



# Pharmaceutical Patent Strategies

-The Competition between Originator and Generic Companies  
within the European Union

Master's thesis in Commercial Law

(Intellectual Property law and Competition law)

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Title: **Pharmaceutical Patent Strategies** -The Competition between Originator and Generic Companies within the European Union

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## **Abstract**

The pharmaceutical market is a billion euro industry and the competition on the market is highly intensive. Primarily there are two competitors on the market, partly the originators which provide the market with new drugs, and partly the generics which produce copies of the originators' drugs. The originators are able to be granted patent protection of the drug under the European patent system, provided that the drug fulfils the requirements for patentability. During the period of patent protection the generics are not able to produce copies of the drug, but once the duration of the patent has expired the generics are able start the production. Thus, in order to hinder the generics to make copies of the drug, the originators apply various patent strategies. This has been noted by the European Commission, which conducted a sector inquiry of the pharmaceutical market in 2009. The presentation of the competition within the market focused on the applied strategies by the originator and concluded that all measures will be taken to hinder restrictions on the competition.

In conjunction, the General Court judged in a recent case that the originator AstraZeneca constituted an infringement of the competition law when their strategies were applied. The complexity of determine whether a strategy is lawful or not, is due to the interface between the intellectual property law and the EC competition law. This implies that the strategy can be lawful under the IP law but unlawful under the competition law. The Court has established that any strategy, regardless of its legality under the IP law, constitutes an infringement of the competition law if it might restrict the competition. The Courts do not provide sufficient guidelines of the conditions that constitute the infringement. Consequently, the strategies' legality is at present time uncertain.

## **Preface**

I want to thank my tutor Solicitor Edward Humphreys for excellent supervision, the provided information and valuable comments. Further on, I would like to thank my opponents for helpful feedback and suggestions during the working-progress of my thesis.

I also want to thank Professor Bengt Domeij at Uppsala University for valuable discussions regarding the pharmaceutical market with respect to intellectual property and competition law.

Finally, I want to thank my family for their invaluable support, both emotionally and financially, during my studies at Jönköping International Business School, who always been there for me as well as my friends.

With this Master's Thesis in Commercial Law (Intellectual Property and Competition Law) I finish my studies at Jönköping International Business School, which have been an enjoyable academic journey, with competent lecturers and enthusiastic fellow students, intensive studies, valuable legal knowledge and many unforgettable memories. That being said, I am now looking forward to the new challenges of future with positive expectations.

Jönköping December 2010

Johanna Bergström

## List of Abbreviations

Art.	Article
AZ	AstraZeneca
CPC	Community Patent Convention
e.g.	"exempli gratia" meaning "for example"
i.e.	"id est" meaning "that is"
ECJ	the Court of Justice of the European Union
ECR	European Courts Report
ECT	European Community Treaty
EMA	European Agency for the Evaluation of Medical Products
EPC	European Patent Convention
EPO	European Patent Office
etc.	"et cetera" meaning "and so on"
EU	European Union
f./ff.	Folios following
INN	International Non-proprietary Names
IP	Intellectual Property
LoE	Loss of Exclusivity
NCE	New chemical entity
OJ EPO	Official Journal of the European Patent Office
OJEC	The Official Journal of the European Union
Para.	Paragraph
p./pp.	Page/pages
ParC	Paris Convention for the Protection of Industrial Property
PCT	Patent Co-operation Treaty
R&D	Research and Development
RDP	Regulatory Data Protection
SPC	Supplementary Protection Certificate
TRIPs	Agreement on Trade-Related aspects of Intellectual Property Rights, 1994
TFEU	The Treaty on the Functioning of the European Union
WHO	World Health Organization

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# 1 Introduction

## 1.1 Background

### 1.1.1 Part One – The pharmaceutical market

The pharmaceutical industry is a billion euro industry, where the total revenue of the Europe's leading pharmaceutical companies is nearly equivalent to €58 billion.<sup>1</sup> In additions, it could be mention that a successful drug, so-called blockbuster, achieves annual revenues of over US\$ 1 billion at global level.<sup>2</sup> In order to protect these blockbuster medicines form being copied the pharmaceutical company applies for protection in form of patent. Thus, the patents have a very decisive position in the industry in which a pharmaceutical product's ability to have commercial presence and hence sales are entirely dependent on a valid patent covering the product. The reason for the significant importance of being able to obtain adequate patent is based on the considerable cost- and time-consuming expenditures that are related to the development of new innovative medicines.

There are two types of businesses that operate on the pharmaceutical market, partly the pharmaceutical companies which are patent holders of the original medicines and partly the companies that produce copies of the already existing drugs. The selling of generic medicine can be done, without constitute intellectual property infringement, when the product is no longer protected by a valid patent. In order to hinder the generic companies from producing copies of originator companies' original medicine these companies applies different types of methods, *pharmaceutical patent strategies*, which aim to prevent or delay the generic companies' enter on the market.

In response to the applied strategies on the pharmaceutical market, the European Commission has conducted an inquiry of the pharmaceutical sector. The conclusion of the report was above all a belief that originator companies are engaged in strategies which hinder the generics to enter the market, which *might* restrict the competition. The conclusions were based on the view that originators deliberately and systematically apply

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<sup>1</sup> See Pharmaceutical sector inquiry – Final Report, European Commission, adoption date: 28 November

<sup>2</sup> Final Report, Glossary, p. 13.

the various strategies. In conjunction, the General Court of the European Union judged in a recently case<sup>3</sup> that AstraZeneca constituted an infringement of the competition law when their strategies were applied. The originator was fined € 60 million for the breach of the EC competition law. In the Judgement the Court determined that the company abused their dominant position by applying different strategies. However, the company recently, on 16 September 2010, appealed the judgement and brought the case before the Board of appeal, which therefore is still pending.

### **1.1.2 Part Two - Problem analysis**

Based on the above described information, a number of issues are affecting the respective parties within the pharmaceutical market. The originator companies and generic companies are acting side by side where their respective legal positions, both in the view of an intellectual property (IP) law and a competition law perspective, are related to each other and where regulation that strengthens one party will be at the expense of the other party.

The conclusions adopted by the Commission in the report of the sector inquiry and the General Court's judgment as well as the, *at present time*, unknowing judgment of the Board of Appeal, constitute uncertainty regarding the originators' legal position. This is due to the fact that the applied strategies can be deemed as an infringement of the EU competition law, even if they are lawfully under the patent law. Therefore, the reason why this problem occurs is because the intellectual property law does not correspond with the competition law in all areas. In simple words one could say that the IP law increases the protection of the patent whilst the competition law decreases the possibility to protect the patent. This consequently means that applied strategies by the originator companies are lawful according to IP law. But, it is not legal according to competition law. Therefore a problem occurs which is uncertainty of which strategies can be applied without risking penalties.

In summary, due to the sector inquiry, in relation to the issue of the interface between the intellectual property law and the competition law, has gained practical relevance regarding the applied strategies within the pharmaceutical market. Still, and therefore, there is an uncertainty of what impact the judgment will have for the originators regarding their right

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<sup>3</sup> Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010], not yet reported.

to protect their patents by applying strategies without the risk of breach the rules of competition law.

## 1.2 Purpose and question formulations

The aim of the thesis is to determine the originators' applied strategies' legality, with regards to the interface between competition law and intellectual property law. In order to meet the purpose of the thesis essay, the following sub-questions is formulated and will be answered;

- I. - *Which* strategies are applied by the originator companies in the pharmaceutical industry that might be or de facto is a breach of competition law?
- II. - *How* can originators, with certainty, determine a strategy's legality, with respect that the manner is de facto lawful under the intellectual property law, but not under the competition law?
- III. - *What* are, and potentially could be, the consequences of the commission sector inquiry as well as the *AstraZeneca* Case for the originator companies' applied strategies?

## 1.3 Method and Material

In order to achieve the purpose and be able to answer the sub-questions of the thesis, a comparative judicial method is applied. This implies that both a descriptive method as well as a problem-oriented method is applied in order to be able to compare different legal sources. Therefore, a description is made of the legal framework of the European patent system and the European Union (EU) competition law, as well as their interface. In addition, the pharmaceutical sector inquiry, the decision by the Commission and the judgment by the General Court are presented. This constitutes the foundation of the thesis and facilitates the understanding of the issues for the reader. Further on, a problem-oriented method is applied, where the current problems referring to the laws are identified, analyzed and compared with the aim to make conclusions, and hence be able to determine the strategies' lawfulness. The legal sources are systemized, then analyzed and interpreted before they are applied on the relevant issue of the thesis.

The materials that are used in this thesis mainly consist of sources of law within the European intellectual property law and competition law. Primarily, secondary law is applied in the thesis. Nevertheless, the primary law also applied, where the Treaty on the Functioning of the European Union (TFEU)<sup>4</sup> has the focus for the investigation of the competition within the Union. However, is the mainly the focus on the international agreements, particular the European Patent Convention (EPC). In addition, to be able to interpret the EPC, information has been provided from the Guidelines for Examination in the European Patent Office. Some regulations are only briefly dealt with while certain regulations are given more space due to their greater relevance. Furthermore, are legislations that is explicitly applicable on pharmaceutical patent and medical product investigated.

Further on, the legal sources are treated in accordance with the hierarchy established by the judicial and are legitimate within the jurisprudence. The materials have mainly been obtained by the publications in the Official Journal of the European Union and European Patent Office.<sup>5</sup>

Regarding the pharmaceutical sector inquiry by the Commission, the provided information and statements has been investigated and analysis has been carried out and the report's conclusion. The reason for the investigation of the sector inquiry is due to its relation to the decision by the Commission<sup>6</sup> as well as the judgment by General Court,<sup>7</sup> in regards of the competition between originators and generics. The specific decision investigated in order to determine the consequences of the conclusions of the inquiry report. The reason why this decision is chosen to investigate is because it is the only current decision which is directly relevant to and based on the report's statement of the legal situation of the pharmaceutical market. The subsequent judgment of the Commissions' decision by the General Court<sup>8</sup> is investigated in order to understand the legal measurements of determining the strategies legality. The judgment is also investigated with the objective to conclude the potential impact it might have. The reason for chosen this judgment explicitly

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<sup>4</sup> Rename of the Rome Treaty amended by the Treaty of Lisbon (former Treaty establishing the European Community, EC-Treaty).

<sup>5</sup> Eur-lex.europa.eu.

<sup>6</sup> Decision 2006/857/EC *AstraZeneca Plc* (Case COMP/A. 37.507/F3) [2005] OJ L 332/24.

<sup>7</sup> Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010], not yet reported.

<sup>8</sup> Rename of the Court of First Instance.

is due the same reasons as for the decision, because of their relevance to the questions to be answered in the context of the purpose, i.e. strategies lawfulness. Due to of the date of the judgment, July 2010, is the ability to find interpretations and opinions of the judgment in any greater extent difficult. Consequently, has thoughts by persons with less authority contributed to some conclusions of the judgment. Yet, I am aware that too much importance cannot be put on these opinions, nevertheless it could possible indicate similar perceptions.

To obtain a deeper knowledge of the issues involved and to reach further understanding of the current issues, information from researches and academic writing of the European intellectual property and competition law are gathered. Further on the doctrine which specifically treats pharmaceutical patent are in particular devoted. Information is also gathered from Internet-based sources, mainly those which are produced by authorized European organizations. Moreover specifically the internet-based sources which concern the pharmaceutical industry explicitly are viewed, primarily information provided by the European organization EMA,<sup>9</sup> which are considered as reliable sources with high validity.

Finally the materials that are investigated are treated objectively, with no intention to have any biased views nor take party for the originator legal position for the aim of subjectively increase their supremacy.

## **1.4 Delimitation**

Even though the European Patent law partly is based on national law, has solely the European patent law been reviewed and interpreted in the thesis. Therefore, none of the domestic patent laws have been taken into consideration. This decision is mostly based on two reasons, partly because it is not directly relevant to the sector inquiry and the judgment. Partly due to the fact that it would be hard to explain or defend why particular States' laws have been chosen to investigate. .

Some of the European regulatory framework as well as the international agreements, for instance the Paris Convention and the TRIPs agreement, regulates intellectual property and

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<sup>9</sup> European Medicines Agency.

are applicable in several cases. Instead the European Patent Convention is object for a thorough presentation and investigation. Nor, the regulations regarding the transfer and licensing of patents, such as the Technology Transfer Regulation, or compulsory licensing are presented in the thesis. In addition, the regulation applicable on biotechnological inventions, arising from genetic engineering, will not be investigated since it a special field within the R&D distinguished from pharmaceutical products in general. The procedure of filing patent application will be presented in the thesis, albeit briefly. But, the determination and assessment of patent claims, except when a regulation or a directive is exclusively applicable on pharmaceutical patents or if it concerning the applied strategies. This is due to the need to possess the knowledge to understand biotechnology science.

Regarding the European competition law, only article 101 and 102 of the Treaty on the Functioning of the European Union (hereinafter TFEU) will be investigated and interpreted, which is based in the sector inquiry and the judgment. Moreover these articles are only illuminated, examined and interpreted in the light of the patent law in directly relation to the applied strategies. Yet, article 102 TFEU is the main object for the investigation, since the judgement was based on a breach of that article. Further on, the constitution of patent infringement is not presented, even though alleged infringement is used as a patent strategy.

In terms of the sector inquiry, the procedure or approach is not described extensively. Nor the similarities or the discrepancies between the preliminary report and the final report are being presented. Hence, only the key findings and conclusions are given attentions which are in directly correlation with the strategies. Further on, the inquiry also provides information regarding competition between originators, this will however not be given any attention. Regarding the *AstraZeneca* case, the focus will only be on the applied strategies in relation to the competition law. The decision by the Commission, which the judgement derives from, will not be presented in any greater extent.

Finally, protections for pharmaceutical products are not only sought through patent but also through trade mark protection for the package with the companies' name and the design of it. This will not be discussed at all. Given the complexity of biotechnological concepts and chemical formulas of the assessment criteria for filing of patents of drugs,

they have been left without consideration on the grounds that they are better suited to the subject of an essay in biomedicine because of its pharmaceutical intricacy.

## 1.5 Outline

*In chapter 1* of the thesis an introduction of the thesis is presented. This includes a background, where a description is given of the circumstances and why a legal problem has arisen. Furthermore, based on the background, a purpose has formulated which represents the core of the thesis. Finally, the selected method, delimitation and structure of the thesis are presented. *In chapter 2* of the thesis an introduction of the pharmaceutical industry is presented, where a general description is given of the competitors of this industry as well as the R&D of drugs and their characteristics. *Chapter 3* attends to the European patent system, both in regards of patents in generally and with focus on pharmaceutical patents. A presentation is given by the existing regulatory framework which includes a presentation of the requirements of patentability, patent applications and claims as well as scope of the patent exclusivity in regards of infringement. In *Chapter 4* a presentation is done of the competition law of the European Union, where the abuse of dominate position has the main focus.

Further on, in *Chapter 5*, the interface between intellectual property law and the competition, with regards to patents is investigated. To understand the reason for the General Court's judgment, there is a need to be familiar with the performed sector inquiry and its conclusion, which therefore is presented in *chapter 6*. Subsequently, *chapter 7* provides a presentation, investigation and interpretation of the judgment by the General Court. The thesis ends with an analysis of the uncertainty of pharmaceutical patent strategies' legality (*chapter 8*) and a conclusion where the thesis presents a determination of the strategies' legality (*chapter 8*).

## **2 The Pharmaceutical Industry**

### **2.1 General information**

The pharmaceutical industry is not, from an economic perspective, a uniform or collective term, but rather consists of particular and individual companies separated from each other, whose pursuance on the drug market are entirely based on individual circumstances, history, organization structure, contacts as well as national and international establishments etc. The market's structure distinct itself from other markets in general, due to the fact that it consists of a few multinational companies, many small companies, but in essence no middle size companies.<sup>10</sup> International established pharmaceutical companies comply with regulations based on each nation's own rules, depending on where each subsidiary its permanent establishment. Thus each separate subsidiary has different legal conditions, which consequently has an impact on sales, distribution the extent of the patent protection etc. with respect to how favourable or unfavourable the regulation of the state is, from the business perspective. This is not only due to the respective regulation, but other incitements such as the authorities', approach, the price supervision's strength, the position of the competitors and so on, which consequently leads to more or less advantages.<sup>11</sup>

### **2.2 Competitors**

#### **2.2.1 Originator Companies**

The originator businesses are the only ones conducting in Research and Development (R&D), where the activity is designed to provide the pharmaceutical market with new chemical entities (NCEs) i.e. new efficient substances of drugs. This is done by new inventions of chemical compounds as well as new biological effects of an already invented chemical compounds.<sup>12</sup> The R&D is in generally concentrated to a specific area of the pharmaceuticals and usually measure up to 15-20 percent of the total turnover.<sup>13</sup>

Due to the fact that the pharmaceutical research is an expensive<sup>14</sup> and time-consuming process it is tremendously important, or even essential if you will, to gain a satisfactorily

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<sup>10</sup> Domeij, B. *Läkemedelspatent*, p. 4, Werkö, L. *Medicin för Miljarder*, p. 18.

