

Is there a requirement for 'good faith' or a 'duty of honesty' under article 102 TFEU, as regards misuse of public procedures and regulations, when establishing an abuse of a dominant position?

Master's Thesis in Commercial and Tax Law (EU Competition Law]

Author: Haddis Akbari

Tutor: Roger Sandberg

Presentation date 2012-05-14

Jönköping May 2012

Master's Thesis in Commercial and Tax Law (EU Competition Law)

Title: Is there a requirement for 'good faith' or a 'duty of honesty', under

article 102 TFEU, as regards misuse of public procedures and regu-

lations, when establishing an abuse of a dominant position?

Author: Haddis Akbari

Tutor: Roger Sandberg

Date: 2012-05-14

Subject terms: abuse of a dominant position, infringement of article 102

TFEU, infringement of article 82 EC, misuse of government procedures and regu-

lations, special responsibility of an undertaking, competition law

Abstract

Article 102 of the Treaty on the Functioning of the European Union (TFEU) (ex article 82 TEC) states that:

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

In the recent case of *AstraZeneca*, decided by the General Court, a court has for the first time decided in a case concerning the misuse of public procedures and regulations in relation to an abuse of a dominant position under article 102 TFEU.

The case of AstraZeneca has given rise to the purpose of this thesis, which is to examine: if there is a requirement for 'good faith' or a 'duty of honesty', under article 102 TFEU, as regards misuse of public procedures and regulations, when establishing an abuse of a dominant position. This paper shows that there is in fact a requirement for 'good faith' or a 'duty of honesty' under article 102 TFEU, as regards misuse of public procedures and regulations, when establishing abuse of a dominant position. Nevertheless, the finding of an abusive conduct in question must primarily be based on an objective test. However, if an ob-

jective abuse test does not point towards an abuse, but there are reasons to believe that an abuse exists nevertheless, a court can try to establish whether or not the undertaking was in good faith. Similarily, if an abuse is not found through an objective abuse test, but there are reasons to believe that an abuse does exist in reality, a court can try to establish the good faith of the undertaking.

Table of Contents

Ak	brevi	iations	3
1	1.1 1.2 1.3 1.4	Defluction Background Purpose Method and materials Outline	4 5 5
2	2.1 2.2	Regulatory framework The concept of abuse 2.2.1 Introduction to the concept of abuse 2.2.2 The objective of article 102 TFEU 2.2.3 Case law and literature 2.2.4 Abuse as regards exclusionary conduct	8 9 9 10
3	The	case of AstraZeneca	13
4	The 4.1 4.2	Findings of the Court	15 17 17
-	The	·	
5	5.1 5.2	second abuse in AstraZeneca Regulatory framework for the second abuse Findings of the Court	23
6	Anal 6.1 6.2 6.3	Introduction to the analysis of the case The first abuse: a pattern of misleading representations	27 27 28 30 30 32 34
7	Fina	I analysisFinal analysis as regards good faith in general	

	7.2	Special responsibility	37
8	Con	nclusion	39
Lis	st of	references	41

Abbreviations

COJ – European Court of Justice (The highest court in EU)

The Court – The General Court

The SPC Regulation - Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products

I Introduction

I.I Background

Article 102 of the Treaty on the Functioning of the European Union (TFEU) ¹ (ex article 82 TEC²) states that:

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

The article continues after its first sentence with a non-exhaustive list of abuse by exemplifying what abuse of a dominant position can consist of.

In the up to date case of *AstraZeneca*³ from 2010, the General Court (hereafter the Court) gave a ruling in favour of a decision⁴ from 2005 from the Commission, where the company AstraZeneca, was found breaching article 102 TFEU and accordingly fined €52,5 million for an abuse of dominant position. This was the first time the question of abuse through misuse of procedures and regulations was brought before a European court.

Although there are abuses specifically mentioned in article 102 TFEU and case law providing some clarification on the concept of 'abuse of dominant position', the Court seems to have introduced a requirement of 'good faith' or a duty of honesty for companies in a dominant position, as regards misuse of public procedures and regulations. This issue is vital for all companies in a dominant position, since the judgement of the Court results in complications extending further than the pharmaceutical area, to all companies considered as dominant being subject to some sort of regulation. The use of what seems to be legiti-

¹ 2010/C 83/01 Consolidated version of the Treaty on the Functioning of the European Union.

² 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 (EC Treaty).

³ T-321/05 AstraZeneca v Commission – 1 July 2010.

⁴ European Commission's Decision Case COMP/A.37.507/F3 – AstraZeneca, of 15 July 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement.

mate loopholes can result in considerable anti-competition fines, for example when extending the duration of patent protection.

1.2 Purpose

The judgement in the case of *AstraZeneca* has amounted to the raise of a number of different questions relating to possible new turns in EU competition law, one of them being if the concept of abuse comes with more requirements than has been expected until now.

The question has given rise to the purpose of this thesis, which is to examine: if there is a requirement for 'good faith' or a 'duty of honesty', under article 102 TFEU, as regards misuse of public procedures and regulations, when establishing an abuse of a dominant position.

The purpose needs to be fulfilled by using the case of *AstraZeneca* as a central base, as this is the first case where considerations relating to good faith or a duty of honesty can be found in relation to misuse of public procedures and regulations.

I.3 Method and materials

The highly valuable sources witin the EU consist of primary legislation such as for example the Treaty on the Functioning of the European Union, but also regulations, EU-principles, case law and literature. This is why the paper in question mainly process these materials when aiming to fulfil the purpose of the thesis. However, the Commission's Guidance paper concerning abuse of dominant position contributes to the understanding of the concept of abuse of dominant position and helps to fulfil the purpose of the thesis, which is why it has been used. The reasons for using the Guidance paper is explained and discussed in more detail later in the this paper.

The mentioned sources have been used to find answers in the same order as they appear in the above paragraph. However, at times it has been necessary to use for example case law or literature in order to understand how for example the treaties could be used in a certain aspect.

⁵ Bernitz, Ulf, *Finna rätt: juristens källmaterial och arbetsmetoder*, 10th edition, Norstedts juridik, Stockholm, 2008, [Bernitz] p. 61.

When determining the purpose of a legislation in the EU one finds guidance in the preamble of the same, as opposed to in some states where preparatory works are of high importance. With this in mind, the thesis excludes search in preparatory works to find answers.

An essential interpretive method used in the EU is the teleological method, where the purpose, function and effect of provision in the legislation is taken into consideration. This method is used when trying to ascertain what the provision in question contains. The teleological method has been an important tool in ascertaining what the concept of abuse actually contains (which is of direct importance when fulfilling the purpose of the thesis). The reason being for one, that the teleological method contributes with better help when speaking of abuse by an undertaking in a dominant position. Moreover, the teleological approach is the one used to a greater extent by courts in the EU when discussing the concept of abuse under article 102 TFEU, for the same reason as just mentioned in the sentence before.

1.4 Outline

In the second chapter of this paper the reader is first introduced to the basics of article 102 TFEU and what it actually contains in order to have the necessary background. The concept of abuse of a dominant position holds more than meets the eye and there are some aspects that can not be detected just by reading the article itself. This chapter is divided in subchapters, the reason being that the reader should be introduced to the article first, before getting into more detail in what the concept of abuse consists of. This way, the reader gets a more pedagogical overview of the assessment itself when defining abuse according to the article. This chapter seeks to sort out how the concept of abuse is looked upon today in more certain terms and what can constitute abuse of a dominant position. This part is important as it is helpful later when understanding the gap between how the concept has been conceived uptil now and after the possible new requirement coming from the General Court in *AstraZeneca*.

In the third chapter the author presents the case of *AstraZeneca*, giving a shorter summary on what it contains. The case is very complicated and there are many aspects to go through,

⁶ Bernitz, p. 65.

⁷ Bernitz, p. 68.

⁸ Whish, Richard, Competition Law, (5th edition Oxford University Press, Oxford, 2005), p. 194.

which is why an overall picture of the case is given before entering into specifics in following chapters.

