

**The boundaries between the protection of IPR's and abuse of
dominance in the pharmaceutical sector under European
Competition law**

Master thesis

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Introduction

Nowadays various intellectual property rights are strongly protected and the importance to reward the right holders is often highlighted in the EU law. Exclusive status and protection of these rights is noted in the Treaty of the Functioning of the European Union (hereinafter TFEU), the Article 36, which allows the express derogations from the prohibitions laid down in Articles 34 and 35 of TFEU. Article 36 states that: *“The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports in transit justified on grounds of <...> the protection of industrial and commercial property. <..>”*¹. There are several industrial property rights, which are protected under EU law, such as copyrights, trademarks, patents.

As one can understand, granting certain exclusive protection for IP rights, for instance for patents (which will be relevant for the research done in this thesis) is vital in order to compensate the right proprietors for their expenditures, as the research and development processes of innovations are usually very costly and time consuming. Without such protection the inventors would be discouraged to invest into new researches and therefore progress in various sectors would be slowed down. At this point it is important to note that in order to maintain a proper functioning of the European Internal Market and the EU Competition rules - the protection has to be well balanced. On one hand, the right proprietors must be able to exercise their rights under certain exclusive protection, but on the other, such protection cannot be unlimited and used in abusive ways. Other internal market participants eventually have to be granted access to these rights as well. This is could be considered especially necessary for less powerful companies in order for them to be able to fairly compete with the powerful dominant undertakings, produce, market and develop production on equal grounds. It is not only essential for the dependant undertakings, but also for consumer welfare and the proper functioning of the internal market. In other words, there has to be a fair balance between the protection of intellectual property and competition law. Although it might sound rather uncomplicated at the

¹ Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, *OJ C 83 of 30.3.2010, Article 36.*

first glance, such task proves to be quite complex in its fulfillment in various areas. The question of where and how exactly the line is drawn between the protection and legitimate exercise of the right and the abuse of it still remains.

Moreover, major undertakings, mainly the most powerful ones, having a dominant position in the relevant market, are often unwilling to give up their rights easily and let the others have access to the production and marketing of their products. These companies seek to extend their IPR (intellectual property rights) protection as long as possible and delay or block the entry into the market of other potential producers. Therefore, in some of those cases the undertakings might be engaging into variety of practices, which might also constitute abuses of a dominant position, something which is clearly prohibited under the common rules on competition in the TFEU, namely Art 102.² However, due to special characteristics of certain sectors it is not always an easy task to determine whether certain actions are legitimate protection of rights or the abuse actually occurred. Moreover, new forms of abuse may also be developed.

Currently the area causing controversial opinions on this matter is the pharmaceutical sector. The competition - related abuses in this sector at EU level also are particularly relevant as the Commission has conducted its first ever pharmaceutical sector inquiry. The preliminary report of the inquiry reflected that “(...) originator companies (the ones that develop and sell medicines) used a variety of methods with the objective of delaying or blocking market entry of generic companies (that sell medicines equivalent to original medicines once patents have expired) and other originator companies (...)”.³

The mentioned sector is of a very specific nature due to a number of factors, such as strict regulation of pricing, complexity of market access on both national and EU level and so on. Regulatory measures and the case-law in this area are fairly fresh and yet developing, since *only in the year 2005 the EU Commission adopted its first abuse of dominance decision in that sector.*⁴ The latter *AstraZeneca v. Commission*⁵ case, which was later challenged before the General Court and the Court of Justice is of a

² *Ibid*, Art 102.

³ Press release by the EU Commission- *Antitrust: preliminary report on pharmaceutical sector inquiry highlights cost of pharma companies' delaying tactics* [2008]

⁴ Nadia de Souza, “*Copetition in Pharmaceuticals: the challenges ahead post AstraZeneca*”, Competition Policy Newsletter (Spring 2007) p. 39.

⁵ Case T-321/05 *AstraZeneca v Commission*, [2010] II-02805.

high importance. Not only was it a first decision adopted by the Commission on the abuse in pharmaceutical sector, but the appeal brought by AstraZeneca (AZ) to the General Court⁶ (CFI at that time) was the first one for the General Court at that time as well. The case, however, did not stop there and although the appeal before the Court of Justice is still pending, the importance and the influence of the Commission's decision and the General Court's ruling should not be underestimated. The complexity and novelty of the matter is also evident, as the Commission found AZ to be guilty of two *newly* introduced abuses⁷ of dominant position. The General Court upheld the majority of the decision and dismissed AZ's claims, however, did not support Commissions findings in their entirety. To underline the delicate matters at stake and an important impact of this case, M. Negrinotti points out that *"On one hand, the incentive to innovate and to undertake research and development is at stake; on the other, the uncertain boundaries between competition and intellectual property law should once again be explored"*⁸.

Moreover, the case is of a seminal importance, since, as the aforementioned pharmaceutical sector inquiry by the Commission has proved, majority of the originator companies engaged into similar and other kinds of practices by trying to prolong their patent protection and remain dominant in the relevant product market. However, the question whether all those practices are abuses is yet left open. As the case law in this sector develops, it is important to understand why and how those practices were found to be abusive. It is crucial not only for the sake of legal certainty for the pharmaceutical undertakings, but also for the proper functioning of the market and the consumer welfare.

One of the aims of this thesis is to research the importance of IPRs for the industry and the reasons causing the specificity of the pharmaceutical sector and to find out whether the competition in the sector functions in distinct ways from the others.

The main goal is to research and determine the development of the concept of abuse of dominant position and its impact on the pharmaceutical sector; to indicate which circumstances could cause the abuse and which could be lawfully used by the undertakings in order to protect their IP rights.

⁷ TFEU, Article 102 (ex art 82) provides with the list of abuses of dominant position. The list is not exhaustive and new forms of abuses may be indicated.

⁸ Matteo Negrinotti, "Abuse of Regulatory Procedures in the Intellectual Property Context: The AstraZeneca Case", ECLR (2008), issue 8, p. 446.

Due to the significance of the *AstraZeneca* case for the development of the concept of abuse of dominant position in the pharmaceutical sector, the case will be analyzed in detail in this thesis in order to achieve its goal.

Chapter I

I. The notion of dominance and an abuse of a dominant position

First of all, in order to conduct consistent research on this subject a few important notions within the framework of EU Competition law must be examined. The notions will be researched to the extent necessary for the contents of this thesis, without going into depth and extended critique of the relevant terms.

Article 102 TFEU is one of the main means in achieving the goal set by the European Union, which aims at establishing a stable system ensuring that competition in the internal market is not distorted. Therefore, as one of the necessary elements for the existence of fair competition on the market, Article 102 prohibits the “abuse of a dominant position” and provides a list of instances whose occurrence may amount to abuse of dominance. However, the Treaty itself does not provide the definition of these important concepts, namely dominance and the abuse of a dominant position.

I.I. Assessment of the relevant product market (Market definition)

A crucial element in understanding the abuse of dominance and applying Article 102 is the market definition. Assessment and definition of a relevant product market is the first step in cases concerning competition issues. In order to prove the existence of dominance, it has to be identified in a certain market. Therefore, the definition of the market becomes a precondition itself in order to prove any abusive conducts. If a firm is dominant, it is dominant within a defined market⁹. Therefore, it is a geographical and a product market that has to be defined in the first place.

⁹ E. Fox, *The Competition Law of the European Union in Comparative Perspective - Cases and Materials*, West, 2009, p. 72.

An important document for the definition of the market is the *Notice on the Definition of the Relevant market issued by the Commission*¹⁰. The notice indicates the definitions of relevant geographic and product markets, as well as the purpose of market definition. The main points of the purpose are as follows:

- a) systematic way to identify competitive constraints faced by the undertakings involved
- b) identification of actual competitors of undertakings
- c) calculation of market shares that would convey meaningful information regarding market power for the purposes of assessing dominance¹¹

One of the most important points in determining a product market are the competitive constraints. Competitive constraints comprise of demand substitutability, supply substitutability and potential competition¹². In short, it is necessary to establish what is the nature of competition between certain products and whether those products are in any way similar and/or interchangeable. It must be assessed how the market reacts in response to changes in supply and demand of one or the other product, whether relevant consumers consider certain products as appropriate substitutes to each other and what is the volume of other options available on the market. Therefore, usually the products that are used for same purposes and are interchangeable are considered to be on the same product market. These points are of high importance in determining whether an undertaking really abused its dominant position in the relevant market, because if the relevant market offers effective alternative sources of supply and consumers are able to switch with no or at a low loss, the undertaking in question is actually unable to have a significant impact or impose its conditions on that market and therefore distort it.

I.II. Concept of a Dominant position

As it is common practice in a number of areas of EU law, the Court of Justice (hereinafter the Court) has laid down and developed the definitions of these concepts

¹⁰ Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, ([1997] OJ C 372)

¹¹ Ibid, Introductory articles

¹² E. Fox, *The Competition Law of the European Union in Comparative Perspective - Cases and Materials*, West, 2009, p. 74

in its relevant case law. In the pharmaceutical case *Hoffman-La Roche v. Commission* the Court defined a dominant position as “a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers”¹³. Thus, the definition suggests that dominance of it places it into a position where due to its obtained economic strength, an undertaking is no longer under the significant influence of its rivals or customers and therefore, **may** impose its own terms on the market and preclude the full effectiveness of competition. Moreover, it becomes an unavoidable business partner for its competitors and, basically, an imposed choice on the consumers. Further, in the same case the Court also highlighted that a mere existence of a dominant position does not itself preclude competition, but allows a dominant undertaking “if not to determine, at least to have an appreciable influence”¹⁴ on the competition development in the market.

Furthermore, the meaning of a “position of economic strength” must be explained as well, as it does not simply occur in the abstract.