<sup>11</sup> Werkö, L. *Medicin för Miljarder*, p. 19-20.

<sup>12</sup> Werkö, L. *Medicin för Miljarder*, p. 20.

<sup>13</sup> Domeij, B, *Läkemedelspatent*, p.7.

<sup>14</sup> See Attachment 2.

patent of the NCE in order to protect the invention. Therefore, the patent needs to be awarded in an early stage in order for the patentee, the originator, to ensure that only they will enjoy the advantages of a particular efficient substance of the drug. The reason for the benefits of an early patenting is related to the aim of preventing duplicative research which leads to inefficient research on the same compounds. In contrast, with an early awarded patent, the company can pursue parallel, i.e. co-ordinate, research efforts which is more beneficial from an investment point of view. The reason why this can be done is due to the fact that the requirement of industrial applicability is then judged only on the basis of an early stage of the test-process.<sup>15</sup> The originator's R&D efforts are part of the aim to advance in different ways and increase the extension of the exclusivity of each NCE's by constructing an extensive product-portfolio of each drug. Ergo, these efforts constitute the R&D strategies that are tied into the larger competitive strategies applied by the company.<sup>16</sup> *(Explained more detailed below, in chapter 6 of the thesis)*

### **2.2.2 Generic Companies**

The generic companies produce already invented drugs, where the patent time has expired and thus can be produce without the risk of constitute an infringement of the intellectual property. The copies of the old NCEs have the same chemical formula and biological effects but just produced and promoted under a different generic name, i.e. trade mark (symbol <sup>TM</sup>). These names are by the World Health Organisation (WHO) referred as International Non-proprietary Names (INN). The WHO has listed these names in the so-called INN system, which is growing every year by some 120-150 new INN Each INN is a unique name that is globally recognized and is public property, which identifies the pharmaceutical substances or active pharmaceutical ingredients.<sup>17</sup> The generics are a significant force in the competitive pharmaceutical market with the strategy to competing in a different way, in contrary to the originators among themselves, for the same customers. When the generic companies, which could be several, enter the market with a competitive drug the originators, according to statistic, lose approximately 50 percent of

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<sup>15</sup> Domeij, B., *Pharmaceutical Patents in Europe*, pp. 25, 26.

<sup>16</sup> Bogner, W., C., *Drugs to market*, p. 3.

<sup>17</sup> <http://www.who.int/medicines/services/inn/innguidance/en/index.html>.

their turnover for a successful drug<sup>18</sup> within a couple of weeks.<sup>19</sup> The generics are more often solely national established and relies on the price-cutting as well as aggressive sales tactics in order to increase their position of the market. The reason why the out-of-patent generic drugs are much cheaper is due to the absence of financing expensive R&D.<sup>20</sup> Consequently their prize setting affects the originators, which possible could be forced to stop the production of that drug, since it is not profitable. Another strategy, how peculiar it may sound, is to increase their price even more and thereby only have the brand-loyal customers as targets on the market.<sup>21</sup>

### 2.3 The technical features of drug and the R&D

The pharmaceutical technology innovation involves NCEs which the companies through R&D aiming to develop which have one or several sector of applications. A NCE is a substance which never before has been introduced in a drug on the pharmaceutical market. It basically means a unique chemical compound, consisting of various molecules where their composition can be deduced by its chemical formula. When a NCE has been detected, it is applied on a certain sector of application, i.e. a disease or medical condition where it has a biological and therapeutic effect.<sup>22</sup> In addition, when a product has been judged to be a pharmaceutical technology, it can be divided into two types of categories, the *first medical indication* and the *second medical indication*, which is determined depending on the drug's innovation of origin. The two classifications are related to partly the NCE and partly the sector of application. The first indication comprise that a medical sector of application of a substance or a specific chemical compound has been invented, where the substance, NCE, already is known but *not as a drug*. The second indication comprise that a medical sector of application of a substance or a specific chemical compound has been invented, where the substance is already known *as a drug*. It shall be emphasized that the term *second* is in some way misleading since the term include all, the second, third and so on, medical indications.<sup>23</sup> The R&D is a costly process for the originators is mainly due to

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<sup>18</sup> Example; When the patent of the stomach ulcer medicine ZANTAC expired.

<sup>19</sup> Domieij, B., *Läkemedelspatent*, p.8, Bogner, W., C., *Drugs to market*, p. 134.

<sup>20</sup> Andersson, F., *The International diffusion of new chemical entities*, p. 26.

<sup>21</sup> Domieij, B., *Läkemedelspatent*, p. 9.

<sup>22</sup> Andersson, F., *The International diffusion of new chemical entities*, pp. 14-15.

<sup>23</sup> Domeij, B., *Läkemedelspatent*, pp. 314-315, 319.

the time-consuming fact, where the time to develop a drug usually takes up to approximately ten years and more than often longer.<sup>24</sup> Obtaining a comprehensive and adequate pharmaceutical patent is therefore a vital prerequisite for the originator to be able to carry out any research at all.<sup>25</sup> The reason for the extensive time consumption is due to the several steps that must be done in the manufacturing of the medicinal products. The steps involve several various tests in order to launch a drug. After a NCE has been discovered, both preclinical and toxicological tests must be performed. After these reviews are completed and evaluation has taken place, the company can apply for permission to advertise and sell the medicine.<sup>26</sup>

## **2.4 Regulatory Framework**

### **2.4.1 Marketing Authorisation of pharmaceutical products**

Regarding the regulatory framework regarding the pharmaceutical market, three areas of legislation seems according to the Commission, to be of particular importance. Firstly, the legislation governing patents, secondly the legislation governing marketing authorisations and finally, the legislation governing pricing and reimbursement of pharmaceutical products. The rules governing these areas set the framework in which the companies operate and therefore determine the conditions for competition.<sup>27</sup>

In order to be able to set a drug on the market, i.e. marketing and selling the product, the pharmaceutical companies are obligated to apply for an approval of marketing authorization, according to the Directive 2001/83/EC.<sup>28</sup> Any medicinal product for the human use which is intended to be placed on the market in the Member States and either prepared industrially or manufactured by a method involving an industrial process, is object for the Directive.<sup>29</sup> Hence, this implies that all both the originators and the generics are obligated to apply for permission to put the medical product on the market. The applicant has the possibility to choose to apply centrally to the Community, where the application is

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<sup>24</sup> Domeij, B., *Läkemedelspatent*, p. 12, See Attachment 3

<sup>25</sup> Andersson, F., *The International diffusion of new chemical entities*, p. 36.

<sup>26</sup> Domeij, B., *Läkemedelspatent*, p. 11-17, Andersson, F., *The International diffusion of new chemical entities*, p. 35.

<sup>27</sup> Final Report, paras. 249, 302.

<sup>28</sup> Art. 6 Directive 2001/83/EC of the European Parliament and of the council of 6 November 2001 on the community code relating to medicinal products for human use OJ L 311/67.

<sup>29</sup> Art. 1 (a)-(b), 2 Directive 2001/83/EC.

submit to the EMEA. Or, apply nationally for authorisation to a Member State of the EU, where the application is sent to the competent authority of the State.<sup>30</sup>

In order to be granted a marketing authorisation the applicant needs to provide the competent authorities of the Member State with adequate information, e.g. test results, in accordance with article 8 of the directive. Yet, provision in article 8 regarding the requirement of submit all the information regarding the tests of the NCE, presented in the chapter above, has a derogation. This implies that the generics are able to apply for marketing authorisations without the test-results, a so- called ‘abridged application’. This provides that it can be proven that the concerned medical product is a generic of the original product, i.e. the reference medical product. In addition, the original drug needs to be authorised or has been that for at least eight years in a Member State or the Community. The generic applicant can also apply for marketing authorisation in a member State even though the originator has not applied for an approval in that state, but, has obtained authorisation in another.<sup>31</sup>

#### **2.4.2 The Regulatory Data Protection and the ‘Bolar-type’ Provision**

As explained above, the generics are not obligated to submit results from the R&D for the generic products, however is the abridged application restricted in regards of a time limit. This implies that the generics are not able to use or refer the data from the submitted results until ten years have passed from the day when the originator obtained the marketing authorisation. This rule is called the Regulatory Data Protection (RDP), and implies that the originator has exclusivity of the data that provides information of the tests of the drugs, e.g. preclinical-test, toxically-test. The duration of protection can be extended to a maximum of eleven years.<sup>32</sup> Further on, the Bolar-type provision has been established in article 10(6) of the Directive 2001/83/EC. The article provides the right to conduct pre-marketing tests of a generic product, even though the patent protection of the original drug has not expired yet.<sup>33</sup>

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<sup>30</sup> Art. 4 Regulation 2309/93 EEC, art. 8 Directive 2001/83/EC, Final Report, para. 144.

<sup>31</sup> Art. 10 Directive 2001/83/EC, Final Report, para. 860.

<sup>32</sup> Art. 10 (1) Directive 2001/83/EC.

<sup>33</sup> Art. 10(6) Directive 2001/83/EC.

### 2.4.3 The transparency of measures regulating the prices of drugs

As a further step in the process of the ability to put the medical product on the market, the pharmaceutical companies need in several Member States to get an approval by each relevant authority regarding the pricing and reimbursement for their medical products. The requirement of approval of price-setting are therefore based on national law, and where it is obligated the Transparency Directive<sup>34</sup> regulates the approval of the determined price. Further on, the requirements of the application are set out by each Member State's national laws.<sup>35</sup> Thus, in summary, when the pharmaceutical company has obtain an approval of the price-setting of the drug, provided that it is required, and has been granted a marketing authorization, the drug can be put on the market where applications is approved.

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<sup>34</sup> Directive 89/105/EEC of the Council of 21 December 1988 relating to the transparency of measures regulating the process of medicinal products for human use and their inclusion in the scope of national insurance systems OJ L 40/11.

<sup>35</sup> Art 3(1) Directive 89/105/EEC, Final Report, para. 147.

## 3 The European Patent system

### 3.1 General information

Intellectual property is a term which is used to cover both industrial and artistic forms of property rights. Intellectual property rights (IPRs) constitute an exclusive right for the proprietor. Intellectual property has lately gained a lot of attention. Mostly because of its great value as an intangible asset it represents. But also for its features which promote innovation and competition. In addition, since the technology constantly has been developed in the last decades, its importance is highly appreciated for both companies and private persons.<sup>36</sup> An invention which is governed by a patent, which is one form of IPR, means that the inventor possesses exclusivity and hence cannot be produced or exploited by others, unless the inventor has given his/hers permission to do so. Yet, after the inventor has enjoyed exclusive protection, albeit for a limited time, the disclosure of the invention allows free use by the public. This is one of the most fundamental incentives within the patent system and enables an advancing of the practical arts by increasing public knowledge.<sup>37</sup>

The inventor has the possibility through the European patent system to gain protection in all countries within the EC by one single application. But, it should be emphasized that the obtained patent does not have judicial effect directly in all contracting states; ergo protection of the invention will not have the extent of the entire Community. Instead, the legal meaning of obtaining a European Patent, i.e. EPO-patent, is that the protection of the invention has a territorial limitation in regards of which states that have been designated in the application. Thus, protection of the invention will not have the extent of the entire EC.<sup>38</sup> Since the European patent system is based on national regulations, albeit partly, the inventor deals with the issue of dissimilar national patent laws, with different treatment of the patent in regards of various matters. Thus, matters of, among other things, infringement and revocation are based on national laws and procedures resulting in different outcomes.<sup>39</sup> Further on, if anyone infringes the patent, one must go to each

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<sup>36</sup> Levin, M., Koktvedgaard, M., *Lärobok i Immaterial rätt*, p. 21.

<sup>37</sup> Levin, M., *Immaterialrätten- En introduction*, p. 11-12, Francis, W., Collins, R., *Cases and Materials on Patent law*, p. 7.

<sup>38</sup> Domeij, B., *Fokus på Patenträtten*, p.11, Muir, I., et al., *European Patent Law*, p. 2.

<sup>39</sup> Prime, T.,B.A., *European Intellectual property Law*, p. 176.

country's court. Obviously this is both expensive and complicated processes, leading to many smaller innovative companies have neither the opportunity to obtain protection throughout the EU, nor defend themselves against intrusion.<sup>40</sup> The European patent system is primarily based on; the Paris Convention for the Protection of Industrial Property (ParC)<sup>41</sup>, the Patent Cooperation Treaty (PCT)<sup>42</sup> and the Patent Cooperation Treaty (PCT)<sup>43</sup>. The latter only be presented due to the purpose of the thesis.

## 3.2 European Patent Convention

The EPC only regulates the central parts of the granting of European patents<sup>44</sup>, i.e. rules regarding the application, the procedure of examination and the granting of patent protection.<sup>45</sup> The obtaining of a European patent comprises two different phases in the application process, which are complementary and cannot be separated. The first phase takes place when the application is filed to and then subsequently, provided that all requirements are satisfied, granted by the European Patent Organization (EPO).<sup>46</sup> The applicant must, when filing the application, indicate the Member States in which he wishes to obtain protection. An acceding tax is then payable for each State, also known as the designation fee. The second phase is supervised by the authorities of the designated countries of the application. This comprises a validation of the granted patent by means of the filing of the respective translation, in accordance with the requirements of each country. Hence, the patent validation process does not end with the grant-decision given by the EPO, since it must be completed at each of the designated countries' authorities.<sup>47</sup> It should be added that the Convention is open, which means that any individual person or legal entity can apply for a European patent.<sup>48</sup>

A European patent has, according to article 2 (2) EPC, in each of the contracting states for which it is granted; the effect of and is subject to the same conditions as a regular national

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<sup>40</sup> [http://www.svensktnaringsliv.se/kommentaren/stort-steg-mot-eu-patent\\_94389.html](http://www.svensktnaringsliv.se/kommentaren/stort-steg-mot-eu-patent_94389.html).

<sup>41</sup> Paris Convention for the Protection of Industrial Property of March 20, 1883, (referred as ParC).

<sup>42</sup> The Patent Co-operation Treaty Done at Washington on June 19, 1970(referred as PCT).

<sup>43</sup> The Patent Co-operation Treaty Done at Washington on June 19, 1970(referred as PCT).

<sup>44</sup> Art. 1EPC.

<sup>45</sup> Dybdahl, L. *Europeisk Patent*, p. 15.

<sup>46</sup> See art. 4 EPC

<sup>47</sup> Cruz, J., *The Community Patent Convention -What Sort of Future?*, p. 819-820.

<sup>48</sup> CRUZ, J., *The Community Patent Convention- What Sort of Future?*, p. 819.

patent granted by that state, unless otherwise provided in the EPC. Therefore, the convention defers to national law in several matters of the patent regulation but sets up certain minimum protection, e.g. the acts of infringement in article 64 (3) EPC and the protection conferred by publication of the application according to article 67 (2) EPC.<sup>49</sup>

Primarily, the EPC sets three important demands of national patent laws regarding the effect of a European patent. The first one is regarding the term of the patent, which is 20 years from the date of filing but which should not limit any extent of this term, according to article 63 EPC. Secondly, the revocation of European patents according to article 138 EPC. The Convention states that a European patent may be revoked with effect for a Contracting State only on specific grounds listed in the article. The last provision concerns the extent of the protection, stated in article 69 EPC, which shall be in correspondence with the claims and with the description and drawings as tools for the interpretation of the claims.<sup>50</sup> Regarding the entitlement of patent protection, the invention must be patentable which is determined based on whether the invention meets certain requirements, as mentioned above. Subsequently, the application is subjected to a substantive examination to assess whether or not the invention meets the requirements. The examination proceeding of the invention involves four types of requirements.<sup>51</sup>

### 3.3 Requirements for Patentability

#### 3.3.1 General information

In order to be entitled to be granted a pharmaceutical patent, or any European Patent for an invention for that matter, the drug needs to be patentable under the law. This implies that the invention needs to meet up to a number of requirements to possess patentability.<sup>52</sup> In the first paragraph of article 52 EPC four requirements are established;

*European patents shall be granted for any inventions, in all fields of **technology**, provided that they are **new**, involve an **inventive step** and are susceptible of **industrial application**.*

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<sup>49</sup> Muir, I., et al *European Patent Law*, p. 131.

<sup>50</sup> Dybdahl, L. *Europeisk Patent*, p. 17.

<sup>51</sup> See art. 52-57 EPC, Muir, I., et al *European Patent Law*, p. 134.

<sup>52</sup> Art. 52 EPC, Domeij, B. *Pharmaceutical Patents in Europe*, p. 19.