In the fourth and fifth chapter the reader is introduced to the findings of the General Court in *AstraZeneca* in greater detail. This is in part in order to determine wheather or not a new requirement of 'good faith' has been introduced through the case before the General Court, and in part to be able to value the strengths and weaknesses of the findings. The fourth chapter deals with the first abuse situation in the case, and the fifth deals with the second. The relevant regulatory frameworks for each are introduced in respective subchapters, before the findings of the General Court are assessed.

The sixth chapter contains analysis for the two abuse situations under different subchapters. However, an analysis for the two abuses are also provided together in a separate subchapter, to compare and contrast the differences and highlight the similarities.

The seventh chapter is a final analysis where further aspects common to both abuse situations are brought to the attention of the reader which give an overall picture.

Finally, the author draws the conclusion in the thesis in the eighth chapter, where the results of the paper are presented.

2 Introduction to abuse of dominant position

2.1 Regulatory framework

The first sentence in article 102 TFEU states that:

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

The article continues by exemplifying what abuse can consist of, however, this list is not exhaustive:

"Such abuse may, in particular, consist in:

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

A linguistic approach to fully comprehend article 102 TFEU only gives restricted guidance in understanding what an abuse of a dominant position consists of. The exemplifying list is as already mentioned not exhaustive, but at least there are some cumulative criterias in the first sentence which needs to be met for the article to be applicable. These requirements are that:

- The conduct must have been carried out by one or more undertakings
- The undertaking/These undertakings must have a dominant position

- The dominant position must be found in the common market or in a substantial part of the common market
- The dominant position must be abused
- An actual or potential effect on trade between Member States must be found

It should be highlighted that the article only becomes relevant in situations where the company in a dominant position abuses its dominance, since the dominance as such is not prohibited. Nowhere in article 102 TFEU is there a definition to be found on what 'abuse' or 'dominance' consists of. This is why these concepts are so difficult to understand, especially for companies which might be affected by them.

2.2 The concept of abuse

2.2.1 Introduction to the concept of abuse

Seeing that the wording of TFEU does not give any guidance on the concept of abuse (by a company in a dominant position), the author will try to clarify the concept, by providing the reader with explanations from case law and furthermore, by interpreting the article in light of the aim with the treaty, in other words approaching the problem by using a teleological interpretation. This teleological interpretation will sometimes be made by the author independently. Other times the interpretation will be made by approaching the concept of abuse and what it contains through clarifications from case law and other valuable sources, where guidance on the concept has been made on the basis of teleological arguments.

2.2.2 The objective of article 102 TFEU

Since the wording of article 102 TFEU does not help in gaining more knowledge of what the concept of abuse contains, one can turn to the greater objectives of the EU in order to find answers. The provision of 102 TFEU is aimed at hindering companies in a dominant position to act in a manner that is abusive. The aim can be seen through an objective of the EU, namely to ensure that competition is not distorted in the internal market, ¹⁰ as set out in Article 3 of the Treaty on European Union¹¹. The difference between article 101 and 102

⁹ Case 322/81, Nederlandsche Banden-Industrie Michelin NV v Commission [1983] ECR 3461, [hereafter Nederlandsche] para 57.

¹⁰ 2010/C 83/01 Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union, Protocol (No 27) on the internal market and competition,

¹¹ 2010/C 83/01 Consolidated version of the Treaty on European Union.

TFEU within this objective is that the first mentioned aims at agreements which are to the detriment of competition, whereas the latter only concerns companies in a dominant position that also behave in an abusive manner.

2.2.3 Case law and literature

According to case law, the concept of abuse is an objective one, which refers to the behaviour of an undertaking in a dominant position. This behavior is conducted in a way that influences the structure of a market, where as a result of the presence of the undertaking, the level of competition has been weakened already and where the undertaking has used different methods than normal in competition on the basis of trader's performance. For the concept of abuse to be established the used methods should have had the effect of hindering the maintenance of the degree of competition which still can be found on the market or the growth of the competition.¹²

It has been underlined through case law that companies with a dominant position has a 'special responsibility' to behave in a way that does not harm competition on the internal market. This 'special responsibility' becomes greater the greater the company's dominance is, especially in cases where there is a 'super-dominance', where it is more likely that the behaviour will infringe article 102 TFEU. The super-dominance occurs in situations when the company in a dominant position has a market share close to that of a monopolist. 14

It should be pointed out that carrying out business and competing 'on the merits' is not wrong, whereas abuse can be found in situations where a company in a dominant position is superior due to abnormal conduct, rather than because of a conduct based on a 'trader's performance'. A 'trader's performance' has also been referred to as 'superior economic efficiency' in some places and by some authors, such as Whish.¹⁵

¹⁴ Jones, Allison & Sufrin, Brenda, EC Competition Law: Text, Cases and Materials (3rd edition, Oxford University Press, Oxford, 2008 [hereafter Jones & Sufrin], p. 337.

¹² Case 85/76 Hoffmann-la Roche v Commission, [1979] ECR 461, [hereafter Hoffmann] para 91 and Case C-62/86 AKZO v Commission, [1991] ECR I-3359, [hereafter AKZO] para 69.

¹³ Nederlandsche, para 57.

¹⁵ Nederlandsche, para 70, and Whish, p. 199.

2.2.4 Abuse as regards exclusionary conduct

Abuse can be categorized as being exploitative or anticompetitive/exclusionary, depending on what kind of effect the abuse produces. ¹⁶ Some months after the Commission gave its decision against the company AstraZeneca in 2005 (before the judgement by the Court), the Commission released a discussion paper with its approach as regards exclusionary abuses. ¹⁷ The discussion paper turned into a guidance paper from the Commission on its application of article 102 TFEU as regards abusive exclusionary conduct by companies in a dominant position. ¹⁸

The final Guidance paper came before the judgement by the Court in *AstraZeneca*. The Guidance paper is not legally binding and without prejudice to interpretation of article 102 TFEU, by the Court of Justice or the General Court, according to article 3 of the Guidance paper. However, it is a valuable source for understanding article 102 TFEU as regards abusive exclusionary conduct, as it shows how the Commission acts when applying the article and helps companies assess if their behaviour will fall under the article or not.¹⁹

The Guidance paper is much relevant for the discussion in this thesis, as it helps in fulfilling the purpose of the same and as it contributes to better understanding the angle taken by the Court in *AstraZeneca*.

In the Guidance paper it is stated that the purpose of the paper is to make sure that undertakings in a dominant position do not hamper effective competition as regards exclusionary conduct. At least not in a way by foreclosing competition through anti-competitive practices. The reason being that consumers welfare might be affected negatively.²⁰

Articles 28 to 29 of the Guidance paper will be cited in their entirety below, as the considerations are very central throughout the thesis. There is no need for the author to comment on these at this stage, since the elements in the Guidance paper will be commented on

¹⁶ Bellamy & Child, *European Community Law of Competition*, 5th edition, edited by Peter Roth and Vivien Rose, Oxford University Press, Oxford, 2008, [hereafter Bellamy & Child] 10.065.

¹⁷ DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses, Brussels December 2005 [hereinafter discussion paper].

¹⁸ Communication from the Commission – Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, (2009/C 45/02) [the Guidance paper].

¹⁹ Article 2, the Guidance paper.

²⁰ Article 19, the Guidance paper.

many times in the paper later, in connection to the Court's judgement in *AstraZeneca*, as well as in the different analysis.

"In the enforcement of Article 82, the Commission will also examine claims put forward by a dominant undertaking that its conduct is justified. A dominant undertaking may do so either by demonstrating that its conduct is objectively necessary or by demonstrating that its conduct produces substantial efficiencies which outweigh any anticompetitive effects on consumers. In this context, the Commission will assess whether the conduct in question is indispensable and proportionate to the goal allegedly pursued by the dominant undertaking."²¹

"The question of whether conduct is objectively necessary and proportionate must be determined on the basis of factors external to the dominant undertaking. Exclusionary conduct may, for example, be considered objectively necessary for health or safety reasons related to the nature of the product in question. However, proof of whether conduct of this kind is objectively necessary must take into account that it is normally the task of public authorities to set and enforce public health and safety standards. It is not the task of a dominant undertaking to take steps on its own initiative to exclude products which it regards, rightly or wrongly, as dangerous or inferior to its own product."²²

²¹ Article 28, the Guidance paper.