In *Hoffman-La Roche* the Court concluded that a dominant position might be caused by several factors, the most important among them being the ‘existence of very large market shares’¹⁵. According to the Court, by virtue of large market shares an undertaking becomes an unavoidable trading partner for the undertaking having low market shares, whereas granting itself freedom of action – one of the special features of an undertaking enjoying a dominant position¹⁶. In the same case the Court of Justice has indicated that market shares of 40% and upwards, combined with other significant factors, such as market entry barriers and buyer power, presumably confer dominance. The Court has confirmed this in its further case law, namely in *AKZO*¹⁷ case, where it pointed out that a 50% market share, as found in the case, showed the existence of dominance¹⁸. In line with this settled case law and in order to bring in more legal certainty in assessing the market power, the Commission has also issued a set of Guidelines¹⁹, which provide with certain rules on the assessment of a dominant

¹³ Case 85/76 *Hoffman-La Roche v. Commission*, [1979] ECR 461, para 38.

¹⁴ *Ibid*, para 39.

¹⁵ *Ibid*, para 39.

¹⁶ *Ibid*, para 41.

¹⁷ Case 62/86 *AKZO Chemie BV v. Commission*, [1991] ECR I-3359

¹⁸ *Ibid*, para 60.

¹⁹ Communication from the Commission — Guidance on the Commission's enforcement priorities in

position. The Guidelines also confirm that for a dominant undertaking ‘the competitive constraints are not sufficiently effective’.²⁰

In the light of the given notion of dominance, another important line of reasoning of the Court must be presented. In the *Michellin*²¹ the Court points out another essential element of a dominant undertaking: “<...> *irrespective of the reasons for which it has such a dominant position, the undertaking concerned has a **special responsibility** not to allow its conduct to impair genuine undistorted competition on the common market.*”²². The notion of special responsibility, however, has not been yet explained by the Court in more detail. It suggests, that once an undertaking is in a possession of exceptional economic strength, it must be very cautious in performing certain activities on the market that other non- dominant undertakings can perform freely²³. Following the description of certain activities of a dominant undertaking, the research of the meaning of abuse of dominant position will be explored.

I.III. The notion of abuse of a dominant position

As already mentioned above in this chapter and as concluded in the case law, a mere state of dominance is not an abuse in itself. However, dominance is a clear precondition for triggering the application of Article 102 TFEU. Therefore, there must be an actual action conducted by a dominant undertaking constituting an abuse.

Article 102 provides four conditions under which the abuse of dominant position may occur. The analysis of each single example is beyond the scope of this paper and, therefore, will not be performed herein. However, as the settled case law²⁴ and the wording of the article itself suggests²⁵, the list of abuses is non- exhaustive. This is of a high importance to the further researched *AstraZeneca* case, as the abusive conducts indicated in this case were newly introduced by the Commission and did not fall into

applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ, C 45/7 of 24.2.2009.

²⁰ *Ibid*, para 10.

²¹ Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communities*, [1983] ECR 3461.

²² *Ibid*, para 57.

²³ Ekaterina Rousseva, *The Concept of ‘Objective Justification’ of an Abuse of a Dominant Position: Can it help to Modernise the Analysis under Article 82 EC?*, March 2006, *The Competition law review*, Volume 2, Issue 2, p 30.

²⁴ Case 6/72 *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities*, [1973] ECR 215.

²⁵ “<..> Such **abuse may**, in particular, consist in <..>”

the listed categories. Therefore, the general concept of abusive conduct will be researched, as it is relevant for the further evaluation of Commissions and General courts decisions and AZ's conducts.

A classical, yet, wide definition of the notion of abuse is once again provided by the Court of Justice in *Hoffman-La Roche*. It is described as “*an objective concept relating to the behavior of an undertaking in a dominant position which is such as to influence the structure of the market, where as a result of the very presence of the undertaking, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition*”²⁶. The main idea of the definition suggests consumer welfare as a priority to be protected. Accordingly, the consumers should be in a better situation where competition in the market stands strong and is not influenced by abusive conducts of dominant undertakings.

However, an interesting point to take into account, as some scholars argue, is that the European Courts case law clearly shows that it is not only the consumer welfare that is the aim of protection, but also the competitors access to the market, “*thereby disguising a concern about competitors’ freedom of action with concerns for maintenance of a degree of competition to the consumers’ benefits*”²⁷. As it will be seen later and specifically in the context of the *AstraZeneca* case, these two elements indeed interplay in the Commission’s and the General court’s reasoning.

I. IV. Exclusionary conducts

Generally, the abusive conducts in the EU Competition law can be divided into two major groups: exploitative (excessive and discriminatory pricing) and exclusionary or foreclosing practices²⁸. The latter will be presented in more detail due to its importance for the research conducted herein as the situations examined further are related with these particular abuses.

²⁶ *Ibid* 10, para 6.

²⁷ Ekaterina Rousseva, “*The Concept of ‘Objective Justification’ of an Abuse of a Dominant Position: Can it help to Modernise the Analysis under Article 82 EC?*”, March 2006, *The Competition law review*, Volume 2, Issue 2, ISSN 1745-638X (Online), p 30.

²⁸ E. Fox, *The Competition Law of the European Union in Comparative Perspective - Cases and Materials*, West, 2009, p. 76.

Exclusionary practices have been examined by the Commission's Discussion Paper on the Application of Article 82 (ex Art. 82, currently 102)²⁹. The aim of the document is 'to ensure that dominant undertakings do not impair effective competition by foreclosing their rivals in an anticompetitive way and thus having adverse impact on consumer welfare'. It is emphasized that "*with regard to exclusionary abuses and the objective of Article 82 [old numbering], is the protection of competition on the market as a means of enhancing consumer welfare and of ensuring an efficient allocation of resources.*"³⁰ The benefits of the effective competition are the ones such as low prices, high quality products, a wide selection of goods, services and innovation.³¹ Moreover, as the Paper suggests, Article 102 TFEU does not protect the competitors of dominant firms from genuine competition due to "factors such as higher quality, novel products, opportune innovation or otherwise better performance, but ensures that these competitors are also able to expand in or enter the market and compete therein 'on the merits', without facing competition conditions which are distorted or impaired by the dominant firm."³² It is noteworthy, that on this point the document refers to the Commission's Decision *AstraZeneca's*. Therefore, it is suggestive that the outcome of the case is of high importance for the notion of abuse in general, whilst the imminent ruling of the Court of Justice might cause even greater change in this assessment. It will be particularly important for the pharmaceutical undertakings in the EU as it will define the boundaries of application of Article 102 TFEU in the pharmaceutical sector cases.

To conclude, the problematic point of the notion of abuse of dominance is that up until this day it is not always entirely clear which conducts should or could be seen as abusive in the light of EU law, especially in such specific sectors as pharmacy. Therefore, the assessment is performed on a case-by-case approach and sometimes is rather confusing. The Court of Justice and the General Court has previously ruled a few quite unexpected judgments in this area of law that were later fiercely contested by legal scholars and lawyers in the EU. Such highly contested decisions were often related to the exercise IP rights owned by dominant undertakings. Prominent

²⁹ European Commission Directorate General for Competition, "*DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses.*"

³⁰ *Ibid*, para 4

³¹ *Ibid*, para 4.

³² *Ibid*, para 54.

examples of such cases are the *Microsoft*³³ and of course the debated *AstraZeneca* case.

However, in practice the Commission has obviously put a lot of effort in clarifying what is an abuse of dominance. It has attempted to do so by issuing a number of Communications, such as the so-called Guidance on the *Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings* or the aforementioned *Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary abuses*. The rationale behind the adoption of these documents, the idea was to flesh out the relevant concepts, grant more legal certainty for undertakings by forming a kind of universal set of principles, which would be easy to apply in order to find out whether certain conducts should be seen as abuses in the light of EU Competition law.

It is clear that that the goal in the EU is to protect an overall effective competitive process and not just one part of it, such as competitors or the consumers.

However, as noted before, the Commission highly prioritizes the consumer protection and often in the case law or relevant press releases stresses the importance of benefits for the final consumers. However, such aim set by the Commission is not always in line with the case law of the Court of Justice, as it tries, on the contrary, to set the principle that only proving that rivals would be excluded from the market is a fact enough to prove the abuse. Therefore, the Court is still using a wide interpretation of the Article 102. The relevant issue also arose in the *British Airways*³⁴ case, where the Court of Justice explicitly confirmed that the Commission has no power to overrule its rulings. In response to the Court, the Commission explained that it will only aim to prioritize the cases related to consumer welfare upon opening up a case and starting an infringement procedure, without the intent of affecting the concept of abuse of a dominant position itself.

At this point it is interesting to note that the Court and the Commission are not any more solely entitled to apply Article 102. Previously Article 102 could be applied only exclusively by the Commission and the European Court of Justice. However due to the Commissions inability to deal with the associated workload, the system was changed, in order for Article 102 be applied also by the relevant national courts. Therefore, the contradictory practices used by the Commission and the Court of

³³ Case T-201/04 *Microsoft v Commission* [2007] ECR II-03601.

³⁴ C-95/04 *British Airways PLC v. Commission*, [2007] ECR I-2331.

Justice are sending a quite confusing message to the national courts and/or the national competition authorities and the undertakings in general.

I.V. Objective justifications of abuses

A dominant undertaking, which allegedly performed an action of abuse of its dominant position has always an opportunity to objectively justify such action and therefore fall out of the scope of Art. 102. However, as Rousseva points out, *the concept of objective justification remains one of most vague concepts associated with the application of Article 102. The exact scope, meaning and operation of the concept have never been clarified by the Community courts and remain highly speculative.* In analyzing the scope of objective justifications, the author points out that generally accepted justifications, such as public policy concerns were rarely invoked in the case law and the modernization in this area was inevitable.

In my opinion, the latter concern should be well taken into consideration upon the examination of the boundaries between the protection of IP rights and infringement of competition law rules as it is reasonable and possible that the undertakings which engaged into abusive conducts acted so in order to protect and exercise their intellectual property rights without the intent to distort the competition. Therefore, the final outcome of the AZ case should as also contribute to the scope of objective justifications generally and specifically in the context of pharma cases.

I. VI. Dominance of pharmaceutical undertakings

Given the aforementioned definitions, it is clear how highly likely is that originator pharmaceutical companies are to be dominant. As it will be shown later in the analysis, in order to be innovative and able to invest sufficient sums into costly pharmaceutical research and development (R&D), a company has to have access to extremely large resources. Therefore, inventions of drug formulas that could be patented derive from significantly wealthy pharmaceutical undertakings, which are usually already well established in the market and specialize in innovations, enjoying economic strength and are able to handle innovation related losses occurring during the process.