These criteria operates as threshold devices to determine if a specific invention makes a sufficient contribution to human knowledge and experience, and thereby are qualified to be awarded the advantage of monopoly status. These requirements are not just applied in regards of the granting of European patents, but in countries not affiliated with EPC as well. In order to ascertain that it is agreed upon in all countries these requirements for patentability are the relevant criteria, article 27(1) of the TRIPS is established. Yet, the requirements get different practical effect due to the dissimilar interpretation of each national court.<sup>53</sup>

### 3.3.2 Technical character

The requirement of *Technical Character* is essential for the foundation of patentability and the invention *must* be of a technical nature.<sup>54</sup> As mentioned above, the requirements in article 52 EPC is supplemented by requirements in the EPC's Rules in regards of the technical character. According to the Rules as well as the case law of the EPO, the invention must have "technical character", that is; should constitute an industrially applicable technical solution to a technical problem, and must be reproducibly obtainable without undue burden.<sup>55</sup> In terms of pharmaceutical patents and the determination of the patentability regarding the requirement of technical character, it is based on the technical effect, i.e. the therapeutic effect. The NCE itself is not valuable in regards of this requirement, but the property of the drug as an invention. The determination of the technical effect can be deriving from the preclinical testing, i.e. *in vitro* or *in vivo*. Ergo, if a biological effect can be established having the character to be considered as a solution of a technical problem, i.e. a disease or medical statement, the requirement accomplished.<sup>56</sup>

### 3.3.3 Novelty

In order to be able obtain a European Patent the invention needs to meet up with the substantive requirement *Novelty*, established in article 52 (1) and further explained in article 54 EPC. The requirement is absolute, which means that it is valued objectively, hence it

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<sup>53</sup> McQueen, H., et al, *Contemporary Intellectual Property – Law and Policy*, p. 409.

<sup>54</sup> Guidelines Part C. Chapter IV, 1 and 2.2., Muir, I., et al *European Patent Law*, p. 134.

<sup>55</sup> (Rule 42(1) (a)), (Rule 42(1)(c)),(Rule 43(1)), Guidelines Part C. Chapter IV, 1.2 (ii), V8/94, Oj EPO 1995 p.388

<sup>56</sup> Domeij, B. Läkemedelspatent, p.48.

needs to be new within all fields of the technical area, and with regard to the whole world.<sup>57</sup> The invention shall according to the article considered to be new if it does not form part of the state of the art. In order for novelty for a claimed invention it is required that at least *one* essential technical feature which distinguishes it from the state of art. The "state of the art" is defined as "everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application", i.e. already known invention<sup>58</sup> To determine whether the leading compounds, NCEs, are classified as novel a research is done, investigating all approved patents within all convention states linked to EPC. The judgment of novelty consists of several phases.<sup>59</sup>

Further on, article 54 of the EPC is supplemented with provisions in article 55 EPC, which states reasons, solely and specifically two, why a disclosure of the invention shall not be taken into consideration. An essential condition for the non-prejudicial of novelty is that the disclosure having in view occurred no earlier than six months preceding the filing of the European patent application. Further on the article lists the measures of exception which relates to abuse of the applicant's legal predecessor.<sup>60</sup>

### **3.3.4 Inventive step**

The invention also needs to involve an *Inventive Step*, stated in article 56 of the EPO, a question that only arises if the invention is novel.<sup>61</sup> According to the article, in order for the invention to be deemed as an inventive step, the invention shall not be obvious for a skilled person in the specific technical field. The purpose of this requirement is to prevent the continual development of technology, e.g. originators R&D of new biological effect, based on the normal skill of the expert, from being hindered by monopoly rights.<sup>62</sup> The term "obvious" means that the invention does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art, i.e. something which

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<sup>57</sup> Dybdahl, L. *Europaisk Patent*, p. 63

<sup>58</sup> Guidelines Part C. Chapter IV, 6.1, G 2/88, OJ EPO 1990 p. 93.

<sup>59</sup> Muir, I., et al *European Patent Law*, p. 177.

<sup>60</sup> 55(1)(a)-(b) EPC, Guidelines Part C, Ch., IV, 10.1-2, Dybdahl, L. *Europaisk Patent*, p. 63.

<sup>61</sup> Guidelines part C, Ch., IV, 11.1.

<sup>62</sup> Muir, I., et al *European Patent Law*, p. 189.

does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art.<sup>63</sup>

### **3.3.5 Industrial applicability**

Last presented is the requirement of *Industrial Applicability* according to article 57 EPC. The basic principle, in correspondence with the article, is the broad definition that an invention is susceptible to industrial application if it can be used in an industrial area. In addition, the term "Industry" should be understood in its broad sense as including any physical activity of "technical character, i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts."<sup>64</sup>

## **3.4 The Supplementary protection certificate**

Supplementary Protection Certificates (SPC) is important for the term of a patent. The SPC regulation of EC (ECC) No. 1768/92<sup>65</sup> for medical products enables to apply for an extent of the limited patent protection. This enables originators to prolong the life time of the patent exclusivity of the market authorised medical product which hinder the generics to produce copies of the original drug. The reason for the establishment of this right for extension of protection is with respect to the expensive as well as time-consuming process of R&D. The right is also in the view of the period that elapses between the filing of an application for a patent and authorization to place the medicinal product on the market is a reason for the Regulation.<sup>66</sup> The granting of SPC is made by respective Member State's authority which granted the basic patent, and a unified cross-recognition does not exist of an approved SPC. Consequently, the patent-holder needs to file and be approved on a country-by-country basis.<sup>67</sup> During the SPC-period, equivalent rights and obligations exist as during the time that the drug was protected by the basic patents, but with one exception. The right to an extended patent protection only applies to those drugs which have obtained authorizations to be put on the market. Ergo, the SPC is not granted for the entire NCE

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<sup>63</sup> Guidelines part C, Ch., IV, 11.4

<sup>64</sup> Guidelines part C, Ch., IV, 5.1, Muir, I., et al *European Patent Law*, p. 147.

<sup>65</sup> Council Regulation EEC No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, *OJ No L 182/1* (Referred as SPC Regulation).

<sup>66</sup> See Preamble SPC Regulation, Muir, I., et al *European Patent Law*, p. 302.

<sup>67</sup> Art. 9(1), 10(1) SPC Regulation.

per se and its sector of application.<sup>68</sup> The originator needs to file the application within six months of the date on which the authorization to place the product on the market as a medicinal product was granted. It shall also be mentioned that products which were protected by a valid patent when the regulation came into force in 1992, are only able to obtain a SPC if; the date of the first authorization to place the product on the market as a medicinal product was *after* 1 January 1985. The requirement of specific the date varies in some of the Member States, where the date could be either 1 January 1988 or 1 January 1982.<sup>69</sup>

The SPC takes effect, pursuant to article 13 SPC Regulation, as from the lost of the exclusivity (LoE). This implies at the end of the lawful term of the basic patent, i.e. after the twenty-year term in article 63 (1) EPC. The EPC has in addition been amended in order to correspond with the SPC regulations. It is stated in article 63 (2) b) EPC that even though the term of a patent is twenty years, nothing shall limit the right of a Contracting states to extent that period, on condition that the product has to undergo an administrative authorization procedure required by law.<sup>70</sup> The duration of the certificate is based on a calculation formula. The term is equal to the period which elapsed between the date of filing for the patent application and the date of the first marketing authorization in the Community, minus five-years.<sup>71</sup> The maximum duration of the SPC is however five years, starting from the date on which it takes effect.<sup>72</sup> In addition, however, the patent-holder is entitled to a six-month extension of the SPC-duration, ergo 5, 5 years, when the data from clinical trials in accordance with an agreed Paediatric Investigation Plan (PIP).<sup>73</sup> Hence, the originator's LoE falls when the protection through a patent, and the possibly extended by the SPC, has expired. The duration of this time is maximum 25, 5 years. After that date the generics and other competing originators can start to manufacture and supply the concerned drug.<sup>74</sup>

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<sup>68</sup> Art. 1(a),(b),4, 5 SPC Regulation.

<sup>69</sup> Art. 7, 19(1),(2), 23 SPC Regulation.

<sup>70</sup> 63 (2)b) EPC, Muir, I., et al *European Patent Law*, p. 302.

<sup>71</sup> Art. 13(1) SPC Regulation.

<sup>72</sup> Art. 13(2) SPC Regulation.

<sup>73</sup> Art. 36 Regulation (EC) no 1901/2006 of the European Parliament and of the Council of 12 December 2006 on Medicinal Products for pediatric use and amending Regulation (EEC)

<sup>74</sup> Art. 13(2) SPC Regulation., Final Report, Glossary p. 13.

## 4 European Union Competition law

### 4.1 General Information

The Treaty of Rome was established with the aim of creating a common market, and the Single European Act to create an internal market, with this in respect was the competition law for the Community, and still is for the Union, of central importance.<sup>75</sup>

The European competition law is one of the areas where the European Union has exclusive competence.<sup>76</sup> This area of the Union covers mainly four policies; anti-competitive agreements between companies, e.g. cartels or control of collusion, abuse of dominant position, e.g. monopolies, mergers and finally State aid.<sup>77</sup> The competition law of the Union is established in order to ensure that free competition prevails and hence prevent corporations abusing their market power.<sup>78</sup>

The European competition law has a couple of outset objectives that shall be emphasized. One of the primary purposes of competition law is to remedy some of the situations in which the free system breaks down. Further on, the objective of competition law per se is to enhance efficiency, in regards of consumers' security and achieving the optimal allocation of resources. In addition to this, another objective is to protect not only the consumers, but other less competitive corporation from larger mergers of economic power on a market. This applies both to companies that occupy monopoly position, and therefore a dominant position, as well as agreements between corporations which co-operates on the market as one single unit, e.g. cartels. Even a third objective can be added since of the European competition law aims to facilitate the conception of *a single European market*, and hence prevent certain proceedings by private undertakings which deprive this goal.<sup>79</sup>

One of the areas of economics where the competition law has the greatest importance is industrial economics, which is a part of the discipline that applies micro-economics tools. Micro-economics implies decisions and behaviours by individual parts of the economy, e.g. companies, where the tools are used to rationalize these decisions and behaviours. These

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<sup>75</sup> Art. 2 ECT, Preamble, art. 2 TEU.

<sup>76</sup> Art. 3(b) TFEU.

<sup>77</sup> See art.101-102, 107 TFEU and Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation).

<sup>78</sup> Furse, M., *Competition Law of the EC and UK*, p. 1.

<sup>79</sup> Furse, M., *Competition Law of the EC and UK*, pp. 1,3 Craig, P., de Burca, G., *EU law*, pp. 936-937.

tools are applied in order to increase the market shares and extend market position.<sup>80</sup> In the pharmaceutical market micro-economics tools could, for example, include price-settings, competing drugs with e.g. less side-effects, wider the product portfolio etc.

The body for the primary role in the observation and enforcement of EU competition law is the European Commission, where its acts have legal effects. This is consistent with the broad function of the Commission as ‘the guardian of the Treaty’. The Commission shall ensure the application of principle stated in article 101 and 102 TFEU.<sup>81</sup> Further on, the Regulation 1/2003<sup>82</sup> provides the Commission, and the national authorities, the power to make certain decisions, which is necessary for the application of article 101 and 102 of the TFEU. The Commission has also the authorization to take steps, e.g. sector investigations, in order to be able to take these decisions. The Commission are also empowered to impose any remedy when a breach of the Regulation has occurred.<sup>83</sup>

In regards of article 102 TFEU, which is the object for the thesis, the article is applicable on abuse by one or more undertakings of a dominant position. The article states that any abuse that affect the trade between Member States shall be prohibited as incompatible with the common market. Further on the article provides a list of examples that constitutes abuse, e.g. unfair purchase and selling, limiting production, markets or technical development etc.<sup>84</sup> Nevertheless, it is important to emphasise that the list do not constitute an exhausted definition of abuse. The essence of the article is the control of the market power, where the applicability is the single, dominate firm which abuse its market power in one or another way. Yet, there is possibility that more than one undertaking can be held for abuse of dominant position. Article 102 TFEU do not prohibit market power or monopoly per se, solely the *abuse*. Rather, the undertakings are encouraged to compete with each other and create an efficient competition within the market. The different elements in the article

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<sup>80</sup> Furse, M., *Competition Law of the EC and UK*, p. 9.

<sup>81</sup> Art. 105 TFEU, Furse, M., *Competition Law of the EC and UK*, p. 31.

<sup>82</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty OJ L 1/1, 04/01/2003.

<sup>83</sup> Art. 4,5, 7, 17, 23, 24 Regulation 1/2003.

<sup>84</sup> Art. 102 (a)-(d)

such as the affect of the trade and the existence of dominate position, demand an economic analysis.<sup>85</sup>

In regards of applicability, the interpretation of terms' definition determines if there exists a possible breach of the competition law. Undertakings are the sole subjects for the substantive competition law. The term 'undertakings' identify the subjects to whom the European competition provisions are addressed to. The identification is essential since it determine the applicability of the articles of competition law. However, the TFEU do not provide any identification of the term. Rather, the task of definition is delegated to the European Courts to interpret and subsequently establish its content and domain. The Courts' jurisprudence has adopted a functional approach of the term's identification, where no consideration is taken to the companies' legal form or their source of funding. The focuses of the approach is that the entity, e.g. company, is engaged in economic activities, with respect to its commercial nature and not the type of entity engaged in these activities.<sup>86</sup> Further on, in regards of the notion of undertaking, basically three coherent incitements are objects to the nature of economic activity. If the entity offering goods or services (1) in the marketplace (2) *and* the activity could, potentially, generate profits (3), it is acting as an undertaking for the purpose of European competition law.<sup>87</sup>

The importance of the definition of undertaking passes also for the definition of the 'relevant market', since it identifies the boundaries of competition between the companies.<sup>88</sup> Markets are where consumers and producers of a products or service interact. With that in mind, the supplied goods or services is an important incitement in order to identify a market with respect to competition law. The question is whether one specific product competes with another specific product.<sup>89</sup>

In 1997, the Commission published a *Notice on the definition of the relevant market for the purpose of Competition law* ((1997) OJ C372/5). The objective of defining a market is according to the

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<sup>85</sup> Craig, P. de Búrca, G., *EU Law*, p. 932.

<sup>86</sup> Case IV/33.384 and IV/33.378 European Commission, [1992] OJ L 326/31, *FIFA- distribution of package tours during the 1990 World Cup*, paras 43 and 44; Case C-364/92 *SAT Fluggesellschaft mbH v Eurocontrol* [1994] ECR I-43, paras 18,19; Ezrachi, A., *EC Competition Law*, p. 1.

<sup>87</sup> Case T-319/99 *FENIN v. Commission* [2003] ECR II-357, paras 36, 37.

<sup>88</sup> Ezrachi, A., *EC Competition Law*, p. 19

<sup>89</sup> Furse, M., *Competition Law of the EC and UK*, p. 15.

notice of the Commission; to identify the competitors of the undertakings involved that are capable of constraining their behaviour and preventing them from behaving independently of an effective competitive pressure. With this perspective, it is possible, inter alia, to calculate and determine market shares which convey meaningful information regarding the assessment of dominance.<sup>90</sup>

The process of identify the market is primarily an economic exercise, with economic information is determine and assist the definition. Nevertheless, the European case law provides knowledge of the methodology of the analysis is designed.<sup>91</sup> The methodology of the definition of the market focus on analyse partly the *product* and partly the *geographical* domain.<sup>92</sup> The product market is generally defined in the proclamation as one which due to the features of the products, in regards of prices and their intended use, comprises all products and/or services which the consumer considers as interchangeable or substitutable.<sup>93</sup> To put this in practical relevance in regards of pharmaceutical products, the features of a drug, e.g. side-effects, are founded on its chemical compound and has therefore a specific sector of application. Another drug has equivalent sector of application and can consequently compete with the first mentioned. This applies even though the latter has a different chemical compound, NCE. The geographical market is defined as the area where the undertakings concerned are involved in, in regards of the supply and the demand of products or services, and the conditions of competition are sufficiently homogeneous and distinguish from neighbouring domains because of the conditions of competition are appreciable different in those areas.<sup>94</sup>

## **4.2 Abuse of Dominant and Monopoly position**

### **4.2.1 General information**

Article 102 TFEU (ex 82 ECT) forms the basis of action which are less often applied than article 101 TFEU, this due to that it applies to fewer undertakings and due to the fact that

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<sup>90</sup>The Commission Notice on the definition of the Relevant Market for the Purpose of Community Competition Law (1997 OJ C 372), para 2.

<sup>91</sup> Ezrachi, A., *EC Competition Law*, p. 19.

<sup>92</sup> Case C-27/76 *United Brands v Commission* [1978] ECR 207, [1978 1 CMLR 429, para 10.

<sup>93</sup> The Commission Notice on the definition of the Relevant Market for the Purpose of Community Competition Law (1997 OJ C 372), para 7.