²² Article 29, the Guidance paper.

3 The case of AstraZeneca

In the fairly new case of *AstraZeneca* the Court seems to have taken a surprising angle when establishing abuse of dominant position. The dispute began with a decision by the Commission against the AstraZeneca group (hereafter called the company or undertaking), which the company later contested and which was brought before the Court.

The company brought action in the Court in the case of *AstraZeneca*. The company opposed the decision by the Commission on a number of points before the Court. The Court confirmed in major parts the position taken by the Commission in its decision, as regards the abuse of dominant position.

However, interesting for this thesis from the case of *AstraZeneca*, is that the Court seems to have introduced a requirement of 'good faith' or a duty of honesty within article 102 TFEU as regards 'abuse of dominant position'. The position taken by the Court could be seen as strange, as there are already exemplified abuses in article 102 TFEU and case law on how to approach the concept of 'abuse of dominant position'.

The company was found in breach of article 102 TFEU in two different abuses. The first abuse concerned the company's misrepresentations to public authorities. The second abuse consisted of the company's withdrawal of a product and replacement with a new in combination with a request for deregistration of a marketing authorization for its product.

As regards the first abuse, the Court held that the company's behaviour did not reflect normal business practice as the company had provided public authorities with misleading information. The Court stated that the company's conduct, acting differently than what was normal practice, was misleading and damaging to competition as it extended the time length of the protection for one of the company's patents. However, it appears as though the Court would have ruled differently if the company would have proved that it was in good faith at the time of the conduct, by providing the public authorities with an explaination to the reason behind the departure from what was normal business practice.

The second abuse concerned the fact that the company had abused its dominant position by withdrawing an older version of its product (Losec capsules) in Denmark, Norway and Sweden, and replacing it with a new version (Losec tablets, also called MUPS). The Court held that the company's withdrawal impeded entry for generic products by competitors. Furthermore, the company had abused its dominant position through a request for a deregistration of a marketing registration for the Losec capsules in Sweden. This constituted an abuse since it was in a way as to limit parallel imports of Losec capsules in the country. The company did not manage to avoid the application of article 102 TFEU, as it did not give an objective justification for its behaviour.

At the time being the company in the case of *AstraZeneca* has appealed the judgment by the Court, regarding the Court's judgment relating to abuse of dominant position. The case is now in progress before the highest court in the EU,²³ the Court of Justice, and an Opinion by the Advocate General is expected to be delivered on May 15, 2012.²⁴

-

²³ C-457/10 P AstraZeneca v Commisson (Case in progress).

²⁴ Information regarding the case in progress is accessible at http://curia.europa.eu/ [2012-05-02].

4 The first abuse in AstraZeneca

In the decision from the Commission, it was found that the company in question had used a practice where *a pattern of intentional misrepresentations* where made before patent attorneys, patent offices and national courts. This was done by the company to gain extension protections for their patented product "omeprazole", which was a substance used in the company's medicinal product "Losec". These extension certificates are called supplementary protection certificates and the company knew that it was not entitled to them. The Commission was of the opinion that the company had made these misleading representations with the intention to hinder competition as regarded generic products and parallel imports.

The Court stated that there was in fact an abuse of a dominant position by the company. The company had abused its dominant position by the misleading representations to public authorities in several Member States. The misleading information consisted of providing dates in the application for the certificates that did not reflect dates which would represent normal practice in the industry. The company had provided the date of the first price approval for its product Losec, instead of the product's first technical marketing authorisation. The company claimed that it had interpreted the rules in an alternative way, since the regulation was unclear, and therefore sent in dates relating to the first price approval. Since the company had acted in a way that not considered as normal practice and not provided the public authorities with more information around this, its conduct was misleading and to the detriment of competition. The result had been unlawful extensions in time that the patent protection for Losec lasted.

4.1 Regulatory framework for the first abuse

In the AstraZeneca case, the Court gave a good summary on the overall aspect with the regulation at issue:

"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, p. 1) provides for the creation of a supplementary protection certificate (the SPC), the purpose of which is to extend the duration of the exclusive right guaranteed by a patent and, therefore, to confer an additional protection period. The SPC is designed to compensate for the reduction in the

period of effective protection conferred by the patent, corresponding to the period between the filing of a patent application in respect of a medicinal product and the granting of authorisation to place that product on the market."²⁵

From the time that the original patent has expired the SPC protection comes into force and lasts for a length of time which corresponds to that of the time elapsed between the patent application filing and "the date of the first authorization to place the product on the marketin the Community reduced by a period of five years". ²⁶ According to article 13(2) of the SPC Regulation, the protection cannot last longer than five years after it takes effect.

Article 3 of the SPC Regulation provides the conditions necessary in order to obtain an SPC. One of the conditions relevant for the thesis is that a marketing authorization has been granted in concordance with Directive 65/65/EEC. Furtherrmore it is required that the just mentioned authorization "is the first authorization to place the product on the market as a medicinal product".²⁷

It should be noted that for products which are already the subject of a patent, and during the time when the SPC Regulation was in force, were already the subject of authorization, (as the Losec product in the case of *AstraZeneca*) there are more relevant issues. In these situations it is necessary that the <u>first authorization to place the product on the market</u> in the EU is approved after January 1, 1985. This date is instead January 1, 1988 for SPCs in Germany, Norway, Denmark and Finland.²⁸ The issue mentioned in this paragraph should be born in mind, because the first abuse in *AstraZeneca* concerned the interpretation of the part underlined in this paragraph.

Article 8(1) of the SPC Regulation specifies among other things the information that needs to be provided in the application for an SPC. In the article it is stated that the number and date of the authorizations should appear on the application, but nowhere it is stated if 'the

²⁵ AstraZeneca, para 295 with reference to 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, p. 1) [hereafter called the SPC Regulation], recitals 1 ff. Note that this version of the regulation was the one in force at the time of the conduct.

²⁶ Article 13(1), the SPC Regulation.

²⁷ Article 3(b) and (d), the SPC Regulation.

²⁸ Article 19(1), the SPC regulation.

first authorization to place the product on the market' means the first technical authorization, or the marketing authorization.

4.2 Findings of the Court

4.2.1 The company's abusive practice

One of the most central findings of the Court which should be brought to the attention of the reader is cited below:

"In the present case, the Court observes that the submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition. Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position not to impair, by conduct falling outside the scope of competition on the merits, genuine undistorted competition in the common market."²⁹

The cited paragraph above is in line with article 6 in the Guidance paper (which came just before the judgement in *AstraZeneca*.

The Court continues its assessment by a reference to the case of *Hoffmann*, sustaining the known thought that the test regarding the abuse of dominant position is an objective one. Therefore, the misleading nature of the information provided to the patent authorities have to be evaluated on objective factors. It is not a requirement to take into account an intentional nature of a conduct and the bad faith of the company in a dominant position, when trying to establish if there is an abuse of a dominant position.³⁰

-

²⁹ AstraZeneca, para 355.

³⁰ AstraZeneca, para 356.

