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The evolution of the concept of dominance
under Article 102 TFEU with special focus
on the pharmaceutical industry

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Summary

This thesis aims to identify the significant stages of the interpretation of the concept of dominance under Article 102 TFEU and it attempts to allocate the issues concerning the pharmaceutical sector into this process. The launch of the Pharmaceutical Sector Inquiry and the Commission's (and subsequently the EU courts) decision in the proceedings against AstraZeneca highlighted the issues permeate this sector of the EU economy from competition law perspective.

After the millennium detrimental transition became noticeable in the pharmaceutical industry. As a response the Commission initiated a sector inquiry to unearth the reasons of this phenomenon and to address the issues found. Its willingness to address the problems arisen is manifest from its treatment of the *AstraZeneca* case. Before this case it was uncertain whether the peculiar characteristics of this sector (regulated price, irregular relationship between products and their final consumers) should influence the well-established methods applied in the assessment of dominance. Apparently, the EU competition authorities concluded they do not. AstraZeneca argued that the Commission had failed to attribute due significance to these special characteristics when it defined the relevant market. First and foremost, the establishment of the relevant product market was challenged by AstraZeneca, claiming that the regular price and demand based test should not be applicable. Although, the existence of these particular attributes referred by AstraZeneca in the initial procedure and in its appeals were acknowledged, nevertheless, they failed to convince either the Commission or any of the EU courts to accept them as a justification to alter the common approach in the determination of the relevant product market. This approach has engendered lively criticism and loud concerns among both scholars and practitioners.

In the conclusion this thesis concludes – in unison with the most frequent critics - that reluctance to take substantial discrepancies into account is liable to transmit a negative message towards undertakings operating in this sector, since it possibly promotes the finding of too narrow market definitions, which easily could have discouraging effect on their willingness to invest into now innovative products. However, as it is elaborated in the conclusion, the conservatism of the Commission and the EU Courts is also understandable bearing in mind the significance of this

sector and the importance of sustaining effective enforcement of EU Competition Law.

Abbreviations

EU	European Union
EU courts	Court of Justice of the European Union
AG	Advocat General
Commission	European Commission
Guidance Paper	Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings
TFEU	Treaty on European Union and the Treaty on the Functioning of the European Union
TEU	Treaty on European Union
R&D	Research and Development
Notice	Commission Notice on the definition of relevant market for the purposes of Community competition law
AZ	AstraZeneca AB and AstraZeneca plc
GC	The General Court
Discussion Paper	DG Competition discussion paper on the application of Article 82 of the Treaty to exclusionary abuses; Brussels, December 2005
EFPIA	European Federation of Pharmaceutical Industries and Associations
DG Comp	Directorate-General (DG) for Competition

1. Introduction

The concept of dominance under Article 102 TFEU, as it will be presented in this paper, has been a controversial topic since its introduction. The interpretation of the concept itself and its crucial elements have been subject to intense dispute. The reasons are wide-ranged. Initially, even the underpinning notion and purpose of EU Competition Law itself was not requisitely configured, let alone these particular aspects of Article 102 TFEU. Subsequently, as the fundamental principles were gradually elucidated, albeit with some delay¹, the equivocal nature of the enforcement of Article 102 TFEU was reduced, which affected positively the interpretation of the concept of dominance. As a part of this process, throughout the history of its application several attempts have been made by the Commission and the EU courts to eliminate the ambiguity surrounding it. How successful these efforts have been is not an easy question to answer.

As an addition to the abovementioned in the beginning of the 2000's a new issue emerged owing to the negative processes begun to prevail in the pharmaceutical industry. A tendency of reduction in the volume of new medicines occurred along with seemingly frequent delay of entry of generic medicines.² These symptoms led to the strong presumption that competition may have not functioned optimally in this sector.³ As this industry is crucial to the economy of both the EU as a whole and its Member States, on account of, inter alia, financial and employment reasons⁴, to address this issue the Commission launched a sector inquiry in order to examine whether agreements between pharmaceutical companies, such as settlements in patent disputes, have blocked or lead to delays in market entry. It also looked into whether companies may have created artificial barriers to entry/expand through the misuse of patent rights, vexatious litigation or other means.⁵

The sector inquiry complemented with the intense debate – generated by the controversial decisions of the Commission and EU courts in *AstraZeneca* case - formed around whether industry specific characteristics should be taken into account

¹ The reasons of this are discussed in sub-chapter 3.3.

² The emergence of generic substitutions can be regarded as one of the possible causes of this

² The emergence of generic substitutions can be regarded as one of the possible causes of this phenomenon. This particular issue will be discussed in details in sub-chapter 3.4.3.

³ Antitrust - sector inquiry into pharmaceuticals – frequently asked questions;

http://europa.eu/rapid/press-release_MEMO-08-20_en.htm?locale=en

⁴ These will be discussed in more details in sub-chapters 2.1 and 2.3.

⁵ <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/>

in the assessment of dominance, have directed more attention to the issues the concept of dominance has, when the pharmaceutical industry concerns.

1.1 Purpose

On account of the aforementioned the purpose of the thesis is to detect the important stages of the evolution of the concept of dominance and to examine whether its interpretation has become more transparent. Additionally, it discusses whether the current state of interpretation is rightly applicable without any amendments in cases in the context of the pharmaceutical sector.

1.2 Method

This research is conducted according to the traditional legal dogmatic method. Descriptive and analytical technique will be employed to identify and describe the important steps in the evolution of the concept of dominance and ultimately to introduce its current state. The purpose of the thesis shall be achieved through introduction and examination of relevant case law (decisions from both the Commission and the EU courts supplemented with opinions of AGs where applicable), related studies, articles and books accessible on the internet or by the courtesy of Lund University Libraries. The thesis will follow the accepted legal method of examination of dominance (in connection with exclusionary abuses) introduced by the Commission's Guidance Paper about its enforcement priorities in applying Article 102 TFEU. Throughout the research references will be made to relevant cases to the pharmaceutical sector and each steps of establishing dominance will be considered with focus on peculiar features of this industry.

Besides the aforementioned, economic perspective will be utilised to a limited extent to highlight the problematic nature of some element of the concept of dominance from an economic point of view.

1.3 Limitations

In order to avoid misunderstandings throughout this paper and to allocate it between the appropriate frames the following limitations should be made.

It is presumed that the reader possesses prior knowledge as to the foundations of EU Competition Law, thus the historical and theoretical background of Article 102 TFEU will not be elaborated any further than it is in sub-chapters 3.1 and 3.3, unless examination regarding the evolution of the concept of dominance requires otherwise.

Scope of the thesis is confined to dominance held by individual undertakings and only regards to exclusionary abuses. Therefore collective dominance, special characteristics of the definition of dominance concerning exploitative and reprisal/discriminatory abuses are not subject of it.

The concept and different forms of abuse will not be discussed either. However, since the theory of dominance and abuse are interrelated, references to abuse possibly will be made, but only to the extent the particular circumstances require.

Finally, as regards to the pharmaceutical industry, differentiation between the market of prescription medicines and non-prescription (over-the-counter) medicines, by virtue of their different nature, is made where the discussed matter requires. As opposed to the fact that most cases involved in the context of this sector concern parallel trade, the examination of this particular issue is not subject to this research.

1.4 Organisation of the Paper

The thesis is divided to four main chapters.

The first chapter is intended to present the purpose of this thesis and to give an explanation why this is an issue.

Then, in the second chapter a brief introduction of the pharmaceutical industry, its special characteristics and its role in the economy of the European Union is presented.

The third chapter at the beginning provides a general introduction to Article 102 TFEU. It consists a short explanation of how its underlying notion evolved and how alterations regarding the objectives of EU Competition Law influenced its interpretation. Then, the Article itself is presented complemented with some

clarifications. Subsequently, the concept of dominance will be examined. It will be executed with a focus on the relevant decisions delivered by the Commission and the EU courts. The structure of this chapter follows the benchmarks set out by the Commission in its Guidance Paper. After a rather general discussion of each point issues relevant to the pharmaceutical industry is examined with critical remarks on the aspects, which were ignored (by the Court or the Commission) or could have been – and should have been – assessed differently.

Ultimately, concluding thoughts are made to present the conclusions have been drawn by the author in connection with the purpose of the thesis.

2. The Pharmaceutical Industry and the environment where it operates and competes

2.1 Introduction

Pharmaceutical industry has always been regarded as one of the most important sectors globally and in Europe too. It is not surprising given the highly sensitive area it encompasses. The protection of human life and health is the first priority of every regime (or at least it is supposed to be) and a fundamental value of today's widespread democratic system⁶.

Naturally, it is not different in the EU. The moral and economic significance of this industry has been acknowledged many times. Neelie Kroes stated in her introductory remarks regarding the opening of a competition law sector inquiry into the pharmaceutical sector in Europe in 2008:

*“The pharmaceuticals sector is vital to the health of Europe's citizens. As well as being a vital sector of the economy, medicines are a major expense. Medicines cost us all a lot of money– we spend around 200 billion euros each year on pharmaceuticals; that's around 400 euros for every man, woman and child in the 27 Member States of the European Union. .”*⁷

Relevant statistics also prove this sector's significance for the EU. According to Commission Staff Working Document⁸ *“the EU pharmaceutical sector produced an output of € 220 billion and employed approximately 800,000 people in 2012. It accounts for around 1.8% of the total manufacturing workforce and is one of the industries with the highest labour productivity”*⁹. In 2011, after the United States, the

⁶ Alfonso Gambardella, Luigi Orsenigo, Fabio Pammoli: Global Competitiveness in Pharmaceuticals, A European Perspective, November 2000; Report prepared for the Enterprise Directorate General of the European Commission

http://ec.europa.eu/health/files/pharmacos/docs/doc2000/nov/compreg_nov2000_en.pdf

⁷ Neelie Kroes (European Commissioner for Competition Policy), Commission launches sector inquiry into pharmaceuticals; Introductory remarks at press conference (Brussels, 16th January 2008);

http://europa.eu/rapid/press-release_SPEECH-08-18_en.htm?locale=en

⁸ Commission Staff Working Document; Pharmaceutical Industry: A Strategic Sector for The European Economy, Brussels, 1.8.2014; [cited: Pharmaceutical Industry: A Strategic Sector]

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/pharmastrategy_en.pdf

⁹ Pharmaceutical Industry: A Strategic Sector p. 2.

European market produced the highest sales figures (26,81% of the total sales of the World) in the World.¹⁰

Therefore, the purpose of this chapter is to serve as an overview of the pharmaceutical industry, to introduce its characteristics making it unique and needful to be examined with closer scrutiny.

