Konkurrenceretligt misbrug af regler og procedurer for patentforlængelse og markedsføringstilladelser – set i lyset af Kommissionens beslutning i *AstraZeneca sagen*

Anticompetitive abuse of government regulations and procedures for patent extension and marketing authorisations – seen in the light of the Commission's Decision in *AstraZeneca*

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Den 15. juni 2005 vedtog Kommissionen sin beslutning i Sag COMP/A-37.507/F3 – AstraZeneca – den første sag i Europa som har fundet, at misbrug af offentlige regler og procedurer kan være et "misbrug" i henhold til Artikel 82 i EF Traktaten vedrørende misbrug af dominerende stilling.

Nærmere bestemt fandt Kommissionen, at medicinalvirksomheden, AstraZeneca, havde misbrugt sin dominerende stilling på to måder: For det første ved at afgive vildledende oplysninger til nationale myndigheder med henblik på opnåelse af patentforlængelse. Det andet misbrug bestod i anmodning om opgivelse af markedsføringstilladelsen for AstraZeneca's mavesårsprodukt, Losec, i kapselform kombineret med lanceringen af Losec i tabletform. I forbindelse med begge misbrug havde AstraZeneca intention om – og succes til – at blokere eller forsinke markedsføringen af generiske og/eller parallelimporterede konkurrerende produkter.

Formålet med denne afhandling er at vurdere, hvorvidt Artikel 82 giver hjemmel for den vide fortolkning, som Kommissionen har lagt til grund i AstraZeneca beslutningen. AstraZeneca beslutningen er analyseret ud fra traditionel juridisk metode, retspraksis fra EF Domstolen (særligt vedrørende chikanerende søgsmål og leveringsnægtelse), EF Domstolens og Kommissionens sædvanlige tilgangsvinkel i Artikel 82-sager, og endelig paralleller til praksis fra det amerikanske konkurrenceretssystem.

Selvom det 'særlige ansvar', som påhviler dominerende virksomheder til ikke at skade eller fordreje konkurrencen på markedet, må antages at være blevet udvidet med Kommissionens beslutning, konkluderes det, at AstraZeneca beslutningen er inden for rammerne af Artikel 82.

AstraZeneca beslutningen diskuteres slutteligt kort i lyset af den igangværende diskussion vedrørende revision af Artikel 82

On 15 June 2005 the European Commission gave its decision in Case COMP/A-37.507/F3 – AstraZeneca – the first case in Europe in which

the misuse of government procedures and regulations has been found to be an "abuse" of a dominant position within the meaning of Article 82 of the EC Treaty.

More specifically, the Commission found that the pharmaceutical undertaking, AstraZeneca, had abused its dominant position in two ways: Firstly, by submitting misleading information to national authorities in order to obtain extended patent protection, and secondly by withdrawing its marketing authorisation for its anti-ulcer product, Losec capsules, combined with the launch of Losec MUPS (tablets). Both abuses were characterised by intentions – and effects – of blocking or delaying market entry of cheaper generic and parallel imported products.

The objective of this dissertation is to assess whether Article 82 provides authority for the decision displayed by the Commission. The AstraZeneca decision is considered on the basis of traditional legal method, case law from the Community Courts regarding inter alia vexatious litigation and refusal to supply, the approach normally taken by the Courts and the Commission, and finally parallels from the US antitrust system.

Although the 'special responsibility' incumbent on all dominant undertakings not to distort competition on the market may be considered to be extended by the Commission in AstraZeneca, it is concluded that the AstraZeneca decision is within the scope of Article 82.

As a final point, AstraZeneca is shortly assessed in the light of the current debate regarding reconsideration of Article 82.

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1. Introduction

1.1. Research Question

According to Article 82 of the EC Treaty[1] any abuse of a dominant position by one or more undertakings is prohibited insofar as the abuse has an effect on trade between EC Member States.

With the Commission's decision in Case COMP/A-37.507/F3 - AstraZeneca,[2] the concept of "abuse of a dominant position" has been extended by interpretation and has thereby had a new and wider meaning.

Thus, in *AstraZeneca* the Commission classified two new kinds of conduct as "abuse" within the meaning of Article 82:

Firstly, the Commission found it to be abusive conduct that the pharmaceutical companies, AstraZeneca AB (Sweden) and AstraZeneca Plc (UK),[3] had misused the patent system in a number of Member States by providing misleading information to the national authorities. Through this AZ obtained an unjustified extended patent protection for its market leading anti-ulcer drug, Losec, cf. the Supplementary Protection Certificates Regulation[4] which under certain circumstances allows a prolonged patent protection for medical products.

The second kind of conduct which the Commission found to be an abuse of a dominant position was AZ's misuse of the procedures for marketing authorisation for pharmaceutical products through withdrawing its market authorisation for Losec capsules combined with a contemporary obtaining of marketing authorisations for and launch of Losec MUPS (tablets).

According to the Commission, the objectives and effects of AZ's market behaviour was the blocking or delaying of market entry

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1 The Treaty Establishing the European Economic Community (EC Treaty), consolidated version as amended in accordance with the Treaty of Nice (OJ 2002 C325/1-184), the 2003 Accession Treaty (OJ 2003 L236/17) and the 2005 Accession treaty (OJ 2005 L157/11) - formerly known as the Treaty of Rome.

2 In the following, "*AstraZeneca*".

3 In the following, collectively "AZ". The abbreviation, AZ, is chosen to bring this dissertation into line with the Commission's terms in *AstraZeneca* (para. 8) and to make it easier for the reader to distinguish between the name of the Commission's decision (the case) *AstraZeneca*, and the name of the undertakings accused of infringement of Article 82, AZ.

4 Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ [1992] L 182/1, in the following, "the SPC Regulation."

of cheaper generic and parallel imported versions of Losec. This entailed additional costs for consumers and health systems in the affected states.

AstraZeneca is the first case in Europe in which misuse of public procedures and regulations are found to infringe Article 82. The objective of this dissertation is to assess whether Article 82 provides authority for the decision displayed by the Commission.

The dissertation should be seen in the light of the criticism which the extensive interpretation of Article 82 in *AstraZeneca* has given rise to.

Thus, some legal experts have considered *AstraZeneca* to be quite controversial because it seems to interfere with dominant undertaking's commercial freedom, inter alia by obliging them to uphold marketing authorisations which they no longer need, only to the benefit of their competitors.[5]

Others have attacked the Commission's decision for shifting the burden of unclear regulations to the industry, which is contrary to the contra proferentem principle.[6]

AZ has appealed the Commission's decision to the CFI.[7] At the time of writing, however, no date for the proceedings has been published.

1.2. Delimitation of the Topic

More specifically, the purpose of this dissertation is to examine whether the Commission in *AstraZeneca* was right in qualifying as an "abuse of a dominant position" within the meaning of Article 82 the misuse of government regulations and procedures in the shape of submission of misleading representations to national authorities and selective deregistration of marketing authorisations combined with product switches with the intent of blocking or delaying market entry of generic and parallel imported products.

Thus, it is examined whether *AstraZeneca* stretches the concept of "abuse" too far.

It should be mentioned that part of AZ's appeal to the Court of First Instance[8] regards the fact that AZ has challenged the Commission's definition of the relevant market as being too narrow. In this connection also the Commission's finding of dominance has been challenged.[9]

However, due to the limitation of magnitude of this dissertation, these issues will not be analysed. Nor will the following discussion

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5 See e.g. Maria Isabel Manley and Anna Wray, 'New pitfall for the pharmaceutical industry', Journal of Intellectual Property Law & Practice [2006] Vol. 1, No. 4, p. 268.

6 Sophie Lawrance and Pat Treacy, 'The Commission's AstraZeneca Decision: Delaying Generic Entry is an Abuse of a Dominant Position', Journal of Intellectual Property Law & Practice [2005] Vol 1, No. 1, p. 7.

7 Action brought on 25 August 2005 – AstraZeneca/Commission (Case T-321/05), OJ [2005] C 271/04.

8 In the following, the "CFI".

9 See Action brought on 25 August 2005 (n. 7).

focus on the specific issues related to the *concrete* situation in *AstraZeneca*, such as the Commission's assessment of evidence etc.

1.3. Structure

The discussion will begin with a short exposition of Article 82. This will be followed by a description of the relevant regulations etc., which AZ allegedly has misused, and a summary of *AstraZeneca*, including a description of the facts which led to the Commission's findings.

The analysis will consist of an assessment of each of the two infringements and will include parallels to EC case law on inter alia vexatious litigation. Parallels will also be drawn to the US approach towards misuse of patent and drug regulatory systems according to the antitrust regulation.

Possible consequences of *AstraZeneca* and future aspects will also be taken into account before the final conclusion.

1.4. Method

The methodology used in this dissertation may be described as an application of legal method. The sources used in the analysis of *AstraZeneca* range from legislation, legal literature and case law to journal articles, speeches by the Commission's Directorate-General for Competition[10] commissioners etc. As regards literature references, footnotes, etc., the OSCOLA system[11] is used as a basis point.

2. Generally about article 82

2.1. Objective

The general objective of Article 82 is to avoid dominant undertakings behaving in an abusive manner. This aim is founded in the broader objectives of the European Union of creating an internal market, economic efficiency and especially, as set out in Article 3 (1) (g) EC, 'a system ensuring that competition in the internal market is not distorted'.[12]

Unlike Article 81 EC which focuses on anti-competitive agreements, Article 82 has its focus on unilateral conduct of dominant undertakings which behave in an abusive way.

2.2. Special Responsibility

It is important to note that dominance as such is *not* prohibited; problems relating to Article 82 only arise when the dominant firm *abuses* its dominance.[13] This, however, does not mean that dominant firms can act completely freely. Thus, it has been stated several times by the

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[10] In the following, "DG Comp."

[11] "OSCOLA 2006, Oxford Standard for Citation of Legal Authorities" (accessible at http://denning.law.ox.ac.uk/published/oscola.shtml).

[12] See also Article 2 EC which emphasises the aim of 'a high degree of competitiveness and convergence of economic performance'.

[13] See Case 322/81 *Nederlandsche Banden-Industrie Michelin NV v. Commission* [1983] ECR 3461, [1985] 1 CMLR 282, paragraph 57.

Community Courts that a firm which enjoys a dominant position has a "special responsibility" not to behave in a way which will harm competition on the common market[14]. Furthermore, certain legal experts have stated that this "special responsibility" increases with the degree of dominance, in particular in the case of so-called "super-dominance"[15] where the risk of being found guilty of infringement of Article 82 is higher[16] due to the particularly high degree of market power.

As it will be seen in the analysis of the Commission's decision in *AstraZeneca*, the concept of "special responsibility" is 'an absolutely key element in the application of Article 82'.[17]

2.3. Conditions for a Finding of Abuse under Article 82

The wording of Article 82 gives very limited guidance on the interpretation of what constitutes an abuse of a dominant position. Subparagraphs a) to d) provide a non-exhaustive list of examples; but the general main five cumulative conditions which must be fulfilled in order for an infringement of Article 82 to be found are all outlined in the first section of the provision: These are that:

- There must be a *dominant position*
- The dominant position must be held by *one or more undertakings*
- The dominant position must be held in *'the common market or in a substantial part' of the common market*.
- There must be an *abuse* of the dominant position
- There must be an actual or potential *effect on trade between the Member States*[18].

The most important of these five conditions are the ones concerning "dominance" and "abuse" which have proved complicated to determine since the EC Treaty does not give any specific definition of any of the two concepts.

Since the following discussion of *AstraZeneca* will concentrate on the interpretation of the concept of "abuse", only a few general remarks about this concept will be given in the following.

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14 See, for example, Ibid.

15 I.e. a situation where the dominant firm enjoys a market position approaching that of a monopolist. See Richard Whish: *Competition Law* (5th edition Oxford University Press, Oxford, 2005), p. 189; Bellamy and Child: *European Community Law of Competition* (5th edition, edited by Peter Roth and Vivien Rose, Oxford University Press, Oxford, 2008), 10.061; and Allison Jones and Brenda Sufrin: *EC Competition Law: Text, Cases and Materials* (3rd edition, Oxford University Press, Oxford, 2008), p. 337 (read in conjunction with the *DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses*, Brussels December 2005 (accessible at http://ec.europa.eu/comm/competition/antitrust/art82/discpaper2005.pdf), para. 92, where it is suggested that "super-dominance" might be found at a market share of 75 %.

16 See, for example, Whish, p. 190; and Jones & Sufrin, p. 323-324.

17 Jones & Sufrin, p. 323.

18 See Jones & Sufrin (n. 15), p. 298.

2.4. The Concept of "abuse"

2.4.1. Description of the Concept of "abuse"

Since Article 82 does not provide any guidance as regards the understanding of the provision, the Community Courts have not been bound by strict boundaries in their interpretation of what constitutes an "abuse of a dominant position". This has resulted in a teleological interpretation approach with the objects clauses of the Treaty in view.[19] Furthermore there has been a clear tendency to interpret Article 82 extensively, leading to an endless list of different abuses of which the alleged abuse in *AstraZeneca* is a recent and much debated one.

