

Pay-for-delay

A competition law analysis of settlement
agreements in the pharmaceutical sector

Christine-Jane Selenhag

Abstract

During the last two decades many pharmaceutical originator companies have struggled with refilling its pipelines with novel pharmaceutical products. At the same time many of these companies have lost patent protection for its most profitable drugs and more are expected to do so in the very near future. When pharmaceutical patents expire it is generally expected that generic manufacturers enter the market with significantly cheaper versions of the pre-patented drugs. Accordingly, generic entry poses strong competitive price pressure on originator companies and the latter may therefore be inclined to hinder these competitors from entering the market.

The preparations for generic launch often starts a few years before patent expiry and it is therefore common that patent disputes arise. Patent disputes are not only highly complex, time consuming and costly, the disputes are often also characterized by a high degree of uncertainty to whether or not the patents are infringed and/or valid. Thus, incentives for settling the disputes out of court are often high for both originator and generic undertakings. Legitimate patent settlement agreements are generally not considered to pose any competitive concern. However, the Commission has observed that these settlement agreements has been used to conceal anti-competitive terms by which the originator companies sets out to buy off its generic competitors for delaying its plans to enter the market. These anti-competitive arrangements are more generally known as *pay-for-delay* settlements.

The Commission has issued two decisions against pay-for-delay settlements of which the GC has confirmed the Commission's assessments. After fulfilling a three-step criteria developed by the Commission, these agreements were considered to have as its object the restriction of competition within the meaning of article 101 (1) TFEU. When an agreement is categorized as a restriction by object it is considered to be by its very nature restrictive of competition, and is therefore presumptively illegal. This approach has been vastly criticized in the legal doctrine for not being sufficiently clear and legally certain. Therefore, the purpose of this essay has been to critically analyze the Commission's approach in assessing patent settlement agreements.

The overall findings of the analysis do however indicate that the Commission's categorization of pay-for-delay settlements as restrictions of competition by object follows the established rules of EU competition law and should therefore be justified.

Abbreviations

AG	Advocate General
API	Active pharmaceutical ingredient
EU	European Union
EPC	European Patent Convention
GC	The General Court
IPR	Intellectual property right
NCA	National Competition Authority
SPC	Supplementary Protection Certificate
TEU	Treaty on European Union
TFEU	Treaty of the Functioning of the European Union
WIPO	World Intellectual Property Organization

Table of contents

Abstract.....	3
Abbreviations	4
1 Introduction.....	7
1.1 Background of the research.....	7
1.2 Purpose and research questions.....	9
1.3 Method.....	9
1.4 Material	11
1.5 Delimitation	12
1.6 Outline	13
2 Competition law, patent law and its interface	15
2.1 Competition law.....	15
2.1.1 Competition law and the EU	16
2.2 Patent law	17
2.3 The interface between EU competition law and patent law	20
3 Competition and settlements in the pharmaceutical sector.....	24
3.1 The competitive race between originator and generic undertakings.....	24
3.2 Incentives for patent settlements.....	25
3.3 Settlement agreements and competition concern?	26
4 Pay-for-delay agreements	29
4.1 What is pay-for-delay?.....	29
4.2 Decisions of the European Commission against pay-for-delay settlements.....	31
4.2.1 Lundbeck.....	31
4.2.2 Servier	32
5 Pay-for-delay agreements - a restriction of competition by object within the meaning of article 101 TFEU	35
5.1 Article 101 TFEU	35
5.1.1 The concept of “agreement”.....	35
5.1.2 Effect on trade concept.....	36
5.1.3 Restriction of competition by object or effect.....	36
5.2 The Commission’s “by object” assessment of patent settlements containing reverse payments.....	41
5.2.1 Potential competition	42

5.2.2	Limitation to entry	44
5.2.3	Value transfer.....	46
5.2.3.1	Side deals as a concealed value transfer.....	47
5.2.4	The conclusions of the GC	49
6	Possible problems with the Commission’s assessment of pay-for-delay agreements	51
6.1	Should the Commission’s “by object” analysis be justified?	51
6.1.1	Possible problems with the “potential competition”-criteria.....	53
6.1.2	Potential challenges with the “limitation to entry”-criteria	55
6.1.3	Criticism against the “value transfer”-criteria.....	56
6.2	The United States’ “Rule of Reason” – a better approach in the name of legal certainty?	59
	Conclusions	62
	Bibliography.....	64

1 Introduction

1.1 Background of the research

In 2018 World Health Organization estimated that over 9.6 million people worldwide would die from cancer, but that between 30-50 % of those cases could be prevented and cured.¹ People living with fatal illnesses such as cancer are depended on developments and innovation in the pharmaceutical sector. Access to new, improved, affordable and safer medicines, techniques and methods are therefore crucial for the safeguarding of public health.² These benefits would however not be possible to achieve without the significant research and development (“R&D”) efforts invested by pharmaceutical originator companies³ willing to take the financial risk of bringing new drugs to the market.⁴ The costs associated with pharmaceutical innovation are however high. There are also high risks for failure in drug development or, if successful, significant risks for imitation from third parties.⁵ Therefore, the pharmaceutical sector heavily relies on patents to protect these investments.⁶

During the last two decades the rate of innovation within the pharmaceutical sector has decreased. As a result, very few novel drugs have reached the market.⁷ At the same time, due to expiry of patent validity, several originator companies have lost patent protection of its most profitable medicines, so called “blockbusters”⁸, and more are expected to do so in the very near future.⁹ Generally, patents act as a barrier to entry as it gives the patent holder an exclusive right to the innovation.¹⁰ Thus, patent expiry generally effects the

¹ World Health Organization, *Cancer prevention*, (retrieved 2019-02-03) “www.who.int/cancer/en/”.

² European Commission, *Executive Summary of the Pharmaceutical Sector Inquiry Report*, 2009, p. 2 [cit. Executive summary of the pharmaceutical sector inquiry report].

³ A pharmaceutical originator company is a company first to develop and produce specific medicine.

⁴ Executive summary of the pharmaceutical sector inquiry report, p. 2.

⁵ European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, p, 97 [cit. Final report of the Pharmaceutical sector inquiry].

⁶ Final report of the Pharmaceutical sector inquiry, p, 97.

⁷ *Ibid*, p, 33.

⁸ A blockbuster is a medicine whose annual global turnover exceeds 1 billion US dollars.

⁹ Executive summary of the pharmaceutical sector inquiry report, p. 3.

¹⁰ Jones A., & Sufrin B., *EU Competition Law*, 6th ed., Oxford University Press, Oxford, 2016, p. 827-828 [cit. Jones & Sufrin].

market structure and acts as an important source for price competition.¹¹ The loss of exclusivity in the pharmaceutical sector allows for market entry of so-called generic versions of drugs, i.e. drugs identical or equivalent to pre-patented drugs of originator companies.¹² What differs generic companies from originator companies is that generic companies generally do not have to invest significant R&D efforts and costs; instead they rely on the R&D efforts invested by originator companies reflected in the patent. As a result, generic companies pose strong competitive pressure on originator companies since they can offer the generic versions at significantly lower prices compared to the original products.¹³ This competitive pressure is often imminent some time before patent expiry when generic undertakings start its preparations for launching its generic version and it is therefore common that patent disputes arise at the time when generic entry is expected.

Patent expiry and the struggle of originator companies in pharmaceutical innovation has been identified by the European Commission as some of the underlying reasons to why originator companies have become increasingly more dependent on the revenues gained from the existing best-selling products such as blockbusters.¹⁴ Originator companies are therefore inclined to take different actions to prolong the commercial lifespan of its patented products for as long as possible in order to maintain its revenues.¹⁵ At the same time the Commission has observed a delay in the expected generic entry on the pharmaceutical markets in the EU.¹⁶

The decrease in generic entry was one of the factors that led the Commission to initiate a sector inquiry into the pharmaceutical sector to monitor the EU market. Several problems have been identified in the strategies used by originator companies that constitute obstacles for generic entry that potentially lead to distortion of competition. One of these identified strategies is the delay or suspension of generic entry through anti-competitive terms in patent settlement agreements entered between originator and generic companies. In exchange for delaying its market entry the generic company is allowed “*a part of [the originator’s] cake*”¹⁷ from the sold units of the original drug.¹⁸ These arrangements are also known as *reverse payments* as they, in contrast to legal patent settlement agreements, result in the patent holder

¹¹ European Commission, *Competition Enforcement in the Pharmaceutical Sector (2009-2017)*, COM (2019) 17 final, Brussels, 28 January 2019, p. 2 [cit. *Competition Enforcement in the Pharmaceutical Sector (2009-2017)*].

¹² The Swedish medical products agency, *Det här är ett läkemedel*, (retrieved 2019-02-03) “lakemedelsverket.se/malgrupp/Allmanhet/Vad-ar-ett-lakemedel/”.

¹³ Final report of the Pharmaceutical sector inquiry, p. 77.

¹⁴ Executive summary of the pharmaceutical sector inquiry report, p. 3.

¹⁵ *Ibid.*

¹⁶ Final report of the Pharmaceutical sector inquiry, p. 13.

¹⁷ Citation found by the Commission in an internal document during a dawn raid of a company, see *Competition Enforcement in the Pharmaceutical Sector (2009-2017)*, p. 2.

¹⁸ Jones & Sufrin, p. 870-871.

paying the alleged infringer instead of the opposite.¹⁹ In turn, the effect of reverse payments is the delay or suspension of generic entry, commonly referred to as anti-competitive *pay-for-delay* agreements.

Upon the sector inquiry, monitoring of patent settlement agreements have been a high priority for both the Commission and national competition authorities (“NCAs”). The Commission has issued two decisions against pay-for-delay settlements in the cases of *Lundbeck* and *Servier*. Based on a cumulative criterion developed by the Commission, the agreements in these cases were considered infringements of article 101 TFEU as restrictions of competition “*by object*”. When a conduct is classified as a “by object”-restriction it is presumed to be anti-competitive by its very nature. Thus, the alleging party, most often the Commission, does not have any burden of proof for showing that the agreements have anti-competitive effects, since these are already presumed.