2.2 Pharmaceutical undertakings

In the Pharmaceutical Industry Profile issued by the International Trade Administration in 2010 the pharmaceutical industry was defined as:

“... companies engaged in researching, developing, manufacturing, and marketing drugs and biologicals for human or veterinary use...”¹¹.

Interpretation of the term of drugs and biological products – or with other words medicinal products – under EU law is provided by Directive 2001/83/EC¹² in terms of human and by Directive 2001/82/EC¹³ as regards to veterinary use. For the purpose of this thesis only the previous will be dealt with. Article 1 (2) of the Directive states:

“Any substance or combination of substances presented for treating or preventing disease in human beings.

Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.”

¹⁰ EFPIA Did you know? The facts and figures;

<http://www.efpia.eu/index.php?mact=FactsFigures,cntnt01,default,0&cntnt01limit=6&cntnt01orderby=category%20ASC&cntnt01page=3&cntnt01returnid=23&cntnt01returnid=23>

¹¹ Pharmaceutical Industry Profile, International Trade Association, 2010; <http://www.ita.doc.gov/td/health/PharmaceuticalIndustryProfile2010.pdf>

¹² Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use; Journal officiel des Communautés européennes, L 311, 28 novembre 2001; <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32001L0083&from=EN>; [cited: Directive 2001/83/EC]

¹³ Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products; Official Journal of the European Communities, L 311, 28 November 2001;

Therefore, an undertaking can be considered to be a participant in the pharmaceutical industry, if researching, developing, manufacturing or marketing of medicinal products - cumulatively or individually – is encompassed by its profile.

For the sake of clarity, further classification of these undertakings needs to be made. Traditionally, on the supply side, two types are differentiated: originator and generic companies. Originator companies “...undertake research into new pharmaceuticals, develop them from the laboratory to marketing authorisation and sell them on the market”¹⁴. Generic companies “...use a business model aimed at the development of a medicine which is identical or equivalent to originator products...” and “...market their products as soon as the originator product encounters loss of exclusivity, and their products are sold at a much lower price than the original product”¹⁵. The document cited before also mentions biotechnology companies.¹⁶ Generally, these are smaller companies with limited resources concentrating on R&D, which often patent their invention to larger companies to obtain necessary resources in order to utilise their invention.¹⁷

2.3 Pharmaceutical market

Globally the structure of the market is concentrated and characterised by a few number of huge corporations combined with larger number of smaller companies, whose target their products to niche markets.¹⁸

The concentration of the market is noticeable in Europe as well, as the following example clearly presents: a relatively small group of big companies were accounted for more than 80% of annual turnover of the pharmaceutical industry in Europe in 2006.¹⁹

¹⁴ ECORYS Research and Consulting: Competitiveness of the EU Market and Industry for Pharmaceuticals, Volume II: Markets, Innovation & Regulation, Final report (Rotterdam, December 2009) p. 12; [cited: ECORYS Research]

http://ec.europa.eu/enterprise/sectors/healthcare/files/docs/vol_2_markets_innovation_regulation_en.pdf

¹⁵ ECORYS Research, p. 12

¹⁶ ECORYS Research, p. 81

¹⁷ Bengt Domeij, Pharmaceutical Patents in Europe, Norstedts Juridik AB, Stockholm, 2000; p. 206; [cited: Bengt Domeij (2000)]

¹⁸ Stuart Anderson, Reinhard Huss, Rob Summers, Karin Wiedenmayer: Managing Pharmaceuticals in International Health; Springer Basel AG (2004)

¹⁹ ECORYS Research, p. 13

As regards to the type of markets where certain medicinal products are marketed two can be distinguished: market for prescription and non-prescription medicines.²⁰

An important distinctiveness of the pharmaceutical market lies in its highly regulated nature. Regularly states prefer to set the rules by themselves in relation this area and are reluctant to give up their national regime for common legislation. The sensitive nature of this industry is two-sided. First of all, it concerns the well-being of their citizens and in an ideal world it is itself would be enough reason to handle it with more care. However, the other side may be more influential. The social welfare system requires the state to ensure the medical treatment for their citizens. Provision of medicines is encompassed to some extent everywhere. Corollary, the assurance of the availability of these services represents a considerable part of national budgets. Therefore, states tend to intervene to set or affect the maximum prices of pharmaceutical products under the flag of safeguarding the budget of the social health insurance funds.²¹ The reason for varying prices in different Member States is the difference between the methods and degree of intervention.²² Hence, understandably states are reluctant to relinquish their own regulations and accept common legislation. This preference is reflected in the pertinent EU legislation too. Member States are obliged to act according to the so-called Transparency Directive²³, otherwise EU law has left their respective legislations relatively intact.

2.4 Special characteristics of the sector

The pharmaceutical sector admittedly holds special attributes, which clearly distinguish it from other industries. Two main differences were identified by Andrea Coscelli, Alan Overd (as far as prescription medicines concern):

- the price of patented drugs is apt to be regulated and

²⁰ SWITCH Prescription to nonprescription medicines switch, World Self-Medication Industry (WSMI) (2009); http://www.wsmi.org/wp-content/data/pdf/wsmi_switchbrochure.pdf

²¹ Lazaros G. Grigoriadis: The Application of EU Competition Law in the Pharmaceutical Sector: The Case of Parallel Trade; (2014) 25, European Business Law Review, Issue 1, pp. 141-201; [cited: Lazaros G. Grigoriadis (2014)]

²² Lazaros G. Grigoriadis (2014)

²³ Council Directive 89/105/EEC, of 21 December 1988, relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems; Official Journal L 40, 11/2/1989 p. 8 - 11

- usually the ultimate consumer (patient), the decision maker (doctor) and the payer (national insurance system) differ.²⁴

On account of the first point between pharmaceutical products the primary mean of competition is not their price.²⁵ Rather it concentrates on other means such as R&D marketing etc. As a result of the high significance of R&D, patents, by virtue of the exclusivity they grant, are extremely valuable assets for companies and are capable of conferring significant market power on their holders.

As regards to the second point, two main aspects ensue this characteristic. Firstly, the phenomenon called ‘inertia’. It stands for the prescribing doctors preference to prescribe drugs they have already tried and their efficacy is proven.²⁶ This aspect can be interesting when new products (or secondary products) entering the market and the assessment of competition constraints is taken place. Secondly, since it is not the final consumer who pays the price of prescribed medicinal products (it is entirely or partially funded by national insurance systems), their sensitivity to price changes is relatively low, which should reduce further the role of price in competition assessment.²⁷

2.5 The Pharmaceutical Sector Inquiry

In addition to the aforementioned in relation to the Sector Inquiry, the Final Report²⁸ was published in 2009. It revealed several conducts – not in the context of the whole pharmaceutical market, only two of its sectors: “*the interface between proprietary products and generic products*” and “*the interaction between manufacturers of proprietary medicines*”²⁹ – which can be questionable from

²⁴ Andrea Coscelli and Alan Overd: Market definition in the pharmaceutical sector; Sweet & Maxwell and its Contributors (2015); E.C.L.R. 2007, 28(5), 294-296; [cited: Andrea Coscelli and Alan Overd (2007)]

²⁵ Andrea Coscelli and Alan Overd (2007)

²⁶ Case T-321/05 AstraZeneca AB and AstraZeneca plc v European Commission, ECLI:EU:T:2010:266; para. 41.; [cited: AstraZeneca, General Court’s decision]

²⁷ Case COMP/A. 37.507/F3 - AstraZeneca, recital (115); [cited: AstraZeneca, Commission’s Decision]

http://ec.europa.eu/competition/elojade/iseff/index.cfm?fuseaction=dsp_result&policy_area_id=1,2,3&ase_title=Astra%20Zeneca

²⁸ Commission Staff Working Document adopted on 8 July 2009

²⁹ Josef Drexler, Nari Lee: Pharmaceutical Innovation, Competition and Patent Law; Edward Elgar Publishing Limited (2013); page 242

competition law's point of view. These conducts concern strategic patenting practices. In the context of competition between originator and generic companies the Final Report expressed two main concerns regarding strategic patenting: firstly, filing of numerous patent applications concerning the same product in order to create patent clusters, thereby rendering more difficult or impossible the entry of generic products; secondly, voluntary "divisional patent" applications filed by originator companies in order to extend the respective patent office's examination period, thereby forcing generic companies to face with even more uncertainty.³⁰

³⁰ Communication from the Commission - Executive Summary of the Pharmaceutical Sector Inquiry Report, point 3.2.1.;
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

3. The Concept of Dominance

As it was mentioned before, that the interpretation of the concept of dominance generated vigorous debates. Since the first interpretation of its elements it has been subjected to endless criticism, and despite the efforts of EU competition authorities it is still not a peaceful area of EU Competition Law. For the better understanding of reasons behind this may be beneficial to begin with a brief explanation of the background of Article 102 TFEU.

3.1 Underlying notion of Article 102 TFEU

The prohibition of abuse of dominant position was introduced in the Treaty establishing the European Economic Community (Article 86)³¹. Since then it has not been significantly rephrased, the numbering has been changed twice though. First by the renumbering made by the Treaty of Amsterdam³², which altered it to Article 82, secondly (and lastly so far) the Treaty of Lisbon³³ altered it to be Article 102.

The purpose of this provision, according to the Court of Justice, was ascertained in the cases of *Hoffman La-Roche*³⁴ and *Continental can*³⁵ (in the 38th and 23th paragraphs of the decisions respectively). It was stated that Article 82 "*is an application of the general objective of the activities of the Community laid down by Article 3(1) of the Treaty, namely the institution of a system insuring that competition in the common market is not distorted*". Although, Article 3(1)(g) of the EC Treaty has been omitted from the body of both the TEU and TFEU³⁶, the Court's interpretation of competition rules makes it impossible to ignore this provision where

³¹ Treaties of Rome (entered into force: 1 January 1958): Treaty establishing the European Economic Community;

³² Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts; 97/C 340/01, Official Journal of the European Communities, C 340, 10 November 1997

³³ Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon; 2007/C 306/01, Official Journal of the European Union, C 306, 17 December 2007

³⁴ Case 85/76 Hoffmann-La Roche & Co. AG v Commission of the European Communities; ECLI:EU:C:1979:36 [cited: Hoffman-La Roche case]

³⁵ Case 6-72 Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities; ECLI:EU:C:1973:22 [cited: Continental Can case]

³⁶ Now its content is in Protocol No. 27 on the Internal Market and Competition

such rules are examined.³⁷ This was reinforced in its decision in *TeliaSonera*³⁸. As a great body of case law showed, system of undistorted competition should be interpreted in the light of the principle of competition on the merits.³⁹

The achievement of an integrated internal market as an objective has been reiterated in the case law⁴⁰ and emphasised by the Commission in the Guidance Paper on Article 102 in paragraph 7:

“Conduct which is directly exploitative of consumers, for example charging excessively high prices or certain behaviour that undermines the efforts to achieve an integrated internal market, is also liable to infringe Article 82...”