As to a general definition of the concept of "abuse", however, the European Court of Justice[20] said in *Hoffmann-La Roche*, para. 91, that 'the concept of abuse' relates to a situation in which abnormal business behaviour influences 'the structure of the market' with the result that 'the degree of competition' on the market is weakened or unable to grow[21]. In general, it can be held that business/competition 'on the merits' is perfectly acceptable, while problems relating to Article 82 may arise when the dominant company is not superior because of its 'superior economic efficiency'[22] but rather because of abnormal and infringing behaviour.

2.4.2. Types of abusive Behaviour and the Commission's Discussion Paper

Traditionally, conduct prohibited by Article 82 has been presented in different categories of abuse distinguished according to their effects: *exploitative abuses* and (more practically relevant) *anticompetitive/exclusionary abuse*.[23]

In this regard, it may be mentioned that the Commission in December 2005 published a discussion paper including a description of the Commission's approach towards *exclusionary abuses*[24] which it defines as 'behaviours by dominant firms which are likely to have a foreclosure effect on the market; i.e. which are likely to completely or partially deny profitable expansion in or access to a market to actual or potential competitors and which ultimately harm consumers.'[25]
The Commission's Discussion Paper underlines inter alia that all specific circumstances of each case must be considered in the application of Article 82.[26]

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19 Especially Articles 2 and 3 (1) (g) EC. See Whish (n. 15), p. 194.
20 In the following, the "ECJ".
21 Case 85/76 *Hoffman-La Roche & Co AG v. Commission* [1979] ECR 461, [1979] 3 CMLR 211, para. 91. See also case 322/81 *Michelin* (n. 13), para. 70 and Bellamy & Child (n. 15), 10.059. Note that all these definitions are given in the contexts of exclusionary conduct – see the Commission's Discussion Paper (n. 15), para. 57, regarding the definition in *Hoffmann-La Roche.* See section 2.4.2., this page, for a definition of "exclusionary abuses".
22 Whish, p. 199.
23 It may be mentioned that the difference between the categories are not massive. See generally Whish (n. 15), p. 194; and Bellamy & Child (n. 15), 10.065.
24 (n. 15).
25 The Commission's Discussion Paper, para. 1.
26 Ibid, 2.

It should be noted that although the Discussion Paper is not legally binding, it still provides valuable guidance in the assessment of Article 82 cases as it reflects the approach the Commission would take in an Article 82 assessment.

2.5. Justification and the Principle of Proportionality

As a final point it may be mentioned that 82 does not include any provision equivalent to the exemption clause in Article 81 (3).[27] Nevertheless, it is clear from the Community Courts' case law and from theory that a dominant undertaking is allowed to protect its own commercial interests and that it is possible for dominant undertakings to defend their conduct through objective justification combined with the principle of proportionality[28].

3. Article 82 controvercy

Over the years Article 82 has been subject to much criticism; thus many legal experts consider the provision to be very controversial, among other reasons because Article 82, contrary to Article 81, interferes with dominant companies' unilateral business behaviour and prohibits certain behaviour of a dominant undertaking which would not have been prohibited if the firm was not dominant. From the dominant undertaking's point of view this may seem as a punishment for being big and successful.[29]

Furthermore, legal commentators have attacked the Commission's application of Article 82 for being too intrusive and too concerned about protecting competitors of the dominant undertakings rather than protecting the objective of competition law: A competitive process on the market as such.[30]

The just mentioned controversy of Article 82 is undoubtedly connected with the fact that Article 82 is very vaguely worded, and especially that there is a lack of a precise definition of decisive concepts such as "abuse". This, connected with the widely formulated objects clauses of the EC Treaty,[31] has left the Commission and the Community Courts with the opportunity of interpreting Article 82 extensively without being bound by a strict framework.

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[27] This may be appropriate, however, since Article 82 does not, contrary to Article 81, prohibit certain conduct *per se*. See Whish (n. 15), p. 199-200, Bellamy & Child (n. 15), 10.063 and Jones & Sufrin (n. 15.), p. 299.

[28] See Bellamy & Child, 10.059 and 10.063; Whish, pp. 207-208; Jones & Sufrin, pp. 298 and 331-338; and the Commission's Discussion Paper (n. 15), section 5.5.

[29] Whish (n. 15), p. 175.

[30] Whish, p. 175 and Richard Whish, 'Editorial', Competition Law Review, [March 2006] Volume 2, Issue 2 (accessible at http://www.clasf.org/CompLRev/Issues/Vol2Issue2Editorial.pdf.). See also the Commission's Discussion Paper (n. 15), para. 54, in which the Commission itself states this objective.

[31] See especially Articles 2 and 3 (1) (g).

Precisely the extensive interpretation of Article 82 has been censured for interfering too much with dominant undertaking's commercial behaviour. In this context, the extensive interpretation of Article 82 in *AstraZeneca* and its consequences for dominant undertakings may have contributed to the debate about Article 82 which during the recent years has involved considerations of a total revision of Article 82.[32]

The following discussion will consider the correctness of the Commission's extensive interpretation of Article 82 in *AstraZeneca*.

4. Astranzeneca

On 15th of June 2005 the European Commission decided to fine AZ 60 million Euros due to infringements of Article 82 of the EC Treaty and Article 54 of the EEA Agreement.[33] [34]

After more than five years of investigation[35] the Commission found that between 1993 and 2000 the medical company, AZ, had abused its dominant position in the PPI market[36] by misusing the procedures for patent extension and by misusing the systems relating to marketing authorisations for pharmaceuticals.

Both of the two abuses in *AstraZeneca* concern AZ's market behaviour regarding its world leading anti-ulcer drug, Losec, and its active substance, omeprazole, for which AZ had received patent protection in Europe in 1979. Since then and until the end of the 1990s, Losec had obtained a position as the best selling prescription medicine ever in the world,[37] being the clearly preferred drug for treating acid-related gastro-intestinal diseases and conditions.

Before turning to the analysis of *AstraZeneca*, it is appropriate to introduce the case with a description of the legal framework which the Commission found AZ to have misused. This will be followed by a summary of the case.

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[32] See for example Whish, 'Editorial' (n. 30).

[33] Agreement of the European Economic Area OJ (1994) L 1/3 (EEA Agreement), as amended.

[34] Note that since Article 54 of the EEA Agreement contains the same prohibition with regard to the EEA as Article 82 does with regard to the EU, any reference in this dissertation to Article 82 and in its context the Member States of the EU is also to be seen as a reference relevant for Article 54 in the EEA Agreement and in its context the Contracting Parties of the EEA Agreement.

[35] The Commission opened its investigation after having received a complaint from two of AZ's competitors on 12 may 1999.

[36] PPI is short for proton pump inhibitors – the leading pharmaceuticals category for the treatment of acid-related gastro-intestinal diseases and conditions. See *AstraZeneca*, paras. 29 and 37. As mentioned above, section 1.2., AZ has challenged this definition of the relevant market in its appeal to the CFI.

[37] The Commission's press releases, IP/03/1136, 31 July 2003 and IP/05/737, 15 June 2005. According to *AstraZeneca*, para. 9, Losec sales amounted to USD 6.3 billion in 2000.

4.1. Legal Framework

The following description of the legal framework relevant for *AstraZeneca* focuses on the framework as it was at the time of AZ's alleged abusive conduct. The legal framework is described here in order to provide a better basis for the reader to understand the alleged infringements of the Commission's decision.

4.1.1. The Regulation of Marketing Authorisations

As it appears from Articles 3 (1) (p) and 152 ff. of the Treaty, public health is a crucial matter within the EU. Therefore great importance is attributed to the pharmaceutical sector and the area is generally characterized by a high degree of regulation at both Community and national level.[38] To mention one example, the EU has adopted careful regulation concerning how, when and under which circumstances new pharmaceutical products may be marketed within the Community.

Relevant for *AstraZeneca*, Council Directive 65/65/EEC[39] prohibits that any 'proprietary medicinal product' is placed on the market in a Member State unless the product has been issued a marketing authorisation by 'the competent authority of that Member State'.[40] The purpose of the directive is to protect public health[41] by ensuring that pharmaceuticals placed on the market are safe, efficient and of a certain quality.[42] [43]

As a starting point, the applicant must submit a long list of documents and data, including the results of several different tests and trials in order to obtain the marketing authorisation. This is a complicated and lengthy procedure.

However, as part of the Community's aim of creating a competitive structure on the market for the benefit of national health systems and consumers, it encourages market entry of generic products, which are normally cheaper than the reference product. Therefore it has facilitated a simplified procedure for generic products to obtain marketing authorisations. This means that the generic manufacturer is allowed to rely on the data submitted by the original product which has already been granted an authorisation, thereby making it easier and faster for generic products to reach the market.

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38 See http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmeu_en.htm.

39 Council Directive 65/65/EEC of 26 January 1965, OJ [1965] L 22/369, as amended by Council Directive 87/21/EEC of 22 December 1986, OJ [1987] L 15/36. These directives which were in force at the time of AZ's alleged abuse were repealed by Directive 2001/83/EC of the European Parliament and of the Council on 6 November 2001, OJ [2001] L 311/67, as amended by Directive 2004/27/EC of 31 March 2004, OJ [2004] L 136/34.

40 Directive 65/65/EEC, Article 3.

41 Ibid, first recital. This objective is repeated in the current Directive 2001/83/EC, as amended.

42 *AstraZeneca*, para. 258.

43 The directive was adopted to avoid a recurrence of the thalidomide disaster of the late 1950s to the early 1960s where many babies were born deformed because their mothers had taken the sleeping/nausea drug, thalidomide, during pregnancy. At this time no control procedure was required before medicines were placed on the market. See http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmeu_en.htm

Thus, in order to be able to use the simplified so-called "abridged" or "generic procedure",[44] the generic manufacturer only needs to prove that its product is "essentially similar" to the reference product, that the data exclusivity period which lasts for six or ten years has expired and that the original reference product 'is marketed in the Member State for which the application is made'.[45] It is the latter condition which was in dispute in *AstraZeneca*.

Regarding products which are parallel imported into a Member State where a marketing authorisation has already been issued to the original reference product, these products are not covered by the requirements of Directive 65/65/EEC since these products are not considered as being 'placed on the market' in that Member State for the first time. However, in the case of parallel imported products, the parallel importer has to apply for a parallel import licence and must be granted a such if the parallel imported product has ' "the same active ingredients and therapeutic effects as" the existing reference product [which has been issued a marketing authorisation], and "complies with the requirements relating to quality, efficacy and safety..." '.[46] In other words, the parallel importer can rely on the existing marketing authorisation issued to the original reference product in the import Member State.

This situation gave rise to uncertainty when AZ withdrew its reference product marketing authorisation from the market in certain countries.

4.1.2. The SPC Regulation[47]

Marketing authorisations are not only relevant in relation to the marketing of pharmaceutical products; they are also relevant factors in relation to issuing of Supplementary Certificate Protection,[48] which is an extension of the basic patent protection enjoyed by medicinal products, granted according to the so-called SPC Regulation.

Since the EU has a great interest in a high level of public health, it tries to create strong incentives for medical companies to invest money in research, development and innovation of new medicinal products. One of these incentives is seen in the shape of intellectual property rights, such as patents which provide the patent holder with a certain period (normally 20 years) of legal "monopoly" to use his patent and thus recoup his (often quite large) investments in research and development.

However, from the moment the patent application for a new medical product is submitted to when an authorisation to place the product on the market is issued, quite a long time frequently passes by, leaving the patent holder with a shortened period of effective pat-

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[44] *AstraZeneca*, para. 259.

[45] Council Directive 65/65/EEC, as amended Council Directive 87/21/EEC, Article 4, point 8 (a) (iii). See for further explanation *AstraZeneca*, para. 261.

[46] *AstraZeneca*, para. 263 and regarding the text in the double quotation marks, Case C-94/98 *The Queen, ex parte Rhône-Poulenc Rorer Ltd and May & Baker Ltd v The Licensing Authority* [1999] ECR I-8789, para. 48.

[47] (n. 4).

[48] In the following, "SPC".

ent protection during which he has the chance of recouping the costs he spent developing the patented product.

The purpose of the SPC is to compensate the patent holder for this time elapsed.[49] Therefore the SPC takes effect at the expiry of the basic patent protection and is granted for a period equivalent to the time which elapsed from the filing of the patent application and to 'the date of the first authorization to place the product on the market in the Community reduced by a period of five years'.[50] A maximum SPC protection is 5 years.[51]

The conditions for being granted an SPC are listed in Article 3 of the SPC Regulation. They include inter alia that a marketing authorisation has been issued in accordance with Directive 65/65/EEC[52] and that this authorisation 'is the first authorisation to place the product on the market as a medicinal product'.[53] Additionally, however, for patented products already authorised at the time when the SPC Regulation entered into force, like Losec, it is furthermore a condition under Article 19 that the first authorisation to place the patented product on the market in the Community is granted after a specific cut-off date, as a starting point 1 January 1985. However, in order to obtain SPC in Denmark, Germany, Finland and Norway[54] the marketing authorisation must be obtained after 1 January 1988.[55] [56] As it will be described below, this last requirement is the centre of the first abuse in *AstraZeneca* since the interpretation of the expression 'first authorization to place it on the market...' was far from clear at the time of AZ's alleged abusive conduct.

4.2 Facts, Effects and the Commission's Decision

This paragraph will focus on the Commission's decision in *AstraZeneca* by describing the two alleged abuses separately in two different sections (4.2.1. and 4.2.2.). Each section will describe the allegedly abusive conduct, its anticompetitive effects and finally the Commission's findings.