It follows from the Court's considerations that the mere situation that a company through its conduct, being representations in the present case, intends to gain a right which it does not have a legal right in, does not need to be misleading as such. The question of this conduct is misleading have to be reviewed by looking at the concrete behaviour underlying the conduct. This test may be different in every case, depending on the specific circumstances of the case in question. One needs especially to examine if, "in the light of the context in which the practice in question has been implemented, that practice was such as to lead the public authorities wrongly to create regulatory obstacles to competition, for example by the unlawful grant of exclusive rights to the dominant undertaking." The Court agreed with the Commission's finding that the public authorities did not have any obligation to make sure that the information given by the company was correct or authentic, and that these authorities had restricted discretion for this. These factors in the sentence just above are relevant factors to take account of when deciding if the conduct at hand is liable to create regulatory restrictions on competition.³¹

What is more, it is required by a company in a dominant position (as a minimum), to make sure that the public authorities are informed of the unlawful exclusive right after it has been given, in order for the authorities to correct the mistake. The requirement becomes relevant when the grant has been made as a result of an inaccuracy on the company's side as regards the communication with the authorities in question. The company is required to do so by its special responsibility not the harm genuine undistorted competition through methods outside the sphere of competition on the merits.³²

As a response to some of the company's arguments³³, the Court clarified that: it is true that evidence of the intentional nature of the behaviour liable to misinform the public authorities is not needed to identify an abuse of a dominant position. Regardless of this, the deliberate nature is a relevant aspect which may, in certain cases, be considered, even though the concept of abuse of dominant position is objective and does not involve an intention to impair anything. The intention to resort to a conduct outside the scope of competition on the merits is not unrelated to the concept of abuse of dominant position. The reason being that the intention can nevertheless be taken into consideration to support the finding that the company in question abused its dominant position. This is the case irrespective of the

³¹ AstraZeneca, para 357.

³² AstraZeneca, para 358.

³³ See AstraZeneca, paras 309, 312 and 314 to read these arguments.

fact that that finding should be based on an objective test at first hand as regards whether or not the abusive behaviour occurred.³⁴

The Court notes that through the examination of the abuse at issue, it is evident that the company's behaviour was constituted by, at first hand, reporting to the patent offices in United Kingdom, Germany, Ireland, Belgium, Luxembourg, Denmark and the Netherlands, the the date of 'March 1988' as date of the first marketing authorisation in the EU, without bringing to their attention any of the grounds on which the date had been elected. The claimed grounds being the alternative interpretation that the company wished to utilise of the concept of 'authorisation to place the product on the market' in the SPC Regulation or the existence of the marketing authorization issued in France on April 15, 1987. The Court also considers that the Commission did not err in finding that that first report to the patent offices was misleading because of its general presentation, which gave the impression that March 1988 was the date of grant of the first technical marketing authorisation in the EU.³⁵

After the company had given an explanation to the basis of the specific date of March 1988, an SPC was issued by the patent office in Germany. According to the Court, the company's actions consisted furthermore in not revealing the date of April 15, 1987 relating to the French marketing authorization, after the patent offices had asked for clarifications regarding March 1988. Because of the not disclosed information, the Dutch, Belgian and Luxemburg patent offices believed that the date of 16 November 1987, corresponded to the grant of the technical marketing authorisation in Luxembourg, was the date of the first marketing authorisation in the EU. Consequently, the offices issued SPCs on the grounds of that date. The specific date of the first marketing authorisation in the EU. Consequently, the offices issued SPCs on the grounds of that date.

Neither did the company try to inform the patent offices of the the irregularity after the SPCs had been granted, even though (i) the company's internal documents show that it

³⁴ AstraZeneca, para 359.

³⁵ AstraZeneca, para 591.

³⁶ AstraZeneca, para 592.

³⁷ AstraZeneca, para 593.

knew of the SPCs' incorrect ground and (ii) an express suggestion that the company could reinform the offices had been made by its Dutch patent attorney.³⁸

The Court admits allthesame that the company did disclose the French technical marketing authorisation of April 15, 1987 after being asked questions by the patent offices in the United Kingdom and Irish. Due to the communication between the Danish and the United Kingdom patent office, the company thought it was needed to withdraw its SPC application in Denmark subsequently.³⁹

Despite everything that had taken place, the company did not seize to make misleading representations to gain SPCs on the basis of the date of March 21, 1988. Such representations were made at the patent offices of the EEA countries (Finland, Austria and Norway). The representations made the offices of the EEA countries grant SPCs on the basis of the date of the misleading information.⁴⁰

As a final remark on the company's behaviour, the Court points out the fact that the company, before the courts in Germany, Norway and Finland, defended the validity of the SPCs which had been issued on the basis of its misleading information.⁴¹

4.2.2 The anticompetitive nature of the conduct and its effect on competition

After having looked at all the facts, the Court puts these together and states that the company used a consistent and linear course of practice. This type of practice could be distinguished by the company's communication with the patent offices through the providing of misleading information, for the purposes of gaining a grant to SPCs. The company did not have a right to some of these SPCs (Denmark, Germany, Finland and Norway), and to others it was only entitled for a lesser length in time (Ireland, Austria, Luxembourg, Belgium and the Netherlands).⁴²

³⁹ AstraZeneca, para 595.

³⁸ AstraZeneca, para 594.

⁴⁰ AstraZeneca, para 596.

⁴¹ AstraZeneca, para 597.

⁴² AstraZeneca, para 598.

According to the Court, the reason for its finding that the company had intentionally tried to mislead the patent offices was: the many pieces of evidence in the documents brought forth, and the extent of the behaviour which lasted from 1993 to 1999 and which was implemented generally consistent, with different amounts of success in nine Member States of the EU and the EEA. The Court highlighted that what the company had reported to the Court, in certain points even verified the Commission's decision, but in any case they did not erase the large scale of documented proof and facts supporting the decision taken by the Commission. It was not enough to defend the company's good faith^{43,44}

It does not matter whether or not the misleading information does in fact produce any effects or not, for an abuse of dominant position to be found. Neither is it necessary for the ones the company is trying to mislead, the public authorities in this case, to actually be mislead. The reason being that for both of these situations just mentioned in this paragraph, it is very likely that the misleading information will amount to a grant of SPCs.⁴⁵

Moreover, even the situation before the United Kingdom patent office, where the company revealed its alternative interpretation of the 'marketing authorisation', and the existence of the French technical marketing authorization, is misleading. This is because the first application for an SPC was objectively misleading. The date on the application did not even reflect the first marketing authorization issued in the EU.⁴⁶

As mentioned, the company withdrew its SPC application in Denmark, but this was still seen as misleading conduct which could lead to an SPC, because of the following parts of this paragraph. The company had revealed its interpretation to the United Kingdom patent office and that country's office communicated with the Danish office. The company wanted to avoid being rejected a SPC in Denmark, since the patent office in Germany might have followed the Danish lead. The possibility of the German office following the Danish decision was due to the fact that neither of the two countries' offices issued SPCs for products that had their first technical marketing authorization before January 1, 1988. (Even the withdrawal of the SPC application in Denmark was a part of the company's

⁴³ Observe that the Court did in fact expressly say 'good faith'.

⁴⁴ AstraZeneca, paras 599 f.

⁴⁵ AstraZeneca, paras 601 f.

⁴⁶ AstraZeneca, para 603. See also AstraZeneca, paras 530, 548 f, for a more detailed explanation of the company's conduct in that part.

practice to mislead the patent authorities to issue SPCs.) The Court found that the application in Denmark could also have led to the grant of an SPC, even though the application was withdrawn.47

As a final remark from the Court, it underlined that the misleading representations by the company for goals in getting SPCs that it was not entitled to, or that it was entitled to for a shorter length in time, formed a conduct entirely on methods outside the sphere of competition on the merits. The practice exclusively aims to restrict generic products from competitors, in an unacceptable way, out of the market by gaining SPCs in a way contrary to the rules governing SPCs. 48 Concludingly, the Court rejects the company's claim as regards abuse of a dominant position and underlines that the Commission was right in finding that the company abused its dominant position within the meaning of Article 102 TFEU.⁴⁹

It should be brought to the attention of the reader that the Court was of the opinion that misleading representations to patent attorneys does not amount to an abuse of dominant position. The abusive practice begins when such representations are made to public authorities.⁵⁰

⁴⁷ AstraZeneca, para 604.

⁴⁸ AstraZeneca, para 608. ⁴⁹ AstraZeneca, para 609-610.

⁵⁰ AstraZeneca, paras 370 ff.

5 The second abuse in AstraZeneca

5.1 Regulatory framework for the second abuse

The relevant version of the directive in force at the time of the company conduct objected to, was Directive 65/65/ EEC of 26 january 1965 (the marketing authorization directive).⁵¹ Article 3 of that directive provides in its first paragraph, that "[n]o medicinal product may be placed on the market of a Member State unless a marketing authorisation has been issued by the competent authorities of that Member State". Through the first recital of the marketing authorization directive it is clear that the purpose of that directive is to protect public health.