1.2 Purpose and research questions

Given the complex nature of patent disputes, it could be questioned whether the classification of patent settlement agreements containing reverse payments as restrictions of competition by object is an appropriate means of achieving effective competition on the market, or if it rather gives rise to uncertain competition law enforcement?

The purpose of this thesis is to critically examine the EU competition law approach to patent settlement agreements in the pharmaceutical sector and analyze whether this approach is sufficiently clear to create foreseeability and efficient competition law enforcement. To fulfill this purpose, the following research questions will be answered:

- i. Under what circumstances can a classification as restriction by object be justified, in contrast to a restriction by effect?
- ii. When and why can a patent settlement agreement be considered to have as its object the restriction of competition?
- iii. Can the Commission’s approach for finding a patent settlement agreement restrictive by its object be justified or is it problematic?

1.3 Method

The legal dogmatic method in combination with the European legal method will be used in this thesis. The European legal method is to be understood as a measure for practical legal interpretation of the EU body of legislation, and not a method for legal research why it is suitable to be combined with other

¹⁹ Jones & Sufrin, p. 870-871.

research methods.²⁰ The purpose of the legal dogmatic method is to interpret and systematize the sources of law to establish the applicable law.²¹ This systematizing part of the method involves an analysis of the relationship between a concrete situation and the applicable law to determine what applies to the given situation.²² The starting point is that the answer should be sought in the generally accepted sources of law.²³

In line with the European legal method, when analyzing EU law the most relevant sources of law are the EU treaties, which are primary law consisting of binding agreements between EU member states that sets out the objectives and principles of the EU. It is from here that secondary law derives, consisting of binding regulations, directives and decisions, as well as non-binding recommendations and opinions.²⁴ Not seldom, both EU primary and secondary legislation are constructed in a rather vague approach describing goals and union values why the need for interpretation often is substantial. In accordance with article 19(1) TEU, the EU Courts holds a certain responsibility to ensure that the interpretation and application of the Treaties observes the law.²⁵ Therefore, the EU legal system is also characterized by the significance of the Courts case law acting as a complement to the statutory law.²⁶ The EU Courts consists of the General Court (“GC”) and the European Court of Justice (“ECJ”), which are the first instance respectively the highest instance in matters concerning EU law²⁷. The case law from the ECJ holds the most precedent value. However if the ECJ has not ruled on a certain matter, but the GC has, then the judgment from the GC is more precedent compared to other sources of law.²⁸

The purpose of analyzing the different sources of law is to achieve a result that is assumed to reflect the content of the applicable law, which in turn can be used in legal problem solving of a concrete situation. This type of analysis constitutes the so-called *de lege lata*²⁹ perspective of the legal dogmatic method.³⁰ The method also comprises a systematizing part and aims to describe the legal system through a measure of scrutiny. This part of the method is characterized

²⁰ Reichel, in Korling F., & Zamboni M., (red.), *Juridisk metodlära*, 1st ed., Studentlitteratur, Lund, 2013, p. 121-122.

²¹ Kleineman, in Korling F., & Zamboni M., (red.), *Juridisk metodlära*, 1st ed., Studentlitteratur, Lund, 2013, p. 22 [cit. Kleineman].

²² Kleineman, p. 26.

²³ *Ibid.*, p. 21.

²⁴ Hettne, J., & Otken Eriksson I., *EU-rättslig metod – teori och genomslag i svensk rättstillämpning*, 2nd ed., Norstedts Juridik AB, Stockholm, 2011, p. 40-41 [cit. Hettne & Otken Eriksson].

²⁵ Hettne & Otken Eriksson, p. 49.

²⁶ *Ibid.*, p. 40-41.

²⁷ *Ibid.*, p. 55-56.

²⁸ *Ibid.*, p. 56.

²⁹ Latin for ”the law as it exists”.

³⁰ Peczenik, A., *Juridikens allmänna läror*, Svensk Juristtidning (SvJt), no. 3, pp. 249-272, 2005, p. 249 [cit. Peczenik].

by a *de lege ferenda*³¹ perspective and is used as a measure to find explanation to how possible loopholes in the applicable law that appears to be unsolved should be solved.³² By demonstrating that the law entails unsatisfactory results on the basis of certain objectives or benchmarks that are important for the situation at hand, this critical approach implies that the legal dogmatic method goes a step further than merely describing what constitutes the applicable law.³³ Thus, under this critical approach, legal doctrine can be of great importance compared to other sources of law as it in many times not only provides an overview of the content of the legal system but also criticizes deficiencies in the applicable law.³⁴

The primary aim of this essay is to conduct a competition law analysis on the pay for delay phenomenon and since competition law has strong connection to economic theory it is necessary to also include some economic aspects in the analysis.³⁵ Furthermore, the essay is not conducted through any comparative legal method, but some comparative elements regarding the approach taken in the United States on the matter is emphasized in the analysis to further enrich the discussion and illustrate a different view on the matter.

1.4 Material

For the given purpose of this essay to be fulfilled a *de lege lata* perspective has been used to present the applicable EU competition rules to patent settlement agreements. Thus, the starting point for this essay lies in primary law of article 101 TFEU, which prohibits anti-competitive agreements. Within EU competition law the compatibility of patent settlement agreements with article 101 TFEU is mainly regulated through secondary law and case law, why there is reason to also regard these sources of law. The case law that has been included as part of the *de lege lata* presentation of this essay focus on the more preceding cases, mainly from the ECJ, but also from the GC where a court ruling has not been given by the ECJ.

In any competition law matter concerning intellectual property rights (“IPRs”) the Commission or national competition authorities (“NCAs”) may assess the scope of IPRs in order to apply the EU competition rules.³⁶ Such assessments were made in the decisions of *Lundbeck* and *Servier*. Both decisions were appealed and the GC has delivered a judgment in both cases. The GC:s review of the Commission’s assessment is however limited to determining

³¹ Latin for “what the law should be”.

³² Kleineman, p. 36.

³³ *Ibid*, p. 38.

³⁴ Peczenik, p. 249 f.

³⁵ Hettne & Otken Eriksson, p. 123-124.

³⁶ Turner, J., *Intellectual Property and EU Competition Law*, 2nd ed., Oxford University Press, Oxford, 2015, p. 32 [cit. Turner].

whether the assessment is reasonable in the light of the applicable law.³⁷ Therefore both the GC:s judgments and the Commission's decisions have been important sources of law for this essay when analyzing how patent settlements are to be assessed by competition law. In this regard it is to be noted that the Commission's decisions in *Lundbeck* and *Servier* were almost 500 respectively 900 pages long and the judgments from the GC contained between 900 respectively 2000 paragraphs. Therefore, only the most relevant aspects and circumstances of these decisions and judgments are discussed in this essay and are not in any way exhaustively complete. Furthermore the GC:s judgment in *Servier* has currently only been delivered in French. Due to a language barrier, case law summaries have been used that have been reviewed against an unofficial translation of the judgment in *Servier* to control its accuracy. References are made to the paragraphs in the official court judgment.

Even though not considered a binding legal source, the Commission's investigations and reports such as the Pharmaceutical Sector Inquiry Report and its subsequent investigations provide important data on inter alia the structure of the market, patent settlement agreements and information on the Commission's view in this regard. These sources has been used only as part of the descriptive presentation relating to the legal and economic structure of the pharmaceutical sector to help the reader understand the context of which the disputed settlement agreements have been concluded in. These reports have not been used as a legal source and should therefore not alter any methodological issues in this essay.

Lastly, when conducting the critical analysis in line with the *de lege ferenda* perspective, it has been useful to examine arguments posed in the legal doctrine on the issue of pay-for-delay. The research material is significant, and a selection has been made based on doctrine with focus on EU competition law. However, as part of the comparative element of discussing the United States' approach towards pay-for-delay agreements, legal doctrine related to this matter has also been a relevant source of law in this essay.

1.5 Delimitation

When analyzing competition law matters, it needs to be borne in mind that the EU holds exclusive competence in establishing the competition rules for the functioning of the internal market.³⁸ As a result, each member state is obliged to apply the EU competition rules where there is an effect on trade between member states. Other matters absent this effect are of national concern and national competition law applies.³⁹ Since this essay primarily concerns EU

³⁷ Turner, p. 32, with reference to C-193/83, *Windsurfing International v. Commission*, paras. 23-36.

³⁸ Article 3(1)(b), TFEU.

³⁹ Jones & Sufrin, p. 99.

competition law aspects on patent settlement agreements, the scope of analysis only includes decisions and case law from the EU institutions and not cases NCAs. Nor has any comprehensive focus been on decisions outside the EU other than what is needed for the comparative elements of the analysis.

The essay is further limited to a discussion and analysis of reverse payment agreements falling under the prohibition against anti-competitive agreements in article 101 TFEU. Any aspects regarding abuse of dominance in article 102 TFEU has therefore not be discussed in this essay. For the interested reader it should however be noted that in *Servier*, the Commission also imposed fines for infringement of article 102 TFEU. This decision was however annulled by the General Court (“GC”).⁴⁰

Lastly, even though the Commission has issued a third decision concerning a type of pay-for-delay arrangement in *Johnson & Johnson/Novartis* this decision has not been included in this essay since it did not concern a patent settlement agreement.

1.6 Outline

In the following, the essay is structured into five parts (chapter 2-6). Chapter 2 introduces the reader to the relevant legal areas to which the essay relates, namely competition law and patent law, and the interface between these two legal areas. Chapter 3 presents a discussion on the competitive relation between originator and generic undertakings in the pharmaceutical sector and the incentives for settling the patent disputes that often arise from this competitive relationship. The final part of this chapter includes a discussion of which settlement agreements that are considered legitimate from a competition law perspective. This is followed by a discussion in chapter 4 on when such settlement agreements reciprocates into being anti-competitive and aims to make the reader understand what pay-for-delay agreements are. In this discussion, the relevant circumstances of *Lundbeck* and *Servier* are also presented to illustrate the phenomenon of pay-for-delay. The following chapter 5 is introduced with a de lege lata examination of the elements of article 101 TFEU and the categorization between object and effect restrictions under the provision is also analyzed. The purpose of this arrangement is to provide the reader with sufficient knowledge about article 101 TFEU in order to understand the Commission’s assessment of the settlement agreements in *Lundbeck* and *Servier*, which are presented in the second part of chapter 5. In the final part of the essay, chapter 6, a de lege ferenda analysis is made in regards to the Commission’s approach for finding a patent settlement agreement restrictive by its object. In this part a discussion regarding whether this approach is justified from a legal certainty perspective and the possible

⁴⁰ T-691/14, *Servier and Others v. Commission*.

problems that the approach give rise to are presented. A discussion regarding the differences in the United States' competition law approach to handle pay-for-delay settlements is also made and whether this approach is more effective compared to the Commission's approach in the EU.