Furthermore, due to the contradictory case law on the notion of abuse of dominance, it is of little surprise that undertakings may be misguided about legality of conducts that they may perform, especially in the area of protection of intellectual property. One could say that dominant undertakings, such as pharmaceutical ones, might attempt to exploit these gaps to their advantage. However, the question of the legitimacy of such actions in the light of EU competition law remains open and is the subject of further research conducted in this thesis.

Chapter II

II. Specific features of the pharmaceutical industry

First of all, it must be noted that the sector-specific features of the pharmaceuticals that may influence competition law analysis were clearly acknowledged by the General Court in the *AstraZeneca* case. Therefore, in order to properly understand the key parts of the litigation further examined in this thesis, it has to be placed into the context of the specificity of pharmaceutical sector, because it must be taken into consideration whilst applying EU competition rules.

Due to the distinguishing features of medicinal products and their undisputable importance to healthcare, pharmaceutical industry strongly differs from any other. These specificities highly influence relevant legal framework as well as litigation of cases brought to courts. Therefore, due to these features, the outcomes in the legal issues regarding EU competition or intellectual property of pharmaceutical sector may significantly vary from those in other industries, which concern not such peculiar products.

In the case-law of the Court of Justice the specificity of pharmaceuticals was clearly pointed out early before the *AZ* case in one of the noteworthy *GlaxSmithKline Unlimited ('GSK')*³⁵ cases. The particular case concerned GSK's adoption of new general sales conditions which aimed at differentiating prices for Spanish wholesalers based on the location where the medicinal products had (Spain or other Member states) to be exported. Although by doing so GSK aimed at restricting parallel import and admitted this intention, the company notified the Commission and requested an exemption on this agreement. The exemption was requested on the basis of specificity of pharmaceutical sector and the company has pointed out that an engagement in to such agreement would satisfy the conditions for an exemption as the outcome of the contract would contribute and promote technical progress in the sector. However, the

³⁵ Joined cases C-501/06 P, etc *GlaxSmithKline Services Unlimited v Commission and Others*, [2009] ECR I-09291.

Commission did not accept this argument and denied the request³⁶. In short, the Commission decided that GSK's general sales conditions were in breach of competition law, because they were based on an agreement restricting competition and that GSK had failed to prove conditions necessary for such an agreement to be able to benefit from an exemption. Consequently, GSK lodged an appeal³⁷ to the General Court, which upheld the Commission's decision not to grant an exemption, finding that the agreement had as its *object* a restriction of competition³⁸. As by the rules of EU competition law, an agreement with such object cannot be present at any circumstances, even when requesting an exemption.

However, although the Court has upheld the Commission's decision, it has also found that the Commission had not examined GSK's request with sufficient thoroughness regarding the economic advantages and innovation. Moreover, whilst analyzing the market definition, the General Court admitted that sector specificity indeed exists due to public authority regulations on pricing and that the sector is "*to a significant extent shielded from free play of supply and demand*"³⁹. Therefore meaning, that although the restriction of parallel imports should not be allowed, this is no ordinary market that functions in expected ways and may have different outcomes, as well as suggesting that in sufficient circumstances certain exceptions could be allowed.

As expected, the case was further brought before the Court of Justice. When deciding on the issues of competition, The Court has then clearly recognized the importance of peculiarity of various sectors, as it has precisely pointed out that an examination for the relevant exemption "*may require the nature and specific features of the sector concerned to be taken into account if its nature and those specific features are decisive for the outcome of the analysis*"⁴⁰. Therefore, such reasoning shows that the peculiarity of a sector should be undisputed while examining related competition and, it may be added, related intellectual property law issues. Moreover, the Court clarifies that such features should be researched in detail as it may affect the whole outcome of the litigation, whereas in regular sectors this would be less likely to occur.

³⁶ Commission Decision 2001/791/EC of 8 May 2001, OJ L 302.

³⁷ Case T-168/01 *GlaxoSmithKline Services v Commission*, [2006] ECR II-02969.

³⁸ *Ibid*, para 147.

³⁹ *Ibid*, para 147.

⁴⁰ C-501/06 *GlaxoSmithKline v. Commission and others* [2009], OJ C282, para 103.

Furthermore, the specificity of this sector is not only highlighted in the case law, but is also featured in a number of other sources, such as relevant legal framework, for instance the Regulation on SPC's⁴¹, where the complexity and sensitivity of the sector is particularly stressed⁴².

Consequently, further part of this chapter is aimed at introducing specific features of pharmaceutical sector in more detail, namely the specifics of state regulated product pricing, complexity of research and development processes, long way to market access and competition issues between originator and generic companies, as well as the issues of the registration of marketing authorizations, meaning and importance of the SPC's.

II. I. Regulation of the pharmaceutical sector on EU and national levels

Firstly, one of the most important and previously mentioned specifics in *GSK* cases should be introduced in more detail: pharmaceutical undertakings are not entirely free to determine the prices of their produced drugs and prices are regulated by the state. As pointed out in one of the relevant competition law reviews, the firms are especially not free to increase the pricing, however usually free to decrease it, when faced with stronger competition⁴³.

However, due to the freedom of movement of goods in the single Market of EU, it is important to mention what is the role, if any, of the Unions regulations regarding the regulations in this sector.

The pricing of medicines is only subject to limited harmonization on the EU level. Article 168(7) of the Treaty sets that in the area of health care, the EU shares competence with the Member States and respects their responsibilities for the organization and delivery of health services and medical care within their territories. Therefore, national authorities are completely in charge of this regulation and are free to include the drugs of choice into their healthcare systems. Directive 2003/63/EC,

⁴¹ Regulation (EC) No 469/2009 of the European Parliament and of The Council concerning the supplementary protection certificate for medicinal products [2009] OJ L-152/1.

⁴² Ibid, for instance para Art 2(10) “<..> a sector as complex and sensitive as the pharmaceutical sector<..>”.

⁴³ Jacob Westin *Defining relevant market in the pharmaceutical sector in the light of the Losec-case-just how different is pharmaceutical market?*, 2011, European Competition Law Review, Westlaw p. 57-62.

relating to medicinal products⁴⁴ ascertains the latter competence by stating that “*the provisions of this Directive shall not affect the powers of the Member States’ authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.*”⁴⁵. The Directive only adds that upon this regulation of pricing and reimbursement, the Member States must act timely and transparently. It is important to underline that by these national regulatory systems and inclusion of certain drugs into various levels of healthcare systems, the states directly influence the prices and the amount of sales of those drugs, which may also directly influence the competitive mechanisms among the pharmaceutical firms.

Therefore, regulation of prices in the pharmaceutical sector are not controlled on the EU level or in other words, *pharmaceuticals are not harmonized within the Single Market*⁴⁶. As the previously mentioned Directive suggests, there are a number of reasons for such non-harmonization. In one of the researches on differential pricing for pharmaceuticals, it is highlighted that by far the most important reason of differential pricing is societal welfare: differential pricing is an effective strategy to improve access to essential medicines in countries which are not as economically developed and therefore, patients would not be able to afford drugs priced comparably to high income markets⁴⁷. As there is also a lot of aspects of national policies involved, it makes any attempt of harmonization in such essential to human health sector very complex. Therefore, it is expected that attempts to reach any kind of harmonization and consensus in this matter on EU or international levels most of the time do not bring desired results.

Nevertheless, this should not imply that the Member States or the pharmaceutical undertakings are free to take unlimited actions regarding this sector and undermine the rules of competition, as one author justly points out “*<...> in carrying out their responsibilities, Member States and health care stakeholders such as national health services and pharmaceutical companies are bound to respect EC Treaty rules on free competition and the free movement of goods and services within the internal*

⁴⁴ Commission Directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [2003] OJ L- 159.

⁴⁵ *Ibid*, Art 4(3).

⁴⁶ Nadia de Souza, *Competition in Pharmaceuticals: the challenges ahead post AstraZeneca*, Competition policy newsletter, Spring 2007, p. 39-43.

⁴⁷ Prashant Yadav “*Differential Pricing for Pharmaceuticals*” August 2010, available at http://pdpaccess.org/downloads/resources/pricing/Differential%20Pricing_Yadav.pdf

*market*⁴⁸.” Accordingly, in the case of possible breach of Union rules, the role of national competition authorities and the EU Commission becomes of significant importance. They are obliged to ensure the application of the EU competition rules and on the basis of article 105 TFEU, the Commission may take initiative and start an investigation of suspected infringements and determine whether certain actions of MS’es or undertakings comprise a breach of the Treaty and what actions should be taken to end it. If, however, an infringement is not brought to an end, the Commission may record such infringement of the competition principles in a reasoned decision and authorize Member State to take appropriate actions. The *AstraZeneca* case is a fair example of such initiative, where the Commission conducted a five-year investigation and imposed a 60 million EU fine on AZ for breaching the rules of competition and abusing its dominant position. Moreover, the Treaty does not provide any exemptions for the public undertakings or undertakings having exclusive status under the laws of a Member State, as Article 106 TFEU provides that even in such case, “*Member States shall neither enact nor maintain in force any measure contrary to the rules contained in the Treaties, in particular to those rules provided for in Article 18 and Articles 101 to 109*”.

Although it is obligatory to act in line with the Treaty and respect EU competition rules, the absence of harmonization in the sector still remains. As noted before, the prices of various medicines are regulated in each country differently and the costs throughout the Member States of EU may highly differ. However, within the EU, these differences often stimulate parallel imports among the low and high priced states and may cause certain disruptions. An example of such parallel trade was in question in the notable Bayer *Adalat*⁴⁹ case, where the cheaper drug Adalat was exported by wholesalers from Spain to UK and consequently caused an enormous, nearly fifty percent drop of sales of that same drug sold by British Bayer subsidiary⁵⁰ and resulted in litigation among the undertakings concerned. Although parallel trade did not play the key importance in *AZ* case, the presented example merely illustrates one of the issues which may arise due to introduced specificities and affect competition in the sector, indirectly affecting related intellectual property as well.

