 29 January 2013, available at http://www.mondaq.com/x/218512/Patent/A+New+European+Patents+Regime

NEGRINOTTI, *Abuse of regulatory procedures in the intellectual property context: the AstraZeneca case*, in *European Competition Law Review*, 2008, no. 29 (8), 446-459.

NORDLANDER and HARRISON, *Abuse of Regulatory Procedures in the Pharmaceutical Sector- Developments Since the General Court's Judgment in AstraZeneca*, in *Competition Policy International*, July 2012.

REY and VENIT, *Parallel trade and pharmaceuticals: a policy in search of itself*, in *European Law Review 2004*, 29(2), 153-177.

SCHICHELS and SULE, *The Pharmaceutical Sector Inquiry and Its Impact on Competition Law Enforcement*, in *Journal of European Competition Law & Practice*, 2010, no.1(2),93-111.

STRAUS, *Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?*, in *Journal of European Competition Law & Practice*, 2010, no.1 (3), 189-201.

TUOMINEN, *Patenting Strategies of the EU Pharmaceutical Industry: Regular Business Practice or Abuse of Dominance*, in *World Competition* 35, no. 1 (2012), 27-54.

WESTIN, *Defining relevant market in the pharmaceutical sector in the light of the Losec case- just how different is the pharmaceutical market?,* in *European Competition Law Review, 2011,* no. 32 (2), 57-62.

Case Law

Italy

Decision of the Italian Competition Authority of 11 January 2012, Case A431- *Ratiopharm/ Pfizer,* Bulletin No. 26/2011.

European Union

European Commission Decision No. 94/770/EC of 6 October 1994 in case IV/34.776- *Pasteur Merieux-Merck*

European Commission Decision of 15 June 2005, 2006/857/EC in case No. COMP/37.507/F3-*AstraZeneca*

GC, 27 September 2006, in case T-168/01 *GlaxoSmithKlein Services Unlimited v Commission*

GC, 26 October 2006, in case T-41/96 *Bayer AG v Commission*

GC, 17 September 2007, in case Case T-201/04, *Microsoft Corp v Commission*

GC, 1 July 2010, in case T-321/05, *AstraZeneca v. Commission*

CJEU, 6 March 1974, in joined cases C-6-7/73, *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents v. Commission*

CJEU, 13 February 1979, in case 85/76, *Hoffmann-La Roche & Co AG v Commission*

CJEU, 10 July 1990, in case T-51/89, *Tetra Pak v Commission*.

CJEU, 6 April 1995, in joined cases C-241/91 P and C-242/91 P, *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission*

CJEU, 17 July 1998, in case T-111/ 96, *ITT Promedia NV v Commission*

CJEU, 26 November 1998, in case C-7/97, *Oscar Bronner*; CJEU, 29 April 2004, in case C-418/01 *IMS Health*

CJEU, 12 December 2000, in case T-128/98, *Aeroports de Paris v Commission*

CJEU, 30 September 2003, in case T-203/01, *Michelin v Commission*

CJEU, 11 December 2003, in case C-127/00 *Hassle AB v Ratiopharm GmbH*

CJEU, 6 January 2004, in joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure v Commission*

CJEU, 29 April 2004, in case C-418/01, *IMS Health GmbH* & Co. OHG v NDC Health GmbH & Co. KG

CJEU, 31 May 2005, in case C-53/03, *Reference for a preliminary ruling from the Epitropi Antagonismou in Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKlein plc and Others*

CJEU, 17 September 2007, in case T-201/04 *Microsoft v Commission*

CJEU, 16 September 2008, in joined cases C-468/06-C-478/06, *Sotiris Lelos kai Sia EE and Others v. GlaxoSmithKlein AEVE Farmakeftikon Proionton*

CJEU, 6 October 2009, in joined cases C-501/06 P, C-513/06 P, C-515/06 P and C-519/06 P *GlaxoSmithKlein Services v Commission*

CJEU, 6 December 2012, in case C-457/10 P *AstraZeneca v Commission*

Official Documents

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products.

Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products can be given as examples for the amended Council Directives.