4.2.1. The First Abuse

4.2.1.1. Facts

According to the Commission, the first of AZ's two abuses consisted of 'a pattern of misleading representations knowingly engaged in by AZ – as part of its overall SPC Strategy – to patent agents, patent offices and national courts in order to acquire (or preserve) SPCs for omeprazole...',[57] the main component in Losec. The aim of this so-called "SPC Strategy" was, according to the Commission, 'to keep

[49] The SPC Regulation, recitals 1 ff.
[50] Ibid, Article 13 (1).
[51] Ibid, Article 13 (2).
[52] (n. 39).
[53] Ibid, Article 3 (d) cf. Article 3 (b).
[54] See *AstraZeneca*, para. 158.
[55] The SPC Regulation, Article 19 (1).
[56] In the following the expression, "the 1988-countries" will cover Denmark, Finland, Germany and Norway.
[57] *AstraZeneca*, para. 626.

generic manufacturers away from the market'[58] by obtaining extended patent protection (SPC) as far into the future as possible.[59] Thereby AZ could maintain its market leading position within the area of anti-ulcer medicine.

As mentioned above, AZ obtained patent protection for omeprazole in Europe in 1979. This meant that the basic patent protection expired during 1999. Therefore AZ filed SPC applications in order to obtain supplementary patent protection for omeprazole under the SPC Regulation within the Member States. The alleged abuse of Article 82 took place in the context of these SPC applications which were filed over two rounds, firstly in June 1993 and secondly in November/December 1994:

During AZ's preparations in relation to the SPC applications it emerged that the first technical marketing authorisation for Losec was granted on 15 April 1987 (in France)[60] – i.e. not after 1 January 1988 as required in "the 1988-countries" according to the SPC Regulation, Article 19 (1).

According to the Commission, this was the reason why AZ in some of its SPC applications chose not to interpret the date of the 'first authorisation to place it [the patented product] on the market...'[61] as the date of the first technical authorisation (15 April 1987, in France) but as the date on which it became practically possible to effectively market Losec for the first time within the Community.[62] According to AZ this date was 21 March 1988 (in Luxembourg), the date of the publication of an official Luxembourgian paper, "Spécialités Pharmaceutiques", which contained an official list including prices of authorized pharmaceutical products including (for the first time) Losec. AZ contended that before such an official publication acknowledging Losec as an authorised medicinal product, effective marketing was not possible.[63]

As indicated above, however, AZ did not stick consistently to the date of effective marketing as it submitted different dates in its applications to different patent offices in different countries.[64] Thus in some countries, such as the United Kingdom and Ireland, AZ submitted different dates of technical marketing authorisation,[65] whereas in relation to other countries (particularly "the 1988-countries") it appeared to the Commission that AZ deliberately concealed the first technical marketing authorisation date (15 April 1987). Furthermore, the Commission found that AZ regarding certain applications abstained from telling patent agents, patent offices and national courts about its "effective marketing theory", thereby creating a false impres-

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58 Ibid.

59 According to the Commission, this strategy clearly appeared from AZ's internal memoranda referred in *AstraZeneca* paras. 163-174.

60 *AstraZeneca*, paras. 163 and 169.

61 The SPC Regulation (n. 4), Article 19 (1)

62 In *AstraZeneca*, e.g. para. 618, the Commission referred to this assumption as AZ's "effective marketing" theory.

63 *AstraZeneca*, e.g. para. 235.

64 Ibid, 646 and 246.

65 Ibid, 697 and 725.

sion for them to think that the date submitted in the SPC applications was the date of the first technical authorisation.[66]

4.2.1.2. Effects

The effects of the unlawful patent extension was, according to the Commission, most importantly a prevention of 'market entry by all potential competitors' who wished to launch generic products based on omeprazole as soon as AZ's patent for omeprazole expired.[67]

The delay of generic market entry was particularly problematic because of its harmful effects on national health systems and consumers who were denied the benefits they would normally have enjoyed. Thus, generic pharmaceuticals' presence on the market generally result in lower costs for national health systems,[68] and this benefits consumers in their capacity of taxpayers and possible contributors to co-payment systems.[69] In paras. 113-138 the Commission emphasised access to generic medicines as 'one of the objectives of Community pharmaceutical legislation and policy',[70]

Furthermore, it may be mentioned that the market entry of generic products may incentivise further innovation because of a stronger competitive pressure on the market.

A final effect of AZ's obtaining of unlawful SPCs and thus the delay of generic market entry was suggested by the Commission in para. 776 as the possibility that the unlawful multi-annual[71] postponement of generic market entry could have had an impact on the prices in other countries than the countries in which AZ was found to be dominant,[72] because countries often apply 'cross-country comparisons when determining pharmaceutical prices'. If prices are high in country A because of lacking competition from generic manufacturers, this may therefore spill over on the fixing of prices in country B.

4.2.1.3. Decision

In para. 773 the Commission concluded that it found that AZ continuously had 'abused its dominant position in Belgium, Germany, the Netherlands and Norway through its patterns of misrepresentations before patent agents, patent offices and national courts. This lead to AZ's obtainment of unlawful patent extension under the SPC Regula-

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66 Ibid, 647.

67 Ibid, 762. See also paras. 763-770 for further effects on competition caused by AZ's behaviour.

68 See also *AstraZeneca*, para. 771. Generic pharmaceuticals are mostly cheaper than the original reference product.

69 See ibid, 772.

70 Ibid. 113. See also Mario Monti (Member of the European Commission in charge of Competition Policy), 'EC Antitrust Policy in the Pharmaceutical Sector', Speech at the Alliance Unichem Conference, Brussels, 26 March 2001 (accessible at: http://ec.europa.eu/comm/competition/speeches/text/sp2001_013_en.pdf).

71 Ibid, 774, in which the Commission stated that the SPC abuse lasted for several years during the 1990s in most of the countries in which AZ was found to be dominant.

72 The countries in which AZ was found to be dominant are mentioned in *AstraZeneca*, para. 601.

tion in certain "1988-countries" and a longer patent extension than justified in certain other countries where AZ in its SPC applications had filed a later date than the correct date as the starting point for the commencement of the (otherwise legal) SPC.[73] [74]

Furthermore, the Commission found that AZ had also abused its dominant position in Denmark and the United Kingdom where AZ had tried, but failed, to obtain unlawful SPCs. In this connection the Commission emphasised the fact that 'the qualification of a practice as abusive does not require that the intended effects were achieved in full'.[75] [76]

It is important to note that it does not have any impact on the Commission's findings that the ECJ has now clarified the interpretation of Article 3 (d) cf. 3 (b) in the SPC Regulation.[77] Thus, the Commission emphasised that the abusive character of AZ's behaviour was *not* its incorrect interpretation of the SPC Regulation. Contrarily, the abuse consisted in the 'pattern of misleading representations to patent agents, patent offices and national courts'[78] as part of its strategy of strengthening its 'position on the market by delaying the entry of generic versions of omeprazole and to create extra hurdles for generic firms'.[79] This was the reason why AZ could not use the ambiguity of the SPC Regulation as an objective justification.[80]

In its findings, the Commission also attached specific importance to the fact that AZ's behaviour 'did not constitute normal business behaviour'[81] and that AZ had deliberately taken advantage of the fact that the patent offices, when granting SPCs only had 'a limited degree of discretion when assessing the information submitted by the

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73 See Article 13 (1) of the SPC Regulation (n. 4).

74 *AstraZeneca*, paras. 760-761.

75 Ibid, 765. See also para. 758 in which the Commission referred to Case T-203/01 *Michelin v. Commission* [2003] ECR II-4071, [2004] CMLR 923, paras. 239 and 241, where the CFI stated that 'For the purposes of establishing an infringement of Article 82 EC, it is sufficient to show that the abusive conduct of the undertaking tends to restrict competition, or in other words, that the conduct is capable of having that effect...If it is shown that the object pursued by the conduct of an undertaking in a dominant position is to limit competition, that conduct will also be liable to have such an effect.'

76 It may be noted that Austria Finland and Luxembourg are not mentioned in para. 773 although they were among the countries in which AZ obtained its unlawful SPCs (see paras. 760-761). This may be explained by the fact that Austria, Finland and Luxembourg were not among the countries in which AZ were found to be dominant (see para. 601). As mentioned by the Commission in para. 775, it is not a requirement for the finding of abuse of a dominant position that the abuse has taken place in the relevant geographic market where the abusing undertaking is dominant. This was also emphasised by the ECJ in Case C-333/94 P *Tetra Pak International v. Commission* [1996] ECR I-5951, [1997] 4 CMLR 662.

77 The clarification came as the response to an Article 234 EC question, referred to the Court by the German Bundesgerichtshof. See Case C-127/00 *Hässle AB v. Ratiopharm GmbH* [2003] ECR I-14781, particularly para. 79.

78 *AstraZeneca*, para. 666.

79 Ibid, 677.

80 Ibid, 666.

81 Ibid, 676-679.

SPC applicants'.[82] The Commission therefore found that AZ has not lived up to the special responsibility which lies with its dominant position.

Moreover, the Commission repeated previous case law, stressing that 'the acquisition of a right may amount to an abuse' and continued that 'there is therefore no reason why the conduct in *the procedure relating to* the acquisition of the right cannot be considered as an abuse'.[83]

As a final point, it could be mentioned that the Commission underlined that 'the fact that the SPC Regulation provides for specific remedies cannot exclude the application of the Treaty rules of competition and their corresponding remedies'.[84]

4.2.2. The Second Abuse

4.2.2.1. Facts

According to the Commission, the second abuse in *AstraZeneca* consisted of AZ's launch of a tablet version of Losec ("Losec MUPS") combined with an almost simultaneous deregistration of its market authorisation for Losec capsules in certain selected countries. The capsule/tablet switch was, according to the Commission, part of AZ's so-called LPPS Strategy,[85] the existence of which clearly appeared from AZ's internal documents referred in paras. 265 ff. The aim of this strategy was to 'prevent or at least delay the market entry of generic versions of omeprazole and to obstruct parallel trade in Losec capsules'.[86] In the long term, however, the purpose of the LPPS Strategy was that the switch to Losec MUPS and the thereby following disadvantages for generic products and parallel trade should help keeping Losec sales volumes and prices at a high level even after the patent expiry of omeprazole (1999) until AZ would be able to launch the successor of Losec, Nexium, which contained the active substance esomeprazole.[87] [88]

By deregistering its marketing authorisation for Losec capsules and removing Losec capsules from the market, AZ removed the reference product/marketing authorisation which was necessary for manufacturers of generic versions of Losec in their use of the generic procedure under Article 4 (8) (a) (iii) of Directive 65/65/EEC, as amended by Directive 87/21/EEC.[89]

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82 Ibid, 626. The limited discretion was caused by the principle of self-control established in Article 10 (5) of the SPC Regulation (n. 4).

83 *AstraZeneca*, para. 742. Italics added.

84 Ibid, 744.

85 "Losec Post Patent Strategy", *AstraZeneca*, para. 255.

86 Ibid, 256.

87 Ibid, 807-810; see also para. 36 which states that esomeprazole was launched during 2000.

88 In different internal documents AZ stated that it would lose market shares if it did not do anything to meet competition from generic competitors; see e.g. *AstraZeneca*, para. 289 where AZ assumed that it would lose 75 % of its Danish market if it acts passively towards generic competitors. Additionally, generic entry would force prices on Losec down and thereby make it difficult to launch esomeprazole at a high price.

89 (n. 39).

As mentioned above, this provision provides that it is a condition for benefitting from the generic procedure that the reference product 'is marketed in the Member State for which the application is made'. Therefore AZ's withdrawal of its Losec marketing authorisation hindered generic manufacturers in filing applications for marketing authorisations under the generic procedure after the deregistration. Moreover, AZ argued that the ambiguous 'is marketed...' condition meant that the marketing authorisation for the reference product had to be in force at the time when the generic manufacturer filed his application through the generic procedure *and* at the time when a decision was made concerning the generic application.[90] This would mean that the generic manufacturers who had already filed marketing authorisation applications at the time of AZ's withdrawal could not obtain an authorisation under the generic procedure.

Although the ECJ clarified this question in 2003 to the benefit of the generic manufacturers,[91] AZ's allegation meant confusion and further delay and hurdles for the generic manufactures.[92]

AZ's withdrawal of its Losec marketing authorisation did not only result in disadvantages for generic manufacturers. It also meant that parallel traders of Losec capsules could not obtain nor maintain their parallel import licences in certain countries, such as Denmark, because the authorisation for their reference product now no longer existed.[93]

As indicated above, the Commission emphasised in its decision the fact that AZ only launched Losec MUPS and subsequently deregistered marketing authorisations for Losec capsules in certain selected countries. According to the Commission, the marketing authorisation withdrawal was decided centrally by AZ[94] to take place only in Denmark, Finland, Norway and Sweden because AZ considered it most likely that it would succeed with its LPPS Strategy here – inter alia that these countries would 'revoke parallel import licences for Losec capsules'.[95]

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90 *AstraZeneca*, Para. 262 and 310.