⁴⁸ *Ibid*, p. 39.

⁴⁹ Joint cases C-2/01 P and C-3/01 P *Commission of the European Communities v. Bayer AG (Adalat)*, [2004] ECR I-23,

⁵⁰ *Ibid*, para 3.

II. II. Market authorization of the pharmaceutical products in the EU

Once a pharmaceutical product is developed and patented it is not yet ready to be put on the market as most other ordinary products. To ascertain that only safe medicines are marketed in the EU, a pharmaceutical product first has to obtain a market authorization⁵¹. The procedure of this authorization is currently laid down in the EU legislation, namely Regulation 726/2004⁵² and Directive 2001/83/EC⁵³.

There are two types of authorization; to get authorization only in one Member State the *decentralized* procedure is used, by lodging the application to local relevant agencies. In order to be granted a marketing authorization for a medicinal product in all Member States, the applicant must use the *centralized procedure* and lodge the application to European Medicines Agency (EMA). However, if the medicinal product has already been authorized at the time of the application, the authorization holder may then take the advantage of mutual recognition procedure and submit a request for recognition of this authorization to other Member States. He must inform the Member State, which has issued the authorization ('reference Member State') of this, as well as the EMA⁵⁴.

Seemingly uncomplicated, general procedures of application for authorization are actually a lengthy process and might take up to almost a year if all the needed data in the application is submitted successfully. The Regulation and the Directive set the requirements for the content of the applications, namely what information has to be provided in order to receive the authorizations. The applicants must provide large amounts of information regarding the clinical results of the drug in question and all the relevant scientific data.

⁵¹ , Commission Directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [2003] OJ L-159, art 6.

⁵² Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) [2004] OJ L- 136.

⁵³ Commission Directive 2003/63/EC amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use [2003] OJ L- 159.

⁵⁴ Summary of the 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, available at: http://europa.eu/legislation_summaries/internal_market/single_market_for_goods/pharmaceutical_and_cosmetic_products/l21230_en.htm

In comparison, the access to the market for the generic medicines is available at the simplified procedure set out in the directive. In such case, if the drugs can be referred to essentially similar authorized product and original drug no longer enjoys the exclusive patent protection and the original medicine was already authorized and marketed in the Member States, then the applicants of the generic product no longer need to carry out additional research or provide with the results of new clinical trials. However, it is important to note that a company owning a market authorization of a certain drug may always deregister it if pleases to do so. Clearly, in such occasion a generic company would be no longer able to use a simplified procedure and rely on the existing product authorization. In such case, the entry to the market of the generic company would be slightly delayed. Moreover, according to the pharmaceutical sector inquiry⁵⁵ conducted by the Commission, practices with the objective of delaying or blocking market entry of competing medicines, are considered as blocking strategies that may distort competition in the sector and could result in significant additional costs for public health budgets, taxpayers, patients and ultimately reduce incentives to innovate.

However, the question of determining whether such a practice really had the objective of delaying or blocking market entry to generic competitors still remains. In my opinion, the line between the legal right to withdraw the authorization (for no particular or confidential reason, known by the withdrawing company) and the use of that same right in order to block the competing medicines is very narrow and should be considered with scrutiny. In addition, it must borne in mind that the maintenance of a market authorizations has significant costs. Therefore, possibility that a negative outcome of the action was unintended could be very likely. Yet, whereas the issue may have an impact on the rules of competition, several factors should not be forgotten and taken into account: such as the possibility of dominant position of the withdrawing company. As introduced in the previous chapters the status of the dominant company is very delicate as its every action must be carried out with great responsibility because it may have crucial impacts on the overall competition in the market.

In the case of *AstraZeneca*, the Commission and the General Court found that such deregistration performed by the company was solely aimed at dampening the

⁵⁵ Press release by the EU Commission- *Antitrust: preliminary report on pharmaceutical sector inquiry highlights cost of pharma companies' delaying tactics* [2008].

competition and was considered as abusive conduct. Further analysis concerning alleged abuse and the impact on intellectual property rights on this point will be fully researched in the following chapter of this thesis based on the context laid in this paragraph.

II. III. Supplementary Protection Certificate ('SPC')

It is important to understand the purpose and the functioning of the SPC as one of the alleged abuses of AZ were the misleading representations given to the patent agents, national patent offices and courts in order to obtain the SPC's that the company was not entitled to.

As the information presented in this chapter shows, the way of a pharmaceutical product from its research, developing and patent registration to the placement on the market is quite a lengthy process. This process might take up to not just a several years, but a decade or even a few. During this time, the term of products patent protection is lapsing and when the drug in question is finally put on the market it is very likely that its protection has already expired or is close to expiry date. Intelligibly, such situations are discouraging for the innovators as they lose the opportunity to recoup their research and development expenditures. As it is noted in the Regulation establishing supplementary protection⁵⁶, such circumstances are even creating the risk of research centers situated in the Member States relocating to countries that already offer greater protection.

In order not to discourage the development of new medicinal products and offer more favorable rules in this area, the EU has introduced a completely *sui generis* IP right - Supplementary Certificate Protection (SPC)⁵⁷. The SPC grants an extra protection for the pharmaceutical product for up to five years after the patent expiry. Therefore, the main idea behind the creation of the SPC is to prolong the protection period for the pharmaceutical products and let the originator companies enjoy the fruits of their exclusive intellectual property right a while longer, therefore recouping for the effort and costs invested. This also possibly leads to the benefit of the consumers as well: as the proprietors have longer time to recoup their investments, the price of the drug on

⁵⁶ Regulation 1768/92 Concerning creation of supplementary protection certificate for medical products 1992, OJ L 182/1.

⁵⁷ *Ibid.*

the market might be reduced as well. It must be pointed out that in the context of pharmaceuticals and by the definitions of the relevant regulation ‘a product’ can mean an active ingredient or a combination of active ingredients and it must be protected by the basic patent⁵⁸. The certificate applies to the product in the same way as the patent from which it benefits after the patent has expired. There is also a possibility of extending the period of duration of SPC on certain conditions, which are set in the Regulation 1901/2006, article 36. According to the article, such extension can be up to five and a half years when the SPC relates to a human medicinal product and the data from clinical trials conducted in accordance with an agreed Paediatric Investigation Plan (PIP) have been submitted. However, a potential problem arising from the regulation of SPC’s and often underlined by IP lawyers, is that there is no harmonized cross - recognition between the EU states. The applications must be lodged and approved in each Member State separately, which might lead to abusive multiple registrations and protection extensions for the same product.

II. IV. Innovation in pharmaceutical industry: research and development costs

The processes of research and development could be named as the feature of core importance the pharmaceutical industry. Clearly, due to the complexity of its products this sector is one of the most R&D intense industries: for instance, as a government conducted research in the US⁵⁹ shows, lengthy and complex innovation, research and development of new drug may cost average of 800\$ million and take even up to 12 years of time. However, it must be borne in mind that this, although a very large amount includes research strategies and drug-development choices made by manufacturers on the basis of their expectations about future revenue and including a possible failure of the research⁶⁰. In economical terms also known as “opportunity costs”.

However, the costs of development depend on other important factor: it depends on whether the drug developed is completely innovative (*a new molecular entity or*

⁵⁸ Carola Lempke, *Review of Supplementary Protection Certificates*, CIPA Journal, September 2011, page 607.

⁵⁹ Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, “*The Price of Innovation: New Estimates of Drug Development Costs*,” *Journal of Health Economics* [2003], vol. 22, no. 2, pp. 151-185.

⁶⁰ *Ibid.*

NME) or based on a previously existing formula (*incremental improvements on existing drugs*). Clearly, the costs of the new drugs that are NME's are significantly higher rather than those which are just developed by making incremental improvements on existing drugs. Expenditures of developing an NME drug may vary widely, from a low of \$800 million to nearly \$2 billion per drug⁶¹, whereas the average costs of improvement of existing drugs may be down to 60% lower than noted amounts.

However, incrementally modified drugs are not less important or insignificant. In fact, these drugs may provide benefits both to the companies and the consumers. As an example, recipients' health may be benefited with more convenient dosing forms⁶² (easier intake by remaking hard tablet into a dissolving one, a stronger pill that can be used at lesser frequency and etc). Despite the arguments that "*the higher prices that are charged for some drugs that are merely extensions of current product lines may not be commensurate with the additional value that those drugs provide*"⁶³, improvements are often so advanced and efficient that eventually the prior version of a drug is completely replaced by a newer one. Moreover, for the pharmaceutical industry the development of such drugs is not only cost efficient, but also **necessary** since novel drugs alone would be not enough to support the expensive R&D costs⁶⁴. Therefore, in order to maintain a balance between these costs and revenue, a balance between production of risky innovative and incremental drugs is crucial. And as A. Wertheimer, the author of the research regarding IPR's and importance of innovation suggests, policies limiting incremental innovation may disrupt this delicate balance, yet not meaning that pharma sector should be free from any limitations but that such limitations should not restrict and prevent innovation⁶⁵. Therefore, both types of the development are equally important as they are interconnected and directly dependant on each other. As it is concluded in the research, "*policy makers should be aware of*

⁶¹ Neal Masia, *The Cost of Developing a New Drug*, Article from the U.S. Department of State publication, *Focus on Intellectual Property Rights* [2008], available at : <http://www.america.gov/st/econenglish/2008/April/20080429230904myleen0.5233981.html>

⁶² *Ibid.*

⁶³ *Ibid.*

⁶⁴ Albert I. Wertheimer, Thomas M. Santella "*Pharmacoevolution: the advantages of incremental innovation*", IPN Working Papers on Intellectual Property, Innovation and Health, available at <http://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf>, p.13.

⁶⁵ *Ibid.*

the significant difference between incremental drugs and mere copycat drugs as the future of drug innovation hangs in the balance”⁶⁶.