The emergence of economic (effect-based) approach in the interpretation of Article 102 TFEU added a new aspect to the debates surrounding the objective issue. As an implication of the Commission’s endeavor to modernise⁴¹ the competition policy of the EU, begun from the mid 1990s⁴², economic efficiency and the enhancement of consumer welfare as goals of competition provisions were promoted and made the situation even more complicated.

The Commission made efforts to provide more certainty, but the reluctance of the Court of Justice to align with its approach⁴³ did not facilitate its task. The first notable attempt was the DG Comp Staff Discussion Paper published in December 2005. In paragraph 4 it said:

“With regard to exclusionary abuses the objective of Article 82 is the protection of

³⁷ Alison Jones and Brenda Sufrin; *EU Competition Law*, Fifth Edition, Oxford University Press (2014); [cited: Jones and Sufrin (2014)]

³⁸ Case C-52/09: Judgment of the Court (First Chamber) of 17 February 2011 (reference for a preliminary ruling from the Stockholms tingsrätt — Sweden) — *Konkurrensverket v TeliaSonera AB*, para. 20-21.; ECLI:EU:C:2011:83

³⁹ Thomas Eilmansberger; *Dominance – The Lost Child? How effects-based rules could and should change dominance analysis*; 2 *Eur. Competition J.* 15 2006

⁴⁰ e.g. *Joined Cases C-468/06 to C-478/06 Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AEEVE Farmakeftikon Proïonton*, formerly *Glaxowellcome AEEVE*; ECLI:EU:C:2008:504; [cit: *Sot. Lélos kai Sia case*]

⁴¹ The key element of this modernisation was the increase of the influence of economics on competition law.

⁴² Mark-Oliver Mackenrodt, Beatriz Conde Gallego, Stefan Enchelmaier: *Abuse of Dominant Position: New Interpretation, New Enforcement Mechanisms?*; Max Planck Institute for Intellectual Property, Competition and Tax Law; Springer-Verlag Berlin Heidelberg 2008

⁴³ Jones and Sufrin (2014) p. 289

competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resource.”

It generated vigorous arguments among competition law practitioners and scholars, and the Court did not appear to be willing to follow this path. The judgments⁴⁴ delivered around the publication of the Discussion Paper showed this manifestly by sticking to former formalistic approach.⁴⁵

Therefore, it is easily noticeable that it was a problematic environment, full of controversies, when the Commission adopted its Guidance Paper in 2009. Probably for this reason, it stated explicitly that it does not intend to be a statement of law, and it does not bind the Court of Justice in any sense.⁴⁶ It ‘merely’ delineated the enforcement priorities of the Commission when it decides to take actions relying on Article 102 TFEU. However, it did not abandon the concept of consumer welfare as it states in paragraph 5:

“In applying Article 82 to exclusionary conduct by dominant undertakings, the Commission will focus on those types of conduct that are most harmful to consumers.”

As far as the concept of dominance under Article 102 TFEU concerns it has been interpreted many ways as well since it was introduced in 1957. Transition has been inevitable by virtue of the unfinished nature of competition policies at the beginning (under the law of the European Community) and the fast-moving/developing attributes of the field, competition law is intended to regulate.

The latter is particularly true for the pharmaceutical industry. Regarding this sector the judgments in *AstraZeneca* arguably had a positive impact⁴⁷ on the elimination of uncertainty by providing a statement of law on the interpretation of certain elements, which have to be taken into account during the establishment of dominant position.

⁴⁴ Case T-271/03 *Deutsche Telekom v Commission*, ECLI:EU:T:2008:101; Case C-95/04 P *British Airways plc v Commission of the European Communities*, ECLI:EU:C:2007:166; Case T-201/04 *Microsoft Corp. v Commission of the European Communities*, ECLI:EU:T:2007:289

⁴⁵ Jones and Sufirin (2014) p. 289

⁴⁶ Guidance Paper para. 3

⁴⁷ White & Case LLP: *AstraZeneca v European Commission*: Case C-457/10 P (6 December 2012) <http://www.whitecase.com/files/Publication/02ee0444-748c-47a3-b17b-ddd6dffa2da8/Presentation/PublicationAttachment/d04c5061-b57e-4c7d-b85f-f355999891c1/alert-astrazeneca-december-2012.pdf>

However, the EU courts' (and the Commission's) evaluation (or, according to some, ignorance) of the unique characteristics of this industry generated further arguments on this already highly debated battlefield of EU Competition Law.

3.2 The prohibition

“Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.

Such abuse may, in particular, consist in:

- (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;*
- (b) limiting production, markets or technical development to the prejudice of consumers;*
- (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;*
- (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”⁴⁸*

Article 102 TFEU prohibits abusive conducts of undertakings, which collectively or individually hold dominant position within the internal market or a substantial part of it, provided that such conduct(s) potentially effect(s) trade between Member States.

The prohibition applies if five conditions are met:

- one or more undertakings are concerned,
- they hold, collectively or individually, dominant position,
- dominant position must be within the internal market or a substantial part of it,
- their unilateral conduct is an abuse according to EU competition rules,

⁴⁸ 2008/C 115/01 Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union (TFEU), Article 102

- potentially it has an effect on trade between Member States.⁴⁹

However, Article 102 TFEU only applies to conduct of undertakings, which are already in dominant position. Therefore, if an undertaking acquires dominance on a certain defined market as a result of the conduct at issue⁵⁰, or the abusive conduct is done by an undertaking not having dominant position (regardless whether it is harmful for consumers), Article 102 TFEU will not apply.⁵¹

Moreover, merely holding dominant position on the relevant market is not prohibited. Dominant undertakings are allowed to compete on the merits as well as non-dominants. However, as they are in possession of presumably substantial market power the Court imposed the burden of special responsibility on them in *Michelin*⁵² case.

*“A finding that an undertaking has a dominant position is not in itself a recrimination but simply means that, irrespective of the reasons for which it has such a position, the undertaking concerned has a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market.”*⁵³

As opposed to the fact that the wording of this article has not been changed substantially since it was introduced, the controversy and confusion as to its interpretation, especially regarding the concept of dominance and abuse, represents accurately the ambiguity and uncertainty around the objectives of EU competition law.

3.3 Definition of Dominance

The Guidance Paper set out that Article 102 TFEU only applies if two essential conditions are met. First, the undertaking concerns must held dominant position on

⁴⁹ Jones and Sufrin (2014) p. 271

⁵⁰ Jones and Sufrin (2014) p. 270

⁵¹ Federico Etro & Ioannis Kokkoris (Editors): *Competition Law and the Enforcement of Art. 102* (Oxford Univ. Press, 2010); Ioannis Kokkoris: *Are we Underenforcing Article 102?* (Chapter 11)

⁵² Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*; ECLI:EU:C:1983:313 [cited: *Michelin case*]

⁵³ *Michelin case* para. 10

the relevant market. Secondly, the conduct being investigated has to be regarded abusive.⁵⁴ For the purpose of this thesis the previous will be discussed in details.

Article 102 does not provide a definition of the concept of dominance. It has been formed by the practice of and documents issued by the Commission and relevant case law of the Court of Justice.⁵⁵

The first known definition of dominance is attributed to Leonardo Lessius⁵⁶. He defined dominance as *“the ability of one or few offerers to sell a specific kind of goods for a certain price, which is freely chosen and independent from competitors as well as buyers”*.^{57,58}

As regards to EU Competition Law, the first attempt of the Court of Justice to provide its interpretation of the concept at issue was taken place in *Sirena v. Eda*⁵⁹ case. There the Court Stated that dominance means

*“... power to impede the maintenance of effective competition over a considerable part of the relevant market, having regard in particular to the existence and position of any producers or distributors who may be marketing similar goods or goods which may be substituted for them.”*⁶⁰

However, the landmark decision concerning this issue was delivered by the Court of Justice in *United Brands*⁶¹ case in 1978. The following was asserted:

*“... a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of its consumers.”*⁶²

⁵⁴ Simon Bishop and Mike Walker: *The Economics of EC Competition Law: Concepts, Application and Measurement*, Third Edition; Thomson Reuters (Legal) Limited (2010) [cited: Bishop and Walker (2010)]

⁵⁵ Ivo Van Bael & Jean-Francois Bellis: *Competition Law of the European Community*; Fourth Edition, Kluwer Law International, 2005; p. 117; [cited: Van Bael and Bellis (2005)]

⁵⁶ Doris Hildebrand: *The Role of Economic Analysis in the EC Competition Rules*; Third Edition, Kluwer Law International BV, The Netherlands, 2009; [cited: Doris Hildebrand (2009)]

⁵⁷ Doris Hildebrand (2009); p. 44

⁵⁸ The concept is highly reminiscent to the wording of the definition deployed today.

⁵⁹ Case 40-70 *Sirena S.r.l. v Eda S.r.l. and others*; ECLI:EU:C:1971:18; [cited: *Sirena v. Eda case*]

⁶⁰ *Sirena v. Eda case*, para. 16

⁶¹ Case 27/76 *United Brands v. Commission*; ECLI:EU:C:1978:22; [cited: *United Brands case*]

⁶² *United Brands case*, para. 65

Thus, according to the ECJ by that time, an undertaking could be considered holding dominant position (on the relevant market) insofar as it possessed the adequate degree of economic strength to set out its market strategy regardless the behaviour of its competitors, customers and consumers, thereby jeopardising the maintenance of effective competition.

Subsequently, the Court reiterated and elaborated this definition to some extent in *Hoffmann-La Roche*.

*“The dominant position thus referred to relates to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of its consumers.”*⁶³

The focus was placed on dominant undertakings’ capability of exploiting their leverage conferred to them by this position by distorting normal conditions of competition.⁶⁴ The Court stated:

*“Such a position does not preclude some competition, which it does where there is a monopoly or quasi-monopoly, but enables the undertaking which profits by it, if not to determine, at least to have an appreciable influence on the conditions under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment.”*⁶⁵

The definition presented above has become the backbone of the concept of dominance, especially after the delivery of the Guidance paper which embraced it in its entirety.⁶⁶

One may ask, why it took more than twenty years⁶⁷ for the competent institutions of the European Community to define such a fundamental concept of competition law. A reason could be the fact that admittedly at the dawn of enforcement of EU

⁶³ Hoffmann-La Roche case para. 38

⁶⁴ Jones and Sufrin (2014) p. 299

⁶⁵ Hoffmann-La Roche case para. 39

⁶⁶ Guidance Paper para. 10

⁶⁷ The origin of Article 102 can be traced back to Treaty of Paris, where Article 66(7) had similar wording and it already used the term of dominant position.