91 See Case C-223/01 AstraZeneca v. Lægemiddelstyrelsen [2003] ECR I-11809, para. 58.

92 In this context it should be noted that the requirements in Directive 65/65/EEC, as amended by Directive 87/21/EEC (n. 39) are now changed by Directive 2001/83/EC, as amended by Directive 2004/27/EC (n. 39), Article 10. The new Article 10 only requires that the reference product is/has been authorised for minimum eight years in a Member State/the Community. Therefore market entry of a generic manufacturer no longer requires that the original reference product actually is on the market at the time of generic entry. A replication of the abuse as described above is therefore unlikely.

93 This legal position has now been changed with the ECJ's ruling in inter alia Case C-113/01, *Paranova Oy* [2003] ECR I-4243, according to which parallel importers should be able to continue to parallel import even after withdrawal of the marketing authorisation of the reference product, unless the withdrawal is based on protection of human health.

94 See *AstraZeneca*, para. 811. This is contrary to AZ's claim that the decision of deregistration was "left to local marketing companies in each country" and was therefore not taken by AZ as part of an anti-competitive strategy, para. 781.

95 *AstraZeneca*, paras. 802-803.

The Commission furthermore stated that it was deliberate that AZ did not launch Losec MUPS in so-called "low price" countries,[96] where prices on pharmaceuticals were very low. It found that AZ refrained from doing this in order to prevent parallel trade of Losec MUPS from these low price countries into countries with higher prices on pharmaceuticals.

The Commission considered the selective deregistration of Losec capsules and launch of Losec MUPS as a proof of AZ's intentions to prevent or at least delay generic market entry and parallel trade.[97]

4.2.2.2. Effects

According to the Commission, AZ's deregistration of its marketing authorisation for Losec capsules in 1998 'foreclosed market access [...] or at least delayed such access' to the markets in Denmark, Norway and Sweden for generic manufacturers post the expiry of the patent for omeprazole in 1999.[98]

In this context it should be noted, as claimed by AZ, that the deregistration of the Losec capsules marketing authorisation did not in principle lead to a *complete* foreclosure of market access for generic products since it only hindered the use of the generic procedure under Article 4 (8) (a) (iii) of Directive 65/65/EEC, as amended by Directive 87/21/EEC.[99] Therefore AZ argued that it was possible for generic manufacturers to use other procedures in order to obtain their own marketing authorisations for their generic products, such as, for instance, the so-called "well-established medicinal use procedure" authorised under Article 4 (8) (a) (ii) of the Directive.[100]

The Commission, however, did not accept this defence since the mentioned alternative procedure was not practically workable for generic manufacturers and since the critical point of AZ's behaviour was the fact that generic entry would in any event have been delayed because AZ did not give any warning that it had plans to withdraw its marketing authorisation for the reference product.[101]

The second effect of AZ's LPPS Strategy was that parallel trade was completely eliminated in Denmark where AZ's marketing authorisation withdrawal had made the authorities revoke the parallel import licences for Losec capsules. The same was the case in Sweden for a short period until the Swedish Administrative Court decided to reverse the revocation of the parallel import licences.[102] However, even after this reversal in Sweden and also in Norway where no revocation had taken place, AZ's marketing authorisation withdrawal had caused a situation of strong legal uncertainty which made parallel import of Losec capsules decrease significantly.[103]

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96 Such as inter alia Italy, Spain, Greece and Portugal, see *AstraZeneca*, para. 803
97 *AstraZeneca*, para. 800.
98 Ibid, 849-850.
99 (n. 39).
100 *AstraZeneca*, para. 851.
101 Ibid, 852-854.
102 Ibid, 857.
103 Ibid, 857-858.

For the same reasons as mentioned as regards the first abuse,[104] the prevention/delay of generic market entry and the decrease/stop of parallel import in Losec capsules caused great disadvantages for national health systems and consumers.[105] The risk of spill-over effects to other countries was also mentioned by the Commission concerning this second abuse.[106]

4.2.2.3. Decision

In paras. 860-861 the Commission concluded that AZ's selective 'deregistration of capsules in Denmark, Norway and Sweden combined with the tablet/capsule switch...as part of its LPPS Strategy with a view to preventing or, at least, delaying generic market entry and parallel trade' was an abuse of AZ's dominant position in those three countries.[107]

Attention should be drawn to the fact that the Commission explicitly stressed that 'single acts involving the launch, withdrawal or requests for deregistration of a pharmaceutical product would not normally be regarded as an abuse'[108] and furthermore that it was 'not the Commission's case that the launch of a new formulation of Losec (Losec MUPS) and/or the withdrawal of Losec capsules would as such constitute an abuse.'[109] The Commission also conceded that Directive 65/65/EEC did not prevent a marketing authorisation holder from withdrawing his authorisation.[110]

The Commission maintained, however, that 'in certain circumstances' the withdrawal of the authorisation might 'be qualified as an abuse within the meaning of Article 82...'.[111] In this connection it especially emphasised the underlying motives of distorting competition on the market as a factor which could make Article 82 applicable.

The Commission furthermore maintained that AZ with its behaviour had neglected the special responsibility which applies to dominant undertakings and which 'also covers the possible use of public procedures or regulations with the clear purpose of excluding competitors'.[112] Again, the Commission emphasised the fact that the authorities did only have 'little – if any – discretion' in their application of those regulations/procedures when AZ requested deregistration of its marketing authorisations for Losec capsules.[113] In other words, the authorities did not have much choice as regards not meeting AZ's request.

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[104] See section 4.2.1.2..
[105] *AstraZeneca*, para. 859.
[106] Ibid, 861 and section 4.2.1.2..
[107] It may be mentioned that Finland was not mentioned in the Commission's conclusive section of its decision. This is presumably due to the fact that Finland was not among the countries in which AZ was found to be dominant; see *AstraZeneca*, para. 601.
[108] *AstraZeneca*, para. 792.
[109] Ibid, 793.
[110] Ibid, 832.
[111] Ibid, 833.
[112] Ibid, 818.
[113] Ibid.

In this context the Commission also underlined that dominant undertakings which enjoy exclusive rights are responsible for using these rights reasonably and in a way which is not against the purpose of the right.[114] Thus, it stressed that the aim of marketing authorisations was to allow the owner of a medicinal product to place his product on the market. The Directive did not have any intention of rewarding innovators (i.e. the manufacturer of the original reference product) since this aim was managed by intellectual property rights regulations. Therefore AZ's marketing authorisation did not confer any right to AZ to use it to prevent others from entering the market.[115]

The Commission furthermore maintained that 'selective deregistration of marketing authorisations for reasons unrelated to interests protected by the legislation cannot be deemed as normal competition or reasonable steps to protect the dominant undertaking's own commercial interests'.[116] In other words, the Commission did not see AZ's conduct as normal business behaviour. [117] (In para. 838 the Commission implied that deregistration due to public health concerns would have been normal business behaviour.)

In this regard the Commission did not accept AZ's claims that Losec MUPS was a better product than Losec capsules and that this was the reason for AZ's withdrawal of the marketing authorisation for Losec capsules. Thus, the Commission's approach implied that it considered these claims as a cloak for AZ's real strategy: The foreclosure of competition on the market.

The Commission did not accept the argument that the stop/decrease in parallel trade was due to a successful marketing of Losec MUPS either.[118] On the contrary, it found it more likely that the 'popularity' of Losec MUPS was 'a result of AZ's switch strategy.'[119]

As a final point it should be mentioned that the Commission emphasised that the second abuse did not concern AZ's use of its intellectual property rights – on the contrary, the abuse consisted in AZ's 'misuse of government procedures'.[120] Therefore the uncertain nature of the disputed regulatory frameworks did not amount to an objective justification for AZ either.[121]

5. Analysis

As mentioned in section 1.1., *AstraZeneca* has widened the concept of "abuse of a dominant position" by adding another example of "abuse" to the long catalogue of case law already relating to the concept.

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[114] Ibid, 820 and 837.
[115] Ibid, 843.
[116] Ibid, 821.
[117] Ibid, 791.
[118] Ibid, 785.
[119] Ibid, 857.
[120] Ibid, 817.
[121] Ibid, 830-831.

As it appears from the above mentioned description of the case, AZ's behaviour was, to a considerable extent, possible due to ambiguity and loopholes in the legislation used by AZ. Although those loopholes have now been closed and the ambiguity eliminated, either by clarification from the ECJ or by amendments to the relevant provisions, and although the abuses are therefore unlikely to reoccur,[122] *AstraZeneca* is still highly relevant because the extending interpretation constitutes a milestone in the understanding of the scope of Article 82. The following sections will analyse the case and its consequences, beginning with an assessment of each of the two abuses.

5.1. The First Abuse: Misuse of the Patent System

5.1.1. The Core of the Abuse: 'a pattern of misleading representations...'

As indicated above, the crucial point of the first abuse was 'the pattern of misleading representations' submitted by AZ to patent agents, patent offices and in certain countries national courts 'as part of its overall [exclusionary] SPC Strategy for omeprazole'.[123]

The Commission found that providing deceptive information to the authorities in order to obtain extended patent protection is not normal business behaviour, i.e. competition on the merits. This view is in line with the ECJ's judgment in *Michelin*, in which the Court stated that abusive behaviour is behaviour which cannot be regarded as being based on "traders' performance",[124] a concept which has been rephrased by Whish as "superior economic efficiency".[125]

Transferred to AZ's conduct regarding the SPC Regulation, it can be concluded that the defence of a dominant position by obtaining supplementary patent protection through the submission of misleading information is not evidence of superior economic efficiency or traders' clever performance; rather it is evidence of anticompetitive behaviour which undermines the purpose of the SPC Regulation.[126]

The Commission's finding of abuse seems to be based on a total assessment of all circumstances of the case.[127] Not only could it be held that AZ's conduct was not competition on the merits; the fact that AZ had an intention to mislead the authorities in order to foreclose competition, although it knew that the authorities' discretion regarding information given to them was minimal,[128] was also evidence of disregard of the special responsibility which lay with AZ as a dominant

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[122] See above, section 4.2.1.3, text to (n. 77) and section 4.2.2.1., text to (n. 91, 92 and 93).

[123] *AstraZeneca*, para. 666.

[124] Case 322/81 *Michelin* (n. 13), para. 70

[125] Whish (n. 15), p. 199.

[126] This conclusion is in line with Matteo Negrinotti, 'Commission Decision, Abuse of regulatory procedures in the intellectual property context: the AstraZeneca case', European Competition Law Review [2008] 29(8), p. 452.

[127] This is in line with the approach suggested in the Commission's Discussion Paper (n. 15), para. 2.

[128] The lack of discretion was caused by to the SPC Regulation's principle of self-control. See section 4.2.1.3. (n. 82).

undertaking, since it testified the fact that AZ deliberately took advantage of the way the regulation was constructed.

As it will appear from the analysis below, the negligence of the special responsibility of a dominant undertaking is, besides the abnormal business behaviour, another important factor in the case.

5.1.2. The Importance of AZ's possible Misinterpretation of the SPC Regulation

Although the Commission specifically pointed out in para. 666 that it was not raising any 'objections against AZ for having incorrectly interpreted the relevant law (in *casu* the SPC Regulation)', it may shortly be mentioned that certain legal experts have criticised the Commission's finding against AZ since they assess that what the Commission finds to be "misleading representations" are in reality misunderstandings caused by the lack of clarity in the SPC Regulation. See in this connection for example Lawrance and Treacy who criticise the decision as penalizing AZ for 'misunderstanding a rule which was far from clear at the time of the infringement'.[129] See also Manley and Wray who state that it 'seems disproportionate that the burden of the ambiguity of the EC legislation, drafted by the Commission, has been shifted to AstraZeneca by a novel application of the competition rules and moreover, but notwithstanding that novelty, significant fines were then imposed'.[130]

Since, as mentioned in section 1.2. above, it will be outside the scope of this dissertation consider whether or not the Commission in the concrete situation of *AstraZeneca* in reality attached importance to AZ's understanding of the SPC Regulation and in this connection whether or not the information submitted by AZ was 'misleading'. This assessment will be left for the CFI. *If* the CFI finds that AZ's interpretation of the SPC Regulation has had any impact on the representations it has made before the national authorities, however, it would be natural for it to establish that the risk of unclear legislation must be on the drafter, i.e. the legislator, according to the contra proferentem principle.

5.1.3. Specific Remedies already Provided

In the proceedings, AZ claimed that Article 82 did not apply to its behaviour regarding the SPCs because the misused SPC Regulation already provided for specific remedies. Therefore, AZ argued, the case was not a case for the Commission but rather a case for the national authorities.

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[129] Lawrance and Treacy (n. 6), p. 7.

[130] Manley and Wray (n. 5), p. 270. Here it should be noted that, as mentioned by the authors themselves, p. 266, at the time of publishing of Manley and Wray's article, the Commission had not yet published the full text of *AstraZeneca*. However, this does not mean that the authors were not aware of the Commission's reasoning regarding what constituted the first abuse. Thus, on p. 266 of their article, the authors refer to the article by Niklas Fagerlund and Søren Bo Rasmussen, 'AstraZeneca: The First Abuse Case in the Pharmaceutical Sector', Competition Policy Newsletter [2005] (3), 54-56, in which it is noted that the Commission does not object to AZ's incorrect interpretation (p. 54).

The Commission rejected this argument, arguing that the purpose of competition law is to control anticompetitive conduct and effects. Therefore there was no reason why competition law should only apply when other remedies do not reach. Furthermore, the Commission added that the remedies under the SPC Regulation were insufficient since they would only lead to an annulment of the unlawfully granted SPC, whereas there would be no penalty for the anticompetitive effects which followed AZ's behaviour and nor for attempts to obtain unlawful SPCs.[131]

Additionally, one may argue that the Treaty does not imply anywhere that Article 82 should only be relevant as a "secondary" remedy when no other remedies apply.