2 Competition law, patent law and its interface

2.1 Competition law

Competition law seeks to protect competition within a free market economy. In contrast to the market economy run by central government planning like the one that existed in Soviet, a free market economy is characterized by having the allocation of resources within the market determined by supply and demand. Thus, the economic system cannot be improved by direct government regulation since the market is self-regulated by the demand of consumers and the supply of competitors. This hypothetical market scenario is more generally known as a “perfectly competitive market”.⁴¹

In a perfectly competitive market, buyers and sellers are presumed to have perfect information about any change in demand or price. A change in demand would immediately respond in a change of supply. Each seller would therefore have no impact on the market as sellers cannot control the price level of its products. A seller trying to increase the price above the price of its competitors would consequently result in having the consumers switch to buying products from the less costly competitor since the buyer has perfect information. This is however a scenario not reflecting reality.⁴² In practice, there are however often a few sellers that have power to both increase and maintain prices above the competitive level due to the existence of strong market power.⁴³ This is the case patent intensive markets such as the different markets within the pharmaceutical sector. In order to protect consumers and dynamic competition on the market, some governmental regulation on competition is therefore needed.⁴⁴

The above-mentioned basics of competition law characterize many competition law systems all over the world. Within the EU, competition law is however different from any other system of competition law found outside the union.⁴⁵ What distinguishes the EU competition law system from other systems is that it serves as an instrument for achieving the goals of the wider system of which it exists in, namely the EU.

⁴¹ Jones & Sufrin, p. 2-6.

⁴² Ibid, p. 6-7.

⁴³ Ibid, p. 10-11.

⁴⁴ This position has been emphasized by the ECJ in e.g. C-501/06 P, *GlaxoSmithKline Services and Others v. Commission and Others*, para. 63.

⁴⁵ Jones & Sufrin, p. 35.

2.1.1 Competition law and the EU

The main objective of EU competition law is to prevent the distortion of competition within the *single internal market* to achieve the overall objectives of the EU in creating a *common market*.⁴⁶ The concept “single internal market” is to be seen as the internal aspect of the wider concept “common market”. The ECJ has in its settled case law declared that the creation of the common market is the preparatory step for achieving market integration between member states.⁴⁷ Creating a common market should however not be seen as an end in itself, but rather a means of achieving the wide-ranging and aspirational goals set out in article 2 and 3 of the Treaty on European Union (“TEU”) and article 3 of the Treaty on the Functioning of the European Union (“TFEU”) which forms the constitutional basis of the EU.⁴⁸ These goals include inter alia respect for freedom, democracy, human rights, sustainable development based on economic growth and price stability, environmental protection and the promotion of scientific and technological advancement. These wider goals of the common market have set the frame for the very essence of the single internal market through the “four freedoms”, seeking to guarantee the free movement of goods, services, capital and labor within the EU.⁴⁹

Although not mentioned explicitly as part of the goals stated in the Treaties, undistorted competition is still seen as an essential part for the establishment and functioning of the internal market. In protocol no. 27 on the Internal Market and Competition it is stated “[...] that the internal market as set out in article 3 of the treaty on European union includes a system ensuring that competition is not distorted”.⁵⁰ Thus, by protecting undistorted competition on the pharmaceutical market, the wider goals of the EU are also promoted. Furthermore, since generic companies push down prices of existing drugs and thereby giving rise to cheaper and more available drugs, the protection of the competitive structure in this sector also indirectly promotes inter alia human health.

It is important to understand the role that competition law plays within European law, acting as an instrument for market integration, as it accounts for the underlying nature to which the competition rules and the Courts case law are set.⁵¹ This position has also been accentuated by the EU Courts. In the case of *GlaxoSmithKline* the ECJ emphasized that competition rules are designed to achieve the objectives of the Treaty of integrating member states national markets by establishing a single market. The ECJ stressed that the function of

⁴⁶ Jones & Sufirin, p. 34-35.

⁴⁷ C-15/81, *Schul*, para. 33.

⁴⁸ Jones & Sufirin, p. 31-32.

⁴⁹ Article 26 TFEU. Se also Bernitz U., & Kjellgren A., *Europarätens grunder*, 5th ed., Nordstedts Juridik, Stockholm, 2014, p. 25 [cit. Bernitz & Kjellgren], and Jones & Sufirin, p. 32.

⁵⁰ Consolidated version of the Treaty on European Union, Protocol (No 27) on the internal market and competition.

⁵¹ Jones & Sufirin, p. 34-35.

competition rules need to protect not only the interests of consumers and competitors, but also the market structure as such and thus competition within it.⁵² In *TeliaSonera* the ECJ further emphasized that the functioning of competition rules is “[...] precisely to prevent competition from being distorted to the detriment of the public interest, individual undertakings and consumers, thereby ensuring the well-being of the European Union”.⁵³ The case concerned the interpretation of article 102 TFEU, however the ECJ has stated in the case of *Continental Can* that the competition provisions of article 101 and article 102 seeks to achieve the same aim.⁵⁴ Thus, the statement in *TeliaSonera* also applies to article 101 TFEU.

2.2 Patent law

Drug development in the pharmaceutical industry is a high risk and high cost business. Successful drug development generally includes significant costs for inter alia drug discovery, clinical trials and market approvals. A study from 2012 made by the British Office of Health and Economics has shown that the R&D cost estimate per new medicine has increased during the last three decades, showing an increase in costs from 199 million US dollars in the 1970’s to approximately 1.9 billion US dollars in 2011 - an increase that is almost one hundred times bigger than in the 1970’s.⁵⁵ In order to encourage and protect these essential investments in pharmaceutical development, governments grant patent protection to innovators of new and/or improved innovations.⁵⁶

A patent is a form of intellectual property right granted by a government to the inventor of a technical invention for a limited time period.⁵⁷ The right is bound by the territorial principle and can therefore only be enforced in the country in which the patent has been granted in accordance with the applicable patent law of that country.⁵⁸ Within the EU, the European Patent Convention (“EPC”) provides common rules of patentability and a unitary legal system for the granting of European Patents in order to simplify the application system.⁵⁹ Instead of filing a patent application in each country, a patent granted under the

⁵² C-501/06 P, *GlaxoSmithKline Services and Others v. Commission and Others*, paras. 59-63.

⁵³ C-52/09, *Konkurrensverket v. TeliaSonera Sverige AB*, para. 22.

⁵⁴ C-6/72, *Continental Can*, para. 25.

⁵⁵ Mestre-Ferrandiz, J., Sussex, J. and Towse, A., *The R&D cost of a new medicine*, Office of Health and Economics, December 2012, p. 3.

⁵⁶ European Commission, *Patent protection in the EU*, (Retrieved 2019-02-06)

“www.ec.europa.eu/growth/industry/intellectual-property/patents_fr”.

⁵⁷ Bernitz U., Karnell, G., Pehrson, L., & Sandgren, C., *Immaterialrätt och otillbörlig konkurrens*, 13th ed., Jure bokhandel, Stockholm, 2013. p. 149 [cit. Bernitz, et al.]

⁵⁸ WIPO Intellectual Property Handbook: Policy, *Law and Use*, p. 17, (retrieved 2019-02-06)

“www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf” [cit. WIPO Intellectual Property Handbook].

⁵⁹ Turner, p. 13.

EPC can be used to validate a patent in an EPC-contracting state.⁶⁰ The subject matter of the patent gives the proprietor a sole right, conferring a legal monopoly situation by which the patented invention can normally only be exploited with the authorization from the patent holder.⁶¹ Within EPC-contracting states (all member states of the EU are part of the EPC) a patent can stay valid for a maximum period of twenty years from its filing date, however patents for medicinal products can acquire up to a five years supplementary protection certificate (“SPC”) upon application.⁶²

The purpose behind granting patent rights is to promote the industrial development and advancement within society. Therefore, not all inventions are worthy of receiving patent protection.⁶³ In order for an invention to be considered patentable, it must (in short and very simplified) meet three conditions. The invention must be new and must not be known by anyone before the filing date (the so called novelty-requirement). It must further be inventive in the sense that it significantly differs from prior technology already existing on the market (the inventive-step-requirement). Lastly, the invention must be industrially applicable so that it can be produced and utilized (the industrial-applicability requirement).⁶⁴ These requirements could be seen as a threshold for what society can deem as worth of monopolizing.

After fulfilling the patentability requirements two types of patents can be granted for a pharmaceutical innovative products. The first one is a *substance* patent and protects the chemical substance of the drug by defining the structure of the substance in the patent.⁶⁵ The protected chemical substance is also more often referred to as active pharmaceutical ingredient (“API”), which provides the therapeutic effect of the drug.⁶⁶ The other form of patent is called a *process* patent, often referred to as “product-by-process patent” and protects the series of steps conducted for performing or accomplishing the drug.⁶⁷ In *AstraZeneca* the GC stated that “[t]he ability of a formulation [*process*] patent to confer exclusivity on a product is not equivalent, in any event, to that of a substance patent, since an active substance can be incorporated into different formulations.”⁶⁸ Thus, a process patent generally confers a weaker scope of protection, since it does not hinder competitors from using the same active

⁶⁰ Convention on the Grant of European Patents, of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000, article 1-3.

⁶¹ WIPO Intellectual Property Handbook, p. 17.

⁶² Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, art. 13.

⁶³ Bernitz, et al., p. 149.

⁶⁴ Ibid.

⁶⁵ Domeij, B., *Läkemedelspatent – Patent på läkemedel i Europa ur ett rättsvetenskapligt och rättsekonomiskt perspektiv*, Jure AB, Stockholm, 1998 p. 495 [cit. Domeij, 1998].