Competition law most of attention was drawn to Article 85. More precisely, cartels enjoyed privileged position and were examined with high scrutiny. Additionally, the ambiguity surrounding the expressions such as ‘effective competition’ and behave ‘independently’ ‘to an appreciable extent’ hindered the practical application of Article 102.

The latter concepts were vigorously criticised. Their weaknesses were reiterated at several occasions by economists. Simon Bishop and Mike Walker argued that the Court of Justice attempted to rectify the difficulties brought by the ambiguity of concept of dominance by providing an interpretation phrased with other undefined concepts. According to them terms such as “effective competition”, “normal competition” are also yet to be requisitely defined, hence they are hardly capable of elucidate the problematic aspects.⁶⁸

Regards to independence, it is established that the degree of independence is dependent on the level of competitive constraints exerted on the undertaking concerned. Thus, in order to act independently, and as a result to have dominant position, it must not face with effective competitive constraints.⁶⁹ Therefore, a firm is considered dominant if it is not subject to effective competitive constraints and consequently it possesses significant market power. Following this way of thinking, it is asserted by Bishop and Walker that corollary to the abovementioned “*the legal concept of dominance can be equated with the economic concept of significant market power*”⁷⁰.⁷¹ However, the criterion of acting independently of consumers and competitors entails some issues economically.

First of all, on a sustainable basis no undertakings can act independently of their consumers or customers.⁷² It is derived from the discipline of the demand curve⁷³. Whenever a company, regardless whether it is dominant or not, increases its prices reduction in demand will inevitably occur. Consequently, from an economical perspective, the concept of acting independently of consumers/customers does not

⁶⁸ Bishop and Walker (2010) p. 227

⁶⁹ Doris Hildebrand (2009) p. 311

⁷⁰ Bishop and Walker (2010) p. 227

⁷¹ This theory is also acknowledged by the Guidance Paper (para. 10).

⁷² Joao Pearce Azevedo and Mike Walker: Dominance: Meaning and Measurement; E.C.L.R. 2002, 23(7), 363-367; 2015 Sweet & Maxwell and its Contributors [cited: Azevedo and Walker (2002)]

⁷³ Demand curve: “*a graphic representation of the relationship between product price and the quantity of the product demanded. It is drawn with price on the vertical axis of the graph and quantity demanded on the horizontal axis. With few exceptions, the demand curve is delineated as sloping downward from left to right because price and quantity demanded are inversely related.*”; <http://global.britannica.com/EBchecked/topic/156920/demand-curve>

sufficiently express the difference between dominant and non-dominant undertakings.⁷⁴

It is also contested whether independent behaviour of competitors makes sense economically. The answer is not straightforward. Every firm operating on a market having more than one actor has to face with a certain degree of competition. Therefore, every company – unless it is a true monopolist – is subject to some level of competition constraints. Every undertaking raising its prices above the competitive level will reach that point eventually when it is not profitable anymore. Thus, bearing in mind the latter it can be claimed that independence from competitors - to some extent at least – is not possible. However, in the sense that an undertaking concerned is capable of raising its prices profitably above the competitive level to some extent, it is undoubtedly proven that a dominant undertaking can indeed act independently of its competitors to an appreciable extent.⁷⁵ In other words, if a firm is able to maintain its price wherever between the competitive price and the point beyond the increase becomes unprofitable, it is unquestionably acting independently of competition constraints exerted by its competitors.

Putting this way, it appears relatively easy to determine whether a firm is dominant. Perhaps, between perfect competition circumstances it would be indeed. Unfortunately, in fact the situation is more complicated. The core of the problem lies at the determination of competitive price. There is broad unity that the level of competitive price is virtually impossible to calculate. Regardless undertakings are dominant or not, it is a normal competitive behaviour from undertakings to raise their prices until the constraints imposed on them by competitors allow and the “*demand curve bites*”⁷⁶. Thus nobody forms its pricing policy to a definable competitive level, they rather adjust it to the behaviour of their competitors.⁷⁷ Therefore, as identifying the competitive price is usually impossible, the assessment of dominance needs to be based on other criteria.⁷⁸

As Azevedo and Walker pointed out in their cited work, other factors than price can be taken into account when assessing independence or dominance in general. Dependent on the market at issue the main focus of competition can be in other

⁷⁴ Bishop and Walker (2010) p. 228

⁷⁵ Azevedo and Walker (2002)

⁷⁶ Azevedo and Walker (2002)

⁷⁷ Azevedo and Walker (2002)

⁷⁸ Cellophane fallacy is closely related to this issue, however, it will be discussed in details in the context of the determination of relevant product market.

dimensions such as R&D, quality, service, marketing activity or the combination of these.⁷⁹ A good example is the pharmaceutical industry. Owing to the fact that prices are not formulated arbitrary⁸⁰ by marketer firms instead they are regulated by the Member States concerned, the focal point of competition is rather on other aspects. For instance, between originator companies decisive emphasis is on their willingness to take the risk and invest into R&D. The risk is high, as all these will be worth nothing if competitors overtake them in submitting patent applications or entering the market in relation to a particular product. Furthermore, effective marketing strategies can also be a scene of fierce competition.

3.4 Establishing Dominance

The Guidance Paper sets out the steps the Commission follows during its investigation under Article 102 TFEU. The first is the assessment of whether the undertaking in question is in dominant position and of the degree of market power it has.⁸¹ It is established that in order to conduct these assessments the relevant market in every single case has to be defined separately. After the relevant market is defined the Commission will examine the following factors⁸²:

- competitive structure of the market,
- the market positions of the dominant undertaking and its competitors (market shares),
- barriers to expansion and entry,
- countervailing buyer power.

3.4.1 Market Definition

In order to assess the market power of an undertaking first the market where it operates has to be accurately defined. It possesses particular importance in case of Article 102 TFEU. To examine whether an undertaking holding a dominant position or not – which is the starting point of the competition assessment - it is essential to

⁷⁹ Azevedo and Walker (2002)

⁸⁰ Arbitrary must be construed in accordance with the aforementioned about independence.

⁸¹ Guidance Paper para. 9.

⁸² Guidance Paper para. 12.

define the boundaries between it conducts its business. The necessity of defining the relevant market, before the establishment of an infringement of Article 102 TFEU, was acknowledged by the Court of Justice in *Continental Can*⁸³ and has been reinforced in further decisions⁸⁴.

The purpose of it is “to identify which products and services are such close substitutes for one another that they operate as a competitive constraint on the behaviour of the suppliers of those respective products and services”⁸⁵. The objective of market definition is not an end in itself, rather it is a stage of the process of assessing market power.⁸⁶

Although, the case law of the Court of Justice along with the practice and guidelines of the Commission attempted to provide a practically useable method how the definition should be formed, it is still not as clear-cut as practitioners and businesses may wish it to be. The root of this problem is stemming from the nature of market definition. It is not a mechanical process⁸⁷ where after checking all required aspects the result is provided. First of all, it always must be done individually on a case-by-case basis. The Commission is not allowed to rely on its previous findings⁸⁸, even if the case at issue concerns a situation or sector it examined shortly before. The analysis has to reflect on the circumstances prevailing at the time it is conducted.⁸⁹ It has to be done in the light of all available evidences regarding the structure of the market, the behaviour of actors on the market and it presupposes an overall understanding of the characteristics of a specific sector.⁹⁰

The primary aspect considered, when defining the relevant market is taken place, is substitutability. It describes a certain market as a compilation of products and services

⁸³ *Continental Can* para. 32.

⁸⁴ e.g. Joined cases T-68/89, T-77/89 and T-78/89 *Società Italiana Vetro SpA, Fabbrica Pisana SpA and PPG Vernante Pennitalia SpA v Commission of the European Communities*; ECLI:EU:T:1992:38; para. 159: “*The Court considers, on the contrary, that the appropriate definition of the market in question is a necessary precondition of any judgment concerning allegedly anti-competitive behavior.*”; Case T-29/92 *Vereniging van Samenwerkende Prijsregelende Organisaties in de Bouwnijverheid and others v Commission of the European Communities*; ECLI:EU:T:1995:34; para. 74 : “*For the purposes of Article 86, the proper definition of the relevant market is a necessary precondition for any judgment as to allegedly anti-competitive behaviour ..., since, before an abuse of a dominant position is ascertained, it is necessary to establish the existence of a dominant position in a given market, which presupposes that such a market has already been defined.*”

⁸⁵ Jones and Sufrin (2014), p. 61

⁸⁶ Doris Hildebrand (2009) p. 321

⁸⁷ Doris Hildebrand (2009) p. 321

⁸⁸ Joined cases T-125/97 and T-127/97 *The Coca-Cola Company and Coca-Cola Enterprises Inc. v Commission of the European Communities*, para. 82.; ECLI:EU:T:2000:84

⁸⁹ Jones and Sufrin (2014) p. 305

⁹⁰ Doris Hildebrand (2009) p. 321

which are interchangeable with each other but not interchangeable with others. Substitution may be a different product or the same product from another geographical area.⁹¹ This approach resulted the differentiation between the aspects of relevant market, namely the relevant product and relevant geographical market.

The Commission follows this methodology as it is manifestly noticeable from its Notice on the Definition of Relevant Market. The Notice utilises a “*classical ‘constraints’ approach*”⁹². According to it the three factors precluding the exercise of market power are demand substitutability, supply substitutability and potential competition. The first plays the most significant role in the process of defining the relevant market, the second is taken into account in limited number of cases and the third is relevant at a later stage of the competitive assessment.⁹³

a) Relevant Product Market

The notion of interchangeability permeates the Court of Justice’s definition of relevant market. It is detectable in its early case law, such as *Continental Can* and others⁹⁴.