Moreover, as suggested by Negrinotti,[132] it is not an unknown phenomenon that certain conduct can lead to an application of different remedies under different regulations/areas of law.[133]

5.2. The Second Abuse: Misuse of the Procedures Relating to Marketing Authorisations

5.2.1. The Core of the Abuse: 'misuse of government procedures'

The core of the second abuse was AZ's selective withdrawal and launch of its products 'as part of its LPPS Strategy aimed at excluding generic firms and parallel importers, as well as at artificially partitioning the internal market'.[134]

Unlike what the Commission found as regards the first abuse, the second abuse did not, on the surface, appear to involve behaviour directly against the rules, such as an undertaking's submission of misleading information before the authorities as part of an attempt to obtain a right (SPC) which it was not entitled to. On the contrary, it may seem as if the second abuse was characterized by business tactics involving the utilisation of the regulation in question but *within* the boundaries of what was allowed. Thus, the Commission conceded that the withdrawal of the marketing authorisation as such was not contrary to Directive 65/65/EEC, as amended by Directive 87/21/EEC;[135] nor would individual acts of launching, withdrawing or requesting for deregistration of a pharmaceutical product as such normally be considered as an abuse.[136]

For this reason it may be argued that the finding of abuse as regards the second kind of conduct discussed in *AstraZeneca* is more controversial than regarding the first kind of behaviour: Although AZ ostensibly kept within the realm of the rules, an overall assessment of the combined 'specific circumstances'[137] of the case still led to a finding of abuse.

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131 *AstraZeneca*, paras. 744-746.
132 Negrinotti (n. 127), p. 545.
133 For a further discussion of this point of *AstraZeneca*, see ibid p. 454-456.
134 *AstraZeneca*, para. 830.
135 (n. 39).
136 *AstraZeneca*, paras. 792-793. See also section 4.2.2.3.
137 *AstraZeneca* para. 842. See also para. 833.

5.2.2. Points of Criticism regarding the Commission's Decision

AstraZeneca has been met with much criticism, especially regarding the second abuse. This and the following section will consider some of the viewpoints which have been expressed regarding the second abuse:

One point of criticism is, as implied above, that it was not illegal for AZ to withdraw its marketing authorisation; in fact, the relevant directive did not provide any obligation for undertakings possessing marketing authorisations *not* to withdraw them. Regardless of this, the Commission found it to be an abusive negligence of its special responsibility that AZ requested its authorisation to be deregistered.

This fact has been attacked by several legal experts who state that there may be many legitimate reasons why an undertaking has an interest in withdrawing its marketing authorisation. For example, Lawrance and Treacy suggest that 'the company may have developed an improved version of the drug or the product may be subject to pharmaco-vigilance issues'.[138]

In AZ's case, AZ had in fact developed a new product, Losec MUPS, which it claimed to be a large improvement compared to the original product, Losec capsules.[139] On the surface, it might therefore seem like an obligation for AZ to help its competitors, when AZ was found to have abused its dominant position by withdrawing the marketing authorisation for Losec capsules which the competitors were dependent on, despite the fact that AZ itself no longer needed the authorisation because it wanted to focus on the marketing of Losec MUPS.

The view that the Commission in relation to the second abuse was too concerned about protecting AZ's competitors may be strengthened by the fact that AZ's conduct was found abusive although it could be argued that the foreclosure of parallel import and generic market entry was only possible due to a regulatory gap created by the way the regulation was worded at the relevant time.[140]

Furthermore, generic manufacturers were not completely foreclosed from the market since they still had the possibility to make use of other procedures in order to obtain a marketing authorisation for their products. The problem for generic manufacturers was, however, that the deregistration of AZ's marketing authorisation made them unable to take advantage of all the tests, trials and other efforts AZ had gone through to obtain its authorisation; instead they were forced to go through the laborious and complicated procedures themselves in order to obtain an authorisation; and since AZ had not informed its competitors before it decided to withdraw the marketing authorisation

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[138] Lawrance and Treacy (n. 6), p. 8. See also Manley and Wray (n. 5), p. 268.

[139] *AstraZeneca*, paras. 778-779. As mentioned in section 4.2.2.3., the Commission rejected this claim, however, since it considered it to be a cover for its true strategy of the product switch: to block or at least delay competition from generic and parallel imported products.

[140] As mentioned in section 4.2.2.1. (n. 92) above, the relevant rules have now been changed.

which they were all dependent on,[141] generic market entry would be delayed.

The Commission's finding implies that AZ might have avoided the finding of abuse as regards the impediment of generic market entry if it had supplied its competitors with a timely warning of its plans to withdraw the marketing authorisation for Losec capsules. This would have enabled the competitors to start the process of obtaining a marketing authorisation in time to enter the market as soon as AZ's omeprazole patent expired.

This legal position, however, may give rise to concern for a dominant company since it entails an obligation to inform competitors of certain business strategies which the dominant undertaking might have an interest in keeping secret. In other words, it may be argued that the legal position created by the Commission in *AstraZeneca* entails yet another restriction of dominant undertaking's commercial freedom.

This point has also been emphasised by Manley and Wray in relation to AZ's lack of freedom to withdraw its marketing authorisation: 'The Commission's position implies that an MAH [market authorisation holder] should not take any commercial decision, such as withdrawing a marketing authorization, which could make it more difficult or more costly for a generic company to compete. This raises the issue of whether the Commission could be unduly interfering with AstraZeneca's commercial freedom.'[142]

5.2.3. Refutation of Criticism

5.2.3.1. Abnormal Business Behaviour and Negligence of Special Responsibility

Regarding the above mentioned points of criticism, it is important to note that the crucial point which made AZ's behaviour abusive was, as mentioned above,[143] the "specific circumstances" of the case.

These consisted in AZ's selective withdrawal of Losec and launch of Losec MUPS combined with AZ's exclusionary intentions. For the reasons mentioned in section 4.2.2.3.,[144] the Commission found that AZ's conduct was not "standard practice", i.e. competition on the merits. Therefore AZ had not met the commitments which are the consequences of the special responsibility incumbent on every dominant undertaking not to distort competition on the market.[145]

As maintained by Manley and Wray,[146] a dominant company's commercial freedom to decide its own commercial policy was recognized by the CFI in *Bayer/Adalat*.[147] However, this was only in so far

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[141] *AstraZeneca*, para. 854.
[142] Manley and Wray (n. 5), p. 268.
[143] Section 4.2.2.3.. See also *AstraZeneca*, para. 821.
[144] See also *AstraZeneca* para. 821.
[145] See section 4.2.2.3., See also Case 322/81 *Michelin* (n. 13), para. 57 and section 2.2. above.
[146] Manley and Wray (n. 5), p. 268
[147] Case T-41/96 *Bayer v. Commission* (*"Adalat")* [2000] ECR II-3383, [2001] 4 CMLR 126, paras. 176 and 180 (finally decided by the ECJ in Cases C-2-3/01 *P Bundesverband der Arzneimitte-Importeure EV and Commission v. Bayer AG*

as the dominant company does not abuse its dominant position. In other words, the commercial freedom is only recognised as long as it does not infringe competition rules, and therefore a dominant undertaking cannot excuse anticompetitive behaviour and the use of abnormal business processes through its right to commercial freedom.

On the contrary, a dominant undertaking has a special responsibility to compete on the merits and to make 'reasonable use' of the 'specific entitlements' (or exclusionary rights) it is given, e.g. by being a marketing authorisation holder.[148] As stressed by the Commission, AZ did not live up to this when it decided to launch Losec MUPS and withdraw its marketing authorisation for Losec capsules, despite the fact that it was aware that the consequences of a request of deregistration would be disadvantages for parallel importers and generic competitors.[149] In particular, AZ expected that 'the national authorities concerned considered...that they did not have discretion to maintain the marketing authorisation when its withdrawal was requested'.[150] Thus, although AZ, as mentioned, kept within the realm of the relevant regulation, it deliberately used the way it was constructed to foreclose competition.

5.2.3.2. Focus on Anticompetitive Intentions

Assessing the Commission's Decision, it is clear that one of the important factors which led to the Commission's finding of abuse despite the fact that the relevant regulations were not contravened was AZ's *intention* of strengthening/maintaining its dominant position by making a de facto extension of its monopoly through the foreclosure of competition from parallel importers and generic manufacturers. The emphasis of AZ's intentions is also seen as regards the first abuse – yet, as mentioned in Section 5.2.1., the finding of abuse concerning the "first conduct" might seem less controversial since it consisted in *misleading* representations, whereas AZ had, in theory, kept within the regulatory limits regarding the second abuse.

On the face of it the focus on motives may wonder since the ECJ has clearly stated that 'the concept of abuse is an objective concept'.[151] However, this only means that anticompetitive intentions are not necessary for a finding of abuse – not that the Courts cannot attach importance to such intentions if it is possible to prove that they exist. Thus, case law has several times taken anticompetitive intentions into consideration in the assessment of "abuse". See for example *British*

[2004] ECR I-23, [2004] 4 CMLR 653.). See also Case 27/76 *United Brands Co and United Brands Continentaal BV v. Commission* [1978] ECR 207, [1978] 1 CMLR 429, para. 189.

[148] *AstraZeneca*, para. 820 with reference to inter alia the CFI's statement in Cases T-24-26/93 and T-28/93 *Compagnie Maritime Belge Transports and Others v. Commission* [1996] ECR II-1201, [1997] 4 CMLR 273, para. 108.

[149] In the shape of revocations/problems regarding parallel import licenses and impeded access for generic manufacturers to use the "generic procedure" to obtain marketing authorizations.

[150] *AstraZeneca*, para. 819.

[151] Case 85/76 *Hoffman-La Roche* (n. 21), para. 91.

Leyland[152] or the *AKZO* case in which the ECJ set out the test used in the assessment of predatory pricing. Part of this test includes the criteria that if prices are 'below average total costs...but above average variable costs, [they] must be regarded as abusive *if they are determined as part of a plan for eliminating a competitor*.'[153] [154]

The focus on intentions was finally also seen in the ECJ's judgment in *United Brands* in which it found that a dominant undertaking is allowed to take 'reasonable' and 'appropriate' steps in order to protect its own commercial interests, but only in so far as the actual purpose of the behaviour is not to strengthen and abuse its dominant position.[155]

It was therefore in consistence with case law when the Commission emphasised AZ's exclusionary intentions as aggravating circumstances in its negligence of a dominant undertaking's special responsibility.

5.2.3.3. No Breach of the Rules – Legitimate Expectation?

As regards the fact that AZ did not, in theory, contravene the rules in questions, this is not necessarily an argument which will avert allegations of abuse.

Thus, as seen in Section 5.1.3., the competition rules are applicable concurrent with other legislation. Moreover, it should be remembered that the aim of competition law is to prevent dominant undertaking's anticompetitive behaviour – an objective which may not be guarded by the other legislation in question.

Furthermore, AZ was obliged by its special responsibility. AZ knew that it was moving in a grey zone by using the regulatory framework just to the borderline of what was allowed; it knew the consequences of its conduct and with the intent to foreclose competition it took advantage of the way the different rules concerning marketing authorisations, parallel import licences etc. interacted. Therefore not much regard should be paid to AZ's legitimate expectations.[156] Moreover, a high degree of awareness of competition rules is expected concerning large undertakings.[157]

In this connection it should also be mentioned that it makes no difference that AZ, in reality, did not use its dominance to misuse the

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[152] Case C-226/84 *British Leyland v. Commission* [1986] ECR 3263, [1987] 1 CMLR 185, para. 24.

[153] (Italics added) Case C-62/86 *AKZO Chemie v. Commission* [1991] ECR I-3359, [1993] 5 CMLR 215, para. 72. See the Commission's Discussion Paper (n. 15), paras 64-65 on the meaning of "average total costs" and "average variable costs"; and section 6 as regards the approach as regards predatory pricing, including the assessment of intent, paras. 112 ff.

[154] See additionally Jones & Sufrin (n. 15), pp. 324-325 for other categories of abuse in which the motives of the dominant undertaking are normally taken into consideration.

[155] Case 27/76 *United Brands* (n. 147), para. 189.

[156] Moreover, as concerning the first abuse, the Commission stated in relation to the second abuse that it had not taken into consideration any possible misinterpretation of the relevant regulations in its finding of abuse. The crucial point was AZ's exclusionary intent. See *AstraZeneca*, para. 831.

[157] Bellamy & Child (n. 15), 13.139.

regulations and procedures. Thus, in *Continental Can*[158] and *Hoffmann-La Roche*,[159] the ECJ maintained that there does not need to be a causal link between dominance and the abuse. In other words, it was not necessary that AZ actually *used* its market power and dominance to misuse the procedures and regulations; however, because AZ *was* dominant and therefore had a *special responsibility*, its conduct could fall within Article 82.