<sup>94</sup> The Commission Notice on the definition of the Relevant Market for the Purpose of Community Competition Law (1997 OJ C 372), para 8.

these often large organizations are, but not necessarily, aware of their obligations and provisions under this article.<sup>95</sup> The article has the objective to prevent abuse of one or more undertakings of *a dominant position* which is to the detriment of consumers and/or competitors, and therefore prohibited as incompatible with the common market. The article constitutes one of the principal provisions of competition policies mutually with article 101 TFEU.<sup>96</sup>

The applicability of the article requires that the undertaking or undertakings are in control of market power, i.e. possess a dominant position. Dominance is therefore the essence of the article. Nevertheless, it should be emphasized that the holding of market power or monopoly position or the tactics by undertakings to attain such position is not outlawed per se, but rather the *behaviour*, i.e. an *abuse* of such position on the market. Consequently, a certain practice of an undertaking that is not in correspondence with the competition policies, would have been lawfully if the company still were climbing towards a dominate position.<sup>97</sup> The article provides a list of abusive practice, 102 (a)-(d), which are not an exhaust definition of abuse conduct but rather examples.<sup>98</sup> In order to analyze the applicability of the article, four main questions can be stated, which jointly represents the requirements for the article's applicability;<sup>99</sup>

1. Is there a dominant undertaking or a group of undertakings?
2. Is this dominant position within the Common market or in a substantial part of it?
3. Is this dominant position being abused?
4. Could this abuse affect trade between Member States?

Consequently, if the conduct of the undertaking meets these requirements it is prohibited as incompatible with the common market. Consequently, the breach of article 102 TFEU is

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<sup>95</sup> Furse, M., *Competition Law in the EC and the UK*, p. 279.

<sup>96</sup> Art. 102 TFEU, KÄLLA

<sup>97</sup> Case C-6/72 Continental Can Co. Inc v Commission [1973] CMLR 199, para 26, Raig, P., de Burca, G., *EU Law*, p. 992, Furse, M., *Competition Law in the EC and the UK*, p. 279.

<sup>98</sup> Art. 102(a)-(d) TFEU, Raig, P., de Burca, G., *EU Law*, pp. 992-93.

<sup>99</sup> Ezrachi, A., *EC Competition Law*, pp. 19,119.

subject for the 1/2003 Regulation which may incur penalties, damages and a requirement of conduct modification.<sup>100</sup>

Some of the terms stated in the article has already been generally explained in the previously chapter, in the light of both article 101 and 102 of the TFEU. However, the meaning of the terms differs slight depending whether it is interpreted in the context of article 101 or article 102 TFEU. Therefore, these four questions will therefore be subjects for a deeper analysis in the next sub-chapters in order to be able to determine the meaning of each term and the proper way of interpret article 102 TFEU.

#### **4.2.2 Dominant position and Market Power**

In order to be able to apply article 102 TFEU, there is a need to determine that a dominate undertaking or a dominate group of undertakings exists in the particular case. The article does not provide any definition of what constitutes dominance, equivalent to and mentioned before, other terms. The concept of dominance is determined in the notion of market power and its application necessitates an economic analysis.<sup>101</sup>

It has been held by the ECJ that the dominant position referred in article 102 TFEU relates to a position of economic strength which enable the undertaking to prevent effective competition by possessing the power to behave to an appreciable extent independently of its competitors, costumers and ultimately consumers.<sup>102</sup> Further on, dominance does not require that there be no competition and subsequently some competition do not preclude the finding of dominance. Rather, the materiality is if the undertaking profits from it or at least having an appreciable influence on the condition of the competition and in any case act disregarded of it.<sup>103</sup>

Therefore it do not exist any fixed general formula of the definition applicable on all cases. Rather, the determination of an undertakings position of the relevant market is done by

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<sup>100</sup> See Regulation 1/2003, Furse, M., *Competition Law of the EC and the UK*, p. 278.

<sup>101</sup> Ezrachi, A., *EC Competition Law*, pp .119-20.

<sup>102</sup> Case C-27/76 *United Brands Co. v Commission* [1978] 1 CMLR 429, para 65.

<sup>103</sup> Case C-85/76 *Hoffman-La Roche & Co. AG v Commission* [1979] 3 CMLR 211, para 39.

analysis of each case, which is performed in consideration to three essential variables; the product market (1), the geographical market (2) and the temporal factor (3).<sup>104</sup>

The definition of variable 1, *the relevant product market*, is an important part of the general definition of dominance. Depending on how broadly or narrowly a relevant product market is defined; the market shares can vary from having a total monopoly position to having a insignificant market share. Yet, if the relevant product market is extended to be defined as all motor cars including perhaps the second-hand vehicles, the market shares would decrease in a significant and tremendously extent. Therefore, in order to be able to define the market the substitutability, or the so-called cross-elasticity, is an important tool in the definition-process.<sup>105</sup> Thus it has been stated by the ECJ, in case *Hoffmann- La Roche* that; ‘the concept of a relevant product market presupposes that there is a sufficient degree of inter-changeability between all the products forming part of the same market’.<sup>106</sup> Substitutability can be analysed in two perspectives, partly in the consumer of the product, i.e. demand substitutable, and partly in the perspective of suppliers or potential suppliers of the product, i.e. supply substitutability.

As mentioned above, the Commission has published a notice of the definition of the relevant market. In its notice on market definition, the Commission has chosen to analyse demand substitutability according to a specific test.<sup>107</sup> The test established and applied by the Commission is the so-called Small but Significant and Non-transitory Increase in Price (SSNIP)-test. The test briefly focuses on defining the minimum market as a monopolist or cartel could affect the price of the market. The method asks ‘Can a cartel or monopoly increase the price of a product with 5-10 percents for at least a year with retained product and conditions of sale?’ If a sufficient proportion of consumers are expected to switch to a competing product, so that the price increase becomes unprofitable, the market should not be subject to specific competition regulation.<sup>108</sup>

However the Commission has also indicated that it is not required to apply the test and that the notice on the market definition, rather that the methodology in the notice were

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<sup>104</sup> Furse, M., *Competition Law of the EC and the UK*, p. 281, Raig, P., de Burca, G., *EU Law*, pp. 994.

<sup>105</sup> Furse, M., *Competition Law of the EC and the UK*, p. 281.

<sup>106</sup> Case C-85/76 *Hoffman-La Roche & Co. AG v Commission* [1979] 3 CMLR 211.

<sup>107</sup> Decision 2000/12 EC, *relating to the 1998 football World Cup* [2000] OJ L5/55, paras 66-74.

<sup>108</sup> Furse, M., *Competition Law of the EC and the UK*, p. 281, 291.

merely an illustration of the way that the market operates.<sup>109</sup> The supply-side substitution, which is the other factor in the market definition, requires that suppliers are able to switch production in the short term when permanent price changes, even small, has taken place. It is necessary that the cost of switching production is small and the risk is not substantial, since the switch in supply is likely to result in smaller market shares of all suppliers.<sup>110</sup> In addition, it shall be emphasised that the supply substitution is to distinguish from positional competition. The Commission does not, pursuant to its notice, consider it appropriate to take the potential competition into account.<sup>111</sup> Nevertheless, the potential competition may be subject for the definition of market depending on specific factors and circumstances related to the conditions of entry, but only *after* a determination of the relevant market.<sup>112</sup>

One of the most important European cases that arose in regards of the definition of relevant product market was the *United Brands Continental v Commission* case.<sup>113</sup> The undertaking, United Brands Continental, brought action before the ECJ seeking for annulment of the decision by the Commission where the conduct by the undertaking was fined. The appeal challenge the Commission's has definition of the product market, as the undertaking considered it to be in a too narrowly definition. The undertaking, which were a subsidiary of an American firm accounting 35 per cent of world banana export, oppsed that the product market-definition were specifically for bananas, rather than a general market of soft fruits or all fruits. However, the Court held that a very large number of consumers have a constant need for bananas which cannot be substituted by any other fruit and therefore the banana market is a market which is sufficiently distinct from the other fresh fruit market.<sup>114</sup>

Further on, when the product market has been defined, the definition of variable 2, *the relevant geographical market*, needs by determined. The definition of the geographical market is important to taken into consideration due to the fact that article 102 TFEU requires that the dominate position extend to, at least a substantial part of the Common market (the term 'substantial part' is more thorough explained in next sub-chapter).Consequently an

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<sup>109</sup> See Decision 2000/74, Virgin/British Airways [2000] OJ L30/1.

<sup>110</sup> Furse, M., *Competition Law of the EC and the UK*, p. 282.

<sup>111</sup> See e.g. Case C-6/72 *Europemballage Corp. and Continental Can Co. Inc. v Commission* [1973] CMLR 199.

<sup>112</sup> Furse, M., *Competition Law of the EC and the UK*, p. 291.

<sup>113</sup> Case C-27/76 *United Brands Continental v Commission* {1978} 1 CMLR 429.

<sup>114</sup> Case C-27/76 *United Brands Continental v Commission*, para 35.

undertaking may possess a dominant position in a small area, e.g. a bus company which is the only undertaking that offers transportation on a single route, but is still not subject for the competition provisions in respect of abuse of dominant position. The objective for the definition is to determine the actual and potential competitors of the undertaking in question and possible restrictions that may exist of its alleged market power.<sup>115</sup> The ECJ has clearly stated, in the *United Brands case* explained above in relation to the product market, that two considerations need to be taken into consideration of the definition of the relevant geographical market with respect to the applicability of article 102 TFEU. Partly a clear delimitation of the substantial part of the Common market, where abuse might take place which hinders the competition, and partly where the conditions of competition applying to the product in question are the same for all traders.<sup>116</sup> In addition, the analysis of the geographical market shall also, in the context of article 102 TFEU, take into consideration that an undertaking which appears to have a dominant position within a territory, but as a matter of fact faces, or threats of, competition from outside of the territory which may act as restraints on its conduct. Further on, regarding the *United Brands case*, the ECJ held, in correspondence with the Commission, that three out of nine Member States were excluded from the geographical market, due to the countries' legacy of history relating to special circumstances of the import of bananas. Yet, the undertaking argued that all Member States shall be regarded as separate markets since different conditions exist. But the Court judged that the six countries formed an area which was sufficiently homogeneous to be considered in its entirety.<sup>117</sup> When determining the boundaries of the geographical market it is the conditions that are taken into consideration and not the result of the competition. Thus, the fact that different price-setting exists in various areas is not per se a validated ground of different geographical markets.<sup>118</sup>

The definition of the last variable, *the temporal factor*, must be taken into consideration in order to establish the relevant period in regards of two factors. Partly, over which period of time the dominance is alleged, and partly over which period of time the alleged abuse has been perpetrated.<sup>119</sup> However, it is extremely rare that the definition of the temporal

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<sup>115</sup> Furse, M., *Competition Law of the EC and UK*, p. 2988.

<sup>116</sup> Case C-27/76 *United Brands Co. v Commission* [1978] 1 CMLR 429, para 44.

<sup>117</sup> Case C-27/76 *United Brands Co. v Commission* [1978] 1 CMLR 429, para 53.

<sup>118</sup> See e.g. *Soda Ash- Solvay* 91/299 [1991] OJ L 152/21.

<sup>119</sup> Furse, M., *Competition Law of the EC and UK*, p. 290.

market and its analysis has a significant influence of a decision or a judgment. Usually, the Commission's determination of temporal constraints, for defining the relevant market, is not likely to be successfully challenged. Yet, the duration of the alleged abuse may be argued since it is a factor in assessing the level of any fines imposed, pursuant to the Regulation 1/2003. One of the most notable decisions by the Commission was during the Oil crises in 1973/74.<sup>120</sup> The Commission hold that one of the purposes was to create several temporarily defined separate markets, with the result that the customers were unable to switch suppliers. In addition the consumption was restricted with portion limitation by the suppliers and only available for their traditional costumers. However, the Court ruled in the appeal against the Commission. Nevertheless, the Court held the temporal arguments intact in an acceding judgement of the oil company BP.<sup>121</sup>

In summary, the definition of the relevant market is determined by the three variables explained above. All variables, with their determined definitions, are linked together and are one of the essences for the applicability of article 102 TFEU. An undertaking may appear to abuse a dominant position, but the undertaking must be deemed to have dominance in relation to the determined product and geographical market with additional respect to the time period.

#### **4.2.3 Dominant position within the Common Market or a Substantial part**

When the dominate position of a market has been established in regards of the three variables presented above and before the process of evaluating whether the undertakings practice is abusive, it is necessary to establish that the market power is within the Common market or a sustainable part of it. The requirement of dominate position within the Common market, or at least a sustainable part, constitutes a threshold of the applicability of article 102 TFEU. As mentioned in the latter sub-chapter in respect of the determination of the relevant geographical market, article 102 TFEU requires that the geographical market is extended to an area that is equivalent to at least a 'substantial part' of the Common Market.<sup>122</sup> The term is object for interpretation, were previous case law may not be applicable since a substantial part is an inconstant factor due to the constant

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<sup>120</sup> *ABG Oil companies operating in the Netherlands* 77/327 [1977] OJ L117/1.

<sup>121</sup> Case C-77/77 *Bp v Commission* [1978] 3 CLMR 174.

<sup>122</sup> Ezrachi, A. Ec competition Law, p. 120, Furse, M., *Competition Law of the EC and UK*, p. 288.

change of the Common Market-area in regards for example the number of Member States. One single state can constitute a substantial part of the Common Market, even though the market of sale for a country only represents a few per cent.<sup>123</sup> Thus, the concept of substantial part must be determined with the specific market of product, than just the analyse of the size of the absolute geographic area identified in the market boundary definition.<sup>124</sup> One of the most important cases of the determination of ‘substantial’ was in the case of *Suiker Unie*.<sup>125</sup> The case is rather exceptionally complicated since it involves 16 applicants, challenging the decision by the Commission which imposed fines, cease and desist orders on all these undertakings.<sup>126</sup> One of the plaintiffs had been alleged by the Commission to occupy a dominant position of the sugar production in Belgium and Luxembourg, which constituted a substantial part of the Common market. The Court held that the determination of whether an area amounts to a substantial part it is necessary taken into account the pattern and volume of the production and consumption of the said product as well as the habits and economic opportunities of vendors and purchasers’. Thus, since the production of sugar in the countries total amounted 15 per cent of the total market, these market shares constituted a substantial part.<sup>127</sup>

#### 4.2.4 The concept of Abuse

As stated in the beginning, dominance is not prohibited per se, but solely the *abuse* of such position is the target of article 102 TFEU. The concept of abuse is an objective concept and the focus for the examination is the *behaviour* of a dominate undertaking which influence the market *structure*, resulting in weakened degree of competition and has the effect of hindering the maintenance of the degree of competition or the growth of competition. These behaviours are deemed as abusive since they are different from the normal condition of the competition.<sup>128</sup> The wording of ‘normal competition’ is quite vague, and therefore have many conducts been condemned under the article without being

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<sup>123</sup> Decision 97/ 624/EC *Irish Sugar plc* [1997] OJ L258/1.

<sup>124</sup> Furse, M., *Competition Law of the EC and UK*, p. 300.

<sup>125</sup> Cases C-40-48/73, 50/73, 54-56/73, 11/73, 113-114/73 *Coöperatieve Vereniging ‘Suiker Unie’ Ua a Commission* [1976] 1 CMLR 295.

<sup>126</sup> Decision 73/109/EC *European Sugar Industry* [1973] OJ L140/17.

<sup>127</sup> Cases C-40-48/73, 50/73, 54-56/73, 11/73, 113-114/73 *Coöperatieve Vereniging ‘Suiker Unie’ Ua a Commission* [1976] 1 CMLR 295, para 371, Furse, M., *Competition Law of the EC and UK*, pp. 300-01.

<sup>128</sup> See Case C-85/76 *Hoffman-La Roche v Commission* [1979] ECR 461, [1979] 3 CMLR 211, para 91

abnormal. The reason is that the undertaking already occupies a dominant position and the impact of its conduct therefore draws the Commission's attention.<sup>129</sup>

There are several different categories of behaviour that constitutes an abusive conduct and the list of abusive behaviours in article 102 TFEU merely gives examples and is not an exhaustive enumeration.<sup>130</sup> In addition, it shall be emphasized that a course of conduct may not be per se abusive, but with respect to the fact that the undertaking occupy a dominant position it is deprived of the right to adopt the certain conduct. This is due to the '*special responsibility*' that is imposed on undertakings with dominant positions. The responsibility implies that the undertaking shall not allow its conduct to impair genuine undistorted competition on the relevant market. Thus, even though the dominant undertaking can take action to protect its own interest when they are attacked by competitors, it is not allowed to strengthen its dominant position, which will be deemed as an abuse.<sup>131</sup>

The Commission has stated, regarding the interpretation of abuse, that the aim of competition policies is to protect competition in all perspective, not solely the competitors as such. The subjects for the protection under article 102 TFEU are customers, where the behaviour by the dominant undertaking is harmful for consumers. This abusive behaviour is often referred as exploitation. Nevertheless the article also aims to protect competitors, where the conduct is deleterious for competitors. This abusive behaviour is often named as anti-competitiveness. However, a conduct cannot be generalized into one of these subdivisions, since the conduct can be both exploitation and anti-competitiveness. The ECJ has established that the interpretation of the term abuse in article 102 TFEU shall cover all situations where the competitive market structure is placed in jeopardy. This included classic forms of *behavioural* abuse which operated directly to the detriment of consumers, but also *structural* abuse which weakened the competitive market structure. Thus the article covers anti-competitiveness, where the primary and direct injury was to

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<sup>129</sup> Furse, M., *Competition Law of the EC and UK*, pp. 304-05

<sup>130</sup> Case C-6/72 *Europemballage Corp. and Continental Can Co. Inc v Commission* [1973] CMLR 199, para 26.