*“...the definition of the relevant market is of essential significance, for the possibilities of competition can only be judged in relation to those characteristics of the products in question by virtue of which those products are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products.”*⁹⁵

Its view was further elaborated in *Michelin* where it was stated that two products may be deemed to be substitute to each other, even though they are not completely

⁹¹ Jones and Sufrin (2014) p. 63

⁹² Van Bael and Bellis (2005) p. 134

⁹³ Van Bael and Bellis (2005) p. 134

⁹⁴ E.g. Hoffmann-La Roche case para. 28.: “*The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned.*”

⁹⁵ Continental Can case para. 32.

only partially interchangeable.⁹⁶ The focus is on whether the other product imposes a competitive constraint.⁹⁷

The Court of Justice examined the “*functional interchangeability*” of the products concerned which means that aspects as characteristics, price and intended use constituted the primary determining factors.⁹⁸ This approach was heavily criticised and its weaknesses were highlighted in the *United Brands* case.

The main question was whether bananas constituted a separate market competing to the fresh fruit market as a whole. During its assessment the Court took into account physical characteristics such as “*appearance, taste, softness, seedlessness, easy handling*”⁹⁹ and relying on these findings, it distinguished old, sick and very young people as distinct group of costumers.

It was argued that the Court failed to requisitely support why it attributed decisive significance for these particular characteristics, and additional concerns arose about the differentiation of consumer groups without reliance on any evidence of the volume of their purchase¹⁰⁰. Arguably a more appropriate approach may have provided the same result, however, such handling of these aspects can easily lead to too narrow market definitions generating counterproductive enforcement of competition rules.¹⁰¹

Although, subsequently the Court of Justice delivered several judgments on this matter, the uncertainty surrounding it was not reduced considerably.¹⁰² On account of this the Commission published its Notice on the Definition of Relevant Market. The Notice intended to provide comprehensive guidance on how the relevant market is supposed to be defined in the light of EU Competition Law and to let the ones concerned know the facets taken into account by the Commission. This document must be applied without prejudice to the case law of the Court and it ensued the

⁹⁶ Michelin case para. 48.

⁹⁷ Jones and Sufrin (2014) p. 311

⁹⁸ Jones and Sufrin (2014) p. 64

⁹⁹ United Brands case para. 31

¹⁰⁰ Doris Hildebrand (2009) p. 325

¹⁰¹ Jones and Sufrin (2014) p. 309

¹⁰² See the cases: Hoffmann-La Roche case; Case 66/86 Ahmed Saeed Flugreisen and Silver Line Reisebüro GmbH v Zentrale zur Bekämpfung unlauteren Wettbewerbs e.V., para. 39-40., ECLI:EU:C:1989:140; Case C-53/92 P Hilti AG v Commission of the European Communities, ECLI:EU:C:1994:77; Case C-333/94 P Tetra Pak International SA v Commission of the European Communities, ECLI:EU:C:1996:436

established principles of the practice of the Commission and the EU Courts.¹⁰³ The latter is apparent in its definition of the relevant product market:

*“A relevant product market comprises all those products and/or services which are regarded as interchangeable or substitutable by the consumer, by reason of the products' characteristics, their prices and their intended use.”*¹⁰⁴

As far as the pharmaceutical industry is concerned, a seminal decision was delivered by the Court of Justice in 2012 dealing with this matter. The *AstraZeneca* case was the first ever abuse-case in the pharmaceutical sector, so that the fact that it was eagerly anticipated is understandable.¹⁰⁵ The Commission found – later the General Court as well as the Court of Justice reconfirmed – that AstraZeneca abused its dominant position by making *“deliberately misleading representations to patent agents, national patent offices and national courts in order to acquire or preserve”*¹⁰⁶ extended patent protection and for *“selective deregistrations of marketing authorisations for Losec capsules”*¹⁰⁷.

It was the first case as well where the Commission had to define the relevant market in the context of the pharmaceutical sector and as usual its findings and arguments underpinning them have not been accepted peacefully. The details of the case will be discussed below.

(i) Demand Substitutability

The assessment of demand substitution examines the range of products consumers consider to be substitutes.¹⁰⁸ From a demand-side perspective factors taken into consideration, according to the Notice, are the following¹⁰⁹:

- product characteristics and its intended use¹¹⁰ and
- price.

¹⁰³ Van Bael and Bellis (2005) p. 133

¹⁰⁴ Notice para. 7.

¹⁰⁵ Matteo Negrinotti: Abuse of regulatory procedures in the intellectual property context: the AstraZeneca case: Sweet & Maxwell and its Contributors (2015); E.C.L.R. 2008, 29(8), 446-459;

¹⁰⁶ AstraZeneca, General Court's decision para. 305.

¹⁰⁷ AstraZeneca, General Court's decision Section D

¹⁰⁸ Notice para. 15

¹⁰⁹ Van Bael and Bellis (2005) p. 136

¹¹⁰ Notice para. 36.

Product characteristics and intended use

This evidence serves the detection of products, which are similar to each other to the extent or the responsiveness of the customers indicates that they are substitutes, thus they belong to the same product market.¹¹¹ The Notice clarifies that findings in this relation are not determinative on their own, the examination of them is merely the first step of defining the relevant product market and its purpose is “*to limit the field of investigation of possible substitutes*”¹¹². Then, it adds that the reason why solely functional interchangeability or similarity in characteristics may not provide requisite foundation to define the relevant product market is that “*the responsiveness of customers to relative price changes may be determined by other considerations as well*”^{113, 114}.

This clarification was needed in the light of the earlier case law. Its possible misuse was highlighted in *United Brands*. Mainly this case and the Commission’s and EU courts’ inclination to rely on inadequately substantiated conclusions on this matter generated vigorous criticism.

Although, the Notice intended to resolve this issue and provide an assurance for practitioners by clarifying this aspect’s complementary nature in the assessment of substitutability in the context of Article 102 TFEU, frequently this is the only tool at the Commission’s disposal to conclude an accurate market definition. Owing to the problems stem from the phenomenon ‘Cellophane Fallacy’ in relation to the SSNIP test, it is often impossible to employ it in cases concerning alleged abuse of dominant position.¹¹⁵

Some commentators suggest that special attributes of the pharmaceutical sector – especially those elaborated in sub-chapter 2.4 - require it to be handled differently than other industries.

Jacob Westin distinguished the same characteristics as well when he concluded that in this sector – by virtue of these specific aspects – less focus should be on price and demand elasticity and more attention should be paid to sector specific criteria

¹¹¹ Van Bael and Bellis (2005) p. 136.

¹¹² Notice para. 36.

¹¹³ Notice para. 36.

¹¹⁴ As an example see Michelin case where new and retreated tyres were defined as constituting separate markets despite their similar characteristics.

¹¹⁵ Jones and Sufrin (2014) p. 73

such as products' therapeutic indications.¹¹⁶ As he states, in order to follow this path more reliance on the Anatomical Therapeutic Chemical (ATC) Classification System¹¹⁷ may be adequate. ATC is not unknown for the Commission, it employed the system as a reference to market definition earlier (in merger cases) and it did too in *AstraZeneca*¹¹⁸. Yet, the Commission decided to follow the traditional method, and in its assessment attributed greater importance to the respective characteristics¹¹⁹ and mode of action of PPIs and H2 blockers.

*“As a result, the PPIs have a mode of action which is fundamentally distinct from that of the H2 blockers and - even more so - from those of other categories of medicines used within the field of acid-related gastrointestinal diseases or conditions.”*¹²⁰

*“This direct blocking action which is unique to the PPIs is strongly linked to the therapeutic superiority of the PPIs over the H2 blockers and, whilst insufficient by itself to determine the market ... supports a relevant product market comprising only PPIs...”*¹²¹

Consequently, despite there was manifest overlap¹²² between the therapeutic use of PPIs and H2 blockers – even though PPIs were generally prescribed for more severe form of the same medical condition due to its higher efficiency – the Commission (and the GC and later the Court of Justice too) ignored this fact and found the way to legitimately insist to its established principles.

¹¹⁶ Jacob Westin: Defining relevant market in the pharmaceutical sector in the light of the Losec-case – just how different is the pharmaceutical market?; Sweet & Maxwell and its Contributors (2015); E.C.L.R. 2011, 32(2), 57-62; [cit: Jacob Westin (2011)]

¹¹⁷ Its purpose: *“The ATC/DDD system classifies therapeutic drugs. The purpose of the ATC/DDD system is to serve as a tool for drug utilization research in order to improve quality of drug use.”* and the classification system is the following: *“In the ATC classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified into five different levels. Drug consumption statistics (international and other levels) can be presented for each of these five levels.”*; <http://www.who.int/classifications/atcddd/en/>

¹¹⁸ AstraZeneca, Commission's Decision point 371-372, 905.

¹¹⁹ For the respective mode of action see: AstraZeneca, Commission's Decision point 373-375.

¹²⁰ AstraZeneca, Commission's Decision point 376.

¹²¹ AstraZeneca, Commission's Decision point 377.

¹²² The overlap is seemed to be proven by the facts that the introduction of PPIs was ensued by gradual reduction in the sales of H2 blockers and its manufacturers were compelled to redirect their products to milder forms of this particular medical condition.

Price

*“The exercise of market definition focuses on price for operational and practical purposes, and more precisely on demand substitution arising from small, permanent changes in relative prices.”*¹²³

The Notices embraced the widely known test of examining demand and supply substitutability, the SSNIP¹²⁴ test, also called the Hypothetical Monopolist test¹²⁵. The purpose of this test is to examine *“whether the parties’ customers would switch to readily available substitutes or to suppliers located elsewhere in response to a hypothetical small (in the range 5% to 10 %) but permanent relative price increase in the products and areas being considered. If substitution were enough to make the price increase unprofitable because of the resulting loss of sales, additional substitutes and areas are included in the relevant market. This would be done until the set of products and geographical areas is such that small, permanent increases in relative prices would be profitable.”*¹²⁶

However, whenever this test is applied in the context of Article 102 TFEU the phenomenon called ‘Cellophane fallacy’ must be borne in mind. It means that during the application of the SSNIP test it cannot be identified undoubtedly whether the current price is already manipulated by the purportedly dominant undertaking, thus it is always doubtful whether the prevailing price and competitive price coincide.¹²⁷ This doubt derives from the very nature of profit-maximising firms, as they will always increase their prices as high as it is profitably possible.¹²⁸

This limb of the determination of the degree of demand substitutability is arguably problematic in the pharmaceutical sector. As it was mentioned earlier the price of certain pharmaceutical products (as far as prescription medicines concerned) are not freely determined. This market – as opposed to others – is highly regulated and it particularly applies for prices. Furthermore, another peculiarity, namely that frequently it is not the final consumer who is the decision maker (rather the

¹²³ Notice para. 15.

¹²⁴ It stands for ‘Small but Significant Non-transitory Increase in Price’.