5.3. Is the Commission's Interpretation of Article 82 too Wide?

5.3.1. Intentions and Special Responsibility

As it appears from the above mentioned discussion of the two abuses, the concept of "special responsibility" has been stretched in *Astra-Zeneca*. Although it may be argued that the risk for loopholes in and undesirable effects of the use of the legislation should be on the drafter, cf. the principle of contra proferentem, the Commission maintained that AZ's special responsibility also covered the use of public procedures with the intent to foreclose competition. In other words, keeping within the realm of the legislation is not a safe harbour for a dominant undertaking when it has intentions of foreclosing competition on the market: The concept of 'special responsibility' also covers the duty to make sure that no anticompetitive effects will occur, even when staying within the realm of the law, and even when the anticompetitive effects are likely to occur because of the way the legislator has constructed the relevant rules.

Attention should moreover be drawn to the fact that AZ's behaviour was not subject to any objective justifications.[160] Thus, it did not for example create any economic efficiency;[161] nor was it substantiated by objective necessity grounds, such as the protection of public health etc.

5.3.1.2. Anticompetitive Intentions and Normal Business Strategies

From the industry's point of view the Commission's finding, especially as regards the second abuse, may seem quite intrusive since it may be argued that it clashes with basic economic theory according to which any typical business strategy will involve profit maximisation. Profit maximisation is in many circumstances obtained through market power gained at the expense of competitors/potential competitors.[162]

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[158] Case 6/72, *Euroempallage Corp and Continental Can Co Inc v. Commission* [1973] ECR 215, [1973] CMLR 199, particularly paras. 26-27.

[159] Case 85/76, *Hoffmann-La Roche* (n. 15), para. 91.

[160] Such as for example the ones mentioned in the Commission's Discussion Paper (n. 15), paras. 77-92.

[161] See for this view Neelie Kroes (Member of the European Commission in charge of Competition Policy), 'Preliminary thoughts on Policy Review of Article 82', Speech at the Fordham Corporate Law Institute, New York, 23 September 2005. Published as Speech 05/537, 23.09.2005 (accessible at: http://europa.eu/rapid/pressReleasesAction.do?reference=SPEECH/05/537).

[162] See in general Luís M. B. Cabral, *Introduction to Industrial Organisation* (1st edition, The MIT Press, Massachusetts Institute of Technology, Cambridge, Massachusetts, 2000).

Pushed to extremes, this could imply that any business strategy to a certain degree will involve intentions of inconveniences for competitors.[163] For this reason it may be contained that *AstraZeneca* means that the dominant undertaking must be very careful that it is not infringing competition law when determining its business strategy.

As indicated in *AstraZeneca*, however, the boundary must be set at "normal business behaviour" where the dominant undertaking is superior because of its superior economic efficiency and performance – not because it is not competing on the merits.[164]

Finally, it must be remembered that the very reasoning behind Article 82 is the fact that certain conduct is not allowed for dominant undertakings because it will harm competition on the market. If this is to be changed, it will require a change of Article 82 itself.

5.3.2. Case Law concerning the Abuses

In the assessment of whether the Commission went too far in its extensive interpretation of Article 82 in *AstraZeneca*, it is relevant to take case law into consideration:

Regarding the *effects* of the AZ abuse, numerous cases concern abusive behaviour which resulted in foreclosure of competitors from the market. Thus, abuse leading to hindrance of parallel trade was found in for example *British Leyland v. Commission*[165] and *Suiker Unie v. Commission.*[166]

Since *AstraZeneca* is the first case within the EC to find the misuse of public regulations and procedures abusive under Article 82, however, there is no case law on the area of this specific kind of *conduct*. This is also pointed out, especially with regard to the SPC abuse, by AZ in its statement of June 2005 concerning its alleged infringements of Article 82.[167]

In this connection it must first of all be emphasised that it is not possible to justify abusive behaviour through a reference to lack of case law concerning the explicit situation.[168] Secondly, it should be noticed that although there is no *direct* precedent for the Commission's decision in *AstraZeneca*, it may be relevant to take into consideration case law concerning similar conduct/areas of law.

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[163] If A wants to win a competition against B, A's victory will necessarily be at the expense of B.

[164] See above, section 5.1.1..

[165] Case C-226/84 *British Leyland* (n. 153), where British Leyland's abusive pricing policy led to a reduction of imports of British Leyland cars into the UK.

[166] Cases 40/73, etc. *Suiker Unie v. Commission* [1975] ECR 1663, [1976] 1 CMLR 295, where the abuse consisted in pressure through rebates not to export from Belgium to other Member States.

[167] *AstraZeneca brief on alleged Infringement of Article 82 E.C.*, June 2005, (accessible on: http://www.astrazeneca.com/sites/7/imagebank/typearticleparam511187/astrazeneca-ec-omeprazole-investigation-brief.pdf).

[168] However, the novel character of a case may have an impact on the size of the fine imposed for the infringement. This was the case in *AstraZeneca*, see para. 922.

5.3.2.1. Vexatious Litigation

As suggested by certain legal experts[169] AZ's alleged abusive behaviour may be compared to conduct consisting in vexatious litigation since vexatious litigation and misuse of regulatory procedures are similar types of conduct because they both concern the misuse of statutory rules which regulate specific rights and which are applicable equally for everyone.

The leading case within the area of vexatious litigation is *ITT Promedia*[170]which concerned a conflict about publication of telephone directories.

Promedia claimed that Belgacom had abused its dominant position by 'initiating vexatious litigation against [Promedia] before the Belgian courts'.[171]

The Commission and the CFI both rejected Promedia's complaint, stressing first of all by reference to fundamental human rights that 'access to the Courts is a fundamental right and a general principle ensuring the rule of law'.[172] Therefore, legal proceedings initiated by a dominant company can only be found abusive in 'wholly exceptional circumstances' and when two cumulative conditions are fulfilled:

1. The legal proceedings 'cannot reasonably be considered to be an attempt to establish its [the dominant undertaking's] rights and can therefore only serve to harass the opposite party' *and*
2. The legal proceedings are 'conceived in the framework of a plan whose goal is to eliminate competition'.[173] [174]

These criteria must also be considered to be applicable in *AstraZeneca.*

Yet, similar to the *ITT Promedia* situation, it should be underlined that when an undertaking uses the procedures for the granting of SPCs and marketing authorisations, the undertaking is making use of a right granted by law to use these procedures. Therefore this use may only be considered abusive under Article 82 in exceptional circumstances, e.g. in situations regarding misuse of the procedures.

Since, as mentioned in section 1.2., above, the aim of this dissertation is not to assess the correctness of the Commission's decision in the specific situation concerning AZ's conduct, the criteria deduced

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[169] See e.g. Negrinotti (n. 127), p. 457; and Sophie Lawrance and Pat Treacy, 'Legal uncertainties leave pharma companies in limbo', Managing Intellectual Property, September 2005, p. 44.

[170] Case T-111/96 *ITT Promedia NV v. Commission* [1998] ECR II-2937, [1998] 5 CMLR 491.

[171] Ibid, para. 23 (iv).

[172] Ibid, 60.

[173] Ibid, 30.

[174] It should be mentioned that in its appeal to the CFI, Promedia only challenged the Commission's application of the two criteria – not the criteria as such. Therefore, the CFI expressly stated in para. 58 of its judgment that there was no need for it to assess the correctness of the criteria. As pointed out in Jones & Sufrin (n. 15) p. 582, this is unsatisfactory for the precedential value of the case. However, it must be assumed that the CFI would have objected if it did not approve of the criteria laid down by the Commission; this assumption is supported in Jones & Sufrin, p. 582.

from *ITT Promedia* will not be applied further to the specific conduct of *AstraZeneca*. This will be left for the CFI to do.

The conclusion remains, however, that it is possible to draw a line from the misuse of government procedures and regulations to the principles laid down in case law concerning vexatious litigation.

5.3.2.2. A Fortiori Argumentation: 'The acquisition of a right may amount to an abuse'

As part of its argumentation as regards the first abuse, the Commission mentioned the fact that case law has previously stated that the acquisition of a right may amount to an abuse under certain circumstances.[175] Therefore the Commission found that there was 'no reason why the conduct in the procedure relating to the acquisition of the right cannot be considered as an abuse.'[176]

This a fortiori conclusion seems rational. Nothing in the reasoning behind Article 82 and the general objectives of competition law suggest a different treatment as regards behaviour in the context of the acquisition of a right and behaviour in the context of the processes relating to the acquisition of a right.

5.3.2.3. Parallel to Case Law on Refusal to Supply

As a final point regarding case law relevant for the finding in *AstraZeneca*, it must be mentioned that several legal experts have compared the second abuse to another type of exclusionary abuse: Refusal to supply.[177] This comparison also seems to be suggested by AZ itself in para. 786 of *AstraZeneca*, in which AZ underlined that 'It is only in the most exceptional circumstances that a dominant firm is obliged to assist competitors by allowing them the use of its rights.'

The parallel to refusal to supply is relevant because AZ's withdrawal of the marketing authorisation for Losec capsules may be seen as a refusal to "supply" its competitors with something they needed in order to operate in the market.[178]

5.3.2.3.1. Generally on Refusal to Supply

The finding of abuse in cases concerning dominant undertaking's refusal to supply is generally quite controversial because it conflicts with the principle of commercial freedom according to which any undertaking is entitled to determine with whom it engages in business, including which trading partners it wants to supply.[179] As regards dominant undertakings, however, special concerns are involved and

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[175] See Case T-51/89 *Tetra Pak Rausing SA v. Commission* [1990] ECR II-309, [1991] 4 CMLR 334, paras. 23-24; and Case T-111/96 *ITT Promedia* (n. 171), para. 139.

[176] *AstraZeneca*, para. 742.

[177] Lawrance and Treacy (n. 6), p. 8; Maria Isabel Manley and Pat Treacy, 'Intervention by the Competition Authorities: an Evergreen Problem?' Bristows, Articles, 25/07/2005 (accessible on http://www.bristows.co.uk/?pid=46&level=2&nid=724); and Negrinotti (n. 127), pp. 457-458.

[178] Lawrance and Treacy (n. 6), p. 8.

[179] See e.g. the Commission's Discussion Paper (n. 15), para. 207.

therefore the Community Courts have established that certain circumstances may justify the finding of abuse when dominant undertakings refuse to supply others with their expertise, products or even intellectual rights.[180]

Since, as mentioned above,[181] intellectual property rights are granted in order to "reward" the undertaking's investment in innovation, an obligation to supply other companies with licences of this right is particularly controversial and applies only in 'exceptional circumstances.'[182] Four conditions are therefore required to be fulfilled before a dominant undertaking's refusal to supply may be found abusive: The access to the licence must be *indispensible* for the trading partner in such a way that the refusal to supply will *exclude competition* on a secondary market; the refusal must *not be 'justified by objective consideration'*; and the refusal must *prevent the introduction of a new product* on the market for which there is a '*potential consumer demand'*.[183] [184]

Applying this test to AZ's second abuse, it may be argued that neither the generic nor the parallel traded products were 'new' in the sense of the above mentioned requirements. On the other hand, however, it may be maintained that the generic/parallel imported products differed from AZ's products because they were cheaper – and exactly this factor, the price, was what was crucial for the customers (national health systems and consumers).

As regards the condition of indispensability, it may moreover be claimed that AZ's marketing authorisation was not indispensable for generic manufacturers since they were, in theory, able to use other procedures to obtain a marketing authorisation. Yet, as maintained by the Commission, paras. 852-854, the use of these other procedures was not satisfactory in reality because generic market entry would either way have been delayed since AZ did not in advance inform its competitors of its strategy of withdrawing its marketing authorisation.[185]

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[180] See inter alia Cases C-241-2/91 *P RTE & ITP v. Commission ("Magill")* [1995] ECR I-743, [1995] 4 CMLR 718; Case C-418/01 *IMS Health GmbH & Co OHG v. NDC Health GmbH & Co KG* [2004] ECR I-5039, [2004] 4 CMLR 1543; and Case T-201/04 *Microsoft Corp. v. Commission* [2007] ECR 00000 (CFI, 17 September 2007).

[181] Section 4.1.2.

[182] Case C-418/01 *IMS* (n. 181), para. 35 and Cases C-241-2/91 *Magill* (n. 181), para. 50.

[183] See Case C-418/01 *IMS* (n. 181), paras. 38, 49 and 52. The conditions were recently repeated by the CFI in its judgment in Case T-201/04 *Microsoft* (n. 181), paras. 332-333.

[184] These conditions are found in the Commission's Discussion Paper (n. 15), chapter 9, in particular para. 239.

[185] See above, section 4.2.2.2.; and *AstraZeneca*, para. 851.

5.3.2.3.2. The *Sylfait Cases*[186]

In the specific context of the pharmaceutical sector, the *Sylfait cases* seem to be of particular relevance for *AstraZeneca*.

The cases concerned the pharmaceutical giant GlaxoSmith-Kline[187] which had refused to meet in full the orders of Greek pharmaceutical wholesalers as regards certain medicinal products. The purpose of GSK's refusal was to prevent parallel trade effected by Greek wholesalers who exported pharmaceuticals bought in Greece, which was a "low price country", to other Member States with higher prices on pharmaceuticals. As part of the ECJ's preliminary ruling in the first case, *Sylfait*, Advocate General Jacobs gave his opinion on the refusal to supply.[188] In this opinion Jacobs was very lenient towards the concrete refusal to supply because of the 'highly specific'[189] circumstances regarding the European pharmaceutical sector in its current condition which was especially characterised by a high degree of State intervention.[190]

Due to procedural issues, the ECJ rejected to give a judgment in the case.[191] However, a few years later the ECJ was faced with a new case and a new request for a preliminary ruling regarding the same questions as the ones Advocate General Jacobs had commented. In this new case, *Sylfait II*,[192] Advocate General D. Ruiz-Jarabo Colomer gave his Opinion on 1 April 2008, in which he disagreed with Advocate General Jacobs by suggesting that GSK's refusal to supply was not objectively justifiable.[193]

5.3.2.3.3. *AstraZeneca* in the Light of the *Sylfait Cases*

At the time of writing, the ECJ has still not given its judgment in *Sylfait II*. It will be interesting to see whether the Court rules in line with Advocate General Jacobs or whether it prefers a stricter approach like proposed by Ruiz-Jarabo.