Nevertheless, according to the pharmaceutical sector inquiry⁶⁷ conducted by the Commission, incremental modification of drugs in a way could be considered as a defensive patenting strategy or the so-called “patent clusters” or process patents, which prolong patent protection period and causes new barriers to entry of the market for the generic companies. More precisely, process patents occur when a company willing to modify and improve its existing patented drug, patents also the new process of the improvement of that drug and therefore extends the overall protection of the original formula of the medicine. For example, an existing tablet, whose patent protection has not expired yet, is being incrementally modified in order to make it more effective and the new formula of that modification is patented, meaning that the previous formula would be also covered by the new patent protection as the old one produces exactly the same, just lesser effects and the aim of modification is to improve the already existing formula.

In my opinion, the latter facts regarding types of R&D drugs are especially important to a part of *AstraZeneca* case due to the issues raised in findings that the company was abusing its dominance and in defining the relevant market of the drug in question. First of all, Commission and the Court has claimed that a drug in question (PPI’s) formed a new separate market by itself even though it was used to treat same conditions as the other drugs (H2 blockers), meanwhile the *AZ* has claimed that although a contested drug was novel, it was an improvement of existing drugs treating the same conditions. Moreover, by the reasoning of the Court, one of the indicators in market definition were also price differentials between the products, as *AstraZeneca*’s produced drugs were priced significantly higher. The following may raise a concern whether every innovative pharmaceutical company does not become discouraged of innovation as it places itself at the situation of being found dominant because it manages to negotiate a higher price to its costly innovation in comparison to its pre-existing competitors. In addition, the Commission in a way undermines the assessment of R&D in this case by not taking into account the size of these investments and stating that “in dynamic markets, such as the pharmaceutical sector,

⁶⁶ *Ibid.*

⁶⁷ Press release by the EU Commission- *Antitrust: preliminary report on pharmaceutical sector inquiry highlights cost of pharma companies’ delaying tactics* [2008].

where innovation plays an important role, dominance cannot be limited to situations where the dominant company would simply refrain from investing in R&D. In such markets, a dominant company has to invest regularly if it wants to preserve its market position”⁶⁸.

Secondly, *AZ*'s action of replacing Losec capsules with incrementally modified and more advanced Losec MUPS tablets was considered to be an abusive marketing strategy used in order to block the entry of generic companies. Therefore, considering the prior research regarding NME's, at the first glance such accusation makes an impression that nor the real benefits of incremental modification, nor the importance of economical balance for the firms was considered thoroughly by the Commission.

⁶⁸Case COMP/A. 37.507/F3 ñ AstraZeneca, Commission Decision of 15 June 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement, para 514.

Chapter III

III. Assessment of the AstraZeneca Case

III. I. Summary of the facts

After a five-year investigation, in June 2005, the Commission issued a decision finding AstraZeneca dominant in several Member States in the market of proton pump inhibitors and responsible for having abused its dominance in two distinct ways. For the alleged abuses the Commission has imposed a fine of 60 million EU. Consequently, disagreeing with both of the abuses *AZ* appealed the decision to the General Court (further ref. as the Court or GC). Five years later, in 2010 the GC issued its decision, which in essence upheld the position of the Commission and due to a few changes regarding the second abuse reduced the fine by 7.5 million EU.

AZ was accused of abusing its dominant position by infringing competition rules and using several strategies aimed at blocking or delaying market access for generic versions of the drug “Losec” and preventing parallel imports of the drug. Namely, the Court and the Commission found that the abusive strategies comprised of:

- 1) supplying misleading information and ‘lack of transparency’ to national patent offices in relation to the extension of patent rights (in order to obtain the SPC)
- 2) launch of a new version of Losec tablets and selective deregistration of the market authorizations for “Losec” capsules in several Member States with the intent of blocking or delaying entry by generic firms and parallel traders.

III. II. Market definition

As it has been introduced in the first chapter, definition of a relevant product market is the first step in antitrust cases and is determined by several interchangeable rules. It is the most important element in assessment of dominance or abuse of dominance

because Article 102 is only applicable if an undertaking is found to be in a dominant position on the relevant product market.

The products in question in *AZ* case were medicines known as the H2 blockers and Proton Pump Inhibitors (PPI's). These medicines are used to treat most common stomach acid reflux conditions when there is a lack of acid secretion in the stomach. However, there were several important differences found between these drugs and PPI's were considered to be more efficient drugs for several reasons; First of all, as it was analyzed in the case, acid is pumped into the stomach by a specific enzyme ("the proton pump") inside the so-called parietal cells along the stomach's wall. However, the H2 blockers only block the so-called histamine receptors in the parietal cells and these histamine receptors are only one of the stimulus of the proton pump. In contrast, PPI's reach deeper into the acid-producing parietal cells and pin-point the proton pump itself.⁶⁹ To sum up, H2 blockers only operate indirectly on the proton pump and the PPI's function accurately. Moreover, it was agreed that the therapeutic strength of PPI's was significantly greater than that of H2 blockers.⁷⁰ As it is evident from the information provided in the case, PPI's, which were produced and patented as "Losec" capsules by AstraZeneca, became the best selling prescription medicine and between 1999 and 2000 it even accounted for almost 40% of *AZ*'s total sales⁷¹. However, despite the fact that H2 blockers and PPI's were used to treat the same type of gastrointestinal conditions, AstraZeneca was in disagreement with the Commission concerning the issue of whether the products were interchangeable. Although *AZ* has claimed that the products were on the same market, both the Court and the Commission agreed that the drugs were not interchangeable and did not belong to the same product market. The latter conclusion was drawn on the basis of information provided by medical experts. Although the experts did confirm that the drugs were used for the same diseases, they have also concluded that the medicines were used to treat different stages of those diseases. Namely, as apparent from those statements, PPI's were generally prescribed to treat severe forms of the conditions while H2 blockers were more likely to be prescribed to treat their mild or less serious forms.⁷² Nevertheless, the use of PPI's was expanded and in fact, the medicines could have

⁶⁹ Case T-321/05 *AstraZeneca v Commission*, [2010] II-02805, para 62.

⁷⁰ *Ibid*, para 63.

⁷¹ Commission decision, para 9

⁷² Case T-321/05 *AstraZeneca v Commission*, [2010] II-02805, para 69.

been and actually were prescribed to treat the same less severe forms of gastrointestinal diseases as H2 blockers⁷³. The two drugs were even considered as alternative first-line treatments, according to whether a ‘step-up’ or ‘step-down’ approach was adopted by the prescribing doctor⁷⁴. The Court, however, did not consider this to be an important or influential point to interchangeability and further referred this to be as of “*limited relevance*”⁷⁵. Shortly, such conclusion was made because of the fact that once a disease reaches a certain degree of severity, H2 blockers no longer have desired effectiveness and are replaced by PPI’s⁷⁶, which therefore lets the Court conclude that H2 blockers do not constitute significant competitive constraints over PPI’s.

Further, the Court analyses the pricing of the products. Interestingly, it does not accept AZ’s arguments regarding the pricing specificities in pharma sector, namely the fact that prices are under high regulations of the state authorities and therefore, in the words of AZ could be *inappropriate for competition analysis purposes where competition on the market in question is not based on price*⁷⁷. Instead, the Court upholds the research conducted by the Commission and finds that the prices set by the authorities indicate relative therapeutic value (higher quality – higher price).

One could point out that due to the latter finding, the Court then should have strongly taken into consideration the next noteworthy argument presented by AZ. The company has claimed that the length of the treatments should be taken into account and the price of relevant drugs should be calculated by volume of drug use and not the figures of its value on the market⁷⁸. In other words, due to different levels of effectiveness of the drugs in question, AZ suggested that the length of the treatment with PPI’s would be considerably shorter than of that with the H2 blockers. Therefore, in the long term the costs would be the same. The Court, however, rejected this argument due to complexity and uncertainty of necessary analysis.

Moreover, the Court has also rejected AZ’s arguments related to product quality and ‘inertia’ of doctors to prescribe H2 blockers. Neither did it find the considerably lower adverse side effects of H2 blockers to be relevant to the competition⁷⁹.

⁷³ *Ibid*, para 68.

⁷⁴ *Ibid*, para 70.

⁷⁵ *Ibid*, para 71.

⁷⁶ *Ibid*, para 71.

⁷⁷ *Ibid*, para 112.

⁷⁸ *Ibid*, para 115.

⁷⁹ *Ibid*, para 100.

However, it is clear from the previous research that in pharmaceuticals the side effects are well taken into consideration and that the companies invest a load into R&D and into modifying existing drugs to improve them, among other reasons – to lessen their side effects, as it could be an important feature determining the popularity of the drug among prescribing doctors. Therefore, in my opinion this just raises additional doubts for the pre-determination of relevant market of certain drug and as D.W.Hull observes *“level of adverse effects is a significant factor taken into consideration by doctors choosing between substitutable products, and it will be difficult for companies to exclude this factor in determining whether products fall into the same relevant market”*⁸⁰.

As follows from the presented arguments, AZ’s drug “Losec” was found to be on a separate market and considering its market share, the company was found to be in a dominant position. It can be concluded from the foregoing that such precedent of market definition for the pharmaceutical product raises more questions rather than answers for potentially dominant undertakings or companies launching a product with new or superior therapeutic strength. In addition to this, as Jacob Westin points out *“the fact that innovation protected by IP rights, may give a new medicine a competitive edge over alternative treatment methods for a limited period of time, should not automatically mean that the relevant market should be narrowly defined to just comprise that particular medicine”*.⁸¹

In my opinion, such market definition comes off as a negative impact on drug development and innovation. The decision suggests that superior new products with the purpose of treating the same conditions will not necessarily appear to be on the same market as the older ones, and may as well be significantly influenced by the practices and choices of prescribing doctors. In my view, this makes it very difficult for the companies to determine potential market as it might be nearly impossible to foretell what practice for use of drugs the doctors might adopt, for instance: will they be willing to opt for the stronger drugs from the start or the end of the treatment? Will the adverse effects or state policy about the pricing of the drug be an important

⁸⁰ David W. Hull *“The Application of EU Competition Law in the Pharmaceutical Sector”*, Journal of European Competition Law and practice [2011], vol. 2, no.5 p. 480-488.