<sup>131</sup> Case C-322/81 *Nederlandsche Banden-Industrie Michelin NV v Commission* [1993] ECR 3461, para 57; Case C-333/94P *Tetra pak International SA v Commission* [1996] ECR I-5951, Craig, P., de Búrca, G., *EU law*, pp. 1006-07.

competitors. In summary, a conduct is abusive if it constraints and limits the competition, including entry of new-comers, as well as if it harms the consumers.<sup>132</sup>

In contrast to article 101 TFEU, article 102 TFEU do not use the wording ‘object or effect’. Therefore it is not necessary to be able to demonstrate the actual effect of an abusive conduct. But rather, which has been established by the Court of First Instance (CFI)<sup>133</sup>, it is sufficient to demonstrate that the behaviour by the undertaking of a dominant position tends to restrict the competition, or, in other words, merely have the capability or are likely to do so, both in regards of exploitation and anti-competitiveness.<sup>134</sup> This reasoning by the CFI has meet criticism and some argue that the determination of the term abuse is too low since the threshold of abuse only requires the *potential* for harm, not the actual. In addition has the ECJ not provide any explanation for the rationale of these rules in law or competition policies.<sup>135</sup>

Further on, the categories of abusive behaviour are several. For instance the abuse could imply refusal to supply to other firms wishing to purchase its products. The obligation of the undertaking of a dominant position to supply other firms is based on the special responsibility mentioned above, which may lead to restrictions on the undertakings freedom to chose its trading partners. The refusal may imply several situation, where refusal to licence intellectual property rights (IPRs).<sup>136</sup> A refusal by a dominant undertaking to grant licence is not an abuse per se. But, however, the exercise of an exclusive right by the owner may, in exceptional circumstances, involve abusive conduct. The exceptional circumstances are, in particular;<sup>137</sup>

1. The refusal relates to a product or a service indispensable to the exercise of a particular activity on a neighbouring market,

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<sup>132</sup> Case C-6/72 *Europemballage Corp. and Continental Can Co. Inc v Commission* [1973] CMLR 199, Craig, P., de Búrca, G., *EU law*, pp. 1007-10, Discussion paper on the application of Article 82 of the Treaty to exclusionary abuses(December 2005), para. 54.

<sup>133</sup> Renamed as now the General Court by the *Lisbon Treaty*.

<sup>134</sup> Case T-219/99 *British Airways v Commission* [2004] 4 CMLR 19, para 293; Case T-203/01 *Manufacture francaise des pneumatiques Michelin v Commission* [2004] 4 CMLR 18, para 239.

<sup>135</sup> Kallaugher, J., Sher, B., *Rebates revisited: Anti-competitive Effects and Exclusionary Abuse under article 82*, ECLR

<sup>136</sup> Ezrachi, A., *EC Competition Law*, pp.169-70.

<sup>137</sup> Case C-418/01 *IMS Health GmbH & Co OHG v NDC Health GmbH Co KG* [2002] ECR I-5039, [2004] 4 CMLR 28, paras 34-35; Case T- 201/04 *Microsoft Corp v Commission* [2007] 5 CMLR 11, para 332.

2. The refusal is of such a kind as to exclude any effective competition on that neighbouring market, or
3. The refusal prevents the appearance of a new product for which there is potential consumers demand.

Another example that may be object for the provision under article 102 TFEU is certain price-settings. Even though aggressive price rivalry is a central part to effective competitive market, as it forces competitors to sell their products at the lowest profitable price, it may harm customers rather than benefit them. Such is the case when the dominant undertaking is engaging in predatory pricing. The behaviour implies a deliberated lowering of the prices in the short term of loss-making, in order to eliminate incumbent competitors or hinder new competitors from enter the market. The objective of this conduct is to increase the price above competitive levels, when the competition is eliminated, which ultimately harms customers. Thus, prices below average variable costs by means of which a dominant undertaking seeks the advantage of a monopolistic position are regarded as abusive.<sup>138</sup>

Since the article do not provide any exempting provision, in contrast to article 101 (3) TFEU, a conduct which is regarded as abusive can be excluded from probation. This qualifies that the dominant undertaking can provide an objective justification for its conduct, or show that the behaviour generates efficiencies which outweigh the anti-competitive effects. Therefore, one could ask the third question with a sub-question; 'If the dominate position is determined to being abused, could this be objectively justified? However is the defence claim difficult to proven and usually they are rejected by the Commission and the courts.<sup>139</sup>

#### **4.2.5 Breach of Article 102 TFEU**

The Commission has the power, when it has been found that breaches of procedural law have occurred, or substantive breaches of articles 101 and 102 TFEU have occurred, to impose fines and/or periodic penalty payments on undertaking pursuant to article 23 and

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<sup>138</sup> Case C-62/86 *AKZO Chemie BV v Commission* [1991] ECR I-3359, [1993] 5 CMLR 215, paras. 70-71, Ezrachi, A., *EC Competition Law*, p. 121.

<sup>139</sup> See e.g. Case T-228/97 *Irish Sugar v Commission* [1999] ECR II-2969, [1999] 5 CMLR 1300, Ezrachi, A., *EC Competition Law*, pp. 119, 125.

24 of Regulation 1/2003.<sup>140</sup> National authorities do also have the power to make certain decisions necessary for the application of articles 101 and 102 of the TFEU, with respect of the Commission's apex of the EU competition law under the terms of the regulation.<sup>141</sup>

The Commission's availability of the key power regarding individual cases is set out in article 7 of the Regulation. The article provides the Commission with power to, were it finds infringement, require the undertaking to bring such infringement to end by decision. It is the party or authority that alleging the abusive practices that carries the burden of proof. The onus then switches to the accused undertaking to show that the behavior can be objectively justified.<sup>142</sup> In article 23 (2) of the Regulation, it is listed the conducts that constitutes validated reason for impose fines. The conducts which warrants fines are; infringement of article 101 or article 102 of the TFEU (a), to contravene a decision ordering interim measures (b) or, last fail to comply with a commitment made binding by a decision (c). The imposed fine for each undertaking and association of undertakings participating in the infringement is however limited, and shall not exceed 10 percent of its total turnover in the preceding business year. Penalties can also be imposed if an undertaking, which is subject to investigation, commits procedural breaches, e.g. supply false or misleading information. Further on, article 24(1) list several conducts which validate a periodic penalty payments, e.g. fails to put an end to an infringement of article 101 or article 102 of the TFEU or fails to comply with a decision ordering interim measures etc. The periodic penalty payments are limited as well and shall not exceed 5 percent of the average daily turnover in the preceding business year per day.<sup>143</sup>

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<sup>140</sup> Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty OJ L 1/1, 04/01/2003.

<sup>141</sup> Art. 5 Regulation 1/2003. Furse, M., *Competition Law of the EC and UK*, p. 87.

<sup>142</sup> Art. 2, 7 Regulation 1/2003, Furse, M., *Competition Law of the EC and UK*, p. 87.

<sup>143</sup> 23(1),(2), 24(1) Regulation 1/2003, See e.g. Commission Decision C (2005) 1757 Furse, M., *Competition Law of the EC and UK*, pp. 120-121.

## 5 The interface between IPRs and Competition policy

### 5.1 General information

Exclusive rights protecting intellectual property are sometimes regarded as inherently conflicting with competition. Nevertheless, in contrast, are these rights de facto a prerequisite for effective and undistorted competition in regards of new technology and innovation. It enables inventors to protect their efforts, in contrast to an absence of IP rights (IPRs) where rival undertakings could appropriate the benefit of an inventor's efforts instead of improving the technology and develop new inventions. Thus, do the IPRs restrict some forms of competition, i.e. production and destitution, in order to allow and enhance others, e.g. inventors in innovation and quality, and consequently constitute a need to balance these different forms of competition.<sup>144</sup>

IP law provides, in a large extent, this balance by rules which limit the scope of the protection and the availability to be granted protection of the subject-matter, e.g. the four requirements for patentability of NCE. For instance, the TRIPs agreement limits the exclusive rights by permitting compulsory licence, which force the inventor to licence the product and is common especially within the pharmaceutical industry in order to put the medicaments on the market. However, the EU competition law can be applicable to utilization of intellectual property where this restricts the competition on the market, or alternatively if the exploitation is of such extent that it cannot be justified for the protection of the subject-matter, e.g. the innovation. In these kinds of situations the competition rules are applied in correspondence with the economic functions of both the protection provided by IP law as well as the prohibition of anti-competitive.<sup>145</sup>

When EU competition policies are applied on the utilization of legal rights and protections it should be based on their substantive feature and economic effects, rather than based on merely their classification as intellectual property. This has been established by the Court, which rejected an appellant, *Microsoft*, justification of dominant abuse under article 102

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<sup>144</sup> D.C Turner, J., *Intellectual Property and EU Competition Law*, p. 3.

<sup>145</sup> Art. 31 TRIPs Agreement, D.C Turner, J., *Intellectual Property and EU Competition Law*, p. 3, Domeij, B., *Pharmaceutical Patents in Europe*, pp. 292, 338

TFEU, with the implicit statement that the application of the article shall not differ if the subject-matter, relating to the abuse, is protected by an IPR, in this case by copyright.<sup>146</sup>

In addition, the EU competition law is autonomous, why ECJ has established that it shall be applied uniformly.<sup>147</sup> This also considers cases where the classification of corresponding rights and protections are different due to dissimilar national laws between the Member States, e.g. a subject-matter is regarded to be protected as an industrial or commercial property in one State and where the similar subject-matter is not being regarded as protecting such a property.<sup>148</sup>

In contrast to this, the recognition as intellectual property seem to confer a greater legitimacy and qualifies a right for protection by principles and provisions protecting the intellectual property. As an example two cases can be compared. In the case *Kohl v Ringelhan & Renett*, the ECJ did not consider that unfair competition could justify the restrictions on imports of products of French assignee of trading name. In contrast, in the case *Ideal Standard* with respect to the IP law, the restrictions on imports to Germany of products of French assignee of mark could be justified on the basis of trademark infringement.<sup>149</sup> The applicability of this principle was claimed, among other things, by the defendant company in the recent *AstraZeneca Case*<sup>150</sup>, which, moreover, is the object of analysis in this thesis. But the Court did not consider the principle was applicable. This also indicates that the IP law in a greater extent de facto provides, a possible, justification, in contrast to competition law, since the defendant claimed that the latter should be applied. The company's potential success under the IP law, however, is left unsaid.

The IP law provides the right for protection by, for instance, in article 17(2) of the Nice Charter of Fundamental Rights of the European Union, the TRIPs Agreement etc.

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<sup>146</sup> Case T-201/04 *Microsoft v Commission* [2007] ECR II-3601, [2007] 5 CMLR 11, paras, 227-299, Turner, D.C., J., *Intellectual Property and EU Competition Law*, p. 4.

<sup>147</sup> See e.g. C-245/500 *SENA v NOS* [2003] ECR I-1251, [2005] 3 CMLR 36, para. 23.

<sup>148</sup> Turner, D.C., J., *Intellectual Property and EU Competition Law*, p. 4.

<sup>149</sup> Case C-177/83 *Kohl v Ringelhan & Renett*, [1984] ECR 3651; Case C-9/93 *Ideal Standard* [1994] ECR I-2789, [1994] 3 CMLR 688, Turner, D.C., J., *Intellectual Property and EU Competition Law*, p. 4.

<sup>150</sup> See Case T-321/05 *AstraZeneca v Commission*, n.y.p.

Property rights, not only intellectual, are also given in article 345 of the TFEU as well as in article 1 of the *First Protocol* to the *European Convention of Human Rights*.<sup>151</sup>

Thus, one can conclude that the principal problem of the balancing between the IP law and the competition law is that they are, in several situations, directly incompatible with each other. Both with regard to the specific wording of each rule and policy, but also in conflict with each other with regards to the underlying objectives of the establishment of the EU laws and as the objectives are applied for interpretation of the rules.

Consequently, one could in simple words say that IP law confer rights and competition law restrict these rights. This fact, or statement if you will, subsequently constitutes the question of which discipline shall have priority and be regarded in a sense of being a superior legislation.

## 5.2 The European Courts' solution to reconcile

In several cases, the European Courts have endeavoured to find a solution in order to reconcile the economic criteria of EU Competition policy with respect for the property rights. Within the jurisprudence a principal is established regarding the hierarchy of legislation, in Latin called '*Lex specialis derogat lex generalis*'. The principal implies that that the special law shall prevail over the general law. This would mean that the IP law has priority before the EU competition law. The applicability of this principal was claim by the defendant in the *AstraZeneca* case. This argument has also been discussed by Hans Henrik Lidgard, but who states that it is hardly to be applicable. The General Court has established that so was the case and the principal was not applicable when there is an interface between the IP law and the EU competition law.<sup>152</sup>

Rather, has the Courts applied another solution which is founded on the basis that; EU competition law cannot affect the *existence* of intellectual property rights. But, the EU competition law can impose certain limits in regards of the *exercise* of the IPRs. This

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<sup>151</sup> Case C56, 58/64 *Consten and Grundig v Commission* [1966] ECR 299; case C347/03 *Friuli-Venezia Giulia per lo sviluppo rurale (ERSA v Ministro delle Politiche Agricole e Forestali)* [2005] ECR I-3785, paras. 118-134.

<sup>152</sup> Case T-321/05 *AstraZeneca v Commission*, n.y.p.; Lidgard, H., H., *Konkurrensrättsligt intrång i immaterialrättskyddat område*, p. 360 f.

presupposes that the limitations do not form a disproportionate encroachment which detrimental the *substance* of the rights.<sup>153</sup> The balance between these variables is ambiguous and anything but concrete for an interpretation and determination of the legal position. From a company perspective, such as the originators, it is very important that the balance between the rules and policies are clear in order to ensure that their conduct does not constitute a violence of EC competition law. Thus, a number of cases will be presented and examined with the aim of establish greater clarity of the legal situation.

As a first step, when the EU competition law is applied to a certain conduct, it must first be determine whether relevant IPRs *exist* for the purpose of EU law. If that is the case it must also, as a further step, be determined the IPRs' *justified scope* with regards to their *substance* and *specific subject-matter*.<sup>154</sup> In order to determine whether relevant IPRs exist for the purpose of EU law, three questions shall be taken into consideration;<sup>155</sup>

1. Whether the right which is put forward is correctly characterized as protecting intellectual property,
2. Whether the law which is said to confer it, is compatible with EU law, *and*
3. Whether the requirements of that law are in fact satisfied.

The first question could be hard to determine since the EU law does not provide any definition of the term '*intellectual property*' or any stated requirements for the judgement-process. In article 36 TFEU the older expression '*industrial and commercial property*' is used regarding the provisions on the free movement of goods between Member States. Earlier, in the ParC, the term '*industrial property*' was used. But, if the term '*industrial property*' was narrowly interpreted, it could result in that only rights in technology were object for protection, e.g. patents. Therefore, the TFEU use the earlier mentioned expression in order to not preclude any intellectual property, especially trademarks, which is to be considered as commercial property.<sup>156</sup>

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<sup>153</sup> Turner, D.C., J., *Intellectual Property and EU Competition Law*, p. 5.

<sup>154</sup> Ibid.

<sup>155</sup> Ibid p. 6.

<sup>156</sup> Turner, D.C., J., *Intellectual Property and EU Competition Law*, p. 9.

In regards of prohibition of anti-competitive practice, the term ‘industrial and commercial property’ has not been regarded. Instead the focus has been on ‘*mandatory requirements*’ which justify the precedence over the free movement of goods.<sup>157</sup>

However, in relation to patents, the ECJ has stated that industrial property is the guarantee that the patentee, to reward the creative effort of the inventor, has the exclusive right to use an invention as well as the right to oppose infringements.<sup>158</sup> In contrast, the freedom to use a generic description was held by the ECJ to not constitute a property right.<sup>159</sup>

In regards of the second question, the existence of IPRs validly granted or recognized under national law are, normally, accepted under EU law. But, this provides that the national law has the minimum characteristics and criteria of a law for the protection of intellectual property.<sup>160</sup> For example, a patent granted in a Member State is valid under the EU law if, and only, it meets the requirements established in the EPC. But, in the situations where the EU has adopted legislation with the intend to regulate comprehensively the conditions for protection of a particular form of intellectual property, the protection of such intellectual property provided by national law is, and only, justified if it is in accordance with the EU legislation.<sup>161</sup>

Finally, for the determination of the existence of IPRs, some rights needs to be *officially* granted and maintained in order to exist. That applies to, for example, patents and SPC. The question of whether a patent is in force or not can easily be done by examines relevant register, for instance national patent office. Nevertheless, even though it is in force, its validity can be challenge under the EU competition law.<sup>162</sup>

In addition, it shall be mentioned that the objectives of EU treaties and rules according to international conventions, e.g. TRIPs Agreement, may be taken into consideration when

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<sup>157</sup> See e.g. case C-255/97 *Pfeiffer Grosshandel GmbH v Lova Warenhandel GmbH* [1999] ECR. I -2835

<sup>158</sup> See e.g. case C-15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* [1974] ECR 1147, para. 9.