Assessing *AstraZeneca* in the light of the *Sylfait cases*, however, it should be kept in mind that although both refusal to supply situations were aimed at preventing parallel trade, the second AZ abuse differs from the *Sylfait* situation with regard to an important point: The *Sylfait cases* concerned the refusal to supply a product protected by intellectual property rights, whereas AZ's abuse concerned its refusal to "supply" parallel traders with a marketing authorisation.

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[186] Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias and Others v. GlaxoSmithKline AEVE ("Sylfait")* [2005] ECR I-4609, [2005] 5 CMLR 7; and Cases C-468-478/06 *Sot. Lélos kai Sia EE and Others v. GlaxoSmithKline AEVE FP ("Sylfait II")*, judgment pending.

[187] In the following, "GSK".

[188] Case C-53/03 *Synetairismos Farmakopoion Aitolias & Akarnanias and Others v. GlaxoSmithKline AEVE ("Sylfait")* [2005] ECR I-4609, Opinion, paras. 77-105.

[189] Ibid, 101.

[190] Ibid, 100-105.

[191] Case C-53/03 *Sylfait* (n. 187), paras. 37-38.

[192] Cases C-468-478/06 *Sylfait II"* (n. 187).

[193] Cases C-468-478/06 *Sot. Lelos kai Sia EE and Others v. GlaxoSmithKline AEVE FP ("Sylfait II")*, Opinion, paras. 120-123.

As opposed to intellectual property rights, which are aimed at protecting the incentive to innovate and at rewarding investments in research and development with exclusive rights, the objective of marketing authorisations is, as mentioned in *AstraZeneca*, para. 843, to provide market access for products which fulfil requirements concerning public health; in other words, there is no purpose of granting the marketing authorisation holder an exclusive right.

The regard which should be paid to a marketing authorisation holder is therefore not the same as the one which should be paid to an intellectual property rights holder, and consequently, the controversy in obliging a marketing authorisation holder to "supply" its competitors with its marketing authorisation (by imposing an obligation not to deregister it although the marketing authorisation holder does not need it any longer) is not as great as when an intellectual property rights holder is obliged to license his exclusive rights to his competitors.

In this context it should be remarked that the tests, trials and other efforts which AZ had to go through in order to obtain its marketing authorisation for Losec were protected through the so-called "data-exclusivity" clause in Article 4 (8) (a) (iii) of Directive 65/65/EEC as amended by Directive 87/21/EEC.[194]

In the light of the previous discussion concerning parallel to refusal to supply and to the *Sylfait cases*, it is may be concluded that despite the similarities of the two kinds of conduct, an obligation for AZ to "supply" its marketing authorisation to its competitors does not require same kind of concern as the obligation to licence intellectual property rights, since the purpose of a (non-exclusive) marketing authorisation is not the same as that of an (exclusive) intellectual property right.

5.3.3. International Perspective: Comparison with Abuse of the Patent System under US Antitrust Law

According to the Commission's 2003 press release regarding *AstraZeneca*[195] it is evident that it has taken into consideration the fact that the Federal Trade Commission[196] and US courts have several times found that misuse of the patent system and misrepresentations before the authorities are a violation to US antitrust law (in particular Section 2 of the Sherman Act[197] and Section 5 of the Federal Trade Commission Act[198]).[199]

Section 2 of the Sherman Act is the provision in US antitrust law equivalent to Article 82 of the EC Treaty. Although the two pro-

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[194] See *AstraZeneca*, para. 261; and as regards the directives (n. 39).

[195] Press release, IP/03/1136 of 31 July 2003.

[196] In the following, "FTC".

[197] The Sherman Act, 15 U.S.C., para. 42 – subsequently supplemented by several other statutes, including the Federal Trade Commission Act (in the following, the "FTC Act").

[198] The FTC Act, s. 5, 15 U.S.C. para 45.

[199] See also Georg de Bronett (EU Commission), "EU Competition Policy and Generic Medicines", section 7, Speech at First EGA Legal Affairs Forum, London, 2 February 2005. (Accessible at: http://ec.europa.eu/comm/competition/speeches/text/sp2007_17_en.pdf).

visions do not have identical wording, they still appear similar and therefore it is possible to compare the way they are interpreted in respectively the US and the EU.

5.3.3.1. US Case Law

The US cases which may have had an influence on the Commission's decision in *AstraZeneca* are, as mentioned by Gunther and Breuvart[200], the cases which concern the improper enforcement of a patent which has been obtained by deliberate fraud on US authorities. The leading case within this area is the US Supreme Court *Walker* Case from 1965[201] which found that the mentioned practice may violate Section 2 of the Sherman Act. However, case law from recent years concerning improper listings in the "Orange Book" may also have influenced the Commission in its AZ Decision as it is particularly similar to AZ's conduct, specifically the SPC abuse:

As within the EC, when a medicinal product manufacturer wants to be able to place a new product on the market, he must file a New Drug Application[202] in order to obtain an approval of the product. Patents covering the approved pharmaceuticals are identified in a publication named "Approved Drug Products with Therapeutic Equivalence" – "The Orange Book". It should be mentioned that, similar to the SPC system within the EU, the relevant authority, the FDA (US Food and Drug Administration) does not assess the validity of the applicant's listing in the Orange Book.

As for generic products, the so-called Hatch-Waxman Act[203] provides a simplified procedure according to which the generic manufacturer can file an Abbreviated New Drug Application.[204] Under this procedure the generic manufacturer is allowed to rely on the scientific evidence filed with the NDA; however he must declare that the generic product will not infringe any patent rights related to the original reference product as listed in the Orange Book.

When the original reference product manufacturer has been notified of the generic manufacturer's declaration of non-infringement of Orange Book listings, the patent holder/original reference product manufacturer has 45 days to file a patent infringement suit against the generic manufacturer. Such an infringement suit will automatically suspend the ANDA approval procedure for 30 months, thereby delaying generic market entry.[205]

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[200] Jacques-Philippe Gunther and Charlotte Breuvart, 'Misuse of Patent and Drug Regulatory Approval Systems in the Pharmaceutical Industry: An Analysis of US and EU converging Approaches', European Competition Law Review [2005] 26(12), p. 670 ff.

[201] *Walker Process Equipment, Inc. V Food Machinery & Chem. Corp*., 382 US 172 (1965). For a brief summary of the case, see Gunther and Breuvart, p. 672.

[202] In the following, an "NDA".

[203] The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No 98-417, 98 Stat. 1585 (1984, as amended by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

[204] In the following, "ANDA".

[205] Gunther and Breuvart (n. 200), p. 671-673.

Due to this so-called "30-month stay" mechanism, manufacturers of the original reference product have an interest in obtaining patent rights with the purpose of filing infringement suits in order to keep generic products off the market.

This was the situation in the two US cases: *Biovail*[206] and *Bristol-Myers Squibb.*[207]

In *Biovail*, the FTC filed a complaint alleging that Biovail had effected a patent listed in the Orange Book even though the undertaking knew that the patent could not cover the approved reference product, Tiazac.[208] The improper listing in the Orange Book made Biovail able to file infringement suits against a generic manufacturer, Andrx, who was trying to obtain an ANDA for its generic version of Tiazac. Thereby Andrx' market entry was delayed.

Bristol-Myers Squibb concerned the same kind of misconduct. Bristol-Myers had submitted patents for Orange Book listing although Bristol-Myers was in bad faith that the patents submitted were in fact unenforceable/invalid and thereby did not meet the listing requirements. Bristol-Myers took advantage of the wrongful Orange Book listings by suing generic competitors for patent infringement, thereby triggering the 30-month stay mechanism.

In both cases the FTC complaint alleged that the undertakings by effecting improper listings in the Orange Book had engaged in unlawful monopolisation, thereby infringing Section 2 of the Sherman Act and in particular Section 5 of the Federal Trade Commission Act which prohibits unfair acts, practices or methods of competition.[209] The cases which both ended with consent orders are important as they are the first cases in which the FTC has found that 'improper *Orange Book* listings could constitute a violation of US antitrust laws...'[210]

5.3.3.2. Parallel to *AstraZeneca*

When the United States adopted the Sherman Act in 1890, it was the first jurisdiction to adopt a "modern" competition law system[211]. Therefore American antitrust law has always had a considerable influence on the competition law systems in other jurisdictions, including the one of the European Community, which has adopted several US antitrust phenomena, such as for example the so-called SSNIP test which is used in relation to the definition of the relevant market.[212]

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[206] Biovail Corp. 134 F.T.C. 407 (2002) (consent order); see http://www.ftc.gov/os/caselist/c4060.shtm.

[207] Bristol-Myers Squibb Co., 135 F.T.C. 444 (2003) (consent order); see http://www.ftc.gov/os/caselist/c4076.shtm.

[208] Biovail was able to do this because, as mentioned above, this section, the FCA does not scrutinize a patent which is filed for listing in the Orange Book.

[209] See (n. 197 and 198).

[210] Gunther Breuvart (n. 200), p. 676. For a further analysis of the cases mentioned, including the procedures described above, see in general the assessment in this journal article.

[211] Jones & Sufrin (n. 15), p. 19.

[212] See *The European Commission's Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law*, 09.12.1997, OJ 372/5, [1998] 4 CMLR 177, paras. 15 ff.

Due to this influential position enjoyed by US antitrust law, it appears natural that the Commission had a look at how conduct similar to AZ's SPC abuse has been assessed under the Sherman Act. This assumption is particularly clear because misrepresentations before public authorities and abuse of public procedures had never before been assessed within the context of Article 82 EC. In this connection it should be noticed that, as pointed out by Arezzo,[213] US courts have generally shown reluctance from using antitrust law to interfere with intellectual property rights, whereas European authorities, on the other hand, have proved more willing to use competition law tools when dominant undertakings have abused intellectual property rights to fortify their dominant position. Thus, in the US, intellectual property rights have always been seen as an important incentive for investment in innovation and therefore intellectual property rights have traditionally enjoyed wide protection characterised by the authorities' reluctance to interfere – also in matters involving antitrust.[214] Under EC competition law, on the other hand, the tendency has been an endeavour to assess all circumstances and factors of each case.[215]

In this context, it is remarkable that the conduct as the one performed in the *Biovail* and *Bristol-Myers* cases was held to be violating antitrust law. Therefore the Commission may have seen the cases as strong suggestions that AZ's misuse of governmental procedures and regulations should be found to be an abuse of a dominant position under Article 82 of the Treaty.

Moreover, a recent US case concerning a situation very similar to AZ's second abuse, the de-registration abuse, seems to back the Commission's findings in *AstraZeneca*:

In *Abbott Laboratories v Teva Pharmaceutical*,[216] the Federal District Court of Delaware held that Abbott had infringed Section 2 of the Sherman Act by switching the form of its product, TriCor, with the intention of preventing generic market entry. More precisely, having obtained an approval from the FDA for TriCor in tablet form, Abbott stopped all sales of its existing TriCor capsules and desolated the capsule formulation as "obsolete" in the National Drug Data File. This meant that manufacturers of generic TriCor capsules were prevented from entering the market because prescriptions for TriCor could no

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[213] Emanuela Arezzo, 'Intellectual Property Rights at the Crossroad Between Monopolization and Abuse of a Dominant Position: American and European Approaches Compared', John Marshall Journal of Computer & Information Law [2007] vol. 24, No. 3, p. 505.

[214] Ibid. For an example of the reluctant approach towards intellectual property rights, see *U.S. Department of Justice & Federal Trade Commission: 'Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition', April 2007*. (Accessible at: www.usdoj.gov/atr/public/hearings/ip/222655.pdf.) In chapter 6, p. 122, of the Report concerning 'Practices That Extend a Patent Beyond its Statutory Term', it is mentioned that it should be taken into consideration that 'many restrictions that have the potential to extend the market power conferred by a valuable patent beyond its term *can have demonstrable efficiencies'*. (Italics added)

[215] Arezzo (n. 213), pp. 457 and 505.

[216] *Abbott Laboratories v Teva Pharmaceutical USA Inc*. 432 F. Supp. 2d 408 (D.Del.2006).

longer be fulfilled with generic TriCor capsules. The Court held that Abbott's conduct violated Section 2 of the Sherman Act, inter alia because the switch from capsule to tablet with the removing of capsules (including generic capsules) from the market limited the consumers' choice.[217] [218]

5.3.4. Conclusion concerning the two Abuses

5.3.4.1. Extensive Interpretation within the Scope of Article 82

As mentioned above, two key factors of the Commission's Decision were AZ's exclusionary intentions and its disregard of its special responsibility.