⁸¹ Jacob Westin *Defining relevant market in the pharmaceutical sector in the light of the Losec-case- just how different is pharmaceutical market?*, 2011, European Competition Law Review, Westlaw, p.62

influence in this consideration and so on and so forth. At a first glance, it would seem that a drug intended to treat the same condition, should be on the same market, however, as the case shows, the Court and the Commission take into consideration a lot of other complex medical points, which do not seem to do justice for the specificity of the pharmaceutical sector and their IPR's. Not only does it adopt a quite narrow market definition for a medicinal product in general, but also it *“raises significant issues as it creates the risk that new products could face narrow market definitions during the phase of their introduction”*⁸², namely because it becomes difficult to determine the reasons why the *“legacy”* drugs would remain at the same or lower market share⁸³.

III. III. Dominance

In my opinion, the Court's findings relating to dominance with regard to drug pricing and negotiation of higher price for newer and more advanced pharmaceutical products are particularly concerning. Since it is clear that an undertaking does not have freedom to determine its own product price and relies on strict government regulations, I believe that the undertakings in a way rely on the existing system and do not expect to be found anti-competitive, as there is little in their power on this point. As the research has shown, the governments are more likely to set higher prices for innovative, *“first to go on market”* and superior products because of their therapeutic value. Such price settings would seem fairly balanced: the government adds a beneficial drug into their healthcare systems and the companies are recouped for their innovation with a higher price in comparison to the inferior medicines of their rivals. However, the reasoning of the Court basically suggests that an innovative company which manages to negotiate a higher price for its drug in comparison to legacy products, automatically places itself at a high risk of being found dominant and on the separate product market.

Similarly, *AZ* has also argued that pharmaceutical companies cannot exercise market power in respect of price, even if they have high market shares. In addition, they

⁸² *Ibid*, p. 482.

⁸³ *Ibid*, *“because of (i) the natural inertia of doctors or (ii) the quality of the legacy products. Further, it may not be possible to determine early on in products lifecycle whether it will proceed to take over the entire market, or will it instead reach a plateau, at which point any further growth is constrained due to competition from legacy product.”*

maintain that exceptional circumstances are required in order for a pharmaceutical manufacturer to be dominant.⁸⁴ First of all, maintaining high market shares in the industry requires regular investments into innovation⁸⁵. Even by having high shares on the market, an undertaking in pharmaceutical industry cannot by itself influence factors such as doctors or patients (supply and demand), nor could it hinder independent conduct on behalf of its competitors. In other words, it raises the question whether the established competition rules should be applied in the same manner to a sector which, in fact, does not really function according to the regular competition rules.

III. IV. Abuses of dominant position

Consequently, after being found dominant in the relevant market AZ was subject to the application of Article 102. As noted, the case becomes particularly important as the company has faced the accusation of two new abuses, which could only occur in the pharmaceutical industry. The two abuses in question were highly peculiar as they were closely related or, one could even say, overlapping with the exercise and protection of IP rights.

As the alleged abuses were not in the initial non- exhaustive list under Article 102, they were therefore defined and developed throughout the case.

III. IV. I. Supply of misleading information (SPC abuse)

As introduced in detail in previous chapter, the SPC's is an instrument available exclusively in the medicinal sector, with a purpose of fostering innovation and allowing companies a possibility to extend their exclusive patent rights. A grant of SPC directly excludes generic competitors for an additional period of time and allows companies a longer time to recoup their R&D costs. Therefore, between the years 1993 and 1994 AstraZeneca decided to use the existing opportunity and failed several applications with various national patent offices (Germany, Denmark, Austria, Finland, Norway) in order to obtain the certificates.

⁸⁴ See *AZ* decision, para 225.

⁸⁵ *Ibid*, para 223.

However, the Commission accused AstraZeneca of providing misleading information to those patent offices. It was found that by doing so, AZ would unlawfully additionally prolong the period of exclusive IP protection, which would result in delay of market entry for generic products. In response, AZ has argued that such misleading conduct only might have happened due to lack of clarity in the relevant legislation, namely, at the time Regulation 1768/92. Article 19 (1) of the Regulation established that the applications of the supplementary certificates may be made since the date of first market authorization⁸⁶. However, as AstraZeneca further explains, at the time when the alleged abuse happened the legislation was not clear about the definition of “first authorization”. Namely, unlike the other articles in the Regulation, article 19 had no reference to the technical definition provided in Directive 65/65. As it is evident from several AZ’s applications to various patent offices, the company considered that the day when the medicinal products could be actually put on the market was the starting date for calculating the supplementary protection.

In addition, the evidence has shown that national patent offices were not in unanimous opinion on this definition either.

It is important to mention that only in 2003 the Court of Justice clarified this concept by issuing a preliminary ruling regarding similar, SPC related issues. At that time, the German Court referred the *Hässle AB v Ratiopharm GmbH*⁸⁷ case where the correct interpretation of the meaning of “first authorization” was in question. The Court of Justice basically admitted that the article lacked clarity and that it could be misinterpreted, in particular the Court explained that “*while the wording of Article 19 (1) of Regulation No 1768/92 does not make it clear that the first marketing authorization mentioned therein must be obtained in accordance with Directive 65/65, in the absence of an express reference to that directive, neither does that fact rule out such an interpretation.*”⁸⁸ Further, the Court clarifies that the meaning of first authorization in Article 19 (1) of Regulation No 1768/92 referred only to the marketing authorization relating to provisions on medicinal products in accordance with Directive 65/65.”⁸⁹

Although the ruling of the Court was not in line with the previous interpretation used

⁸⁶Council Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, [1992] OJ L 182/1.

⁸⁷ Case C-127/00 *Hässle AB v Ratiopharm GmbH*, [2003] ECR I-14781.

⁸⁸ *Ibid*, para 54.

⁸⁹ *Ibid*, para 61.

by *AZ*, the reference made by the highest German Court demonstrates that the correct interpretation of that definition was indeed a rather complex matter even for an experienced court. In addition, the Court of Justice agreed that the provision indeed was not clear.

AstraZeneca has argued further that it had no intent to deceive the patent offices or harming the competition. The company makes a reference to *Hoffmann-La Roche v Commission* and argues that abuse of a dominant position is an objective concept and does not depend upon intention but rather on the ascertainment of that effect in fact. Therefore, it is concluded, “neither a mere intention fraudulently to obtain a patent or SPC, nor an application for a patent or SPC, even if made fraudulently, nor the grant of a patent or SPC, which is incapable of immediate enforcement, can amount to an abuse of a dominant position.”⁹⁰ *AZ* also puts forward the arguments based on other case law relating to protection of IP rights, namely *Tetra Pak v Commission*⁹¹ and *ITT Promedia v Commission*. In the light of the decisions made in these cases, it argues that enforcement of a patent can amount to an abuse of a dominant position only when the undertaking has willfully acquired or enforced the patent knowing that it is invalid.⁹² *AZ* also stresses this by pointing out that national laws governing applications of patents and SPCs provide special procedures for the courts or competitors to solve such issues. First of all it may be required to correct or even withdraw applications with errors, no matter the purpose of such errors. Therefore, competing undertakings have a possibility to sue or challenge allegedly fraud SPCs. They point out that “*The role of competition rules is not to police patent applications, and the rules applicable to patent applications and SPCs are normally sufficient to preclude any anticompetitive effect.*”⁹³ In relation to that, *AZ* claims that in order to intervene in such process, the Commission must demonstrate tangible anticompetitive effects.

First of all, while examining this abuse and the arguments of the applicants, the General Court has highly (some commentators consider that even “*exclusively*”⁹⁴)

⁹⁰ See *AZ* decision, para 309.

⁹¹ Case T-51/89 *Tetra Pak v Commission* [1990] ECR II-309, paras 23 and 24.

⁹² See *AZ* decision, para 312.

⁹³ *Ibid*, para 315.

⁹⁴ Kristina Nordlander, Patrick Harrison “*General Court’s AstraZeneca judgment set out to embolden Commission*”, September 2010 (2), CPI Antitrust Journal, p. 5

relied on *Michelin v Commission* case⁹⁵. Naturally, in relation to the case the Court once again put forward and emphasized the “special responsibility” of an undertaking. The Court also emphasizes that Article 102 TFEU covers both practices, which may cause damage to consumers directly, and those that could cause negative impact on them through hindered effectiveness of competition structure.⁹⁶

Namely, by pointing at special responsibility the Court seeks to explain that it is not so much about the incorrect interpretation in itself, as much as it is about ‘manifest lack of transparency’ with the national patent offices on behalf of AstraZeneca. GC’s idea of transparency is that an undertaking should have not speculated with the possible interpretations and should have made it clear to the patent offices what their interpretation of the concept of “first authorization” was and according to what criteria those marketing authorization dates were provided. The Court upheld that AZ’s conduct was not compatible with Article 102 TFEU and that the conduct was not “*in keeping with special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition*”.⁹⁷ AZ’s arguments regarding the absence of bad faith or deliberate intent to deceive were also rejected. The Court refers to the objective nature of the concept of abuse set out in *Hoffmann-La Roche v Commission* and states that the misleading nature of representations made to public authorities must be assessed on the basis of objective factors and that proof of the deliberate nature of the conduct and of bad faith of the undertaking in a dominant position is not required for the purposes of identifying an abuse of a dominant position.⁹⁸ In addition, the Court observed that a mere lack of transparency could be sufficient to hold the company responsible for an abuse, as such lack would be contrary to the special responsibilities of a dominant undertaking⁹⁹. It is further elaborated that in every case misleading conducts have to be examined individually. And if the practice was such as to lead the public authorities to wrongly create regulatory obstacles to competition, for example, by the unlawful extension of exclusive rights to the dominant undertaking, such practice would make an undertaking responsible for an abusive

⁹⁵ See chapter 1, p. 10 for more detail

⁹⁶ *AZ* decision, para 353.

⁹⁷ *Ibid*, para 355.

⁹⁸ *Ibid*, para 356.

⁹⁹ *Ibid*, para 493.

conduct as it would distort competition on the merits.¹⁰⁰ Therefore, not only the Court considers that a requirement for bad faith is not necessary, but also disregards the fact that the outcome did not actually occur and AstraZeneca was unsuccessful in obtaining supplementary protection. As explained in the reasoning, it is only enough that anticompetitive outcomes would be ‘very likely’ to occur and companies should be aware of likely negative impacts on the structure of competition.