<sup>159</sup> Case C-306/93 *SMW Winzersekt GmbH v. Land Rheinland-Pfalz* [1994] ECR I-5555, para. 23

<sup>160</sup> Case C-144/81 *Keurkoop BV v. Nancy Kean Gifts C.* [1982] ECR 2853.

<sup>161</sup> Cases C-129/97 and C-130/97 *Chiciak and Fol* [1998] ECR I-3315 paras. 29-30; Turner, D.C., J., *Intellectual Property and EU Competition Law*, pp. 10-11.

<sup>162</sup> Case C-35/83 *British American Tobacco (BAT) Cigaretten-Fabriken GmbH v Commission* [1985] ECR 363; Turner, D.C., J., *Intellectual Property and EU Competition Law*, pp. 13-14.

determining the existence of IPRs.<sup>163</sup> The TRIPs agreement, even though EU per se and together with its Member States is a party in of the agreement, is not directly applicable on EU's internal legal order. Nevertheless, the EU law as well as the national law shall be interpreted in the light of the agreement's wording and its purpose.<sup>164</sup> But, in regards of primary provisions of the EU law, the CFI has established that the corresponding interpretation is not applicable since international agreements, always, are not superior of these provisions.<sup>165</sup> This is very relevant fact, due to the fact that article 101 and 102 TFEU, is primary law. Therefore, one could ratiocinate that the TRIPs agreement, which confer and enhance the IPRs, does not have the legal authority to limit the competition provisions for the purpose of improving the proprietor's rights, when those two are conflicting with each other.

As explained above, when it has been determined that relevant IPRs do exist for the purpose of EU law, it must also be determined which restrictions are *justified* to protect its substance or subject-matter. When the assessing of the scope of the protection of the subject-matter which can justify the restriction under EU law, certain variables are taking into consideration. This could be the functions and quality of the intellectual property, EU legislation and Other EU objectives and fundamental rights.<sup>166</sup> Therfor some illustrating examples will be provided.

Patents' essential function is to reward the inventor, e.g. originator, for the efforts of innovation, which in this case are the R&D and its conjunctive costs. This statement was established by the ECJ in the *Centrafarm v Sterling Drug* case. The Court held that a patentee are authorized to exercise the rights confirmed by a patent for the purpose of protecting and controlling the distribution of a pharmaceutical product, without responsibility to protect the public against defects from it. This is due to the fact that these considerations

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<sup>163</sup> See e.g. case C-200/96 *Metronome Music GmbH v Musik Point Hokamp GmbH* [1998] ECR I-1953, [1999] FRS 576, para. 25.

<sup>164</sup>See e.g. case C-53/96 *Hermès International v FHT Marketing Choice BV* [1998] ECR I-3603, para 28; Turner, D.C., J., *Intellectual Property and EU Competition Law*, pp. 6-7.

<sup>165</sup> Case T-201/04 *Microsoft v Commission*, para 798.

<sup>166</sup> Turner, D.C., J., *Intellectual Property and EU Competition Law*, p.16

underlying the protection of industrial and commercial property are distinct and not related to the scope of protection.<sup>167</sup>

Further on, the quality of the intellectual property might be relevant to the application of EU competition law, when it affects the scope of protection which has been provided according to properly intellectual property law. In the *Windsurfing International* case, which concerned a licensing agreement, the ECJ held that there was no justification on grounds of the protection of an industrial property right. The reason was mainly because the Court established that the scope of the patent did not cover parts of the sailboard which were object for clauses in the agreement. The scope is determined on the basis of the subject-matter which is specified in the patent claims. Subsequently, the agreement become object for a judgment under article 101 TFEU in regards of restriction of competition and obstacle to intra-community trade.<sup>168</sup>

As a last step of the examination process is to determine the *specific subject-matter* and its scope as well as the *substance* of an IPR. The specific subject-matter of an IPR assesses the inventor's right to pursue certain conducts. Regarding patents, the specific subject matter of the IP has been established by the ECJ in the *Centrafarm v Sterling Drug* case. This case has been mentioned above regarding the function of patents. The specific subject-matter, established in this case, is the guarantee that the patentee has the exclusive right to use an invention. This comprise manufacturing the industrial products and putting them into circulation for the first time, either directly or by the grant of licenses to third parties, as well as the right to oppose infringements.<sup>169</sup>

The specific subject-matter, i.e. legitimate conduct, also includes the right to place a product or a relevant product, which is protected protection, on the single internal market.<sup>170</sup> When the purpose is to put a product on the market, the product is regarded, to be that, and only, when it is *actually* sold in the single internal market to an independent market. Therefore, situation in which the goods are offered for sale to a purchaser who, in all likelihood, will release them for free circulation and market them in the Community.

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<sup>167</sup> Case C-15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* [1974] ECR 1147, paras. 9, 26-30.

<sup>168</sup> Case C-193/83 *Windsurfing International v Commission* [1986] ECR 611, paras. 23-36.

<sup>169</sup> Case C-15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc* [1974] ECR 1147, para. 9; see also case C-316795 *Generics BV v Smith Kline & French Laboratories Ltd* [1997] ECR I- 03929, para 20.

<sup>170</sup> Turner, D.C., J., *Intellectual Property and EU Competition Law*, p. 25.

Regarding whether the product actually has been put on the market, ECJ has stated that the onus of proving is lying with the patentee proprietor who alleges that the goods will not be released for free circulation in the Community.<sup>171</sup>

Further on, as an additional right of conduct, the proprietor has the right to oppose infringements. The infringement arises when a protected product or a relevant market is placed on the market without the proprietor's consent.<sup>172</sup> In the *Volvo case*<sup>173</sup>, the legal issue concerned a potentially infringement of Volvo's sole and exclusive rights in form of a model design by a UK company. The ECJ stated that the right of the proprietor, i.e. Volvo, of a protected design to prevent other parties from manufacturing and selling or importing the products constitutes the very *subject-matter* of his exclusive rights. If the proprietor was obligated to grant a licence to a party, he would be deprived of the *substance* of the exclusive rights. Therefore the conduct is justified by the IP law and a refusal of granting a licence cannot constitute an abuse of dominant position per se under the competition law, in this case article 102 TFEU.<sup>174</sup> However the exercise of an exclusive right by the proprietor of a design could be prohibited under article 102 TFEU. This applies when the proprietor holds a dominate position and pursue certain abusive conducts such as arbitrary refusal to supply even though the product are still in circulation. But, this prohibition applies, and only, when such conduct is liable to affect trade between Member States. This requirement; affecting the trade, is the very core of the limitation of IPRs that the competition law constitutes.<sup>175</sup>

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<sup>171</sup> Case C-405/03 *Class International BV v Colgate-Palmolive Co* [2005] ECR I-8735, paras. 54, 74.

<sup>172</sup> Case C-187/80 *Merck & Co. Inc. v. Stephar BV* [1981] ECR 2063, para 4.

<sup>173</sup> Case C-238/87, *AB Volvo v Erik Veng (UK) Ltd*, [1988] ECR 6211.

<sup>174</sup> *Ibid* para 8.

<sup>175</sup> *Ibid* para 9.

## **6 Pharmaceutical sector inquiry**

### **6.1 Description of the inquiry's content**

The pharmaceutical sector inquiry,<sup>176</sup> by the European Commission, was launched in 2008-2009 under Article 17 of Regulation 1/2003<sup>177</sup> with the aim to investigate the competition in the pharmaceuticals sector. The purpose was to conduct inspections at the premises of a number of innovative and generic pharmaceutical companies. The inquiry focused on the alleged obstacles to enter the market. The focus of obstacles were mainly in regards of generic drugs to enter the market, where behaviors and applied conducts by the originators were objects for the investigation, with the awareness that these behaviors in generally relies on the regulatory environment<sup>178</sup>

### **6.2 Applied Strategies within the Pharmaceutical Industry**

#### **6.2.1 Strategies during the Drug Life Cycle**

In chapter 2 of the thesis, a presentation has been given of the different processes of the development of a drug as well as the obligation of receiving approval from the medical authorities. Further on, the exclusive rights has been presented in terms of patent protection, its duration and so on. Consequently, the life cycle of a drug can be divided into three phases, which first is the pre-launch period where R&D as well as regulatory approval taken place. Secondly the marketing and sales phase, which is the period that the originators enjoy the exclusivity through patent protection. The last phase is after the LoE, when the generics and the competitive originators can start to produce the drug since the patent protection has expired. Between the first and the second phase, the company aim of to maximizing the profit derived from their patented products in order to finance the cost of the R&D as well as the NCE which failed the test-processes. During each of these phases of the drug's life cycle, different patent strategies are applied by the originators. These strategies are used to the benefit of the companies in relation to the generics. The originators use the patent law system in order to be able to apply the various strategies. The

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<sup>176</sup> Pharmaceutical sector inquiry – *Preliminary Report*, European Commission, adoption date: 28 November 2008 (hereinafter referred as Primarily Report); Pharmaceutical sector inquiry – *Final Report*, European Commission, adoption date: 8 July 2009 (hereinafter referred as Final Report).

<sup>177</sup> Council Regulation (EC) No 1-2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.

<sup>178</sup> Final Report paras. 2,3.

business strategies of the drug are crucial for the originators, in order to maintain and protect their market position, which many times are a dominant. The measures vary from strategic patenting in regards of the timing and scope of filing, to patent litigation and interventions before national regulatory authorities. But also other measures such as enhancing product loyalty or the introduction of product differentiation or a commercial switch to a follow-on product.<sup>179</sup> Important in this context is to be aware of the fact that the generics might try to enter the market before the patent protection has expired. Obviously, the generics are only able to do so if they do not constitute infringement. Therefore they are trying to find ways, e.g. loophole of the protection, to enter the market. It could also imply to discover that the patent which the originator is relied upon is not valid, in particular if it is annulled prior to the formal patent expiry date.<sup>180</sup>

### **6.2.2 Patent clusters**

The concept of creating a patent cluster is to file several patent applications, sometimes over thousand as mentioned, to increase the protection and make it more imperviously. The originators are able to file and obtain different patents due to the different claims. The claims could differ in terms of dosage forms, the production process or for particular pharmaceutical formulations. But, still, it is essentially the same medicine with the same NCE. Hence, if the generic company succeeds to get the one of the patent invalidated, they still cannot enter the market due to the fact that the originator has another, several, patent that protect the drug. This is usually called ‘a multilayered defense’. The same pass for the generic’s entering to the market after LoE. If several additional patents have been filed and obtained during the base patent duration of protection, the term of protection of the drug extends beyond the twenty-year, and the possible SPC, term. Further on, the commission could in its investigation confirm that patent applications are filed at regular intervals over a 20-year period following the first filing of an application for a given NCE.<sup>181</sup>

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<sup>179</sup> Final Report, paras. 128-130, 465-467 and Glossary p. 9.

<sup>180</sup> Final Report para. 464.

<sup>181</sup> Final Report paras. 476-477, 496, Preliminary Report, Conclusion p. 401, See Attachment No. 4.

### 6.2.3 Divisional patent application

Another applied strategy by the originators is, according to the Commission, to file so-called divisional patent application. This type of application is commonly filed before the EPO and legitimate by the EPO.<sup>182</sup> A divisional patent application implies that the applicant divides out from a main patent application, the so-called ‘parent application’, one or several, either identical or narrower, patent applications, the so-called ‘divisionals’. This type of conduct can be applied voluntarily or mandatorily. A divisional application can only be done when the examination of the parent application is still pending.<sup>183</sup> But, when the divisional has been created, it is an individual application and separated from the parent application. This implies that it would still be pending even if the parent patent application is refused or revoked.<sup>184</sup> The main reason for divisionals, in conformity with patent clusters, is to prevent and delay the generics’ entry. This is due to the fact that the divisional applications prolong the period of legal uncertainty since the procedure ‘reset the clock’, given the originators more time for patent examination, thus extending the period where applications are pending. In addition, as above mentioned, each divisional application needs to be assessed individually. Consequently, a successful challenge of a parent application will not create legal certainty as long as several other divisional applications are still pending. Thus, it obstruct the generics to gain clearness and an overview of which claims that have been granted, which have been refused and which are still pending, regarding the same drug and its NCE. Subsequently the generics are unsure as to what they can reproduce without infringing any patents, even if the parent patent application has been refused or revoked.<sup>185</sup>

### 6.2.4 Patent litigation

The above explained strategies have, as mentioned, the aim of hinder or delay the generics’ enter of the pharmaceutical market. However, despite the fact of a possible infringement, the generics might start producing generic copies of the original drug and enter the market at risk. In those cases, the originators apply procedural enforcement strategies, which

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<sup>182</sup> Art. 76 EPC.

<sup>183</sup> Rule 36(1), (2) EPC.

<sup>184</sup> Final Report, paras. 431, 507, 509.

<sup>185</sup> Final Report, paras 507, 517- 518, 523.

normally lead to patent litigation, but can also result in settlements.<sup>186</sup> Enforcement of the patent's exclusivity is an indirectly right of the protection of the product.<sup>187</sup> The reason for why patent litigations are efficient strategies is mainly cause of its duration. According to the sector inquiry, the duration of patent litigation varied considerably between Member States with an average duration of 2.8 years.<sup>188</sup> During this period the originator has the possibility to apply for the court to issue an interim injunction pursuant to the Enforcement Directive<sup>189</sup> An interim injunction is a provisional restraint and implies that the generic are not allowed to sell the generic drug until a final judgment of the merits of the case has been given. In addition, the originator needs to provide the court with minimum grounds for its claim pursuant to the Directive.<sup>190</sup>

### **6.2.5 Development of Patents Portfolio by Follow-on drugs**

Finally, a last strategy will be presented which is related to all the above presented strategies since it constitutes a foundation of the business strategy. Follow-on products are part of a life cycle strategy that goes beyond the pure patent strategies and that in addition involves marketing and promotion strategies, as well as other practices discussed in previous sub-chapters.<sup>191</sup> The strategy is related to the originators' R&D processes and the aim of create new inventions. The inventions do not need to be a NCE, but could be develop and improve an already existing drug. These products are called the follow-on products and might only imply small changes of the original drug, but still have a satisfactory applicability for a need. For example, it could imply a change of the medical administration trough tablets that are easier to swallow. The purpose is then to switch from first NCE to the follow-on product.<sup>192</sup>

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<sup>186</sup> Final Report, para. 538.

<sup>187</sup> Art. 64(2) EPO, art. 7 The European Convention on Human Rights, Rome 4 November 1950, Final Report, para 537.

<sup>188</sup> Primarily Report, p. 10.

<sup>189</sup>See art. 1, 4, 10 Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights OJ L 157/ 45 (the Enforcement Directive)

<sup>190</sup> Art. 6(1), 13 (2) the Enforcement Directive; Final Report, paras. 544, 640

<sup>191</sup> Final Report, para. 989.

<sup>192</sup> Final Report, paras. 987, 1016. Domeij, B. *Läkemedelspatent*, p. 11,313.

### 6.3 Conclusions and analysis of the Sector Inquiry

By the pharmaceutical sector inquiry, the Commission presented information regarding the pharmaceutical market within the EU. Both sides of the competing companies were obligated to provide the Commission with information, both official and unofficial. In addition the companies had the opportunity to present their view of the conduction within the market, such as in regards of applied strategies. The main reason for the inquiry was due to indication that the competition between originators and generics might be restricted or distorted. The report emphasized that patents are key in the pharmaceutical sector, as they allow companies to recoup their often very considerable investments. Further on, the Commission could see a trend of less innovation of NCE. The reason for the lack of such innovation, among other things, was and still is the preferable development of follow-on products. In addition, the Commission could conclude that the applied strategies prevented and delayed the generics entry. Hence, the Commission could clarify how industry operates in the existing legal framework. The results of the sector inquiry suggest that the behavior of originators contribute to obstacles for generic entry, but acknowledged that other factors, e.g. the regulatory framework, might also play an important role.<sup>193</sup>

The sector inquiry *identified* a number of issues that justify further inspection under the competition rules as well as an identification of *specific needs* for action with relation to the competing companies' behavior. The knowledge of these identifications will according to The Commission benefit all interested parties in their understanding of the competitive relationships in the sector.<sup>194</sup>

One could say that the sector inquiry report is a summary, or if you will; an official printed document of unofficial information, of the facts and conducts on the pharmaceutical market. However, the parties on the market are already, obviously, aware and have knowledge of the identified circumstances since it is a part of their day-to-day faced problem with the aim of overcoming with different measures. When the originators gave input regarding the applied patent strategies, they stated, rather than were forced to admit, that it was an important part of their business and that the conduct de facto is strategies

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<sup>193</sup> Final Report, paras. 4, 1554-56.