Although the focus on intentions of competitive foreclosure was emphasised as aggravating circumstances, the decision clearly also stretches the concept of "special responsibility" thereby pushing the limits of the scope of Article 82. The result of this approach is that a dominant undertaking must behave very carefully when operating within the market.

Yet, as it appears from the above mentioned discussion, the assumption that misuse of government procedures and regulations can be an "abuse" within the meaning of Article 82 does *not* seem to bring the concept of "abuse" to a level *outside* the scope of the broadly worded Article 82:

5.3.4.2. Accordance with Case Law

The Commission's decision in *AstraZeneca* appears, as shown in section 5.3.2., to be in line with case law concerning similar exclusionary abuses, such as vexatious litigation and case law concerning certain situations of acquisition of rights.

As regards the parallel to refusal to supply intellectual property licences, this is also relevant in the assessment of *AstraZeneca*. Yet, it is remarked that the approach towards AZ could be stricter than the approach taken towards intellectual property rights holders, since the "right" in question was not an intellectual property right aiming at providing an exclusive right to its holder. On the contrary, the "right"

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[217] For a further analysis of this case seen in the context of *AstraZeneca*, see Negrinotti (n. 127), p. 456.

[218] It should be mentioned that in the US, the *Abbott Case* caused fear that innovative companies would lose their incentive to innovate because of the strict application of antitrust law in this case. However, in a recent case from February 2008 concerning AZ's switching from Prilosec (US Losec) to its new product, Nexium, the Federal District Court of Columbia limited the scope of the *Abbott Case*, holding that product switching which does not involve removing the old product from the market will not harm consumers (choice) in a way which makes it necessary for antitrust to interfere. On the contrary, it will widen the consumer's choice and thereby strengthen competition on the market. See *Walgreen Co. v. AstraZeneca Pharm.*, 534 F. Supp. 2d 146 (D.D.C. 2006); and Amy Miner (Associate with the law firm of Drinker Biddle and Reath LLP) 'Dubious Antitrust Claims can Harm Innovation in Drug Industry' Update November/December 2007, "Associate's Corner". (Accessible at: http://www.drinkerbiddle.com/files/Publication/99e53c63-1b76-4d74-aa92-138b4bb1d9b1/Presentation/PublicationAttachment/30b1a81e-8941-46e6-bdd4-0fbb556a3323/FDLIArtilcle.pdf).

which AZ "refused" to supply was a right to place its products on the market – a right which was non-exclusive and which AZ was therefore not entitled to use tactically as part of its business strategy. This fact supports the strict approach taken by the Commission towards AZ.

5.3.4.3. Accordance with US Antitrust Law

Furthermore, it can be concluded from section 5.3.3., that that the Commission's approach in *AstraZeneca* is also in line with the approach taken in the US as regards misuse of patent systems and regulatory procedures, just like recent US antitrust law (the Abbott case[219]) is also in line with the Commission's approach in *AstraZeneca*. These concordances between the two systems are hardly coincidental.

5.3.4.4. Accordance with the Commission's Discussion Paper[220]

It may moreover be mentioned that *AstraZeneca* is consistent with the approach towards exclusionary abuses which the Commission presented in its Discussion Paper on exclusionary abuses a few months after its final AZ Decision.[221] Thus, *AstraZeneca* can be considered to be in line with inter alia the so-called 'effects-based' approach encouraged by the Commission, since, it may be argued that in its findings, the Commission focused more on the effects of AZ's conduct, rather than the actual behaviour (form-based approach).[222]

In this regard it may be mentioned that AZ's behaviour must be categorised as 'exclusionary' within the meaning of the Discussion Paper, because it foreclosed and was indeed intended to foreclose its competitors from the market, thereby creating a de facto extension of its monopoly on omeprazole, and thereby also extending its possibilities to gain high monopoly profits.[223] Parallel to the *Abbott* case (n. 216), the behaviour limited the customer's choice between different omeprazole products and thereby harmed national health systems and consumers.

5.3.4.5. Accordance with the Community Court's traditional Interpretation of the Treaty

As a final point, it may be relevant to consider the fact that Community Courts have traditionally engaged in purposive/teleological and dynamic interpretation of Community law, thereby paying specific regard to the objectives of the Treaty.[224]

Regarding cases concerning infringements of competition law this means that the Courts will normally take into consideration the objectives of competition rules, which include the securing of 'a high

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[219] (n. 216).

[220] (n. 15).

[221] For a definition of "exclusionary abuse", see the Commission's Discussion Paper, para. 2 or section 2.4.2. above.

[222] For further description of form-based and effects-based approaches in relation to the Commission's Discussion Paper, see Jones & Sufrin (n. 15), pp. 296-297.

[223] For a definition of "exclusionary abuse", see the Commission's Discussion Paper, para. 2 or section 2.4.2. above.

[224] Whish (n. 15), p. 194 and section 2.4.1. above.

degree of competitiveness and economic performance' and the establishment of 'a system ensuring that competition in the internal market is not distorted';[225] in *AstraZeneca* it must be presumed that other objectives of Community law, such as the 'contribution to the attainment of a high level of health protection' (Article 2 (p) EC) and 'a contribution to the strengthening of consumer protection' (Article 2 (t) EC) will also be considered.

Since, as it appears from the above mentioned discussion, conduct as AZ's in *AstraZeneca* is clearly against the objectives of competition law, the view taken in section 5.3.4.1., that the Commission kept within the scope of Article 82 in its interpretation of Article 82 in *AstraZeneca*, must therefore presumably be supported by the CFI.

5.4. Consequences of the extensive Interpretation of Article 82 in *AstraZeneca*

5.4.1. Lack of Incentives to Innovate?

As part of its defence towards the Commission's allegations AZ pleaded that a finding of abuse would remove the incentive to innovate because it would result in a limitation in dominant undertakings' commercial freedom as regards how they are allowed to behave in relation to their intellectual property rights.[226]

AZ did, however, not gain any support for its argument. Thus, the Commission specifically maintained that the abusive behaviour concerned AZ's misuse of governmental procedures and regulation - not AZ's intellectual property rights.[227] Therefore the matter of AZ's intellectual property rights was not at stake and there was no need to protect AZ.

Specifically as regards the second abuse, the Commission stressed that because the aim of marketing authorisations was not to provide its holders with exclusive rights, AZ was not entitled to use its marketing authorisation as a strategic weapon.[228]

As Competition Commissioner Neelie Kroes said in her comment on the Commission's finding in the case, 'it is not for a dominant company but for the legislator to decide which period of protection is adequate.'[229] The competitive advantages AZ gained by its conduct were unlawful and were only obtained because AZ took matters into its own hands. Therefore there is no clash between competition law and intellectual property rights in *AstraZeneca* as claimed by AZ.[230]

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[225] Article 2, respectively 3 (1) (g) of the Treaty.

[226] *AstraZeneca*, paras. 602 and 787.

[227] Ibid, 741 and 817.

[228] Ibid, 843.

[229] The Commission's Press Release IP/05/737, 15 June 2005.

[230] In line with this view, see Negrinotti (n. 127), p. 453; and Ian S. Forrester, 'Regulating Intellectual Property Via Competition? Or Regulating Competition Via Intellectual Property? Competition and Intellectual Property: Ten Years On, the Debate Still Flourishes', published in Claus-Dieter Ehlermann and Isabela Atanasui (eds.), '*European Competition Law Annual 2005: The Interaction between Competition Law and Intellectual Property Law*', Hart Publishing, Oxford/Portland, Oregon, 2007, p. 59.

5.4.2. Lack of Due Process and Legal Certainty?

Following *AstraZeneca* it has been indicated by certain legal experts that the Commission's Decision leaves dominant undertakings with a lack of due process because it means that a dominant undertaking may be held responsible for abuse of a dominant position although it has kept within the realm of the law. Thereby, as indicated by Manley and Wray,[231] the burden of ambiguous legislation is on the industry rather than on the legislator.

In this connection, however, it must be emphasised that the Commission did not only see the negligence of AZ's special responsibility as an important factor of the finding of abuse. Also the intentions of competitive foreclosure were emphasised as regards both abuses, and precisely the anticompetitive intentions may therefore justify not paying much regard to AZ's rule of law and legitimate expectations.

A dominant undertaking which behaves directly against the purpose of competition law is unlikely be assumed to have any fair and honest legal expectations which are worth protecting.

Moreover, it is relevant in this context to repeat the assumption that dominant undertakings are expected to have a 'high degree of awareness of antitrust rules'[232] which, as mentioned in section 5.1.3., above, must be complied with along with other rules.

6. Future prospects

6.1. Sector Inquiry

As a result of *AstraZeneca* the Commission feared that that competition was not working as it should within the pharmaceutical sector, in particular as regards generic medicines; the Commission suspected inter alia that market entry of generic medicines was delayed through artificial barriers to entry, such as for example misuse of patent rights and vexatious litigation, resulting in harm for national health systems, consumers and possibly in the end public health.[233]

Therefore, and as part of the Commission's recent policy of prioritising competition in the generic sector,[234] on 15 January 2008 the Commission launched an unannounced inquiry into the pharmaceutical sector.[235] A final report on this inquiry is expected in the spring 2009.[236]

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[231] Manley and Wray (n. 5).

[232] Bellamy & Child (n. 15), 13.139.

[233] Commission's press release, IP/08/49, 16 January 2008. (Accessible at http://europa.eu/rapid/pressReleasesAction.do?reference=IP/08/49&format=HTML&aged=0&language=EN&guiLanguage=en).

[234] See the Commission's 'Overview' of the pharmaceutical sector. (Accessible on http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/overview_en.html).

[235] The objective of creating better conditions for generic medicines must moreover be seen as part of the Lisbon Strategy which involves inter alia the aim of strengthening the competitiveness of the European economy, particularly by the strengthening of EU's knowledge-based sectors, such as the pharmaceutical in-

6.2. Boehringer

The sector inquiry is not the only action taken by the Commission since *AstraZeneca*. More specifically, a new case concerning conduct similar to AZ's is in the pipeline. This appears from a Commission's DG Comp notice which states that on 22 February 2007 the Commission decided to initiate Article 82 proceedings against two undertakings of the Boehringer Group regarding misuse of the patent system 'in order to exclude potential competition in drugs to treat chronic obstructive pulmonary disease (COPD)'.[237]

At the time of writing no news has been published regarding the Boehringer investigation.

7. Conclusion

7.1. AstraZeneca

As described above, the Commission's broad approach to Article 82's concept of "abuse" in *AstraZeneca* is quite intrusive and sets strict limits for how a dominant undertaking is allowed to act in the market. With its findings the Commission underlined that dominant undertakings must always behave carefully and in accordance with their special responsibility – including as regards the way they use government procedures and regulations and as regards their business strategies for the future.

In the light of the foregoing discussion, however, it may overall be concluded that although the understanding of dominant undertaking's 'special responsibility' might be stretched with *AstraZeneca*, and although this might seem a bit controversial, it appears correct to consider it as an abuse of a dominant position when a dominant undertaking submits misleading representations to patent agents, patent offices and national courts and introduces product switches as part an overall strategy of eliminating or at least impeding competition.

AZ has, as mentioned above, section 1.1., appealed the Commission's decision to the CFI[238]. At the time of writing it is uncertain when a final judgment from the CFI may be expected. However, it is certain that the result of the case will be eagerly awaited by the phar-

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dustry. See Bronett (n. 199); and the Commission's 'Overview' of the pharmaceutical sector (n. 233).

236 See http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html. A preliminary report is expected on 28 November 2008. See also the Commission's press release, IP/08/49 (n. 232).

237 Case COMP/B2/39246 – Boehringer; See http://ec.europa.eu/comm/competition/antitrust/cases/decisions/39246/initiations.pdf.
See also Boehringer's press release of 1 April 2007 (accessible at: http://www.boehringeringelheim.com/corporate/news/press_releases/detail.asp?ID=4514).

238 Action brought on 25 August 2005 (n. 7).

maceutical industry and legal experts etc. in the field of EC competition law.

7.2. The Article 82 Debate

As mentioned in section 3. above, the wide interpretation of Article 82 in *AstraZeneca* is possible inter alia due to the provision's vague wording seen in conjunction with the broad objectives of competition law.

Considering the fact that Article 82 concerns a prohibitory injunction with risks of large fines in case of infringement, it may be questioned whether the current construction of Article 82 is expedient. Thus, a vaguely worded prohibition leaves little legal certainty for private citizens and companies which are affected by the provision, inter alia as to where the limits are. A parallel could be drawn to the free movement rules of the Internal Market in the Treaty[239] which are also open for interpretation and which have led to innumerable cases before the Community Courts.

In AZ's case, the abusive conduct was carried out with the intent to foreclose competition from generic and parallel traded products. Therefore, as mentioned in section 5.4.2., above, it is not likely that the CFI will pay much regard to AZ's due process and legal expectations. Yet, for dominant undertaking's future understanding of Article 82 it may be desirable if further guidance/instruction on the interpretation of the provision and in particular the specific contents of dominant undertaking's special responsibility were published.

Therefore, the guidelines which were supposed to follow the Commission's Discussion Paper[240] are still relevant and awaited.

AstraZeneca finally shows that the limits of Article 82 are not yet reached. This may add fuel to the flaming and ongoing discussion[241] of whether it is time to reconsider/elaborate Article 82 as such in line with other areas of competition law, such as for example merger control which has been clarified with the ECMR[242].

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Advocate General Opinions

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