¹²⁵ Bishop and Walker (2010)

¹²⁶ Notice para. 17.

¹²⁷ Jones and Sufrin (2014) p. 71

¹²⁸ Bishop and Walker (2011) p. 125

prescribing doctor or national healthcare authority who is the payer) in terms of medicines, renders the situation even more intricate.¹²⁹ Corollary, competition in the pharmaceutical sector is not based on price. It is rather on non-price means e.g. detailing activity to doctors, advertising in medical journals, funding clinical studies, etc.¹³⁰ Therefore, the conventional application of the SSNIP test easily can be misleading in the estimation of demand elasticity¹³¹, let alone the difficulties arise regarding the determination of competitive price or the prevailing market price.

In *AstraZeneca* in its appeal to the General Court, AZ argued that the Commission attributed significance to price difference between PPI and H2 blockers to greater extent than it would have been appropriate.¹³² It employed the regulated market argument, briefly, that, as a result of the regulated nature of the market, prices are determined or influenced by public authorities, competition is based on non-price related factors, thus utilising them as determinative factors in assessing the intensity of competition between the two products is apt to provide false results.¹³³ The General Court dismissed this argument by stating that strength of the position of pharmaceutical undertakings have in negotiations with public authorities is highly dependent on the features of the particular product e.g. its added therapeutic value, cost-effectiveness, prices for the same or similar products on the domestic and foreign market, etc., hence the price of a particular product indicates authorities' perception of its therapeutic efficacy comparing to other products.¹³⁴ The significant price difference between PPI and H2 blockers – in favour of the preceding – reflects manifestly that national authorities attributed considerably higher therapeutic efficacy to PPIs, consequently the Commission rightly evaluated this factor as an indication of defining two separate markets.¹³⁵ The GC also affirmed the Commission's stance, according to which despite the specific features characterising the pharmaceutical product market (it explicitly refers to prescribing doctors and patients relatively limited sensitivity for price changes) “*an economic approach based on the observation of the reaction of demand to relative price changes*”¹³⁶ is not invalidated.

¹²⁹ Jacob Westin (2011)

¹³⁰ Andrea Coscelli and Alan Overd (2007)

¹³¹ Andrea Coscelli and Alan Overd (2007)

¹³² *AstraZeneca*, General Court's decision para. 112.

¹³³ *AstraZeneca*, General Court's decision para. 112.

¹³⁴ Lazaros G. Grigoriadis (2014)

¹³⁵ *AstraZeneca*, General Court's decision para. 161-165.

¹³⁶ *AstraZeneca*, General Court's decision para. 91.

This statement was not deemed to be erroneous by the Court of Justice either.

Thus, based on the approach of the Commission and the EU Courts, it has been concluded that, albeit the peculiar features of the pharmaceutical sector should not be ignored, they do not render the general principle of market definition inapplicable.¹³⁷ In effect, in this way the coherence was maintained regarding this matter, as the Court did not go against its decision in *Sot. Lélos kai Sia*, where it did not accept, that the specific nature of the pharmaceutical industry justifiably preclude the application of the Community's competition law.¹³⁸

(ii) Supply substitutability

As it was mentioned earlier this aspect plays lesser role in the process of defining the relevant (product) market.

The Court of Justice ruled in *Continental Can*, that accurate definition of the relevant market requires the examination of substitutability not only from the demand side, but the supply side as well.¹³⁹ Supply substitutability is also defined in the Notice:

*“... means that suppliers are able to switch production to the relevant products and market them in the short term without incurring significant additional costs or risk in response to small and permanent changes in relative prices.”*¹⁴⁰

This side is only considered if its influence is equivalent to the demand side's in terms of effectiveness and immediacy.¹⁴¹

In the pharmaceutical industry due to patent protection for new, innovative products supply side substitution is more likely to be taken into account in the context of competition between generic companies. When they enter the market generally the protection assured by respective patents, upon their expiry, is over – apart from situations involving patent settlements -, hence it is more conceivable that attempts

¹³⁷ Lazaros G. Grigoriadis (2014)

¹³⁸ *Sot. Lélos kai Sia* case para. 5.

¹³⁹ *Continental Can* case para. 33.

¹⁴⁰ Notice para. 20.

¹⁴¹ Notice para. 20.

are made by these companies to alter their production in order to compete with each other.

(iii) Further factors possibly relevant to the pharmaceuticals

Distinct group of customers can be pertinent to the determination of relevant product market in this sector. According to the Notice,

“A distinct group of customers for the relevant product may constitute a narrower, distinct market when such a group could be subject to price discrimination”¹⁴².

However, it can be relevant to the assessment only if two cumulative conditions are met:

“(a) it is possible to identify clearly which group an individual customer belongs to at the moment of selling the relevant products to him, and (b) trade among customers or arbitrage by third parties should not be feasible.”¹⁴³

This factor can have particular significance in relation to pharmaceutical products as certain medicinal products are aimed to their respective circle of customers. For example, pain killers for adults and for children. It is unlikely that an adult’s response for a price increase – unless it is unrealistically enormous – would be to buy child painkillers for themselves. The same applies for the reverse as nobody in their right mind would sedate their child intentionally in order to save money. Accordingly, irrespective of the fact that they are both painkillers, it would be incorrect to rule that they constitute the same market.

It is also worth to mention that Andrea Coscelli and Alan Overd in their article about market definition in the pharmaceutical market suggested some further aspect which should be taken into consideration in the determination of relevant market when pharmaceutical sector concerns. They recommended three aspects which should

¹⁴² Notice para. 43.

¹⁴³ Notice para. 43.

influence the assessment of market definition in order to make the traditional approach more sensitive to “*the drivers of demand*” of the pharmaceutical industry.¹⁴⁴

Firstly, in its essence a similar stance is represented as it was shown above by the opinion of Jacob Westin. They support the emergence of therapeutic substitutability by taking “*information from medical literature, labeling information and expert witness statements*”¹⁴⁵ into account in the assessment of market definition. Perception of doctors as regards to the products appropriate to treat the particular conditions should be treated as an indication when narrowing of the relevant product market is taken place.

Secondly, prescribing patterns would serve well as indicators as regards to the use of medicinal products. If two of them are mainly prescribed as treatment to the same or similar symptoms this strongly suggests that those two belong to the same market.

Thirdly, they support the inclusion of “*different competitive factors on sales of a specific product*” (e.g. detailing and advertising activity, entry of competing products, etc.) in the assessment of market definition.¹⁴⁶

All these suggestions sound reasonable, however, it appears neither the GC not the Court of Justice embraced them. The decision of the previous in *AstraZeneca* case was delivered on 1 July in 2010, three years after this article had been published. It seems for some reason the GC (and subsequently the Court of Justice) was unwilling to take these aspects into consideration in a decisive manner.¹⁴⁷

Unfortunately, the Commission’s decision in *Servier*¹⁴⁸ case is not publicly available at the moment, it would be interesting to see whether the Commission treated differently the question of relevant product market than it did in *AstraZeneca*.

b) Relevant geographical market

The meaning of relevant geographical market, under the scope of EU Competition Law, was first defined by the Court of Justice in *United Brands*. The Court stated that along with the particular characteristics of the product in question reference has to be

¹⁴⁴ Andrea Coscelli and Alan Overd (2007)

¹⁴⁵ Andrea Coscelli and Alan Overd (2007)

¹⁴⁶ Andrea Coscelli and Alan Overd (2007)

¹⁴⁷ For instance, indirectly it referred to the ATC, however, its decision was apparently based on other considerations. (Jacob Westin 2011)

¹⁴⁸ Case COMP/AT.39612 – Perindopril (Servier) Commission Decision of 9 July 2014

made to the geographical area where it is marketed and “*where the conditions of competition are sufficiently homogenous for the effect of the economic power of the undertaking concerned to be able to be evaluated*”¹⁴⁹. Further, it was added in paragraph 44 of the judgment that “*this is an area where the objective conditions of competition applying to the product in question must be the same for all traders*”.

The Notice, as it could be seen in the context of the relevant product market too, aligned its definition with the established principles regarding this matter. Its definition virtually combines the two paragraphs cited above:

*“The relevant geographic market comprises the area in which the undertakings concerned are involved in the supply and demand of products or services, in which the conditions of competition are sufficiently homogenous and which can be distinguished from neighbouring areas because the conditions of competition are appreciably different in those areas.”*¹⁵⁰

Article 102 TFEU clearly states that it only applies if dominant position is held within at least a substantial part of the internal market. It is established in case law¹⁵¹ that, albeit the continual enlargement of the EU may be able to change this stance, even one single Member State – or only parts of it – can be considered to be a substantial part of the internal market.¹⁵² This issue is particularly important in the context of the pharmaceutical sector. As a consequence of the discrepancy of the methods and degrees of state interventions and the relatively low level of Community harmonisation in this area, in respective cases the relevant geographical market is frequently deemed to be one single Member State.¹⁵³ As a matter of fact, the Commission in every case concerning pharmaceuticals has defined geographical market as a single Member State by this date. Given the causes of this practice it is hard to see this changed until further harmonisation is taken place.

¹⁴⁹ United Brands case, para. 11

¹⁵⁰ Notice para. 8.

¹⁵¹ See: Case 226/84 British Leyland Public Limited Company v Commission of the European Communities, para. 3-10., ECLI:EU:C:1986:421; Case 26-75 General Motors Continental NV v Commission of the European Communities, para. 9-10., ECLI:EU:C:1975:150

¹⁵² Jones and Sufrin (2014) p. 282

¹⁵³ AstraZeneca, Commission’s decision recital (503)

3.4.2 The position of undertakings on the relevant market

The first step – after the definition of relevant market - of the assessment of dominance in the Guidance Paper is the determination of market position of the allegedly dominant undertaking and its competitors.¹⁵⁴ The Commission followed the footsteps of the Court of Justice, as this has been established in case law since *Hoffmann-La Roche*.¹⁵⁵

For several years competition authorities were heavily criticised for their inordinate reliance on market shares in finding dominance. The Court acknowledged in *Hoffmann-La Roche* that there could be other relevant factors as to the finding of dominance, albeit it stated that large market shares held for some time is in itself indicative of dominance.¹⁵⁶ The meaning of large market was clarified in *AKZO*¹⁵⁷ case, where it was defined as being over 50 percent.¹⁵⁸

However, the Commission in its Guidance Paper asserts explicitly that market shares merely “*provide a useful indication*”.¹⁵⁹ Further, it reiterates that market share of the allegedly dominant undertaking always has to be assessed in the light of relevant market conditions.^{160,161} For instance barriers to entry needs to be taken into account, as if entry to the particular market is costless and relatively easy, it will be unlikely even for a monopolist to be capable of increase its prices profitably.¹⁶² Additionally, it sets the threshold of 40 percent or above where dominance is likely to occur, but it states that even if an undertaking’s market share is below this level, dominance still can be established insofar as “*competitors are not in the position to constrain effectively the conducts of*” the undertaking concerned.¹⁶³

Nonetheless, market share still has a significant role in finding dominance as it can be seen from *AstraZeneca*, where both the General Court and the Court of Justice

¹⁵⁴ Guidance Paper para 12.