<sup>194</sup> Final Report, paras. 1555, 1663.

applied in order to prevent or delay the generic entry. However the originators cannot be blamed for applying these strategies, since it is a natural part in each and every company, regardless of which industry it is engaged in. In addition, the patent law does not provide any restrictions of the patenting strategies nor limitation of the conducts since it, according to the EPO, are and also should be no difference between patenting a NCE or a follow-on product, as long as the requirements for patentability is fulfilled<sup>195</sup>

However, even if the strategies are lawful and the follow-on product are considered to meet the requirements under the patent law, EPC, the strategies also needs to be judged under the EU competition law. The strategies might therefore in spite of everything constitute a breach of the law, since it constitutes unfair competition. Since, the Commission could establish that the applied strategies de facto hinder the generic enter of the market and consequently it stated that these conducts *may* interfere with the development of a competing medicine. So is the case especially when the strategies mainly focus on excluding competitors without pursuing innovative efforts, the co-called ‘defensive patent strategies’.<sup>196</sup>

Consequently, the Commission do not state whether the strategies are lawful or not under the competition law and on which grounds such judgment would be based on, if a strategy considered being illegitimate after all. The Commission confirmed this lack of determination and stated several times that the purpose of the investigations was not to provide guidance as to the compatibility of certain practices with EC competition law.<sup>197</sup> In addition, the Commission did not provide any reasons or answer why the sector inquiry did not investigate and judge the strategies legality from an EU competition law-perspective. This occurs to be odd, since the EU institution has the authority as well as its task to ensure fair competition within the Union.<sup>198</sup> Further on, the Commission stated that the strategies do delay generics entry, and therefore will be subject to competition examination *if* they are used in an anti-competitive way, which may constitute an infringement under Article 102 or 102 TFEU. In addition, the Commission will, where *appropriate*, make full use of its powers under antitrust rules, e.g. articles 101 and 102 TFEU, and closely cooperate

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<sup>195</sup> Final Report, Footnotes 375-76, 391.

<sup>196</sup> Final Report, para. 1562.

<sup>197</sup> See e.g. Final Report, paras. 703, 992.

<sup>198</sup> Art. 105 TFEU, Regulation (EC) No 1/2003.

with the national authorities to pursue any antitrust infringement in the sector.<sup>199</sup> In conformity with the non-answered lawfulness of the strategies, the Commission does not provide any guidance when or on which grounds a strategy can be determined to be used in an anti-competitive way, and therefore is appropriate to be object for a more thorough investigation. This constitutes the question of whether all conducts that are similar or may initially be perceived as strategies shall be investigated under the competition law.

The Commission also stated that both intellectual property rights and competition promote innovation and a competitive market economy, by encouraging undertakings to invest in developing new or improved products and processes.<sup>200</sup> However this is a truth with slightly modification. The patent law, in regards of the judgment of the patentability of an invention, does not make any difference between the new drug and follow-on drug. Therefore the law indirectly de facto conduces to the hinder of the generic entry, which would not be the case if the requirements of patentability differed between the two types of innovation. Yet, one could not say that IPRs do not promote competition, although in practice it leads indirectly to limitation of the competition within the market.

However, since the follow-on product many times is similar to the first drug, the originators continue to profit from the original product, although the patent protection has expired. Therefore, one could say that these types of strategies de facto extend the patent period provided in the EPC. Still the question stands; whether the conduct of R&D constitutes unfair competition or if the follow-on product is a 'purely' innovation which should enjoy exclusivity in contrast to be considered as a conduct that constitutes a breach of the EU competition law.

Regarding the interface between the IP law and the competition law, the only provision the Commission gives in the question is; *If the existence and exercise of an industrial property right are not of themselves incompatible with competition law, they are not immune from competition law intervention. However, certain practices can only be an infringement in exceptional circumstances.*<sup>201</sup>

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<sup>199</sup> Final Report, paras 1572, 1564.

<sup>200</sup> Final Report, para. 1568.

<sup>201</sup> Final Report para. 1568.

The fact that IPRs is not immune from competition law is well known since a long time back, due to the case law provided by the EU courts, national courts and decisions by the Commission. For instance where a behavior that constitute abuse of dominate position under article 102 TFEU, it cannot be justified with an IPR.<sup>202</sup> Further on, in the Commission do not provide any guidance which cases are to be consider as exceptional, nor which measurements that shall be taken into consideration when judging the strategy, or other conducts by the originators. In summary, the wording is pretty ambiguous and do not assists the legal issue with any solutions in further extent.

In summary, the pharmaceutical sector inquiry by the Commission does not address the legitimacy of the presented strategies which are applied by the originators. This may seem peculiar since it in fact is the most essential question relevant to the problems. Which elements that will form the basis of the assessment of the strategies' legality in relation to the non-correspondence of the patent law and the EU competition law, are still pending and unanswered. Rather, one could say that the survey is a compilation of facts, facts that both the originators and the generics are already, obviously, aware of. Subsequently, the originators' applied strategies' legality is still uncertain, due to the vague statements by the Commission in the report. In order to obtain additional, more apparent and adequate, guidance of the strategies' possible unlawfulness under the competition law, the AstraZeneca case will in next chapter be object for an investigation and analysis.

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<sup>202</sup> Decision 2006/857/EC *AstraZeneca Plc* (Case COMP/A. 37.507/F3) [2005] OJ L 332/24, appealed in; Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010], not yet reported.

## 7 The AstraZeneca Case in 2010

### 7.1 General information

On 15 June 2005 the European Commission adopted a decision<sup>203</sup> where the pharmaceutical companies AstraZeneca AB of Sweden and AstraZeneca Plc of the UK (hereinafter AZ) was fined EUR 60 million for abuse of dominant position.<sup>204</sup> The subject-matter of the issues was the originator's blockbuster drug Losec,<sup>205</sup> which is used for acid-related gastro-intestinal diseases and conditions, and is in medical terms a 'proton pump inhibitors' (PPIs). In relation to that type of drug are the so-called H<sub>2</sub>-blockers, which also are applied for acid-related gastro-intestinal diseases and was first developed by GlaxoSmithKline and put on the market 1976. The drug is AZ's most important drug ever and at the time for the decision, the best selling drug in the whole world, with the total annual revenue of \$ 6, 3 billion in 2000.<sup>206</sup>

In principle all the strategies presented in the chapter above was applied on Losec, in order to hinder competition and maintain the market shares. The drug has been protected by several patents in regards of, for instance the active chemical substance, i.e. NCE, the chemical formulation, the manufacturing process and the first as well as second indications. The company has therefore created a patent-cluster with layers of patents that protect different aspects of the drug. However, the patent protecting the active substance, which is Omeprazol, is one of the most important patents in relation to the generic competition. This is due to its well-defined features and specific formulation of the claims, in contrast to the patent, for instance, that is protecting the manufacturing process which is easier to find alternative processes without constitute infringement.<sup>207</sup> However, the NCE patent for Omeprazol began to expired in 1999, since the date for the expiry of the patent differ due to the fact that each national patent is granted different dates.

Consequently AZ applied the strategy of developing a follow-on product in order to prolong the life cycle of Losec and extend the patent portfolio. The second generation

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<sup>203</sup> 2006/857/EC: Commission Decision C (2005) 1757 final of 15 June 2005 relating to a proceeding under Article 82 [EC] and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 – AstraZeneca)

<sup>204</sup> 2006/857/EC.

<sup>205</sup> Losec®, efficient substance; *Omeprazol*, produced by AstraZeneca.

<sup>206</sup> Lidgard, Hans Henrik, *AstraZeneca-domen – ett tufft besked för originaltillverkare av läkemedel*, p. 575f.

<sup>207</sup> Lidgard, Hans Henrik, *AstraZeneca-domen – ett tufft besked för originaltillverkare av läkemedel*, p. 575f.

product was a development of the chemical formulation where the original patent was for Omeprazol and the follow-on was for Esomeprazole. Thereby, the company aimed to switch patients to the new product with the claim that the follow-on product had improved efficacy over the original omeprazole.

However, since the patent protecting the original product were about to expire and the switch to the second generation product was time consuming since it required extended efforts, a potential time-gap could be detected. This has been confirmed by an internal document of AstraZeneca, in the decision of the Commission;<sup>208</sup> *‘Total omeprazole market share will probably be quite stable, but a big part of the Losec market share will most likely be taken over by generics in 2000-2001. Esomeprazole is scheduled for launch August 2000. It will be very difficult to launch esomeprazole successfully, since Astra by this time will not be the market leader and the price gap between esomeprazole and generics will be large.’*

Thus AZ needed to resort its tool-box in order to delay the generic entry until the switch took place, a so-called ‘bridging strategy’. One of the strategies was to withdraw the marketing authorisation for AZ's own old product, thereby removing the reference pharmaceutical, which generics needed at the time to obtain their market authorisation.

The old product Losec *capsules* were object for a development where the administration of the product were changed resulting in the follow-on product Losec MUPS *tablets*. This strategy succeeded in part in some of the Member States in keeping generics off the market for an additional period.<sup>209</sup> Further on, AZ applied for SPC in order to prolong the exclusivity of the original product Losec and consequently gain additional time for the switch-process. In summary, the two strategies provided AZ with above all two advantages. Partly, could they prolong the time before the LoE of the Omeprazol and partly did it hinder the generics to be able to obtain market authorisation. Due to this conducted strategies, the Commission held AZ for abuse of dominant position due to two main grounds. First, that AZ misused the patent system in order to obtain SPC protection and second, that AZ misused the pharmaceutical regulatory system by selective withdrawal

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<sup>208</sup> Decision 2006/857/EC, para. 299.

<sup>209</sup> Final Report, para. 1033-34, 35

of certain marketing authorisations. The conduct was done with the aim to prevent or delay the market entry of competing generic medicinal products.<sup>210</sup>

The company appealed the decision by the Commission and on 1 July 2010 the European General Court issued its judgment.<sup>211</sup> The Court largely dismissed the appeal, but reduced the total fines due to a failure by the Commission to prove certain aspects related to the second abuse. On 16 September 2010, the AZ appealed the judgment by the General Court,<sup>212</sup> where the company claimed that the Court should set aside the judgement, annul the decision or alternatively reduce the imposed fine. AZ claims that the General Court has erred in law regarding the definition of the relevant product market, where the claim is based on two grounds.

## 7.2 The General Court

### 7.2.1 Relevant market and dominance

As explained in chapter 4, to determine whether AZ's conduct constituted abuse of dominant position pursuant to the decision by the Commission, the General Court examined if the company occupied a dominant position with respect to the relevant market. The relevant product market concerned products that were applied for the treatment of acid-related gastro-intestinal diseases and conditions, where the AZ possessed a significant position due to its blockbuster drug Losec. In addition, did the drug occupy the leading position of PPIs, since the AZ were the patent holder of the NCE, Omeprazol. In addition to the PPIs were the H2 blockers, which also were products that were applied on gastro-intestinal diseases. The question was therefore whether these two jointly constituted the relevant product market or if they could be distinguished from each other. According to the Commission's decision the PPI comprised a separate market of its own.

The determination was based PPIs' mode of action, which is rather unusual since the process of the determination of the product market normally do not investigate the drug

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<sup>210</sup>Lidgard, Hans Henrik, *AstraZeneca-domen – ett tufft besked för originaltillverkare av läkemedel*, p. 575 f..

<sup>211</sup> Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010], not yet reported.

<sup>212</sup> Case C-457/10 P *AstraZeneca AB, AstraZeneca plc v against the judgment of the General Court (Sixth Chamber, Extended Composition)* [2010] OJ 301/27

that thoroughly, but only bases the decision on the medicine's therapeutic effect. The data for the base of the determination contained detailed information on the inter-relationship between the two types of drugs, in regards of price and sale trends, during a ten year period. In addition, were a thorough analysis carried out the Commission could conclude that there was a significant cases where only the PPI would be appropriate for the treatment. The General Court confirmed the determination of two distinct market by the Commission, since the high price of PPIs was not influenced by the lower price of the H2 blockers.

In regards of the dominance, the Commission found that AZ held a dominant position on the PPIs market in Belgium, The Netherlands, Sweden (from 1993 until the end of 2000), Denmark and the UK (from 1993 until the end of 1999) and Germany (from 1993 until the end of 1997). In conformity with the determination of the relevant market, the Court confirmed the dominant position as well. The Court stated that the dominant position of PPIs was not questionable, since AZ had a market share of 55 percent to 100 percent sales of PPIs in the relevant countries in these periods as well as the higher prices of Losec. Due to the fact that AZ was the first on the market with a PPI and upheld patent protection for Losec, which resulted in that they were not significantly constrained by its competitors, customers and suppliers, the court held as a *further* indication of dominance.

### **7.2.2 Abuse of dominance**

The AZ's abuse of dominant position comprised two different behaviors relating to two separate legal systems. The first was regarding the patent system, where AZ had applied for and bin granted SPC for Omeprazol in several Member States. The second abuse concerned procedures and conditions under EU and national regulations of pharmaceutical products relating to the marketing authorization. The below chapters will present the two abuses and the grounds for the general Court's judgment.

### 7.2.3 The first abuse

The first abuse of dominance concerns AZ's 'misrepresentations' of statements in their application for SPC<sup>213</sup> to various national patent offices. The misrepresentations are regarding the date of the granted marketing authorization, which is the basis for the calculation of the duration of the SPC protection of omeprazol. Due to the fact that the calculation of the SPC-duration is based on the date when the first marketing authorisation was granted,<sup>214</sup> the specific date of authorization is the essence of the prolonged exclusivity. Further on, the first date of authorisation in the Union also determines whether it is possible to gain a SPC in a Member State. The member States can be divided into three types; '1982-States', '1985-States' and '1988-State' depending on the required date of the first marketing authorisation. As an example, if the date for the first authorisation was in 1987, protection cannot be given in the '1988-States'. The AZ stated that the 'first authorisation date' was March 1988 in Luxemburg, which provided the company with an additional period of protection in some of the Member States for a period of several months. The Commission opposed the date, whereas it stated that the actual date for the marketing authorisation de facto was in France 1987. Therefore, AZ has wrongly under the SPC system gained additional protecting for Losec, resulting in excluding the possibility of generic competition.

The General Court upheld the Commission's findings of misleading representations to patent offices. The court stated that misleading information to patent office, where the applicant is not entitled or is entitled for a shorter time to SPC, constitutes; "*a practice falling outside the scope of competition on the merits which may be particularly restrictive of competition*"<sup>215</sup>

This conclusion could be reached by the General court without needing proof that the resulting SPCs had been enforced, and without needing proof that AZ was still in a dominant position at the time when the SPCs provided the supplementary protection. Further on, even though patent strategies, i.e. the misleading representations, did not provide AZ with SPC protection in Denmark and the UK, and although the SPCs were

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<sup>213</sup> Regulation EEC No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products OJ No L 182 /1.

<sup>214</sup> Art. 13 Regulation EEC No 1768/92.

<sup>215</sup> Case T-321/05 , para. 355, 375.

revoked in Germany and Norway, did not change that AZ's conducts were of abusive nature. The establishment of the abuse was on the basis that AZ's behavior was objectively of such a nature that it restricted the competition. Therefore the Court stated that there was no need for proof of any deliberate of the conducts liable for misleading the national authorities.

AZ submitted that the relevant legislative provisions regarding the first authorisation date in the Regulation has been interpreted with respect to the date where the company *actually* could put the product on the market, ergo when marketing authorization and; approval of price-setting authorization, have been granted. AZ had, in other words relied upon the 'effective-marketing'-theory, for the determination of the date and therefore the company argued its good faith before the Court. In addition, in regards of the date of authorization, another case can be mentioned. In the *Hässle AB v Ratiopharm* case,<sup>216</sup> it was argued that the wording in article 13 of the Regulation 1768/92, that the wording 'authorization' differs from that used elsewhere in the regulation and can therefore refer to both the marketing authorization as well as the approval of price-setting. However, this argue was rejected by the ECJ and therefore shall the relevant date be the date of technical marketing authorization. In the AZ case, the Court held that proof of bad faith, regardless of the interpretation's legitimacy, was not required and that the abuse subsisted in AZ's failure to disclose the interpretation that it had applied and in the objectively misleading nature of AZ's SPC applications.

#### **7.2.4 The second abuse**

The second abuse of dominance concerns AZ's misusing of the rules and the procedures applied by the national regulatory authorities in order to grant marketing authorization. Since the generics are able to use the data from the tests of the original product, when the RDP has expired, the generics are not required to conduct these expensive and time-consuming tests. Therefore, the generics totally relay on the already submitted data in order to obtain a marketing authorization for the launching of the generic product.