In his recently issued opinion, Advocate General Mazak disagrees with the Court’s vague use of the concept “likely”, however concurs to the Court’s reasoning on this point and adds that “*A finding of anti-competitive effect does not require that the abusive behavior is successful or, I would submit, is successful within a particular time frame, provided that the anti-competitive effect is not too remote as to be implausible.*”¹⁰¹ As AG attempts to explain AZ still could have obtained the SPC’s in certain countries within a certain period of time, but were simply not successful within the timeframe of the investigation.

In my view, the conduct of AstraZeneca indeed did not demonstrate an element of bad faith. And although it is indisputable that the correct interpretation of the relevant legislation was not easy to determine, I agree with findings of the Commission and believe that the company has clearly speculated with an existing ‘loophole’ in law. It was the inconsistency of actions (such as changes of certain information in the applications according to the differences in national patent offices) of AstraZeneca, which demonstrated that the company most likely misinterpreted the concept just to their own benefit. Therefore, as it comes to the argument of legitimate protection of IP rights and the balance between those rights and the application of competition rules, in my view the balance in this place is hardly relevant and not the cause of the issue. Looking back at the initial purpose of SPC it is clear that the legislator has already drawn a balance between these areas as the SPC has a **limited** length for this particular reason. The issue here is that AZ tried to obtain protection for their IP rights in inappropriate ways and sought to obtain something that should not legally belong to them. If their actions were to be successful, it would have caused a negative impact on the market as the entry of generic drugs would be significantly delayed.

¹⁰⁰ *Ibid*, para 357.

¹⁰¹ Case C-457/10 P AstraZeneca AB and AstraZeneca plc v European Commission, Opinion of Advocate General MAZÁK delivered on 15 May 2012, para 67.

However, I also agree with the concern of commentators who argue that such reasoning of the Court may have a few unsettling features. Namely, by putting aside the necessity to establish that the company had bad faith or that its conduct had in fact, anticompetitive effects or moreover, by stating that it is only sufficient to prove that anticompetitive effects would likely happen, the Court seems to set quite a “*low threshold for finding that a dominant company supplied misleading information*”.¹⁰² Moreover, the Court has highlighted a number of times that abuse depended on very specific circumstances to the case and as D. Hull adds “*its analysis was very fact specific – the concept is sufficiently vague, that it harbours troubling potential for IP owners.*”¹⁰³ Indeed, as the research has shown, there was a high possibility of misinterpretation of the legislation. In my view, the decision puts extra responsibility on dominant undertakings when it comes to application of laws. Namely, dominant companies are put into potentially very difficult circumstances and sometimes may be obliged to carry the responsibility of figuring out the ‘real’ meanings of certain legislation. In the absence of harmonization, this might be a challenging task with the additional risk of being found responsible for abusive actions.

On the side note, it is interesting to mention that in the case *Hässle AB v Ratiopharm GmbH*, where the Court clarified the relevant legislation, the company in question for obtaining allegedly invalid supplementary certificates, namely Hassle AB, was a direct subsidiary of AstraZeneca.

III. IV. II. Withdrawal of marketing authorizations

As it was researched in the previous chapter pharmaceutical companies have a legal right to withdraw their marketing authorizations or let them expire for various reasons and are not required by law to submit any reasons for such conduct. It is noteworthy that this position was fully confirmed by the ruling of the Court of Justice in *Rhône-Poulenc Rorer and May & Baker*¹⁰⁴.

¹⁰² David W. Hull “*The Application of EU Competition Law in the Pharmaceutical Sector*”, 2011, *Journal of European Competition Law and practice*, vol. 2, no. 5, p. 484

¹⁰³ *Ibid*, p. 484.

¹⁰⁴ C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789.

In 1998 AZ has upgraded its Losec capsules and launched a new version of the drug under the name of Losec MUPS ('Multiple Unit Pellet System') tablets, which offered significant benefits for the consumers. In relation to the introduction of new product to the market, the company withdrew its previous market authorizations in several countries, namely in Denmark, Norway and Sweden. It is important to note that at the time of the events, Directive 65/65, as amended in particular by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), and Council Directive 93/39/EEC of 14 June 1993, also amending Directives 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22), provided, in Article 3, first paragraph, that *'[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State'*.¹⁰⁵ Which meant that no generics or parallel imports could be put on the market immediately, without an existing market authorization. Therefore, the Commission has claimed that the introduction of the MUPS tablets was abusive and that the following deregistration was a selective action used as another strategy in order to block or delay the entry of generic products. The General Court upheld the Commissions decision on the part of withdrawals and agreed that the conduct was indeed abusive and caused market access obstructions for generic companies as well as restricted the possibility of parallel trade of Losec capsules.

AstraZeneca argued that a withdrawal of marketing authorizations was a legitimate strategy and a part of routine competition in complex pharmaceutical product markets. The applicants pointed out that it is only normal that the owners of expiring patent rights would seek to profit from the sales and maintain its market shares. The company did not agree that the action fell out of the scope of competition on the merits and argued that the purpose of marketing authorizations is not to facilitate the entry to the market of generic products.¹⁰⁶ They explained that new Losec tablets were introduced simply because they were better quality and the older ones that were withdrawn had certain (confidential) shortcomings. Furthermore, AZ argued that their actions were not solely aimed at preventing parallel imports or delaying entry of generic products. The company considered that is only natural to deregister an

¹⁰⁵ See AZ decision, para 614.

¹⁰⁶ *Ibid*, para 697.

authorization of a product that is no longer produced.¹⁰⁷ In addition, maintenance of such authorizations only causes significant financial burden. It was further explained that deregistration was only made in particular countries because of the launch of new tablets in those states and that the tablets were not put on the market in the other countries at the same time due to commercial reasons. Moreover, it was pointed out that marketing companies did not make such strategies to achieve certain effects on parallel trade or prevention of generic entry. AZ explains that one of the main reasons of such marketing strategy was to make their Losec MUPS tablets a successful product.¹⁰⁸

Nevertheless, as regards withdrawal of marketing authorizations, the Court concluded that AZ had no reasonable justifications for authorization withdrawals and that its actions did not fall within the scope of competition on the merits. The GC explains and that a dominant company should not make use of regulatory procedures in order to block the entry of rival companies. The Court also did not accept AZ's justification regarding the financial burden, which results from the maintenance of market authorizations. According to the Court, the burden was not significant. Moreover, the Court noted that the fact that AstraZeneca had a legal right to take such action was irrelevant to the assessment of the abuse.

As researched in previous chapter, the purpose of a market authorization is the process of getting a medicine approved by the relevant authorities and obtaining a right to sell a drug on certain market. Therefore, by definition market authorization is not an established tool in order to protect undertakings IPRs or put the competitors at an advantage or a disadvantage in any way. It is simply to get the products of their IP's approved and ready to be launched on the market to produce tangible fruits. In my view, while considering competition rules related to dominant undertakings, deregistration of market authorization should have not been viewed in such way as to result in an abuse. First of all, in contrast to the first abuse and the nature of SPCs, such action does not completely exclude the entry of generic drugs. In addition, generic companies are themselves capable of obtaining such authorizations independently from previous registration. Secondly, although dominant companies

¹⁰⁷ *Ibid*, para 698.

¹⁰⁸ *Ibid*, para 703.

have the obligations of special responsibilities, I do not agree that they cannot use deregistration as a marketing strategy and that they should be obliged to maintain and moreover to invest in something that they will no longer use in their favor. Furthermore, one could argue that a legitimate refusal to keep up something with a financial burden and no beneficial use, besides facilitating an easy welcome to the competitors into the market, should not in any way be considered as an abuse and should not be considered to fall within a scope of ‘special responsibility’. Recent commentators also put forward a concern that *“for the companies that depend heavily on IP and regulatory strategies to protect their markets, the Court’s analysis of the withdrawal of the marketing authorization is unsettling. For these companies, the ability to use such strategies is critical to their ability to compete successfully.”*¹⁰⁹ Indeed, it raises the question what other means of effective competition besides innovation and development a dominant pharmaceutical undertaking may use without putting itself at risk of abuse. I should be kept in mind that neither development nor innovation by itself help to recoup costs. On the contrary, it requires even more investments. In relation to this, it is appropriate to analyze the part where the Commission has considered an introduction of new Losec tablets and withdrawal of old capsules to be also abusive. However, in the view of General Court on this point, the launch of new Losec MUPS tablet and withdrawal of the Losec capsule version did not constitute an abuse in itself. Therefore, it could not fall under 102 TFEU. The Court held that these strategies were legitimate as they did not ‘raise the legal barriers to generic entry’¹¹⁰ and most importantly that *“the preparation by an undertaking even in a dominant position of a strategy whose object it is to minimize erosion of its sales and to enable it to deal with competition from generic products is legitimate and is a part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers”*.¹¹¹

Furthermore, regarding the withdrawal of marketing authorizations, it is important to note that even before the Commission has issued its decision on AstraZeneca, specific changes were made in the relevant legislation, namely Directive 2001/83 in order to prevent such outcomes in the future. In particular, a withdrawal of authorization

¹⁰⁹ *Ibid ref. 102*, p. 485.

¹¹⁰ See AZ decision, para 493.

¹¹¹ *Ibid*, para 804.

would not result in significant obstruction for parallel trade or the entry of generic companies and as researched previously, companies are now able to use a simplified procedure. Therefore, in my view, this could also raise a question whether in this case it was really an abuse made by a dominant undertaking or perhaps not a sufficiently thorough piece of legislation, which did not foresee a very likely outcome of legitimate actions. On the contrary to the first abuse, there was no occurrence of misinterpretation or speculation of the law.

Next the Court has considered the impact of withdrawals to parallel imports. The Commission concluded that it was capable of restricting parallel trade, since at the time, without an authorization in force, a drug could not be put on the market. The Court generally upheld Commissions findings regarding the abuse and stated that such actions could be an obstruction to competition from parallel trade, nevertheless, it considered that the Commission did not provide sufficient proof and failed to establish that AZ's deregistration of Losec capsules in were able to hinder competing parallel imports. Mainly due to this finding the Court has reduced the amount of fine imposed on AstraZeneca.