⁶⁶ Final report of the Pharmaceutical sector inquiry, p. 348.

⁶⁷ Domeij, 1998, p. 503–504.

⁶⁸ Case T-321/05, *AstraZeneca v. Commission*, para. 607.

substance in its products unless this substance is produced in the way presented in the patent. The two types of patents are often part of originator companies' business strategies to prolong its exclusivity on the market. What is often done is that a substance patent is applied for the API in an early stage of the R&D-process, and at some point after market launch one or several process patents related to the specific API are applied for.⁶⁹ In that way the originator company can try to prolong the protection for its products even after expiry of the substance patent by invoking the valid process patents against potential infringing parties.

What the patent holder can oppose against by enforcing its patent rights is defined by the specific subject matter of the patent. This includes the exclusive right to excluding others from making, using, selling and importing the invention within the territories that the right is granted.⁷⁰ The general principle is also that the subject matter of the patent includes protection against preparatory infringement and a right to oppose infringements.⁷¹ In return for this, yet time limited, freedom from competition the holder is granted the patent in exchange for enabling public disclosure of the invention.⁷² Therefore the invention becomes available to the public and upon patent expiry anyone who wishes to utilize the invention commercially can, theoretically, do so without the authorization from the former patent holder. This is why generic entry is expected upon patent expiry. However, as we will learn, this is not often the practical reality in the pharmaceutical sector.

Within the pharmaceutical industry, the existence of a patent is not in itself a condition permitting the launch of a drug on the market. The pharmaceutical sector is characterized by a high degree of regulatory approvals, such as safety requirements and marketing authorizations, that is needed in order to ensure the safety, efficacy and quality of medicines before they are placed on the market.⁷³ Any pharmaceutical company, both originator and generic, wanting to launch a drug on the market within the EEA must therefore apply for necessary approvals before the product can legally be launched.

⁶⁹ Final report of the Pharmaceutical sector inquiry, p. 51.

⁷⁰ Turner, p. 49.

⁷¹ C-15/74, *Centrafarm v. Sterling Drug*, para. 9 and C-187/80, *Merck v. Stepbar*, para. 4.

⁷² Bernitz, et al. p. 149.

⁷³ Final report of the Pharmaceutical sector inquiry, p. 115.

2.3 The interface between EU competition law and patent law

The fact that a patent ultimately constitutes a legal monopoly situation does however not imply that it is immune from competition law intervention. Neither does it imply that there is an inherent conflict with competition law.⁷⁴

Competition law put pressure to innovate without reducing competition by restricting market player's anti-competitive conduct. The fundamental benchmark of competition law is based on the principle that more competition creates allocative efficiencies, which provides a marginal benefit to consumers.⁷⁵ Where the market maximizes allocative efficiency, the production of goods and services represents the quantities valued by society and prices to consumers are equal to the marginal costs for production. Where the market is allocative efficient it has reached its equilibrium resembling the perfect economy discussed the previous section 2.1.⁷⁶ Consequently, competition law perceives monopolies as harmful to consumers. In the absence of any competitive pressure, a single seller of a monopoly product will be able to price as high as possible, to the detriment of the consumers.⁷⁷ Based on this competition law perspective, it could however be question if not the legal monopoly granted by a patent in fact contradicts the very nature of competition law?

While competition law tends to focus on creating allocative efficiency, it also recognizes the importance of dynamic efficiency, which can be explained as how well the market delivers innovation and technological progress.⁷⁸ Patent rights create incentives for innovation by allowing the innovator to utilize the sole patent right. The rationale for incentivizing innovation is based on an economic principle derived from the Schumpeterian theory where the conferring of monopoly rights provides the innovating firm the market power to extract the appropriate level of returns from its R&D investments, thus providing the ability and incentive to innovate.⁷⁹ To a large extent, the inherent rules of intellectual property legislation provide a balance between competition and the need to protect innovation. Competition is protected by not delaying follow-on innovation from competitors by imposing a time limit of the patent right. This also limits unnecessary long periods of high prices for the consumer, since competitors, like generic companies, can launch cheaper competing

⁷⁴ Vinje T., *The Intellectual Property and Antitrust Review*, 2nd ed., Law Business Research Ltd, London, 2017, p. 45.

⁷⁵ Chowdhury A., & Gaigl A., § 1.01: *The Economics of Competition Law and of Pharmaceutical Patents*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp.5-14, 2016, p. 6 [cit. Chowdhury & Gaigl].

⁷⁶ Jones & Sufrin, p. 7.

⁷⁷ Ibid, p. 8-9.

⁷⁸ Ibid, p. 7-8.

⁷⁹ Chowdhury & Gaigl, p. 6.

products on the market after the limited time of exclusivity.⁸⁰ Likewise, patent law limits the scope of protection through the patentability requirements and may also provide for compulsory licensing in particular circumstances.⁸¹

In the guidelines to technology transfer agreements, the Commission recognizes that both bodies of law share the same overall objective of improving innovation, promoting consumer welfare, economic efficiency and keeping markets competitive, but do so through rather different but complementary means.⁸² Even so, it has been established in the case law of the ECJ that the protection of intellectual property rights are essential to enable undistorted competition in the fields of innovation, which the Treaty is intended to establish.⁸³ Without such protection an undertaking could appropriate the benefits of its competitor's efforts instead of striving to achieve a better product.⁸⁴ Thus, in competition law cases where intellectual property law is involved, competition authorities must "strike a balance between maintaining free competition [...] and the requirement to safeguard proprietor's intellectual property rights and its right to effective judicial protection".⁸⁵

Furthermore, competition law accepts that a patent right leads to a short-term position of substantial market power, but does not consider it detrimental to consumer welfare in the longer run.⁸⁶ Therefore patent holders are free to rely on its patents to exclude competitors from practicing the patented invention.⁸⁷ The interplay between EU competition law and intellectual property law is also evident from the statutory law of the EU. Article 345 TFEU explicitly holds that "[t]he Treaties shall in no way prejudice the rules in Member States governing the system of property ownership". This has been duly accepted in the case law of the Court. In *AstraZeneca* the GC held that when an intellectual property right has been granted by a public authority it is normally "assumed to be valid" and "[t]he mere possession by an undertaking of an exclusive right normally results in keeping competitors away, since public regulations require them to respect that exclusive right".⁸⁸ The presumption for patent validity acts as a barrier to entry but does however not entail that competition is unfeasible, it rather allocates the burden of proof on the competitor claiming the opposite.⁸⁹

⁸⁰ Jones & Sufrin. 830.

⁸¹ Turner, p. 3.

⁸² Communication from the Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2017/C 89/03), para. 7 [cit. Guidelines to technology transfer agreements].

⁸³ C-10/89, *CNL-SUCAL v. HAG*, para. 13; C-232/94, *MPA Pharma v. Rhône-Poulenc Pharma*, para. 16 and Joined Cases C-274/11 and C-295/11, *Spain and Italy v. Council*, para. 22.

⁸⁴ Turner, p. 3.

⁸⁵ C-170/13, *Huawei Technologies*, para. 42.

⁸⁶ Jones & Sufrin, p. 13.

⁸⁷ T-111/96, *ITT Promedia v. Commission*, para. 60 and T-119/09, *Protégé International v. Commission*, para. 49.

⁸⁸ T-321/05, *AstraZeneca v. Commission*, para. 362.

⁸⁹ Case AT.39226 – *Lundbeck*, para. 78.

In case law where there has been an alleged conflict between intellectual property rights and competition law, the ECJ has developed the so called “existence/exercise dichotomy” in order to draw a judicial border between the two legal practices. The doctrine was first developed in the case of *Consten and Grundig*.⁹⁰ The case concerned the use of a trademark but the judgment of the ECJ holds importance for any intellectual property matter. Grundig was a German manufacturer of electrical goods and owner of the trademark “Gint” that was placed on all Grundig products. Grundig entered into an agreement with the French distributor Consten with the intention to grant Consten absolute territorial protection for the Grundig products in France. As part of the agreement Grundig undertook to impose export bans to France from other wholesalers and distributors of Grundig products, and granted Consten the right to register the “Gint” trademark in France. When it came to Consten’s attention that another French distributor (UNEF) had purchased Grundig products from German traders and in turn sold them to French retailers at a lower price than Consten, Consten initiated an action against UNEF for an infringement of the French “Gint” trademark in order to hinder the products from being sold. The ECJ held that the rules of the EU do not exclude the *existence* of an intellectual property right granted by a Member State, but that the EU competition rules “do not allow the improper use [*exercise*] under national trade-mark law in order to frustrate the Community’s law on cartels [article 101]”.⁹¹ Consten’s exercise of the rights conferred by the trademark were not viewed as having the aim of protecting the trademark as such, but rather with the object of ensuring an absolute territorial protection as agreed upon with Grundig. Accordingly, the agreement constituted an infringement of article 85 TFEU (now article 101).⁹²

The existence/exercise dichotomy was reaffirmed in a latter case, *Parke, Davis v. Centrafarm*, where the ECJ held that while the mere existence of a patent right granted by a Member State is not affected by the rules of competition law, the exercise of such rights can come “within the ambit of Community law where such use” contributes to a prohibited conduct under competition law.⁹³ Put differently, where the conditions of competition rules are met, they are not prevented from being applied to the exercise of IPR:s.

The *existence* or *exercise* of an IPR could however be considered to constitute abstract concepts. In latter case law the ECJ has accentuated that the existence of a right must be defined by the specific subject matter of the right in order to differentiate between existence and exercise. In the case of *Windsurfing International* the ECJ held that a clause in a patent licensing agreement that prohibited the licensees from challenging the validity of the licensed patent (a

⁹⁰ C-56/64, *Consten and Grundig v. Commission*.

⁹¹ *Ibid*, p. 301.

⁹² *Ibid*, p. 351.