5.2 Findings of the Court

Before bringing the Courts finding to the attention of the reader, the following should be noted: the Commission did not go against the fact that the company was right in its interpretation of the marketing authorization rules as regards its right to withdraw the marketing authorizations for Losec capsules. The question was rather if the conduct went againt competition law, since the early withdrawal of the authorization related to a general strategy which was deliberate and probable to preclude or holdup the entry of generic products and parallel imports.⁵²

The Court pointed out that the mere fact that the company was legally entitled to deregister its marketing authorization for Losec capsules by the marketing authorization directive, did not mean that the behaviour could not be found to breach article 102 TFEU and constitute an abuse of dominant position. The situation that an abusive practice is illegal under article 102 TFEU is not connected to whether or not the practice is allowed under other legislations and rules. In reality, it is most often the case that a practice which is abusive is lawful under other regimes than competition law.⁵³

The Court noted that the primary purpose of the directive for marketing authorizations is to safeguard public health. It is necessary that the reference medicinal product (the Losec

⁵¹ Directive 65/65, as amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), and Council Directive 93/39/EEC of 14 June 1993, also amending Directives 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22 [the marketing authorization directive].

⁵² AstraZeneca, para 656.

⁵³ AstraZeneca, para 677.

capsules) is continuingly in force, at the time when an application for marketing authorization of generic medicinal products is dealt with. Otherwise the application for generic medicinal products is prevented from being dealt with. When the company deregistered its marketing authorization for Losec capsules, it hindered the generic medicinal products from the procedure which would have been granted to them through the marketing authorization directive.⁵⁴

Because of motives underlying the safeguarding of public health, the withdrawal of the marketing authorization has the effect of hindering manufacturers of comparable products from being exempted to conduct their own tests in order to show that their products are safe and efficient. Regardless of the fact that the company, due to the withdrawal of authorization, no longer itself could make use of the test related to the product, the health rules hindered the procedure leading to marketing authorization for generic medicinal products, even though the manufacturers of these were entited to the procedures.⁵⁵

Just as in the Court's judgement relating to the first abuse, it emphasized the special responsibility of the company, which was to not harm genuine undistorted competition on the internal market, through methods not falling within the sphere of competition on the merits.⁵⁶

In its considerations, the Court upheld that a company in a dominant position has the right to safeguard its own interests when it comes to competition. Nevertheless, it does not have a right to use regulatory procedures in a manner as to hinder or restrict competitor's entry to the market. However, such a right would have been given if the company's conduct is based on legitimate interests of the company's engagement in competition on the merits or through an objective justification.⁵⁷

"[...] the Court observes that the fact that an undertaking in a dominant position is under no obligation to protect the interests of competitors does not make practices implemented solely to ex-

55 AstraZeneca, para 670.

⁵⁶ AstraZeneca, para 671.

⁵⁴ AstraZeneca, para 669.

⁵⁷ AstraZeneca, para 672.

clude competitors compatible with Article 82 EC⁵⁸. The mere desire of an undertaking in a dominant position to protect its own commercial interests and to guard against competition from generic products and parallel imports does not justify recourse to practices falling outside the scope of competition on the merits." ⁵⁹

It should be brought into the light that the company did try to excuse its conduct through an objective justification, but that this was dismissed since the company had raised this justification no earlier than at the time of the proceedings. The objection was that the company had no commercial interest in the Losec capsules anymore, and that it should not be forced to carrying on 'updating' its obligations as regarded the product.⁶⁰ The Court also pointed out that in any case, it has not been proved to the Court that 'updating burden' has been so substantial that it would have justified the conduct.⁶¹

The reader should note that the company's conduct in not continuing to sell Losec capsules, but Losec tablets (MUPS) instead was not abusive in itself. It was the withdrawal of authorization for Losec capsules that was abusive. The change in sales only formed a part of the circumstancesc in which the deregistration occurred. Furthermore, the Commission did not manage to show to the requisite legal standard that the withdrawal of marketing authorization for Losec capsules could preclude parallel imports in Norway and Denmark. However, it was able to establish this as regarded Sweden, since the licences for parallel imports would only be issued if a valid marketing authorization existed.

To summarize and give a final remark for the second abuse in *AstraZeneca*, the Court found that the Commission did not make a mistake in finding an abuse of dominant position on the company's side. Its reasoning was constituted by the fact that the company's deregistration of marketing authorization of Losec capsules in Norway, Denmark and Sweden, *in combination* with a change on the company's side from Losec capsules to Losec tablets

60 AstraZeneca, paras 685 f.

⁵⁸ Old article 82 EC is now replaced by article 102 TFEU, as mentioned earlier.

⁵⁹ AstraZeneca, para 816.

⁶¹ AstraZeneca, para 689.

⁶² AstraZeneca, para 807 f. See para 811 to read about the company's reasons for the switch of products on the market.

⁶³ AstraZeneca, paras 855 and 861 f.

(MUPS), was made in a way to restrict market access for generic products in the mentioned countries.⁶⁴ In addition, the Commission was right in arguing that the company's conduct was in a way as to hinder parallel imports of Losec capsules in Sweden. The restriction of the behaviour towards parallel imports also made it responsible for abuse of dominant position.⁶⁵

⁶⁴ AstraZeneca, para 864.

⁶⁵ AstraZeneca, para 864.

6 Analysis of the abuses in AstraZeneca

6.1 Introduction to the analysis of the case

It has already been brought to the attention of the reader that the case of AstraZenca has resulted in yet another type of conduct falling within the concept of 'abuse of dominant position'. In the case of AstraZeneca a court within the EU, established for the first time that an abuse of dominant position according to 102 TFEU, can consist of misusing public procedures and regulations. This can occur when a company behaves in a way that is considered to be outside the scope of what is 'legal', but also in situations when the conduct falls within what generally has been regarded as 'legal'. In both situations the discussion of the intention of the company becomes relevant, which would seem as a new turn when it comes to the concept of abuse of dominant position, as it has been held in case law numerous times that the test of abuse is an objective one. In the following, two separate analysis will take place, one for each of the two abuses in the case, before giving a final analysis where the two abuses are compared and contrasted, in an attempt to fulfil the purpose of the thesis.

6.2 The first abuse: a pattern of misleading representations

6.2.1 The main aspect of the abuse

Through the Courts judgement in *AstraZeneca*, it is evident that the first abuse consisted of a pattern of misleading representations by the company, to patent offices and in some of the countries national courts.⁶⁶ It should be highlighted here that the abuse did not consist of the fact that the company made a different interpretation than usual of the SPC Regulation. The problem of abuse arose because of the misleading information given to the public authorities regarding the different interpretation.

As can be concluded from the Court's assessment in *AstraZeneca*, the company did not compete on the merits, or in other words, have a conduct within normal business behaviour. The reason being that the company was not entitled to obtain extended right for the length of the SPC, but tried to get the extension nonetheless, by the misleading information given to the public authorities.⁶⁷ This statement by the Court is in accordance with earlier

⁶⁶ AstraZeneca, paras 597-598.

⁶⁷ AstraZeneca, paras 355.

case law, where it was stated that a conduct is abusive if it is not based on a 'trader's [smart] performance' or what is sometimes called 'superior economic efficiency'. ⁶⁸

The Court itself upheld that it is not required to show evidence of a deliberate nature of the behaviour to mislead the public authorities, in order to find an abuse of a dominant position. The reason being that the test of abuse is primarily objective and therefore, an examination of what falls outside competition on the merits (or so called normal business behavior) should be made at first hand. However, the Court continued by observing that intention is a relevant feature, which *may* be taken into account in relevant situations.⁶⁹

6.2.2 Critisism

Some authors raised their voices after the Commission came with its decision and claimed that what seemed to be the case of 'misleading representations', was in fact problems arising from the situation with a regulation (the SPC Regulation) which was unclear at the time of the conduct.⁷⁰ Other authors have adopted the same line of thinking (even before the Commission published its decision) and in addition to that held that it is not proportionate to let the company run the risk of an unclear legislation, especially in a case where article 102 TFEU is applied in a new way.⁷¹

However, in the case of *AstraZeneca*, the Commission was of the opinion that there were inconsistencies and proactive exclusionary strategies on the company's side, and that the evidence of these proved the intent of the company, namely to hinder competition and keep out competitors.⁷² Through the line of reasoning by the Court in *AstraZeneca*, it is quite clear that the Court took the same position as the Commission.⁷³ All the same, the

⁶⁸ Nederlandsche, para 70, and Whish p. 199.