It must be noted that in assessment of this issue, on the basis of case *Rhône-Poulenc Rorer and May & Baker*, the Court observed that the Court of Justice allowed a regulatory practice where a parallel import of a generic drug could be still continued on the basis of new Losec MUPS authorization. And a relevant country in the case, Norway, actually did so.¹¹² The Court then concluded that the Commission has failed to establish to the requisite legal standard that the deregistration in Norway of the Losec capsule marketing authorization was capable of excluding parallel imports of Losec capsules.¹¹³ Nevertheless, the other countries did not apply such practice and therefore, the decision of the Commission was upheld on that part.

In my view, at this point regarding parallel trade and objective justifications to it, it is also appropriate to analyze Advocate General Jacobs opinion issued for *Syfait*¹¹⁴ case. It is interesting that the latter opinion of AG has a lot of points in favor of the potentially dominant undertakings and the appealing parties in *AZ* certainly have

¹¹² *Ibid*, para 857.

¹¹³ *Ibid*, para 861.

¹¹⁴ Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias (Syfait) and Others v GlaxoSmithKline plc and GlaxoSmithKline AEVE*, opinion of AG Jacobs delivered on the 28th of October 2004, [2005] ECR-I 4609.

based some of their arguments on this opinion as they have used a few points regarding dominance. However, AG's findings are also very relevant regarding parallel trade. In his opinion Jacobs stated that "*a dominant pharmaceutical undertaking which restricts the supply of its products does not necessarily abuse its dominant position within the meaning of Article 82 EC [102 TFEU] merely because of its intention thereby to limit parallel trade*".¹¹⁵ AG Jacobs comes to such a conclusion by taking into account specific economic characteristics of the pharmaceutical industry (as previously analyzed in this paper, such as obligations imposed by the Member States, regular large investments into innovation etc.) and argues that obstructions to parallel trade in pharmaceuticals can be proportionally justified in defense of that company's commercial interests. It must be highlighted that Jacobs stresses the point that his conclusion is highly specific to the pharmaceutical industry in the context of its current regulations. Moreover, AG states that "*given the specific economic characteristics of the pharmaceutical industry, a requirement to supply would not necessarily promote either free movement or competition, and might harm the incentive for pharmaceutical undertakings to innovate. Moreover, it cannot be assumed that parallel trade would in fact benefit either the ultimate consumers of pharmaceutical products or the Member States, as primary purchasers of such products.*"¹¹⁶ I strongly agree with the latter opinion of AG Jacobs and share the concern that rules applied too strictly to such specific sector, might really negatively affect incentives to innovate. Although the Commission's aim is to protect a fair system of competition and ultimately and most importantly - the consumer, I am of the opinion that in the long term a discouraged innovation in pharmaceuticals will result into no benefit to either. In particular, it is no secret that the largest generic manufacturers specialize solely in producing generic drugs and not the innovations. Companies like these also craft their IP strategies, which aim at putting their generic drugs on the market as soon as possible, ideally on the first day of patent or SPC expiry. Clearly, due to these firms the consumers have access to unlimited supplies of drugs at much cheaper cost. However, in the long run cheaper drugs are all generic manufacturers have to offer. It should be taken into account that such manufacturers do not invest nearly as much, if any, into R&D as originators, neither do they face potential costs of risk or lengthy processes of product testing and

¹¹⁵ *Ibid*, para 69.

¹¹⁶ *Ibid*, para 100.

approvals.

To sum up, one could say that the reasoning of the Court regarding the second abuse could be considered as heavily restrictive when it comes to the protection of dominant undertakings IP rights. The decision raises concerns as it precludes any use of actually legal IP and commonly used regulatory strategies in order to compete effectively. In my view, overall this could cause a rather negative impact not only on innovation, but also on strategies used by dominant undertakings (in a sense that they might be not willing to give up easily and it could encourage a search of other and perhaps rather illegal ways).

Conclusions

Maintenance of a balanced internal market and effective competition in it, is one of the primary goals in the European Union. As the research conducted in this thesis has shown, the Commission has the aim of protecting system of fair competition for every party participating in it. The Commission underlines the importance of effective competition and particularly stresses and prioritizes the importance of benefits for the consumers. The AstraZeneca case demonstrates that the Commission is determined to show that it would not tolerate any ways of going around the competition rules, even if using regulatory measures. However, the answer whether these measures were indeed misused is rather unsettling and causing a lot of legal uncertainties for the pharmaceutical undertakings.

By concluding the foregoing research in this paper, one could notice that the Commission gives more weight to competition law over the IPRs. Considering the specificity of the sector such preference is quite questionable; State regulated pricing, large regular investments into research and development or regulations for marketing, peculiar system of supply and demand – competition law wise these are just few of important reasons making the pharmaceutical sector very specific and distinct from any other. Moreover, it is evident that both the courts and the legislators in the EU officially admitted the specificity of this industry.

The decision of the Commission and the General Court in AstraZeneca case are concerning for several reasons. First of all, it is highly questionable whether a narrow product market definition does justice to the specifics of the pharma sector. The conditions indicated by the Court that determine the product market of the drug suggest that it is nearly impossible to pre-determine the relevant market for innovative drug, since the conditions highly rely on hardly predictable factors, such as practices adopted by prescribing doctors or even the level of the prices that an undertaking will be able to negotiate with the relevant authorities. Moreover, factors such as the manner in which the same type of medicine is going to be prioritized by doctors evidently even vary at different points in time and certain points (a shift from one

drug to the other usually does not occur immediately but happens gradually, just like with H2 blockers and PPIs). The concerning part is also the Courts disregard of importance of the real cost of the medicine in the long term or significance of side effects. Such market definition might seem rather discouraging for the innovation. By such definition any potentially new or improved drug could be found on a completely separate product market from its rivals and the complexity of other factors involved in determining product market definition is rather extent.

Further, it is clear that in case an undertaking is found to be dominant, the Commission examines its every action in extreme detail. In the light of the special responsibility of a dominant undertaking, it is clear that its actions should be executed with scrutiny. Nevertheless, it is highly disputable whether facilitation (maintenance of market authorizations) of the entry into the market for rival companies should fall within the boundaries of special responsibilities. In the absence of harmonization, the companies are also imposed an extra responsibility of being reassured that they are interpreting certain legislative uncertainties in a proper manner, since any misinterpretations may eventually lead to being responsible for an abuse. Moreover, it is unsettling for the companies since such decision suggests that there is little of possibility for the dominant undertakings to depend on regulatory or other marketing strategies in order to protect their markets.

Although it is evident that AstraZeneca attempted to exploit the lack of legal clarity regarding the SPCs into their advantage, the threshold set for proving similar abuses appears to be significantly low. However, the fact that the Court stresses the specificity of particular circumstances in the case does not contribute to any clarification of criteria either. Overall, the outcome of the case results in bringing in even heavier restrictions in to the pharmaceutical industry.

An effective competition and consumer welfare are indeed very important factors. However, one could suggest that in the light of the pharmaceutical sector specificity, the impact of heavy restrictions for such delicate sector should be considered in a broader, long-term approach. In particular, the “real” benefits brought by originator and generic companies should be weighed against each other. As noted in the research, most generic manufacturers specialize exclusively only in producing generic drugs and do not invest even nearly as much into R&D as originators. It is true that due to the generic drugs, the consumers have a larger supply of drugs at lower costs. However, if we apply heavy restrictions that discourage innovation, it then raises a

concern whether innovation is the real expense of cheap drugs in the long term. Clearly, there would be no beneficiaries from the non-progressing pharmaceutical sector.

Therefore, in my view, in as much as it concerns pharma sector, in the balance of the two, more weight should be given to the IPRs rather than competition. It is important to understand that this sector is driven forward by the innovation and therefore, the IPRs are very high importance to it. It is evident, that only the companies regularly investing into research and development of new or improved medicines are capable of keeping a stable position on the market. Indisputably, the innovation is the key to the success in this sector and undeniably, progress in this sector is crucially important to the final consumer and overall progress of medical care. Therefore, when the cost of development of a new drug might cost more than 800\$ million and take over twelve years, it is more than understandable that an owner of the formula of this new drug will put maximum effort in protecting its intellectual property right and try to recoup as much costs as possible. However, the protection of IPRs clearly should not cause exclusionary effects for the competitors or be of indefinite length. As it is known, the rules generally applying to patents, apply to the pharmaceutical patents just in the same way and patents have a limited protection time exactly for the purpose of balancing between the IPRs and fair competition. However, as it was evident from the research, from being patented to being marketed a pharmaceutical product goes a long way and by the time it is accessible for the consumer, there is barely any time left before the patent expired and not enough time to recoup the invested costs. Therefore, the first significant step, giving more importance to the IPR and admitting the need of 'special treatment' in the sector, was the adoption of the system of Supplementary Protection Certificates. Nevertheless, merely enjoying a limited patent or SPC protection is clearly not enough for an undertaking to maintain its position on this complex market or compete effectively in order to cover the costs of R&Ds. Thus, just as in any other industries, the companies put a lot of effort in crafting efficient marketing strategies. The marketing strategies should not be unlimited, especially for the companies who might be potentially found to be in a dominant position. However, I believe that it should not be restricted to such a high level either, since it should be kept in mind that rival generic companies are free to develop their effective IP strategies and uses the advantage of regulatory procedures to their fullest advantage as well. It is obvious that powerful pharmaceutical companies will not be willing to give

up their efforts easily and might engage into much more harmful practices, which could be difficult to detect or control. Moreover, the effects of such restrictions do not seem to impact the sector well in the long term.

One may only hope that the upcoming ruling of the Court of Justice in AstraZeneca will bring in more clarity and stability into pharma industry. Untill then, as D. W. Hull concludes, “*pharmaceutical companies will continue to face an unhealthy degree of legal uncertainty*”.¹¹⁷

¹¹⁷ David W. Hull “*The Appliation of EU Competition Law in the Pharmaceutical Sector*”, 2011, Journal of European Competition Law and practice, vol. 2, no. 5, p 488.

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