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<sup>216</sup> Case C-127/00 *Hässle AB v. Ratiopharm GmbH* [2003] ECR I-14781.

Since AZ had developed a follow-on product, Losec MUPS tablets, the company deregistered the marketing authorization for the old Losec capsules at the time when new Losec were to be launched. The company selectively chose to withdraw the authorizations in Sweden, Norway and Denmark, where AZ intended to launch the new product. Consequently, the strategy prevented generic omeprazol manufactures to enter the market since they were not able to prove the similarity of their capsules to the reference medical product. The Court stated that AZ's conducts of deregistration were; "*not based on the legitimate protection of an investment designed to contribute to competition on the merits, since AZ no longer had the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials*"<sup>217</sup>

Hence, the withdrawals of the Losec capsule marketing authorizations were to be regarded to fall out of the scope of "competition on the merits". This implied that there were no objective justification for the conducts, since the deregistering were not necessary for the introduction of the tablet form of Losec or in order to facilitate the alteration of sales of *Losec* capsules to *Losec (MUPS)* tablets. Further on, the General Court held that an undertaking that occupies a dominant position cannot use the regulatory procedure to prevent or delay the generic entry. A conduct in that manner always constitutes abuse, if it not is related to the competition on the merits or can otherwise be objectively justified. Hence, AZ's conduct of prevent generics to profit from the submitted data of the test results is not legitimate competition on the merits.

In contrast, AZ claimed that it did not have any malevolent intention, in regards of the delayed generic entry. Nevertheless, the Court held that the claim was irrelevant due to the fact that the conduct's objective nature was capable of delaying or preventing generic competition. In addition, the Court stated that it was obvious from the documentary evidence that AZ did intend to obstruct the introduction of generic products, by the conduct of deregistration.

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<sup>217</sup> Case T-321/05, para 812.

### 7.3 Analysis of the judgement and views of implications

The judgment of the AZ case by the General Court is significant for the pharmaceutical industry, which is a highly competition-intense market where the competing players are entirely dependent on the regulation's restrictions or provided rights. The judgment is also important for the follow up on the pharmaceutical sector inquiry where the Commission presented the applied strategies and stated that all measures will be taken to overcome restrictions of the competition. The judgment deals with the complexity of behaviors' lawfulness with regards to the interface between EC competition law and IPRs in relation to the pharmaceutical regulatory framework.

The judgment has established that the applied strategies, where such misuse the patent law as well as the regulatory procedures, may constitute infringement of the EU competition law. The abuse of dominant position is constituted if the conduct obstructs or delays the generic competition. Consequently, abuse of dominant position when various strategies are applied is a further can be constituted even where the patent law contains a sanction in form of invalidity. Thus, the judgment has affected the systematically applied strategies' legitimacy and whereby originators now are being imposed constraints of their behavior on the market in relation to the generics. The judgment states, in regards of the interface between the IPRs and the competition law, that the fact that an originator is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests when they are attacked. But, nevertheless, the court pointed out that the originator; *'cannot use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.'*<sup>218</sup>

The essence in this paragraph is the wording 'competition on the merits', where applied conducts, which do restrict the competition, can be regarded as normal competition. The meaning of normal competition is not cut in stone, but leaves the court to interpret the legislation in the light of the different variables and current conditions on the specific market. The Court states that the competition on the merits in this case composes of the protection of the data of the test since it is the fruit of the investments of the R&D.

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<sup>218</sup> Case T-321/05, para. 672; Case T-65/89 *BPB Industries and British Gypsum v Commission*, para. 69.

However, when the data exclusivity has expired, the legal right to protect the data, with respect to the competition on merits, has also demised.<sup>219</sup> Consequently the withdrawal cannot be justified, nevertheless is the withdrawal lawful under the pharmaceutical legislation. Both the Commission and the General Court have stated that even though a conduct is lawful under another law is not relevant in regards of the illegality of abusive conduct under the EC competition law. Hence, AZ's lawful withdrawal of its marketing authorization, in compliance with the pharmaceutical law, do not cause that the company can escape from the prohibition laid down in Article 102 TFEU.<sup>220</sup>

This appears to mean that the competition law is superior of other laws, and its applicability does not have any limitations, where a conduct is regarded to be an abuse of dominant position. Important to emphasis in this context is that the pharmaceutical law is formulated in a manner that provides generics with rights, either to use the test data in order to obtain marketing authorization or use the results for their own tests and investigations after the data exclusivity has expired. According to Hans Henrik Lidgard, professor of private law at the University of Lund with legal writings concentrate on the intersection between antitrust and IPR, the application of the competition law appears to be an overuse when the pharmaceutical market is firmly regulated. Further on, professor Lidgard compares the application of the anti-trust law with the United States, where he ascertain that the view of the application is more to be the opposite, which implies that the competition law shall not be applied when an issue is regulated in a special regulation. With respect to that fact, he presents that AZ has consider to move their business to the state, and only continuing the business in Europe at one single place, Sweden Gothenburg.<sup>221</sup>

With this in respect, it is important to bear in mind that the application of the EU competition law shall not be on the benefit from maintaining an innovative pharmaceutical market with leading originators within the Union. If the competition law restricts the conduct of protecting IPRs in a *too* broad manner, the consequences might be a weaker competitive position in comparison with the pharmaceutical market U.S.

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<sup>219</sup> Case T-321/05, para 674.

<sup>220</sup> Decision, para. 656, Case T-321/05, para, 677.

<sup>221</sup> Lidgard, Hans Henrik, *AstraZeneca-domen – ett tufft besked för originaltillverkare av läkemedel*, p. 591.

Further on, the Court has stated that the constitution of abuse of dominance can be established regardless of whether the conduct de facto constituted restriction of the competition, either directly or indirectly. These statements are in accordance with earlier judgments, where the focus is to establish the conduct's effect of restriction or at least its capability.<sup>222</sup> In addition, the intendment of a certain behavior is according to the Court irrelevant, as long as the objectively nature of the conduct is restricting the competition.. Relevant in this context must be to question the difference of the sanction, since an intending abuse de facto must be regarded as a more severe breach of the anti-trust law. Yet, the Court does not investigate or find any reasons to prove whether the conduct of the application for SPC was tended to hinder the generic entry, but simply content to note that the *nature* of the behavior was capable to restrict the competition. Thus the restriction was not proved, nor the enforcement of the SPC. Consequently, this might lead to an unbalanced interpretation of the competition law in regards of conducts to protect IPRs, at least for the actors outside the judicial system. Since the IPR per se is at one point a restriction of the competition, one could argue that the conducts, i.e. protecting the IPRs, has an inherent nature of restricting the competition. Of course such conduct must constitute abuse. But, still if there is a lack of need to investigate the intendment or how the abuser has utilized it, the application of the law might appear as slightly monotonous.

It is of highly importance for the originators to be able to determine how far they are able to protect and defend their IPRs from the generic competition. The conditions that constitutes an abuse of dominate position is at present time obscure. Due to the complicity of the issue is due to the fragile balancing between on one hand the IP law and on the other the competition law. Intellectual property law has the purpose to protect the inventor's property and by IPRs provide the benefit of exclusivity. In the judgment of the AZ case, the Court stated that, in conformity with other cases, that the IPRs do not per se constitute anticompetitive practice just the abuse of it. However, since a right is not static, but needs not be invoked repeatedly, the use of the right in contrast to the abuse is a fine balancing, where the legal system needs to provide clear regulation of acts that constitutes the latter. The legal uncertainty of the strategies' legitimacy does not only affect the originators, but the generic as well. If the strategies, which simply are the conduct of

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<sup>222</sup> See e.g. Case T-219/99 British Airways v Commission [2004] para 293.

protecting the patents, can be challenged in a greater extent, not because of its possible abuse of the dominant position but due to the uncertainty of how to apply the legal sources with regards to the interface between the IP law and the competition law, it would constitute an ineffective market. Further where the generics. One might even go that far by saying that uncertainty per se could harm the competition within the industry. In conjunction, is it important that the simple existence of IPR do not provide legality for conducts that restricts the competition. If the extent of the right to protect the IPRs would go beyond the constraints provided by the competition law, the competition within the market would be utterly eliminated. Therefore, it is important to emphasise the importance the competition law for the functioning of the internal market. In the perspective of the principle of the legal security, the present regulatory framework is at an unacceptable level, leaving the actors of pharmaceutical industry in the dark. The most significant danger in the conflict between the two legal systems could be the risk that the law puts players in a deadlock, where the generics are constrained by the IP law and originators by the competition law.

To consider a reform of the legal system or at least a modification of the current legislation might be at hand. As mentioned above, it has been suggested that a single European patent in pursuant to the CPC would overcome a lot of the current issue. In addition, a proposal to establish a European jurisdiction in the patent field has been developed, which is called the European Patent Litigation Agreement, EPLA.<sup>223</sup> With one jurisdiction and one single European patent, the problems relating to the diversity of national legislation would be solved, as well as the requirement of proceed litigation in each and every state. However, in the meantime, it is important that European legal authorities in the greatest extend aims to provide legal clarity of the regulatory framework, with respect to the interface between IP law and competition law. By, provide case law with, more, clear guidelines of the applied regulation and its interpretation of various conducts, the actors of the market would gain further knowledge of the strategies” legality.

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<sup>223</sup> In November 2003, the Working Party on Litigation agreed on the basic legal instruments needed to set up a European Patent Court with jurisdiction to deal with infringement and revocation actions concerning European patents. See Draft Agreement; <http://www.epo.org/patents/law/legislative-initiatives/epla/latestdrafts.html>

## 8 Conclusion of strategies' legality

The purpose of this thesis is to determine the originators' applied strategies legality and in simple words one can state that; the legality of the strategies is at present time uncertain.

The applied strategies by the originators are lawfully, *more often than not*, under the patent law, but unlawfully, *more often than not*, under the EU competition law. Why? The reason for this complication is due to the non-correspondence of the two legal disciplines.

The strategies are applied by originators in order to protect their drugs from generic competition. Various types of strategies are applied, where for instance the originators create patent-clusters which imply that one drug is protected by several layers of patent protection. Another example is to develop a follow-on product of the original drug with the aim to prolong the life time of the first drug. However, the strategies are able to constitutes infringement of the EU competition law and consequently be unlawful. The difficulty of determining whether a strategy constitutes infringement of the competition law or not, is due to the fact that it is lawful pursuant to the IP law. The IP law provides the originators with rights of protection for their property. But, at the same time, the originators can breach the law when they practice these rights. The European Courts has in the AZ case, as well as other relating cases, stated that any conduct, regardless of its legitimacy under other laws, that might restrict the competition constitutes infringement of the anti-trust law. The word 'might' is one part of the essence of the problem, since the Courts do not provide sufficiently clear grounds on which conditions practices of IPRs constitute a breach of the competition law. The poor statements in the judgments, results in legal uncertainty for the originators in regards of the extent they are able to protect their drug.

In summary, competition between companies in the medical market must be promoted so generics can enter the market within the statutory period, leading to prices being pushed to the benefit of patients and public health in general. Competition law must be applied to maintain this effect to the greatest extent possible. But, consideration must also be taken to the originators enormous costs of the R&D as well as the time-consuming factor. Originators' innovations must therefore be protected under the law in a sufficient extent, in order for the R&D to be considered worthwhile. As mentioned above, there are trends that

originators are considering moving their establishments outside Europe. European Court's views when assessing patent strategy is to promote competition and ensure that the originators behavior do not result in restriction of the competition or hinder the generic entry. However, there is no substantiation of the long-term consequences that this application of the law will have on the medical market. If the originators think that their protection is not utilized, they may choose to move their business outside the European Union. Thus, it is currently important to the legal bodies of the EU carefully consider the possible consequences of their application of the law. The target cannot be at all costs to encourage competition at the expense of intellectual property. In addition the Courts must, even if they in previously judgments may have considered themselves to do it, provide clearer verdicts, where the requirements for what constitutes abuse of dominant position become clearer. This implies that the originators as well as the generics are more likely to effectively adapt their business to the legislation.

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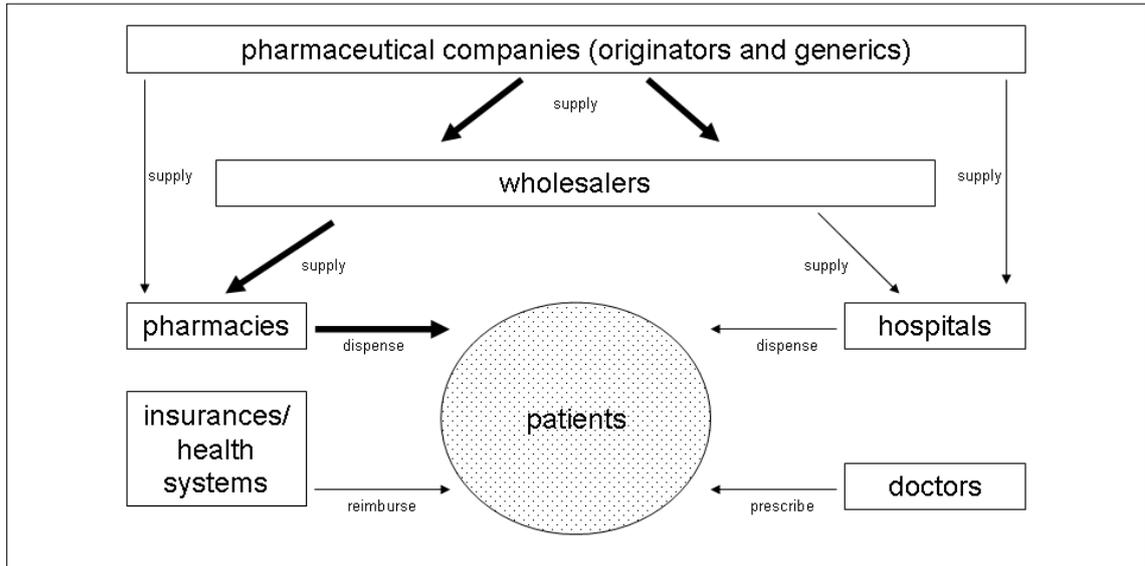
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# Attachments

## 1.

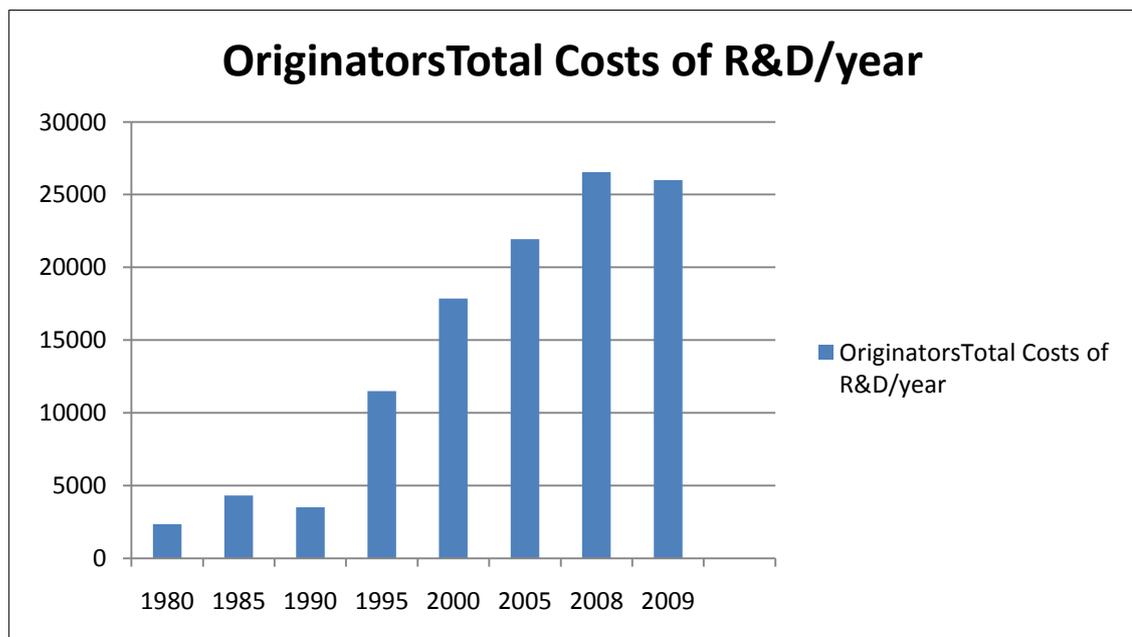
### SIMPLIFIED SUPPLY CHAIN FOR PRESCRIPTION MEDICINES



Source: Pharmaceutical Sector Inquiry, Final Report, European Commission, p. 22

## 2.

### PHARMACEUTICAL R&D EXPENDITURE IN EUROPE (€ MILLION)



Source: EFPIA member associations (official figures)