⁶⁹ See AstraZeneca, para 359.

⁷⁰ Lawrence, S. & Treacy, P., *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, [Hereafter Lawrence & Treacy], p. 7.

⁷¹ Manley, M. & Wray, A., New pitfall for the pharmaceutical industry, Journal of Intellectual Property Law & Practice [2006] Vol. 1, No. 4, p. 270.

⁷² AstraZeneca, para 334 ff.

⁷³ AstraZeneca, paras 598 and 604.

Commission never accused the company for behaving abusive by misinterpreting the law, as the Commission also pointed out as early as in its first decision.⁷⁴

6.2.3 Intentions

According to the author of this thesis, the above mentioned (under section 6.2.2) is where the discussion of good faith and a duty of honesty becomes relevant. The Court brought forward many considerations regarding the way in which the company proceeded when seeking for patent extension protection throughout different countries. This was made by the Court when it was assessing whether or not the misleading representations constituted an abuse of dominant position according to article 102 TFEU. In other words, the opportunity given to the company to show that it was not aiming to abuse its dominant position when providing the public authorities with misleading representations, comes with the demand to prove that it acted in good faith. In the same way, if there is enough evidence to prove that the company's conduct was in a way as to deliberately abstain from giving information to the authorities, an abuse of a dominant position exists. This proof against the company was put forward through comparing the conduct of the company in for example different countries. In some situations where the company knew that some of the countries' national offices had contact with each other in a way as to share information, the company withdrew its application for patent extension protection. This behavior took place because the company suspected that the found rejection in one country would lead to the same in the other.⁷⁵

The author of this thesis believes that the Court did not take this position because there is a duty of honesty or good faith in general within the frames of article 102 TFEU, rather because of the following: in situations where there seems too be ambiguities or vagueness in for example, as the present case a legislation (such as the SPC Regulation in the case of AstraZeneca), this can naturally make room for an alternative interpretation. However, in situations where the public authorities have a much limited discretion or are not obliged to make sure that the information provided by the company is accurate, the 'special responsibility' of the company becomes relevant. The 'special responsibility' makes it necessary for the company to provide the public authorities with information regarding their new angle in interpreting the provision. By not acting with enough 'special responsibility' and provid-

⁷⁴ Commissions Decision, para 666.

⁷⁵ See AstraZeneca, paras 595 for a discussion regarding this specific situation.

ing this information, the company was found having the intention to misuse the the patent system. The 'special responsibility' becomes even broader the bigger the dominant position is. Therefore, the specific scope of the 'special responsibility' for each company in a dominant position, is determinative for the steps that the company in question needs to take in order to avoid infringing article 102 TFEU. The greater the 'special responsibility' is, the greater becomes 'the duty of honesty'. Conclusively, the degree to which the company needs to prove its good faith becomes higher the higher the 'special responsibility' is, due to the extent of the company's dominant position.

Since the company knew that it was making an alternative interpretation and what effect it would have on the market, it should at the very least, have provided the public authorities with information regarding the alternative interpretation. Otherwise, the extension could have been wrongly granted, since it was found that the company was not legally entitled to the right it wished for. The just mentioned would have the effect that competitors were foreclosed from the market, leading to the detriment of competition in the internal market. This effect would not be in line with the objectives or aims of competition law in the EU.

6.3 The second abuse: misuse of government procedures

6.3.1 Critisism

The second abusive conduct could not be found to breach article 102 TFEU through an objective test of abuse of dominant position. Instead, the Court carried on to examine the company's *intention* in this situation as well (even though the objective test did not amount to the finding of an abuse). The Court found that the company breached article 102 TFEU by its second abuse, through an examination of the company's conduct and whether this was *deliberately* trying to restrict competition.

It has been held that the Court's intervention in relation to the second abuse is more farreaching than in the first abuse. In theory, the first abuse could never lead to the grant of a right, as the company was never entitled to the right, whereas in the second abuse, the company had a legal right in support of its conduct.⁷⁶ However, as seen in the case, it was the specific circumstances, although put together, that made the practice in the second

-

⁷⁶ Venegas, V., AstraZeneca – mycket väsen för ingenting?, Ny juridik 1:11, 2011, p. 71 f.

abuse liable for a breach of article 102 TFEU.⁷⁷ The Court noted that the primary purpose of the directive for marketing authorizations is to safeguard public health. It is necessary that the reference medicinal product (the Losec capsules) is continuingly in force, at the time when an application for marketing authorization of generic medicinal products is dealt with. Otherwise the application for generic medicinal products is prevented from being dealt with. The effect of preventing the procedure for applications of a generic medicinal product resulted in the need for manufacturers of these products to carry out their own tests in order to show that their products were safe and efficient.⁷⁸

When the company deregistered its marketing authorization for Losec capsules through the marketing authorisation rules, it hampered the purpose of the rules that allowed the deregistration right in the first place. Even though the regulatory framework did permit the company to deregister its authorization, this should be done in light of the purpose of the directive, which is to safeguard public health.⁷⁹ If the right would be used by the company for other reasons than public health, there would be no need to deregister at all. The company could have just let the authorization expire without renewing it, and by doing this not hindering generic products and parallel imports from benefitting of the authorisation. No justifiable reason in connection with public health was brought forward by the company, leading to the fact that the company only withdrew its authorization to impair competition. Differently speaking, the company was in bad faith.

After the Commission came with its decision, prior to appeal before the Court, some legal experts criticized the finding that the company abused its dominant position by deregistering its marketing authorization, since it was the company's legal right to do so. These experts claim that there might be justifiable motives to why a company wants to deregister its marketing authorization. These critics suggest that there could be a situation when the company in question has produced a better version of the medicament.⁸⁰ Other critics also

⁷⁷ See section 4.2.1.

⁷⁸ AstraZeneca, 670.

⁷⁹ Such a reason to withdraw an authorization connected to public health could for example be that new tests have shown that the authorized product is in fact dangerous, rendering it important to deregister.

⁸⁰ Lawrence and Treacy, p. 8.

comment on the company's interests, stating that limiting the company's right to deregister its product is an improper intrusion in the company's commercial freedom.⁸¹

However, through the case of *United Brands* it is evident that a company in a dominant position is permitted look after its interests by ways that are appropriate and reasonable, and only if the real aim of the practice is not to abuse its dominant position.⁸² That means that the company's commercial freedom is not without limitation, and that the focus on intensions is in line with earlier case law.

Even if there was a legitimate interest such as the suggested, these experts forget that it would be unlikely for such a justification to be accepted. The reason being that this commercial interest would be weighed against the interest of public health, and it is not likely that the company's interest would be significant enough to outweigh the safeguarding of public health.

Furthermore, the criticism brought forward by the critics is the very reason why the Court examines whether or not the company had an *intention* to hinder competition. The Court made its assessment by looking at the different stages of the company's conduct, to see if the claimed interest is genuine overall, or simply an excuse for the purpose of restricting competition. In addition, the Court takes into account whether the positive aspects the conduct brings for the company is more important than the proper functioning of competition.

6.3.2 Not normal commercial practice and disregard of special responsibility

The Court found that the company's conduct was not normal practice or as also referred to 'competition on the merits. This was due to the specific circumstances of the case which consisted of a *selective* deregistration and exclusionary *intentions*. By acting in this manner, the company had disregarded its special responsibility which was to not impair competition on

_

⁸¹ Manley & Wray, p. 268. Following cases ankowledges that a company has commercial freedom: T-41/96 Bayern v Commission, [2000] ECR II-3383 paras 176 and 180, and C-27/76 United Brands CO and United Brands Continentaal BV v Commission [1978] ECR 207, [United Brands] para 189.