⁹³ C-24/67, *Parke, Davis v. Centrafarm*, p. 72.

non-challenge clause) was not a right conferred by the subject matter of the patent. Instead the possibility of challenging the validity of a patent was assumed to lie in the public's interest of eliminating "any obstacle to economic activity which may arise where a patent was granted in error".⁹⁴ Prohibiting competitors from challenging patent rights did not fall under the subject matter of the patent that could be deemed as one of the core rights that the owner of the patent enjoys under national patent law. The conditions under article 85 (1) (now article 101 (1)) were met, why the non-challenge clause was seen as an exercise that could be caught by competition rules. Accordingly, the non-challenge clause was found to restrict competition under article 85 TFEU (now article 101).⁹⁵

On the face of it, patent law and competition law are two very different legal practices with primary interests that could be viewed as contrarious to one another. The alleged antithesis between competition law and patent law lies in the clash between the scope of exclusivity granted by patent law and the aim of competition law to keep markets free and open for competition. However, as has been discussed, a balance seems to have been struck between competition law and intellectual property law (and thus also patent law) allowing for the two to co-exist. The mere existence of a patent right cannot be restricted by the competition rules, but if the exploitation of a patent restricts competition to an extent not justified by its specific subject matter it is and must nevertheless be constrained and scrutinized by the rules of competition. As will be seen in the following, this has caused patent holders in the pharmaceutical sector to try to find ways to escape the radar of competition law intervention, by acting as if the patents covered more than justified by its subject matter.

⁹⁴ C-193/83, *Windsurfing International v. Commission*, para. 92.

⁹⁵ *Ibid*, para. 93.

3 Competition and settlements in the pharmaceutical sector

3.1 The competitive race between originator and generic undertakings

There are two levels in the pharmaceutical sector where competition generally occurs. The first level is competition between different originator undertakings that competes by engaging in the same R&D activities with the aim of being the first to launch a treatment for a certain disease, or to launch an alternative product to already existing products.⁹⁶ On the second level competition occur between originator companies and their generic competitors in the very same product markets competing for the same consumer demand.⁹⁷ The exercise of patent rights on the first level are open to the application of EU competition law, but it is the activity on the second level that are of interest for the following discussion.

Innovation and the protection of such are highly indispensable for the economic survival of originator companies within the pharmaceutical sector.⁹⁸ During the period of patent protection, the originator company has been able to price above the marginal cost of production due to the absence of competition. If a product reach significant sales, as with blockbuster medicines, many generic companies often start preparations for launching generic versions already some time before patent expiry.⁹⁹ Thus, competition also occurs between generic companies in a race to be the first to enter the market after patent expiry. The time of generic entry is important for the potential profits to be made and the first generic company to launch a generic version of a drug will be able to charge the highest price before having to gradually decrease it as more generic market players enter the market.¹⁰⁰ Considering that preparations often occur even before patent expiry one could think that even though a launch is estimated after patent expiry, the generic companies preparatory

⁹⁶ Final report of the Pharmaceutical sector inquiry p. 379.

⁹⁷ Ibid, p. 181.

⁹⁸ De Mello-Sampayo, F., de Sousa-Vale, S., & Camões, F., *Substitutability Between Drugs, Innovation, and Fiscal Policy in the Pharmaceutical Industry*, *annals of economics and finance* 16-2, 273–289, 2015., p. 274.

⁹⁹ Case AT.39226 – *Lundbeck*, para. 69.

¹⁰⁰ Case T-472/13, *Lundbeck v. Commission*, para. 93.

activities would constitute a preparation for patent infringement, certainly where there is a valid substance patent where the scope of protection is maximized. However, the preparatory activities such as studies, tests and experiments carried out by generic undertakings in order to obtain approval for sale (e.g. Marketing Authorization) is exempted from the exclusive right conferred by a patent.¹⁰¹ Any full-scale production of patent protected drugs by generic companies before patent expiry would nevertheless fall within the scope of the patent and constitutes an infringement. This is of course highly depended on whether the patent covers a substance or process. If there is a valid substance patent there would not be any legal way for competitors to produce the API before patent expiry. But when a drug is only protected by a process patent, the scope of protection is limited and the generic companies are, at least in theory, able to use other production methods to produce a generic version of a certain API.¹⁰² Whether or not the generic undertaking has succeeded in finding another method, they are easily targets of patent disputes initiated by defensive originator companies that enforce its rights against any possible new market entrant.

Since a patent is a proprietary right it only fulfills its purpose if infringements in the right is actively monitored and opposed by the holder of the right.¹⁰³ Enforcing the patent against infringing parties is therefore a legitimate procedural dimension of the sole right.¹⁰⁴ Accordingly, patent disputes are common in patent-intensive industries such as the pharmaceutical sector.¹⁰⁵ Patent litigation between originator and generic companies generally involves two simultaneous processes, often initiated by infringement allegations from the originator company against the generic company. As a result, the generic company may oppose to the infringement allegation through a cross-action to invalidate the patent, claiming e.g. that the patent does not fulfill one or more of the patentability requirements.¹⁰⁶ Such challenges are inherent to the competitive process between originator and generic companies.¹⁰⁷

3.2 Incentives for patent settlements

Litigation due to procedural enforcement of patent rights are associated with certain risks and incentives can be high for ending disputes through settlement

¹⁰¹ Directive 2004/27/EC art. 10(a). See also the Swedish Patents Act, Swedish Statute Book, SFS, 1967:837, in the version in force from July 1, 2014) article 3, paragraph 2, item 4.

¹⁰² Case AT.39226 – *Lundbeck*, para. 72.

¹⁰³ WIPO Intellectual Property Handbook, p. 17.

¹⁰⁴ Final report of the Pharmaceutical sector inquiry, p. 199 and Case T-111/96, *ITT Promedia v. Commission*, para. 60.

¹⁰⁵ Executive summary of the pharmaceutical sector inquiry report, p. 11.

¹⁰⁶ Domeij, B., *Patenträtt*, Iustus Förlag AB, Stockholm, 2007, p. 117-120 [cit. Domeij, 2007] and Case AT.39226 – *Lundbeck*, para. 73.

¹⁰⁷ Case AT.39226 – *Lundbeck*, para. 73.

agreements for both disputing parties for several reasons. By settling disputes both originator and generic companies can avoid the economic risks from costly patent litigation. In the pharmaceutical sector inquiry, the Commission observed that the legal costs stemming from patent litigation in the EU relating to 68 medicines exceeded 420 million Euros between the period 2000-2007.¹⁰⁸ Further, patent disputes often comprise technically complex situations and the outcome of the disputes is characterized by a high degree of uncertainty. When launching an infringement action originator companies often has insufficient knowledge about the exact production method used by the generic companies and can therefore not know for certain whether the generic actually infringes the patent before such is confirmed in a court verdict.¹⁰⁹ Furthermore, since patent rights are governed by the territoriality principle, patent litigation can occur between the same parties in more than one country at the same time, thus giving rise to a risk of courts reaching contradicting decisions on the same underlying issues. The Commission found such contradicting decisions in 11 % of the final judgments that were reviewed in the sector inquiry from courts of different EU member states.¹¹⁰ The Commission declared this as a “significant finding” that “inevitably harms the legal certainty for the companies that are active in a given product on other EU markets”.¹¹¹

Considering the vast amount of time, investments and R&D efforts put into developing a patentable pharmaceutical product, losing validity of a patent before its due expiry date can have significant consequences for originator companies. Likewise, a patent found valid in an invalidity action, or a successful infringement action can have equally severe consequences for a generic company ready to launch its product to the market. Both disputing parties may therefore have an interest in reaching a compromise through a settlement.¹¹² Patent settlement agreements can also lie in the interest of the public since it can save courts or competent administrative bodies both time and effort, allowing for a more efficient allocation of society’s resources.¹¹³

3.3 Settlement agreements and competition concern?

The outcome and effects of a settlement to a patent dispute between an originator and a generic undertaking may vary depending on what the parties are willing to commonly agree to. If the underlying reasons to settling a dispute is that it proves to be too costly, time consuming or uncertain to move forward

¹⁰⁸ Executive summary of the pharmaceutical sector inquiry report, p. 12.

¹⁰⁹ Case AT.39226 – *Lundbeck*, para. 74.

¹¹⁰ Final report of the Pharmaceutical sector inquiry, p. 237.

¹¹¹ *Ibid.*

¹¹² *Ibid.*

¹¹³ Cf. the Commission’s statement in Case AT.39226 – *Lundbeck*, para. 5 and Case AT.39612 – *Perindopril (Servier)*, para. 1102.

with a court litigation, the parties may agree to settle its disputes and include a licensing term whereby the originator grants a license of the disputed patent to the generic undertaking. The Commission does not consider such arrangements to pose any competitive concern if it is likely that the generic undertaking, absent the license, would be excluded from the market.¹¹⁴ That would be the case where the generic product, absent the license, would infringe the originator's patent. Under such circumstances the Commission considers that a licensing term would be pro-competitive since it allows both parties to exploit its technology after the settlement agreement is concluded.¹¹⁵

Patent settlement agreements between originator and generic companies may also result in that the generic company is limited in its commercial autonomy for the duration of the patent's remaining validity period without any license being granted (i.e. a non-compete). When such is the case, the limitation of the generic undertaking's entry to the market must be based on the parties' recognition of the patent's validity and the likelihood of the generic product infringing nature of that patent.¹¹⁶ Thus, the generic's submission to a non-compete clause cannot be based on an incentive given from the originator company through e.g. a monetary inducement.

As discussed in the previous chapter it has been established in case law that prohibiting a competitor from challenging its patents rights does not fall under the subject matter of the patent right and is therefore an exercise that can be caught by competition law.¹¹⁷ However, the Commission considers that it is inherent in patent settlements to include non-challenge clauses whereby the parties agree not to challenge the patent rights after the conclusion of the settlement agreement. The reason behind this is that since the very purpose of the agreement is to settle an ongoing dispute, it is inherent that the parties also want to make sure that no disputes occur on the very same matter in the future.¹¹⁸ Thus, in the context of patent settlements the inclusion of non-challenge clauses in such agreements is not generally considered to be anti-competitive. Similar to the case where the generic undertaking accepts a non-compete clause, the submission to a non-challenge clause cannot derive from an inducement made by the originator company.¹¹⁹ Rather, such submission must be based on the parties' mutual will to settle the actual dispute.