¹⁵⁵ Jones and Sufrin (2014) p. 336

¹⁵⁶ Hoffmann-La Roche case para. 39-40.

¹⁵⁷ Case C-62/86 *AKZO Chemie BV v Commission of the European Communities*; ECLI:EU:C:1991:286; [cited: AKZO case]

¹⁵⁸ AKZO case para. 60.

¹⁵⁹ Guidance Paper para. 13.

¹⁶⁰ Guidance Paper para. 13.

¹⁶¹ The Court recognised this in cases like: *Hoffman-La Roche*, *United Brands*, *Michelin*, *AstraZeneca*

¹⁶² Bishop and Walker (2010) p. 65.

¹⁶³ Guidance Paper para. 14.

approved AZ's high market share (held for a long period of time) as a factor supporting the Commission's decision on dominance.¹⁶⁴

3.4.3 Barriers to entry/expand

In order to determine market power of a given undertaking the identification of factors which can be regarded as barriers to entry or expansion is instrumental.¹⁶⁵ Hence, to define them accurately is crucial.

This term has been attempted to be defined plenty of times in the academic literature on the structure of the market.¹⁶⁶ Essentially these definitions can be originated from two fundamental approaches. The first definition (created by Joe S. Bain, a decorated representative of the Harvard School¹⁶⁷) focused on the ability of incumbent firms to earn above normal profits without being threatened by the entry of competitors¹⁶⁸:

*“The extent to which, in the long run, established firms can elevate their selling prices above the minimal average costs of production and distribution ... without inducing potential entrants to enter the industry.”*¹⁶⁹

The other definition was formed by George J. Stigler whose approach concentrated on the cost differences must be borne by new entrants but not by incumbents by virtue of their already well-established position on the market concerned¹⁷⁰:

*“a cost of producing ... which must be borne by a firm which seeks to enter the industry but is not borne by firms already in the industry.”*¹⁷¹

¹⁶⁴ For the sake of completeness it must be added though, that this was one of the five elements led to the Commission's conclusion.

¹⁶⁵ Jones and Sufrin (2014) p. 88

¹⁶⁶ Bishop and Walker (2011) p. 75.

¹⁶⁷ Jones and Sufrin (2014) p. 21.

¹⁶⁸ R. Preston McAfee, Hugo M. Mialon, and Michael A. Williams: Economic and Antitrust Barriers to Entry; December 2003; http://papers.ssrn.com/sol3/papers.cfm?abstract_id=594601; [cited: R. Preston McAfee, Hugo M. Mialon, and Michael A. Williams (2003)]

¹⁶⁹ Joe S. Bain: Economies of Scale, Concentration, and the Condition of Entry in Twenty Manufacturing Industries; American Economic Review. Mar1954, Vol. 44 Issue 1, p15. 25p

¹⁷⁰ R. Preston McAfee, Hugo M. Mialon, and Michael A. Williams (2003)

¹⁷¹ George J. Stigler: The Organization of Industry; Homewood, Ill., 1968 328

Competition law policy makers preferred Bain's definition. This is reflected in relevant case law¹⁷² of the Court of Justice and related documents of the Commission. The Commission in both of its Discussion Paper and its Guidance Paper approached this aspect from price's point of view. Both of them emphasise the importance of barriers to entry/expansion, as significant market share not necessarily enables the undertaking at issue to exert its market power insofar as the potential of entry by potential competitors or expansion by existing competitors functioning as a deterrence for it to increase its prices.¹⁷³

As far as the different types of barriers to entry concerns an important source is the OECD report¹⁷⁴ on this matter. It distinguishes two basic and an additional types. It also asserts that overlap is possible between the categories and none of them should be employed and interpreted in isolation as interrelations may occur.¹⁷⁵ According to the report there are structural and strategic barriers. Structural barriers derive from standard attributes of the given industry (such as cost, demand, technology), and these factors are commonly out of the incumbent companies control.¹⁷⁶ Strategic barriers encompass conditions created intentionally by incumbents – not necessarily but occasionally – to deter new entrants.^{177,178} Additional category is sunk costs. These are costs the entrant incurs on the entry of the market, but which cannot be recovered in case of exit (e.g. expenses of recruiting and trainings, advertising and promotion costs, expenses of complying with government regulations).¹⁷⁹

Neither the Discussion Paper nor the Guidance Paper utilise such sophisticated differentiation, albeit they set out the categories in the same notion. As a matter of fact the Discussion Paper is more elaborative than the Guidance. However, for the purpose of this research the one provided by the Guidance suffice. It provides a non-exhaustive list of aspects constitute barriers to entry or expansion in paragraph 17:

¹⁷² See cases: *United Brands* para 122-123; *Hoffmann-La Roche* para 48; OJ L65/19 (1988) *Eurofix-Bauco v. Hilti* para 69-70.

¹⁷³ Discussion Paper para 34.; Guidance Paper point 16.

¹⁷⁴ OECD Policy Roundtables Barriers to Entry, DAF/COMP(2005)42; <http://www.oecd.org/daf/competition/abuse/36344429.pdf>

¹⁷⁵ OECD report, point 3.

¹⁷⁶ OECD report, point 3.2

¹⁷⁷ OECD report, point 3.3

¹⁷⁸ Some of these can constitute an abuse for the purposes of Article 102 TFEU.

¹⁷⁹ OECD report, point 3.1

“They may be legal barriers, such as tariffs or quotas, or they may take the form of advantages specifically enjoyed by the dominant undertaking, such as economies of scale and scope, privileged access to essential inputs or natural resources, important technologies ... or an established distribution and sales network ... They may also include costs and other impediments, for instance resulting from network effects, faced by customers in switching to a new supplier. The dominant undertaking's own conduct may also create barriers to entry, for example where it has made significant investments which entrants or competitors would have to match ..., or where it has concluded long-term contracts with its customers that have appreciable foreclosing effects. Persistently high market shares may be indicative of the existence of barriers to entry and expansion.”

Some of these forms have been awarded with special attention due to the Commission's Sector Inquiry in the pharmaceutical sector. Namely, barriers constituted by the legal and regulatory environment, especially issues regarding intellectual property rights and regulatory procedures.

a) Intellectual property rights and patenting strategies

Intellectual property rights by their very nature are capable of functioning as barriers to entry or expansion. Exclusivity granted by them to their owners is the essence of the whole concept. Accordingly, it is established in case law that the mere possession of IPRs is not anti-competitive and certainly not a sole indication of establishing dominance¹⁸⁰ and it cannot be regarded as an abuse¹⁸¹. Nevertheless, their significance in competition issues is undoubted.

It is not different in the pharmaceutical industry, however, some peculiarities regarding patents are worth having a closer look. As IPRs in general, the purpose of granting patents is also to confer exclusive rights to their holders, which may have

¹⁸⁰ Joined cases C-241/91 P and C-242/91 P Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities; ECLI:EU:C:1995:98; para. 46

¹⁸¹ Hanns Ullrich: Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection, p. 260; Josef Drexler, Nari Lee: Pharmaceutical Innovation, Competition and Patent Law; Edward Elgar Publishing Limited (2013); [cited: Hanns Ullrich (2013)]

undesirable consequences (such as blocking of R&D activities of competitors)¹⁸² and are capable of constituting barriers for actual or potential competitors. However, the abovementioned Sector Inquiry and cases concerning this matter (*AstraZeneca, Boehringer*¹⁸³) revealed that different strategies of undertakings have to be taken into account too.¹⁸⁴

The Sector Inquiry Final Report dealt with two form of strategic patenting, both conducted by originator companies:

- filing of patents to extend the exclusivity period of certain patents, thereby delaying generic companies' entry to the market ('dilatatory' patenting),
- defensive patenting in order "*to impede the innovative effort of competing originators*".¹⁸⁵

Defensive patents, dependent on their objective, can be defensive blocking patents and aggressive blocking patents. The latter's objective is to restrict the activity of competitors, the previous intends to "*protect the applicants own innovation*"¹⁸⁶ and "*to broaden the applicant's own field of activity*"¹⁸⁷.

An effective mean of defensive patenting is the creation of patent clusters. It is realised by filing numerous additional patents for the same medicine¹⁸⁸, thereby creating a 'fence' or protective bastion around the protected active substance. Thus, even if the main patent expires the bunch of secondary patents¹⁸⁹ surrounding it make the situation of competitors (both originators and generics) excessively difficult. Therefore these actions can easily be considered strategic barriers to entry/expand, nevertheless, they possibly constitutes an abuse for the purpose of Article 102 TFEU.

Accordingly, these aspects - it is, however, not easy to detect them - should also be taken into consideration in the assessment of existence of different barriers on the relevant market. Some of these barriers may only be unearthed when the Commission

¹⁸² Josef Drexl: *AstraZeneca and the EU sector inquiry: when do patent filings violate competition law*; Josef Drexl, Nari Lee: *Pharmaceutical Innovation, Competition and Patent Law*; Edward Elgar Publishing Limited (2013); [cit: Josef Drexl (2013)]

¹⁸³ COMP/39246 *Boehringer Ingelheim*

¹⁸⁴ Many of these can be considered as abuses of dominant position if the undertaking concerns holding dominant position at the time of execution.

¹⁸⁵ Hanns Ullrich (2013) p. 244

¹⁸⁶ Hanns Ullrich (2013) p. 248

¹⁸⁷ Hanns Ullrich (2013) p. 248

¹⁸⁸ Sector Inquiry Final Report, recital (502)

¹⁸⁹ For difference between primary and secondary patents see: Sector Inquiry Final Report, recital (138)

faces them in an investigation against a particular undertaking, however, complete ignorance of them in other cases would increase the possibility of concluding false market definitions, hence inducing competition authorities to take unnecessary actions.