⁸² United Brands, para 189.

the internal market. This line of reasoning is within the frames set by earlier case law. ⁸³ The special responsibility thus limits the company's freedom to use business strategies that are not within normal practice, as a consequence of the conduct's *purpose* to create obstacles with anticompetitive effects. The rights granted to a company could, put differently, only be used when used reasonably. This could naturally be seen as causing legal uncertainty for undertakings in a dominant position, as they can not be sure that their legal rights will come within the boundaries of what is accepted by competition rules. On the other hand, an overall evaluation of the specific circumstances of the case shows that the company knew how their conduct, the deregistration, would affect generic manufacturers and parallel imports. In fact, the conduct was a part in a *general strategic plan* to restrict competition.

Finally, it should be noted that the company knew about the public authorities limitation in verifying the accuracy behind the company's conduct (they will not do an abuse of dominance test as the Court before they grant companies a right that comes within the regulatory framework), and the company still requested the withdrawal of authorization. The company did not go against the marketing authorization rules as such, but misused it for purposes of hindering competition.

6.3.3 Infringement of competition law regardless of legal conduct under other laws

As stated (under section 6.3.1), some legal experts criticised the fact that the company's was found to abuse its dominant position even though it had a legal right to deregister its authorisation. of the most central aspects of competition law, which is that competition rules are applicable, irrespective of the conduct being lawful under other regimes, which was also why the Commission never disputed the legality of the conduct under pharmaceutical law. In addition, it must be born in mind that the purpose of competition law is to hinder the anti-competitive practice of an undertaking (see section 2.2.2). Such a purpose does not necessarily need to come within the purpose of another legislation.

_

⁸³ Nederlandsche, para 57.

⁸⁴ T-201/04 Microsoft v Commission [2007] ECR II-3601, paras 331 ff.; C-418/01 IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG. [2004] ECR I-05039, para 35; C-7/97 Oscar Bronner GmbH & Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG, Mediaprint Zeitungsvertriebsgesellschaft mbH & Co. KG and Mediaprint Anzeigengesellschaft mbH & Co. KG., [1998] ECR I-07791 paras 43 ff; Joined cases C-241/91 P and C-242/91 P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities, [1995] ECR I-00743, para 25.

The fact remains that the company was aware of the effect its behaviour would have on the internal market and still did not follow the special responsibility it had to not impair genuine undistorted competition. On the contrary, the company had as it intent to foreclose competition and did this by misusing a regulatory framework which also was connected to other rules concerning parallel imports.

6.4 Analysis for the two abuses taken together

6.4.1 The possible existence of a requirement for 'good faith'

By studying the Court's judgement in AstraZeneca, it is clear that the second abusive conduct lied in the company's selective deregistration of Losec capsules. A difference between the second abuse in relation to the first is that the second did not seem to be abusive at a first glance, due to the fact that it was within what was allowed by pharmaceutical law. In the first abuse situation with the misleading representations, the company tried to get a right that it did not have a legal right in, so the company would be found to objectively abuse its dominant position. However, the Court did not stop there but gave the company a chance to justify its conduct by looking at the intention and good faith of the company. Additionally, the Court held that the company, at the very least, should have tried to inform the public authorities of the unlawful right given so they could rectify the misleading information. Put in other words, could be said that the company had a duty of honesty in this particular case, but not at a primary stage, since the test of abuse is primarily objective. However, the company was found guilty of the first abuse at the end anyway. It should not be forgotten that for both of these abuses it was also necessary for the abusive conduct to be capable of producing a negative effect on competition. The mere intent was not enough in itself.

6.4.2 The possible existence of a 'duty of honesty'

It should be noted that the company knew about the public authorities' limitation in verifying the accuracy behind the company's conduct and the company still requested the withdrawal of authorisation. Even in the first abuse, the company knew that the public authorities did not have discretion to verify the information provided, which made it necessary for the company to give the public authorities more information.

If a duty of honesty is existent, the mentioned in the paragraph above could be a step that that duty requires the company to take to show its good faith. Worded differently, if a duty of honesty exists, it might involve, notifying the public authorities of the ambiguity of the conduct and let them decide whether or not it is valid. In these concrete abuse situations, a practical example for the first abuse would be to notify the relevant authorities of the alternative interpretations and what their information is based on. A practical example for the second abuse would be to bring to the attention of the public authority for marketing authorisations that the company's right to deregister might not be in line with the purpose of the regulatory framework granting that right. This way, it would be up to the authority to judge whether or not the company should be granted the right. However, as it has been seen, the Court takes into account all specific circumstances of a case, so abuse of dominant position could still be found, if the circumstances put together point towards an abuse.

In the end, it is not likely that a duty of honesty exists in general, rather that the company's conduct is not in a way as to show that it has deliberately acted to restrict competition. As an example, it is not the misleading information as such in the first abuse that shows the company's intent, rather the overall *pattern* of its behaviour. The line of reasoning in the Court's judgement in the two abuses, renders one to draw the conclusion that: when different elements of conducts leads to the finding of a practice on a company's behalf, which seems to constitute a *general scheme* or a *strategic plan* to achieve a stronger position on the market, by means of impairing or foreclosing competition, a company's *bad faith* is found. So when saying that there is a requirement for good faith within article 102 TFEU (even if not at a first objective stage of an examination), this good faith is still formed by other relevant factors that need to be evaluated.

6.4.3 Special responsibility

The strong emphasis on the company's special responsibility in *AstraZeneca*, could seem farreaching for some, as companies could be responsible for unwanted effects by aiming to get a right they believe to be entitled to (but are not) or that they are actually legally entitled to. Such effects could be tricky to evade, as it could be difficult for companies to know the results in advance. After having examined the two abuses in *AstraZeneca*, (the first case to deal with abuse of a dominant position as regards misuse of procedures and regulations) it is apparent that the special responsibility now includes making sure that competitionrestricting effects will not take place even when following the law and because of the way the law is structured. Nevertheless, the company's behaviour was not the subject of an objective justification, meaning basically that the company did not have a reason to act the way it did, if not for hindering competition. Put differently, the possible criticism of the raised bar in 'special responsibility' does not affect those 'in good faith'.

Since the Court has expressed that the bad faith and deliberate nature of a practice is not required for an abuse of dominant position to be found, the Commission will find it easier in the future to take action against companies.⁸⁵ It will be easier for the Commission to take action because it does not carry the burden of needing to prove the bad faith of a company. It is enough for the Commission to find an abuse through an objective test. The same applies in situations where an abuse is *not* found through an objective test, since the Commission *may* examine the company's intent.

_

⁸⁵ Marschollek, J.P. & Steinbarth, S., How the Application of Patent Law May Upset the Stomach of The European Commission – Delaying or Limiting the Market Entry for Competing Generics is an Abuse of a Dominant Position, European Law Reporter 1/11, 2011 p. 17.

7 Final analysis

7.1 Final analysis as regards good faith in general

Even though the concept of abuse has said to be an objective one until now, the Court specifically expresses 'good faith' in the case of *AstraZeneca*. However, it is not the first time that the courts have made considerations relating to intentions. As an example, in the *AKZO* case, it was said that conducts can constitute abuse, "[...] if they are determined as a part of a plan for eliminating a competitor.". ⁸⁶ Yet another example is the case of *British Leyland* , where it was stated that:

"It follows from the foregoing that BL's conduct can only be construed as the manifestation of a deliberate intention on its part to create barriers to re-importations which come into competition with its approved distributors. That conduct must therefore be regarded as an abuse of a dominant position."

However, these cases did not expressly say that a 'good faith' on the company's side was needed, and what is more, they concerned other types of abuses than the ones relevant in *AstraZeneca*, which is misuse of procedures and regulations. Nevertheless, they could be used to demonstrate the fact that a requirement of good faith under article 102 TFEU is supported in general.