On the one hand, the Commission has recognized that settlement agreements concluded in the context of patent disputes are in principal a

¹¹⁴ Guidelines to technology transfer agreements, para. 236.

¹¹⁵ Ibid.

¹¹⁶ Geradin, D., Ginsburg, D.H., & Safty, G., §2.07: *Reverse Settlements in the European Union and the United States*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp. 125-146, 2016, p. 139 [cit. Geradin, et al.], with reference to the Commission's statement in Case AT.39226 – *Lundbeck*, para. 638.

¹¹⁷ See section 2.3.

¹¹⁸ Guidelines to technology transfer agreements, para. 242.

¹¹⁹ Ibid, para. 243.

legitimate means of finding a mutually acceptable compromise to a legal dispute. Settlements are therefore not *per se* a threat to the competitive structure on the market.¹²⁰ On the other hand, settlement agreements de facto result in a limitation of the generic undertaking's commercial freedom and thus limit competition on the market. It is therefore important to establish if a generic undertaking submits to limit its commercial behavior based on the parties' genuine recognition of the patents' validity and/or the infringing nature of the generic products, *or* if such submission is actually based on an inducement made from the originator company. Consequently, the individual terms of the agreement and the payments made between the settling parties must be scrutinized on a case-by-case basis.¹²¹ A detailed assessment is certainly required where the settlement agreement deviates from what can be considered as normal settlement conditions. Such deviations may be at hand where the parties' recognizes the disputed patent's validity and the infringing nature of the generic products, but the originator at the same time pays the generic undertaking for entering the agreement and not the other way around. Where it is found that the originator has induced the generic undertaking into accepting the restrictive terms of the settlement agreement, the agreement will no longer be recognized as a genuine patent settlement. Instead, the settlement agreement is seen as an agreement whereby the originator has paid off its generic contenders not to enter the market, also known as pay-for-delay.

¹²⁰ Guidelines to technology transfer agreements, para. 235.

¹²¹ Case AT.39612 – *Perindopril (Servier)*, para. 1102.

4 Pay-for-delay agreements

4.1 What is pay-for-delay?

As discussed in the previous chapter, settlement agreements are not per se prohibited. As a matter of fact, settlement agreements may in some cases be the best alternative to settle disputes regarding patent validity or infringements of such rights. While these agreements can be an efficient tool for dispute resolution, they can also be an efficient tool to shield collusive deals between originator and generic companies, creating benefits for the involved parties at the expense of society. Despite the legitimacy of the underlying legal disagreement of a settlement, the agreement and its individual terms are not immune to the rules of competition law.¹²²

The monitoring of patent settlements was among the main topics in the Pharmaceutical sector inquiry and aimed at assessing whether the decrease in generic entry were directly attributable to settlements concluded between originator and generic manufacturers. In the inquiry it was found that over 200 patent settlement agreements were made between these actors, of which 63 % of the agreements involved disputes regarding the best-selling medicines of originator companies where patent expiry was impending.¹²³ The generic companies' abilities to enter the market were restricted in more than half of the reviewed settlements.¹²⁴ 45 of these cases also involved a value transfer (reverse payment) made from the originator to the generic company, instead of the usual opposite relation in patent settlements.¹²⁵

A pay-for-delay agreement can involve different arrangements between originator and generic companies.¹²⁶ What is common for all arrangements is that it involves the generic company agreeing on either limiting, delaying or entirely suspending its market entry in exchange for a value transfer from the originator company.¹²⁷ The aim of a pay-for-delay arrangement can therefore be said to restrict competition on the market.

¹²² Anderman, S., & Schmidt, H., *EU Competition Law and Intellectual Property Rights - the Regulation of Innovation*, 2nd ed., Oxford University Press, 2011, p. 22-23.

¹²³ Executive summary of the pharmaceutical sector inquiry report, p. 12.

¹²⁴ *Ibid.*, p. 13.

¹²⁵ Final report of the Pharmaceutical sector inquiry, para. 762.

¹²⁶ Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 24.

¹²⁷ *Ibid.*

What happens on the market when one or several pay-for-delay agreements has been concluded is that the originator company is able to reap the extra profits made from its prolonged exclusivity on the market and remain, or even increase, the price of the drug. The value transferred to the generic company can be a small price paid in relation to the loss of profits that the originator would have faced in the case of generic entry.¹²⁸ For example, in the sector inquiry from 2009 it was observed that generic drugs were on average priced 25 % below the price of the original drug. Within two years, this price was further decreased to 40 % below the original price.¹²⁹ More recent numbers are found in an American study from 2012 where it was observed that generic drugs generally were sold at 50 % of the price compared to the original drug. This study also show that the original companies experienced a steep drop in its market shares, retaining only 16 % of the market one year after generic entry.¹³⁰ The price drop followed by generic entry has an important impact on health care expenditure within the EU. The Commission has observed that in markets where generic medicines become available, average health care spending were reduced with almost 20 % within one year after generic entry.¹³¹

With respect to the generally steep price drop followed by generic entry, it is clear that generic undertakings assert great competitive pressure on originator undertakings. Accordingly, originator undertakings may therefore be inclined to try and block generic entry in any way possible. Such incentives are certainly higher in times where the originator company experiences difficulties in refilling its pipelines with new products at the same time as patent expiry for its blockbuster medicines are impending. It is therefore fairly easy to understand that originator companies have a lot to benefit in making collusive deals with its competitors. However, it is not only originator companies that can benefit from these collusive deals. There can also be strong incentives for generic companies to enter pay-for-delay agreements. By sharing the profits made from the originator's prolonged exclusivity, the generic company is able to make significant earnings without even having to enter the market.¹³² By entering a pay-for-delay agreement any risks for the generic undertaking of a failed market entry or costs associated with such are eliminated. But when so is done, these benefits are made on the expense of the welfare of society and diminishes citizens accessibility to affordable substitute medicines. Consequently, these agreements goes against the objectives and aims that competition law seeks to achieve, why it is clear that such arrangements cannot, and has not, been allowed by competition law.

¹²⁸ Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 25.

¹²⁹ Executive summary of the pharmaceutical sector inquiry report, p. 9.

¹³⁰ Castanheira, M., Orangi, C., Siotis, G., de Frutos, M.A., *The consequences of generic entry: price, promotional effort and market share*, July 5 2016, p. 5.

¹³¹ Executive summary of the pharmaceutical sector inquiry report, p. 9.

¹³² Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 25.

4.2 Decisions of the European Commission against pay-for-delay settlements

Upon the sector inquiry, the Commission and NCAs have made a yearly monitoring of patent settlements concluded between originator and generic companies. As a result, the Commission issued two decisions against settlement agreements that included reverse payments from the originator to the generic companies. These agreements were considered to have as its very object the restriction of competition and the parties were therefore fined for infringements of article 101 TFEU.

4.2.1 Lundbeck

In 2013 the Commission imposed a EUR 93.8 million fine against the Danish originator company Lundbeck and a total fine of EUR 52.5 million on four generic companies for conducting a pay-for-delay arrangement through settlement agreements.

In 1977 Lundbeck developed Citalopram, an anti-depressant drug that quickly became one of Lundbeck's best-selling blockbuster medicines responsible for 85 % of Lundbeck's turnover.¹³³ The company was granted both a substance patent for Citalopram and two process patents in most European countries, which all were expected to expire around the year 2000.¹³⁴ In 1985 Lundbeck developed a more efficient process for purifying citalopram, which it obtained patents in all EEA countries (the "crystallization process patents").¹³⁵ In 2002, when the crystallization process patents were near the end of its validity period, four generic companies (Merck, Alpharma, Arrow and Ranbaxy) were preparing to enter the market with generic versions of Citalopram. As a result, Lundbeck threatened to initiate infringement proceedings against each company for infringements of the crystallization process patents. However, before litigation before court had been initiated, Lundbeck had resolved the disputes through settlements with each alleged infringer.¹³⁶

Each agreement included a value transfer to the generic companies from Lundbeck amounting to a total of EUR 66.8 million.¹³⁷ In the agreements, the payments were stated to be compensation for several purposes. In all agreements Lundbeck undertook to purchase the generic companies' stocks of produced Citalopram (stocks that were bought with the purpose of destroying them). The payments were also compensation for not launching any generic versions of Citalopram, irrespective of whether such products would have been

¹³³ Case AT.39226 – *Lundbeck*, para. 623.

¹³⁴ *Ibid*, para. 109

¹³⁵ *Ibid*.

¹³⁶ *Ibid*, para. 4

¹³⁷ *Ibid*, para. 193.

produced through another process not covered by Lundbeck's crystallization process patents.¹³⁸ The Commission found that each respective payment either considerably exceeded the sales value of the purchased stocks¹³⁹ or were equivalent to the level of what the generic companies estimated that they would have earned if they had entered the Citalopram market.¹⁴⁰ The agreements were said to avoid costly and time-consuming patent litigation of which the outcome could not be predicted with absolute certainty.¹⁴¹ Despite this, neither of the agreements contained any commitment from Lundbeck to refrain from initiating infringement proceedings against the generic companies after the expiry of the agreements.¹⁴² Thus, the Commission found that the agreements did not settle any disputes, only postponed it. In the internal documents found during the Commission's investigation, the parties referred to the agreement as a "*club*" being formed that would share "*a pile of \$\$\$*".¹⁴³

The Commission challenged the agreements and found that Lundbeck had delayed the entry from the generic companies to the Citalopram market. The generic undertakings were considered potential competitors of Lundbeck and the agreements had the object of restricting this competition and enabled Lundbeck to maintain a monopoly position on the market thereby continuing to charge the same high prices for Citalopram.¹⁴⁴

4.2.2 Servier

One year after the decision against Lundbeck the Commission imposed fines totaling EUR 427.7 million on the French originator company Servier and five generic manufacturers for conducting similar agreements to those in Lundbeck.

The agreements concerned Servier's blockbuster medicine Perindopril, a medicine used for the treatment of cardiovascular diseases such as high blood pressure. The substance patent for the API Perindopril expired between 2003-2005 in most EU Member States (depending on different legislations in each respective country).¹⁴⁵ By the end of patent expiry, Servier applied for and was granted several process patents covering methods for producing Perindopril. Even though the patent for the API had expired, Servier held a broad protection for its blockbuster medicine through the different process patents.¹⁴⁶

When it came to Servier's attention that five generic companies were preparing to launch generic versions of Perindopril, Servier made use of

¹³⁸ Case AT.39226 – *Lundbeck*, paras. 824, 962, 1013, 1087 and 1174.