Another phenomenon, which is worth mentioning, is the lately emerged practice among originator companies, namely the introduction of follow-on products. Originator companies, as a response to the popularity of generic substitutions, altered their strategies, and instead of concentrating on the discovery of new, innovative medicines, their efforts directed to the enhancement of their existing products. As a part of this strategy before the expiry of their patents (ergo before the launch of the generic version of the original medicine) they engage in excessive marketing campaigns to regroup their customers behind the new, allegedly enhanced product.¹⁹⁰ Therefore, even if the first generation patent is expired and generics are allowed to enter the market there will be no customers interested in their products.

Although, the anti-competitive nature of this trend is problematic to prove, it is certainly influence generic companies willingness to enter to a particular market.

b) Market Authorization

The GC stated in *AstraZeneca*, that regulatory procedures cannot be used to prevent market entry or make entry more difficult for competitors unless it relates to competition on the merits or it is objectively justified.¹⁹¹

Accordingly, the aspect, which has been highlighted by AstraZeneca and can be interesting in relation to identification of barriers, is market authorization.

It is compulsory to obtain it in order to allocate a new medicine on the market. Its particular importance lies in the relationship between originator and generic companies. Before the authorization is granted, in case of completely new medicines, evidences of safety and efficacy is required to be provided by results of pre-clinical tests and clinical trials. However, generic companies are exempted from these requirements insofar as their product is considered essentially similar to the reference

¹⁹⁰ Jacob Westin: Product switching in the pharmaceutical sector - an abuse or legitimate commercial consideration?, E.C.L.R. 2011, 32(12), 595-601; 2015 Sweet & Maxwell and its Contributors

¹⁹¹ AstraZeneca, General Court's decision para 24.

medicinal product (abridged application).¹⁹² At the time AstraZeneca withdrew the market authorization of Losec, generic companies could only benefit from the abridged procedure if the reference medicine still possessed market authorization¹⁹³, therefore it forced generic companies to conduct the expensive trials if they intended to apply for authorization in the respective countries.

Although, the barrier created by AstraZeneca cannot be reprised owing to the amendment of the respective provision of Directive 2001/83, this example clearly shows that shortcomings of regulatory systems can indeed hinder firms entering/expanding to/on the market, thereby behave as barriers to entry/expansion.

3.4.4 Countervailing buyer power

As the third limb of the assessment of dominance the Commission assesses the “*constraints imposed by the bargaining strength of the undertaking’s customers*”¹⁹⁴. It asserts later that it is conceivable that competitive constraints may be exerted by customers on a given market in addition to or instead of by actual or potential competitors.¹⁹⁵ Even if an undertaking at issue possesses significant market share, its customer or customers, by virtue of their size or their significance for that undertaking and by means of their capability of turning to other suppliers swiftly or promoting new entry, may function as a deterrence for the undertaking to increase its prices profitably.^{196,197} However, in order to take this aspect into consideration it is not sufficient that only a limited number of customers are capable of resisting the market power of the allegedly dominant undertaking.¹⁹⁸ Therefore, when countervailing buyer power is weighed, it needs to be examined whether it protects smaller buyers as well.¹⁹⁹

¹⁹² For more detailed explanation see: Directive 2001/83/EC, Article 10 as amended by 2004/27/EC

¹⁹³ Bengt Domeij: Anticompetitive marketing in the context of pharmaceutical switching in Europe; Josef Drexl, Nari Lee: Pharmaceutical Innovation, Competition and Patent Law; Edward Elgar Publishing Limited (2013); [cit: Bengt Domeij (2013)]

¹⁹⁴ Guidance Paper para 12.

¹⁹⁵ Guidance Paper para 18.

¹⁹⁶ Guidance Paper para 18.

¹⁹⁷ Seminal case regarding this issue: Case T-228/97 Irish Sugar plc v Commission of the European Communities; ECLI:EU:T:1999:246

¹⁹⁸ Guidance Paper para 18.

¹⁹⁹ In connection with this matter the “waterbed effect” is notable. Briefly, it means when bigger buyers defeat the dominant undertaking’s attempt to increase its prices, therefore it tries to gain its lost profit by imposing higher prices for its smaller customers. For more detailed discussion see: Bishop and Walker (2010), point 3-032, p. 84.

As regards to the pharmaceutical industry, owing to the Member States' preference to set prices²⁰⁰ – as far as prescription medicines concerns - some may think since prices are not freely determined, perhaps competition rules should not apply.²⁰¹ This was argued by the appellant in *Sot. Lélos kai Sia* case, however, it fell on deaf ears. AG Ruiz-Jarabo Colomer writes in his Opinion²⁰² that “*although the pharmaceuticals market does not operate under normal competitive conditions, the price regulation system is not completely free from the influence of the manufacturers, which negotiate prices with the Member State health authorities, enjoy a degree of strength in the market ...*”²⁰³. Therefore, since undertakings do have some influence on the formulation of price, this characteristic does not extract such cases from the scope of EU Competition Law. The Court of Justice agreed, so that this argument was swiftly dismissed. Moreover, Member States' price policies are not as rigid as they appear at first sight. They are mitigated by the Transparency Directive and for instance by particular patent rights held by respective undertakings.²⁰⁴ The Opinion of AG Ruiz-Jarabo Colomer highlighted these aspects. In Article 2 (1) of the Transparency Directive it is clearly stated that in price setting procedures the national authority is obliged to provide objective and verifiable grounds in case of refusing the marketing of a given medicine on the proposed price.²⁰⁵ Article 2 (2) loosens even further the process by introducing the principle of ‘administrative silence’ stating that insofar as the competent authority fails to issue an official response in ninety days from the submission of the application, the applicant is entitled to market the product.²⁰⁶

²⁰⁰ In addition to the fact that often states are the monopsony buyer of prescription medicines.

²⁰¹ Emmanuel Dieny: *The pharmaceutical industry and competition law between the present and the future*; E.C.L.R. 2007, 28(4), 223-232; 2015 Sweet & Maxwell and its Contributors

²⁰² Joined cases C-468/06 to C-478/06 *Sot. Lélos kai Sia EE and Others v GlaxoSmithKline AVEE Farmakeftikon Proionton*, formerly *Glaxowellcome AVEE*; Opinion of Mr Advocate General Ruiz-Jarabo Colomer delivered on 1 April 2008; ECLI:EU:C:2008:180; [cited: Opinion of AG Ruiz-Jarabo Colomer, *Sot. Lélos kai Sia*]

²⁰³ Opinion of AG Ruiz-Jarabo Colomer, *Sot. Lélos kai Sia*, point 93.

²⁰⁴ Lazaros G. Grigoriadis (2014)

²⁰⁵ Opinion of AG Ruiz-Jarabo Colomer, *Sot. Lélos kai Sia*, point 89.

²⁰⁶ Opinion of AG Ruiz-Jarabo Colomer, *Sot. Lélos kai Sia*, point 89.

4. Conclusion

The purpose of this research was to examine and present the evolution of the interpretation of dominance under Article 102 TFEU. However, has this concept really evolved? As it can be seen from the definition of fundamental elements of it, such as dominance itself, relevant product and geographical market, etc., more or less they have been embraced by the Commission in the Notice of defining relevant market and the Guidance Paper as they were settled in the early case law of the Court of Justice without any crucial amendments. Thus, it cannot be stated with confidence that the definitions themselves evolved virtually anything since they were provided by the Court of Justice in its seminal decisions.

On the other hand, such statement unquestionably cannot be made as to the interpretation of these essential concepts. For instance, as opposed to the initial treatment of market share of the Court of Justice, today it is settled that even very large market share is not sufficient in itself to support the presumption of dominance. It is only indicative along with other equally important factors. The gradual infiltration of economic theories to the assessment of competition issues can be held responsible for this change of approach and probably it can be considered a step forward in the evolution of the concept of dominance after the early years when economic analysis were barely employed.

However, is it enough? The incremental diversification of different fields of the industry, which is ultimately the subject of competition law, suggests otherwise. The importance of the consideration of sector specific characteristics has been argued by scholars and representatives of certain industries. Yet, both the Commission and EU Courts appear to be reluctant to take these aspects into account, at least to the extent as commentators and undertakings would desire.

A good example is the pharmaceutical sector and the infamous *AstraZeneca* case. The existence of peculiar attributes of the pharmaceutical industry was not rejected, nevertheless, no decisive significance was attributed to them. The Commission in fact considered these aspects, albeit eventually it managed to find the way to insist to its well-established principles. The EU Courts subsequently affirmed the findings of the Commission and asserted that the existence of special characteristics should be taken into consideration in the assessment of dominance, however, without prejudice

to the general approach²⁰⁷ utilised in this assessment. Some scholars expressed their concerns in connection with this approach. Jacob Westin argues that the current approach leads to too narrow market definitions which is detrimental in general but even more in connection with innovative products – such as the products of the pharmaceutical industry -, as it discourages easily the development of new innovative medicines, that, in principle, is everybody's interest.²⁰⁸ Thus, it is questionable whether narrow market definition is the right tool to the promotion of consumer welfare, especially in such an innovation-focused industry as pharmaceuticals.²⁰⁹

On the other hand, reluctance of competition authorities to yield to these critics is also understandable. As pharmaceutical products absorb a substantial part of national budgets the sensitivity of the issue is apparent. Furthermore, multinational companies operating in the sector possess significant economic power which cannot be ignored by the Member States nor the EU as a community. These may explain the careful approach adopted by the Commission and EU courts towards the meaningful consideration of the aforementioned special characteristics, viz. if they attributed decisive significance to these, it would decrease their latitude and the scope of cases they would be able to legitimately intervene. The acceptance would ensure better possibilities for undertakings to seek immunity from the ambit of Article 102 TFEU and the financial strength of them assures that they would certainly find the way to exploit this opportunity.

Therefore, the discovery of balance between the interests of fast-paced, innovation-focused industries - and arguably consumer welfare as far as pharmaceuticals concerns - and the interests of EU Competition Law, then the implementation of a mutually acceptable solution to the enforcement of Article 102 TFEU may constitute the next step in the evolution of the concept of dominance. Until then, expectedly several cases will be referred to EU courts by appellants, challenging the market definition and other controversial findings of the competent competition authorities.²¹⁰

²⁰⁷ Instead of relying on the ATC code it focused on the generally applicable aspects: product characteristics, price and intended use.

²⁰⁸ Jacob Westin (2011)

²⁰⁹ Jacob Westin (2011)

²¹⁰ It is already happening by a pending case before the GC, Servier challenges the Commission's decision, inter alia, in connection with its market definition.; Announcement from the EU Commission – Servier's response 9.7.2014; <http://servier.co.uk/content/announcement-eu-commission-%E2%80%93-servier%E2%80%99s-response-972014>

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