7.2 Special responsibility

In the case of AstraZeneca, the special responsibility of a company in a dominant position has been emphasised more than one would normally expect. This could find its motive in the fact that the Commission wants to take stronger action against companies in a dominant position that abuse the dominance. Adding to this motive, the conduct in AstraZeneca concerned exclusionary abuse, yet another factor making it more attracting to take (strong) action against. The reason being that the Commission has stated itself in its Guidance pa-

⁸⁶ AKZO, para 72.

 $^{^{87}}$ C-226/84 British Leyland v Commission [1986] ECR 3263.

⁸⁸ British Leyland, para 24.

per that it prioritise exclusionary abuses at this stage, since these are very harmful. ⁸⁹ It has been brought to the attention of the reader that the Commission has set up new frames and guidelines regarding exclusionary conduct and believes it to a crucial abuse to take action against. What is more, the case of *AstraZeneca* was particularly special, as it concerned a pharmaceutical company. Public health is a vital issue that is expressed in article 168 TEU, and safeguarding this interest is of high importance. Article 168 TEU states that "a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."

Finally, as regards the findings in *AstraZeneca* compared with the Commission guidelines, the following can be stated. The Guidance paper show what the Commission bases its investigation on when it examines the existence of exclusionary abuse of a dominant position. Since the Court confirmed the considerations of the Commission in major parts, the Guidance paper is a good source for understanding how to approach the requirement of 'good faith'.

-

⁸⁹ The Guidance paper from the Commission concerns exclusionary abuse

8 Conclusion

In short, a requirement for 'good faith' or a 'duty of honesty' does not exist at the primary (and often only) stage when establishing abuse of a dominant position. However, if an objective abuse test does not point towards an abuse, but there are reasons to believe that an abuse exists nevertheless, a court can try to establish whether or not the undertaking was in good faith. Similarily, if an abuse is found through an objective abuse test, but there are reasons to believe that an abuse does not exist in reality, a court can try to establish the good faith of the undertaking. In other words, a requirement for 'good faith' or 'duty of honesty' does exist under article 102 TFEU when establishing abuse of a dominant position, as regards misuse of procedures and regulations. However, if this requirement streatches to other types of abuse is unclear.

To give a more detailed conclusion of the thesis, the main elements of what constitutes 'good faith' will be provided in the following. In general it should be noted that it is not required to show evidence of a deliberate nature of a behaviour in order to find an abuse of a dominant position. The reason being that the *test of abuse is primarily objective* and therefore, an examination of what falls outside competition on the merits (or so called normal business behaviour) must be made at first hand. Therefore, there is not a duty of honesty or good faith in general. However, *intention is a relevant feature*, which may be taken into account in relevant situations.

Whether or not intention should be a factor to take into account, should be decided on a case-by-case basis. Companies in a dominant position have a special responsibility not to harm competition that is genuine and undistorted, by a conduct that is not in the sphere of competition on the merits. The specific circumstances of each case are decisive for the possible finding of an abuse. If the practice could come to create obstacles in competition, one has to turn to the special responsibility of the company and see how far this specific special responsibility stretches. The scope of the specific special responsibility is decisive for the steps the company needs to take in order to try to avoid impairing competition.

In situations where a conduct has taken place by a company which could give the company a right it is *not legally entitled to*, as in the first abuse situation in *AstraZeneca*, it would normally also be enough to say that the conduct was abusive through an objective test. However, if the conduct could be the result of ambiguities of the regulation in question, a court may give the company a chance to prove that it was in good faith, leading to article 102 TFEU

not being applied. When a company has acquired a right to which it *is legally entitled to*, this can still result in an abuse of a dominant position, if the granting of that right in the specific situation would go against the purpose of the regulatory framework providing that right.

The good faith can be examined through an assessment of the company's actions at the time of the behaviour. So for example, if the company is considered to have known about the ambiguity and in some situations the public authorities limitations in correcting a wrong interpretation, it must take steps to make sure that its conduct can not harm competition on the internal market. These steps can, as in the case of *AstraZeneca* at the very least consist of informing the relevant public authorities of its line of thinking and its alternative way of proceeding. This way, it is up to the public authorities to evaluate the situation. If the company does not prove the good faith through an objective justification or a legitimate interest, it can be found to be in bad faith, only trying to foreclose competition. The effect of foreclosure of competition would not be in line with the objectives or aims of competition law in the EU.

List of references

Legislation

Treaties

2010/C 83/01 Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union

2010/C 83/01 Consolidated version of the Treaty on European Union [TEU]

2010/C 83/01 Consolidated version of the Treaty on the Functioning of the European Union [TFEU]

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 (EC Treaty)

Regulation

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, p. 1) [the SPC Regulation]

Directives

Directive 65/65, as amended by Council Directive 87/21/EEC of 22 December 1986 (OJ 1987 L 15, p. 36), and Council Directive 93/39/EEC of 14 June 1993, also amending Directives 75/318/EEC and 75/319/EEC in respect of medicinal products (OJ 1993 L 214, p. 22 [the marketing authorization directive]

Case Law

COJ cases

- Case C-27/76 United Brands CO and United Brands Continentaal BV v Commission [1978] ECR 207 [United Brands]
- Case 85/76 Hoffmann-la Roche v Commission, [1979] ECR 461, [hereafter Hoffmann] para 91 and Case C-62/86 AKZO v Commission, [1991] ECR I-3359 [AKZO]
- Case 322/81, Nederlandsche Banden-Industrie Michelin NV v Commission [1983] ECR 3461 [Nederlandsche]
- Case C-226/84 British Leyland v Commission [1986] ECR 3263 [British Leyland]
- Joined cases C-241/91 P and C-242/91 P, Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities, [1995] ECR I-00743
- Case C-7/97 Oscar Bronner GmbH & Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG, Mediaprint Zeitungsvertriebsgesellschaft mbH & Co. KG and Mediaprint Anzeigengesellschaft mbH & Co. KG. [1998] ECR I-07791
- Case C-418/01 IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG. [2004] ECR I-05039

Case C-457/10 P AstraZeneca v Commisson (Case in progress)

General Court cases

Case T-41/96 Bayern v Commission, [2000] ECR II-3383

Case T-201/04 Microsoft v Commission [2007] ECR II-3601

Case T-321/05 AstraZeneca v Commission – 1 July 2010

Commission Decision

European Commission's Decision, Case COMP/A.37.507/F3 – AstraZeneca of 15 July 2005 relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement

Official publication

Communication from the Commission – Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, (2009/C 45/02) [the Guidance paper]

Other legal reference

DG Competition Discussion Paper on the Application of Article 82 of the Treaty to Exclusionary Abuses, Brussels December 2005

Literature

Books

Bellamy & Child, European Community Law of Competition, 5th edition, edited by Peter Roth and Vivien Rose, Oxford University Press, Oxford, 2008, [Bellamy & Child] 10.065

Bernitz, Ulf, Finna rätt: juristens källmaterial och arbetsmetoder, 10 uppl, Norstedts juridik, Stockholm, 2008, [Bernitz]

Jones, Allison & Sufrin, Brenda, EC Competition Law: Text, Cases and Materials (3rd edition, Oxford University Press, Oxford, 2008 [Jones & Sufrin]

Whish, Richard, Competition Law, (5th edition Oxford University Press, Oxford, 2005)
[Whish]

Articles

Manley, M. & Wray, A., New pitfall for the pharmaceutical industry, Journal of Intellectual Property Law & Practice [2006] Vol. 1, No. 4

- Marschollek, J.P. & Steinbarth, S., How the Application of Patent Law May Upset the Stomach of The European Commission – Delaying or Limiting the Market Entry for Competing Generics is an Abuse of a Dominant Position, European Law Reporter 1/11, 2011
- Lawrence, S. & Treacy, P., 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, [Lawrence & Treacy]

Venegas, V., AstraZeneca – mycket väsen för ingenting?, Ny juridik 1:11, 2011

Internet sources

Information regarding the case in progress C-457/10 P AstraZeneca v Commisson http://curia.europa.eu/ [2012-05-02]