Council Directive No. 2001/83/EC of 6 November 2001 on the Community Code Relating to Medicinal Product for Human Use

Council Regulation No. 1768/92/EEC of 18 June 1992 concerning the Creation of a Supplementary Protection Certificate for Medicinal Products

Council Regulation No. 141/2000 of 16 December 1999 on Orphan Medicinal Products

European Commission Communication to the Council and the European Parliament on the Outlines of an Industrial Policy for the Pharmaceutical Sector in the European Community, COM (93) 718 final of 2 March 1994

European Commission Communication on the Single Market in Pharmaceuticals, COM(98)588 final of 25 November 1998

European Commission Communication of 24 February 2009 on the Guidance on the Commission's Enforcement Priorities in Applying Article 82 EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings

European Commission Decision No. 2004/48/EC of 29 April 2004 on the enforcement of intellectual property rights, Recital 3, OJ L 195/16-25

European Commission Guidance on the Commission's Enforcement Priorities in Applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings of 27 April 2009, O.J. (C 45) 02

European Parliament and Council Directive No. 2001/83/EC of 6 November 2001

European Parliament and Council Directive No 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community Code Relating to Medicinal Products for Human Use

European Parliament and Council Regulation No. 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

Other Documents of European Commission

European Commission, *The Single Market Review: Subseries I: Impact on Manufacturing, Vol.2: Pharmaceutical Products*, in European Commission, *The Pharmaceutical Sector in the EU*, 1997.

European Commission, Directorate General for Competition, *Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses*, December 2005, available at http://ec.europa.eu/comm/competition/antitrust/art82/discpaper2005.pdf

European Commission, Commission launches sector inquiry into pharmaceuticals with unannounced inspections, Press Release No. IP/08/49 of 16 January 2008.

European Commission, *Public-Private Research Initiative to boost the competitiveness of Europe's pharmaceutical industry*, Press Release No. IP/08/662 of 30 April 2008.

European Commission, *Pharmaceutical Sector Inquiry Preliminary Report*, 28 November 2008, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

European Commission, Final Report of Sector Inquiry into Pharmaceuticals, 8 July 2009, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

European Commission, *Commission confirms surprise inspections in the pharmaceutical sector*, MEMO/09/435 of 6 October 2009, available at: http://europa.eu/rapid/press-release_MEMO-09-435_en.htm

European Commission, *The 2010 Industrial R&D Investment Scoreboard*, available at http://iri.jrc.es/research/docs/2010/SB_2010_BXL_17-11-2010.pdf

Other Sources

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *Intellectual Property and Pharmaceuticals,* 2008, available at http://www.efpia.eu/intellectual-property-and-pharmaceuticals-june-2008

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *The Pharmaceutical Industry in Figures,* Edition 2009, EFPIA Publication, p. 17, available at *http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA%20in%20Figures%202009-20080612-009-EN-v1%20(1)_0.pdf*

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *Considering the Impact: A European Patent with Unitary Effect and Unitary Patent Court,* 2012, available at http://www.efpia.eu/blogs/considering-impact-european-patent-unitary-effect-and-unitary-patent-court

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *Research and Innovation*, 2012, available at http://www.efpia.eu/topic-list/17

EUROPEAN FEDERATION OF PHARMACEUTICAL INDUSTRIES AND ASSOCIATION (EFPIA), *The Pharmaceutical Industry in Figures*, Edition 2012, EFPIA Publication, available at http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA_Figures_2012_Final-20120622-003-EN-v1.pdf

EUROPEAN GENERICS MEDICINES (EGA), *EGA Fact Sheet on Generic Medicines,* p.1 available at *http://www.egagenerics.com/images/EGA_factsheet_09.pdf*

European Patent Office, *Unitary Patent* available at http://www.epo.org/law-practice/unitary/unitary-patent.html

KALLAUGHER, *Pharmaceutical Sector Inquiry Competition Law Issues,* 2009, p.5 (PowerPoint presentation), available at http://www.ucl.ac.uk/laws/ibil/docs/ibil_21jan09_kallaugher_pp.pdf

KROES, *European Competition Policy: Delivering Better Markets and Better Choices, Remarks at European Consumer and Competition Day*, London," 15 September 2005, available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/05/512

MONTI, *Remarks at the 28th Annual Conference on International Antitrust Law and Policy*, New York, European Competition Policy for the 21st Century (20 October 2000),

available at http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/00/389&format=HTML&aged=0&language=EN&guiLanguage=en

MONTI, Commissioner for Competition Policy, *The New EU Policy on Technology Transfer Agreements*, SPEECH/04/19, Ecole des Mines, Paris, 16 January 2004.

OECD, *Pharmaceutical Pricing Policies in a Global Market, Report of OECD Health Policy Studies,* Paris, 24 September 2008.

Office of Fair Trading, *The Pharmaceutical Price Regulation Scheme. An OFT Market Study*, Office of Fair Trading: London, 2007a.

http://financial-dictionary.thefreedictionary.com/monopsonist

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I declare that this and the work presented in it are my own and have been generated by me as the result of my original research.

None of the part of this thesis has previously been submitted for a degree of any other qualification at this University or any other institution.

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