¹³⁹ *Ibid*, para. 1174.

¹⁴⁰ *Ibid*, paras. 824, 962, 1013, 1087 and 1174.

¹⁴¹ *Ibid*, paras. 348, 522, 567 and 842.

¹⁴² *Ibid*, paras. 824, 962, 1013, 1087 and 1174.

¹⁴³ Competition Enforcement in the Pharmaceutical Sector (2009-2017), p. 26.

¹⁴⁴ Ezrachi A., *EU Competition Law – An Analytical Guide to the Leading Cases*, 6th ed., Hart Publishing, Oxford, 2018, p. 407.

¹⁴⁵ Case AT.39612 – *Perindopril (Servier)*, para 95.

¹⁴⁶ *Ibid*, paras. 5-8.

warning letters and initiated litigation against the companies by enforcing its process patents in court.¹⁴⁷ Just like in *Lundbeck* settlement agreements were concluded between Servier and the five generic companies before any court ruling was given. The settlements included clauses by which the generic companies submitted not to challenge any of Servier's patents (non-challenge clauses) or launch any generic versions of Perindopril that was covered by Servier's process patents (non-compete clauses).¹⁴⁸ Large payments were made from Servier to the generic undertakings, which were said to compensate for several reasons. In the agreements it was stated that the payments compensated for the incurred litigation costs of the generic companies, but also the production and development costs of the generic medicines that were already produced. To some of the generic companies, the payments also compensated for costs that would occur due to the generic companies' termination of third-party supply contracts of the API Perindopril.¹⁴⁹

As part of one of the settlement agreements, Servier granted Krka a license to Servier's patents within a limited territory of the EU in return for a 3 % royalty on Krka's net sales.¹⁵⁰ Through an assignment agreement Servier also acquired Krka's existing technology for producing its generic version of Perindopril for EUR 30 million.¹⁵¹ The assignment agreements were concluded two months after the settlement agreement.¹⁵² The Commission held that these agreements constituted so called "side deals" that were linked to the settlement agreement and were to be seen as concealed value transfers that reduced the incentives of the generic undertakings to independently pursue its efforts of entering the market.¹⁵³

The Commission took the view that neither of the settlement agreements that had been concluded between Servier and the generic undertakings were genuine settlements to ongoing disputes. Instead, the agreements had merely been used to shield Servier's object of preserving its exclusive position on the perindopril market by paying of its generic contenders. As in *Lundbeck* the Commission found that the agreements were restrictive of competition by its very nature, and thus constituted "by object" restrictions under article 101 (1) TFEU.

However, In both cases there actually were ongoing disputes about both Lundbeck's and Servier's patents and whether the generic undertakings had committed infringement or not. It could therefore be questioned how the Commission is able to determine that the object of these agreement was not to genuinely settle those disputes, but rather to pay of its competitors from

¹⁴⁷ Case AT.39612 – *Perindopril (Servier)*, paras. 5-8.

¹⁴⁸ *Ibid*, paras. 5-8 and 1309.

¹⁴⁹ *Ibid*, paras. 1333, 1461, 1592 and 1969.

¹⁵⁰ *Ibid*, paras. 907-911.

¹⁵¹ *Ibid*, para. 1670.

¹⁵² *Ibid*, para. 1678.

¹⁵³ *Ibid*, para. 1670.

entering the market? The answer to this question requires a deeper understanding of the applicable competition rule, namely article 101 TFEU that prohibits anti-competitive agreements, which will be analyzed in the following chapter.

5 Pay-for-delay agreements - a restriction of competition by object within the meaning of article 101 TFEU

5.1 Article 101 TFEU

Article 101 (1) TFEU aims to protect not only the interests of competitors and consumers, but also the competitive structure on the market.¹⁵⁴ The article prohibits “as incompatible with the internal market all agreements between undertakings [...] which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market”. If an agreement is found to restrict competition within the meaning of article 101 (1), it is deemed null and void under article 101 (2) unless the undertakings in question can prove that the agreement produces efficiencies in so that it outweighs the negative effects and is therefore exempted under article 101 (3). The efficiencies that EU competition law deems legitimate to outweigh any negative effects are pre-defined in a closed list under article 101 (3).¹⁵⁵

5.1.1 The concept of “agreement”

The concept of an agreement within the meaning of article 101 (1) has been developed in the case law of the EU courts. In *Bayer AG v. Commission* the GC held, with reference to established case law, that an agreement presupposes that the undertakings in question have a concurrence of wills whereby they have “expressed their joint intention to conduct themselves on the market in a specific way”.¹⁵⁶

The Commission assumes that patent settlement agreements is a result from a concurrence of wills between the originator and generic companies involved. According to the Commission such agreements are “just like any other civil law

¹⁵⁴ C-8/08, *T-mobile Netherlands and Others*, para. 38.

¹⁵⁵ Bernitz, U., *svensk och europeisk marknadsrätt 1*, 2005, Nordstedt Juridik, p. 127 [cit. Bernitz, 2005].

¹⁵⁶ T-41/96, *Bayer AG v. Commission*, para. 67; C-41/69 *ACF Chemiefarma v. Commission*, para.112; Joined Cases 209/78 to 215/78 and 218/78 *Van Landuyck and Others v. Commission*, para 86, and T-7/89 *Hercules Chemicals v. Commission*, para. 256.

contracts” concluded voluntarily between the parties.¹⁵⁷ The Commission also emphasize the findings in established case law of the ECJ explaining that the ban in article 101 (1) TFEU does not take into consideration whether the aim of the agreement is to put an end to litigation or not.¹⁵⁸ This assumption also goes in line with the above mentioned dichotomy between the existence/exercise and subject matter of IPR:s. The settling of patent disputes is not part of the patent’s subject matter; it is not an inherent right conferred by the patent, why it can be scrutinized by competition law. Since the overall conditions in article 101 (1) are met, settlement agreements are not immune from the application of article 101 simply because they are concluded in the context of protecting a patent right.

5.1.2 Effect on trade concept

The requirement that the agreement may (also called ‘appreciably’) affect trade between Member States was not something that was contested in the decisions, neither by Lundbeck nor Servier. However, for the sake of creating a complete understanding of article 101, a description of this condition will be made.

The effect on trade concept is intended to differentiate between areas where EU competition law apply from those where national competition law has jurisdiction.¹⁵⁹ In the established case law of the ECJ an agreement may affect trade when it is possible to foresee “with a sufficient degree of probability” that the agreement may actually or potentially influence the pattern of trade between Member States that it might hinder the attainment of a single market between States.¹⁶⁰ The sales of an undertaking and the market positions within the EU may be sufficient to support a finding of an appreciable effect on trade. Where the turnover and market shares exceed certain thresholds, a presumption that the agreement appreciably affects trade applies.¹⁶¹

5.1.3 Restriction of competition by object or effect

The *object* or *effect* of an agreement to prevent, restrict or distort competition is alternative requirements and only where an agreement is not found to be restrictive by its object, the Commission must show that agreement has anti-competitive effects.¹⁶² Thus, the distinction between the two different

¹⁵⁷ Case AT.39226 – *Lundbeck*, para. 600.

¹⁵⁸ *Ibid*, with reference to Case 65/86, *Bayer AG and Maschinenfabrik Hennecke v. Heinz Süllhöfer*, para. 15.

¹⁵⁹ Turner, p. 80.

¹⁶⁰ Commission Notice: Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, C 101/81, 27 April, 2004 [cit. Guidelines on the effect on trade concept], para. 23, referring to jurisprudence of the Court.

¹⁶¹ Guidelines on the effect on trade concept, paras. 47-48.

¹⁶² Case 56/65, *Societe Technique Miniere (STM) v. Maschinenbau*, p. 249.

requirements is essential for EU competition law because it specifies the degree of the Commission's burden of proof.¹⁶³ An agreement that restricts competition by its object has been delineated in the Courts case law as certain types of coordination that reveals a "sufficient degree of harm to competition" that it, by its very nature, has the potential to restrict competition within the meaning of article 101 (1).¹⁶⁴ Article 101 (1) (a-e) explicitly prohibits a number of agreements that are *in particular* considered as "by object" infringements. These include (to name a few) agreements that "limit or control production, markets, technical development, or investment"¹⁶⁵ and "share markets or sources of supply"¹⁶⁶. The list in article 101 (1) (a-e) is not closed and the categories of restraints that can be considered as restrictions by object can be extended. Such extension is justified if a certain type of agreement is repeatedly and by experience found to have severe negative effects on competition that it "seems reasonable to penalize it directly for the sake of procedural economy", as Advocate General Wahl has put it.¹⁶⁷

The rationale behind the presumption-based rule towards certain types of anti-competitive agreements is to avoid the necessity for complicated and prolonged economic investigations when it is already apparent that the agreement is harmful to competition.¹⁶⁸ It is also intended to provide predictability and legal certainty by enabling undertakings to identify *ex-ante* the legal consequences of the agreements and thus enables them to modify their conduct accordingly.¹⁶⁹ In the early case law the ECJ accentuated that a textual analysis is to be made to determine if an agreement has as its object the restriction of competition.¹⁷⁰ The assessment calls for an analysis of the agreement's purpose and the economic context that it operates in to determine if the agreement reveals sufficient harm to competition.¹⁷¹ This analysis is textual in so that it is limited to "the four angles of the agreement" and the analysis of the context is only relevant for interpreting the content and economic function of the agreement.¹⁷² However, the parties' intention may be

¹⁶³ Schröder, V., *Pay-for-dela settlements in the EU: did the Commission go too far?*, European Competition Law Review, 37(12), pp. 506-512, 2016, p. 507 [cit. Schröder].

¹⁶⁴ Turner, p. 88 and referenced case law under footnote 119.

¹⁶⁵ Article 101 (1)(b) TFEU.

¹⁶⁶ Article 101 (1)(c) TFEU.

¹⁶⁷ Opinion of Advocate General Wahl in case C-67/13 P, *Groupement des cartes bancaires v. Commission*, para. 55 [cit. AG Wahl opinion in C-67/13 P].

¹⁶⁸ Kolstad, O., Report from the Swedish Competition Authority, *Object contra effect in Swedish and European competition law*, 2009, p. 5.

¹⁶⁹ AG Wahl opinion in C-67/13 P, para. 35.

¹⁷⁰ Case 56/65, *Societe Technique Miniere (STM) v. Maschinenbau*, p. 249; C-209/07, *Beef Industry Development and Barry Brothers (BIDS)*, paras. 16-21 and C-8/08, *T-mobile Netherlands and Others*, para. 43.

¹⁷¹ Case 56/65, *Societe Technique Miniere (STM) v. Maschinenbau*, p. 249.

¹⁷² Nagy, C. I., *The Distinction between Anti-competitive Object and Effect after Allianz: The End of Coherence in Competition Analysis?*, Law and Economics Review, Kluwer Law International, The Netherlands, 2013, p. 544 [cit. Nagy].

an indicative factor of an agreement's restrictive object, but is not a determinant factor.¹⁷³ Only where an analysis of the agreement's content does not reveal by its very nature having the object to restrict competition, a more detailed analysis is required to establish the agreement's actual or potential effects on the market.¹⁷⁴

The detailed analysis under the effect-based approach comprises a market analysis and a counterfactual method. Regard must be had to the consequences that the agreement poses on the market and the position that would have occurred absent the agreement (i.e. a counterfactual analysis). It is further necessary to show the factors that are present which demonstrates that competition has or have the potential of being prevented, restricted or distorted.¹⁷⁵ In doing so the economic and legal context in which the undertakings operate must be considered, as well as the nature of the goods or services affected and the conditions of the functioning- and structure of the market.¹⁷⁶ Put differently, the Commission must prove that the agreement in question actually has or is likely to have negative effects on competition. This is to be done by conducting an extensive analysis of the agreement in its market context and show that the position would have been different absent the agreement.

As seen, the comprehensiveness required under the object respectively the effect approaches are clearly different. The first presumption-based approach is justified because certain types of agreements reveals harm to competition already by looking at the face of it, while the latter extended analysis of the agreement's effects is required when the agreement does not reveal a harmful nature. What further differentiates the two is the practical possibility of benefiting from an individual exemption under article 101 (3) TFEU that is open for both effect and, at least in theory, object restrictions.¹⁷⁷ However, object-type infringements are in practice rarely considered having any outweighing positive effects on competition and therefore unlikely to produce efficiencies.¹⁷⁸ An agreement may still have a restrictive object even if it also pursues legitimate objectives.¹⁷⁹ The line that distinguishes between agreements

¹⁷³ C-501/06 P, *GlaxoSmithKline Services and Others v. Commission and Others*, para. 58.

¹⁷⁴ C-8/08, *T-Mobile Netherlands and Others*, paras. 28-30; Case C-67/13 P, *Groupement des Cartes Bancaires v. Commission*, para. 49; C-209/07, *Beef Industry Development and Barry Brothers (BIDS)*, para. 15, and C-32/11, *Allianz Hungária Biztosító and Others*, para. 34.

¹⁷⁵ C-501/06 P, *GlaxoSmithKline Services and Others v. Commission and Others*, para. 55.

¹⁷⁶ C-1/12, *Ordem dos Técnicos Oficiais de Contas*, para. 70 and C-238/05, *ASNEF-EQUIFAX*, para. 49.

¹⁷⁷ T-17/93, *Matra Hachette v. Commission*, para. 48 and Guidelines on the application of Article 81(3) of the Treaty, para. 20.

¹⁷⁸ Jones & Sufrin, p. 193 and Guidelines on the application of Article 81(3) of the Treaty, para. 46 and 76.

¹⁷⁹ See e.g. C-209/07, *Beef Industry Development and Barry Brothers (BIDS)*, para. 21 and the case law cited.

that constitute by object restrictions vis-à-vis those that require an effect analysis has however been blurred by latter case law.

In *Allianz Hungária* the ECJ had to decide whether an agreement, which did not fall under any previously found object-type categorization, had an anti-competitive object. The ECJ referred to the textual “by object” analysis that was used in previous case law, but extended the analysis in a way similar to the analysis made under the effect approach. The ECJ held that when determining the context of the agreement it is also necessary to consider “the nature of the goods or services affected and the conditions of the functioning and structure of the market”.¹⁸⁰ As recon from the description above, these factors are the very same as those to be analyzed under the effect-approach.

Following the judgment in *Allianz Hungária* it has been suggested that the object categorization has been divided into two kinds of restrictions. The first are those that are obvious “hardcore” object restrictions that are found by the use of a mere textual analysis and are contained in the pre-defined list under article 101 (1). The second type is the “by object” restrictions that require an application of the “same” contextual analysis as effect restrictions as described in *Allianz Hungária*.¹⁸¹ Some critics mean that this latter analysis must be made on a case-by-case basis by constructing a detailed market analysis in order to determine if an agreement restricts competition by object. These critics mean that a case-by-case assessment it is contradictory to very notion of the “by object” categorization since it defeats the purpose of automatic condemnation.¹⁸² Advocate General Wahl raised a similar critique in his opinion to *Cartes Bancaires*. While referring to the judgment in *Allianz Hungária* Wahl stated that it “contributed to blurring the boundary between the concepts of restriction by object or restriction by effect” and calling for “the view that recourse to that concept must be more clearly defined”.¹⁸³ Wahl continued explaining that the method for identifying an anti-competitive object has a very broad scope as it can be imposed as a “precautionary measure and thus jeopardize future contracts, irrespective of the evaluation of the effects actually produced”.¹⁸⁴ In line with AG Wahl the ECJ stressed in its judgment in *Cartes Bancaires* that the concept of restriction by object must be interpreted restrictively.¹⁸⁵ The reason for a restrictive approach towards extending the “by object”-category is that it would otherwise exempt the Commission from proving the actual effects on the market of agreements that has not previously been established to be restrictive by object and might therefore not be by their

¹⁸⁰ C-32/11, *Allianz Hungária Biztosító and Others*, para. 36.

¹⁸¹ Van Cleynenbreugel, P., *Article 101 TFEU and the EU Courts: Adapting legal form to the realities of modernization?*, *Common Market Law Review*, 51, United Kingdom, pp. 1381–1436, 2014, p. 1435.

¹⁸² Nagy, p. 542-544.

¹⁸³ AG Wahl opinion in C-67/13 P, para. 52.

¹⁸⁴ *Ibid*, para. 54.

¹⁸⁵ Case C-67/13 P, *Groupement des Cartes Bancaires v. Commission*, para. 58.

very nature harmful to competition after examining its effects.¹⁸⁶ The ECJ repeated the contextual assessment established in *Allianz Hungária* and clarified that for an agreement to be considered restrictive by object, it is sufficient that the Commission shows, by paying regard to the legal and economic context in a particular case, that the agreement in question is *capable* of restricting competition. It is not necessary for the Commission to prove that the agreement *actually* restricts competition.¹⁸⁷ Quite contrary, if the Commission or the General Court when conducting the contextual analysis of an agreement finds it necessary to also examine the agreement's actual or potential effects on competition, it is an indication in itself that the agreement at issue does not reveal "by its very nature" a sufficient degree of harm to competition.¹⁸⁸

Conclusively, the case law shows that there is a difference between establishing an agreement's anti-competitive object and effect. The object analysis is about determining "within the four angles of the agreement" whether the agreement in itself reveals that its object is to restrict competition, while the effect-analysis moves beyond the content of the agreement to establish the agreements actual or potential effects on competition on a given market. What also differs is that by object restrictions are in practice not capable of being exempted under article 101 (3) since there is a presumption that those agreements are not capable of having outweighing pro-competitive effects. The case law further shows that where the Commission contends that an agreement restricts competition by object but at the same time purports to prove the consequences of the individual agreement, the Commission has on its own made it clear that the agreement is not in itself an agreement that deserves to be automatically condemned under the object-approach. The dichotomy between by object and effect restrictions does however not contain a bright-line test. Critics mean that a lot of uncertainty remain for companies and their legal advisers to predict whether agreements, that cannot be ascribed to an obvious "by object" categorization contained in any pre-defined list, will risk being characterized as restrictions "by object" through the more contextual approach developed in *Allianz Hungária* and *Cartes Bancaires*.¹⁸⁹ In turn, this entails a difficult task for the Commission and the NCAs to carry out an analysis that is just enough to understand the context of the agreement but not so much that it transcends into being an effects analysis, rendering the "by object"-classification pointless.¹⁹⁰ This difficulty is reflected in the Commission's analysis of pay-for-delay settlements and has drawn the attention of a vast amount of criticism opposing *inter alia* that the term "by object" has been used

¹⁸⁶ Ibid.

¹⁸⁷ Case C-67/13 P, *Groupement des Cartes Bancaires v. Commission*, paras. 54-56, with reference to the opinion of AG Wahl, para. 124-125.

¹⁸⁸ Case C-67/13 P, *Groupement des Cartes Bancaires v. Commission*, para. 82.

¹⁸⁹ Murray, G., *In search of the obvious: Groupement des cartes bancaires and "by object" infringements under EU competition law*, *European Competition Law Review*, 36(2), 2015, p. 47. [cit. Murray].

¹⁹⁰ Murray, p. 50.

by the Commission as an excuse to avoid precise analysis of the agreements effects on competition.¹⁹¹ The Commission's decision in both *Lundbeck* and *Servier* were appealed and the GC has ruled on the Commission's assessments of the agreements in both cases. Thus, the following analysis of the Commission's assessment in *Lundbeck* and *Servier* will also include the GC's judgments.

5.2 The Commission's "by object" assessment of patent settlements containing reverse payments

Prior to 2009 there were no guidance or case law available concerning the legality of patent settlements containing reverse payments under EU competition law.¹⁹² Although the final report to the pharmaceutical inquiry was not meant to provide any guidance on the compatibility of patent settlements with EU competition rules, it was nowhere indicated that the Commission would view settlements containing reverse payments as restrictions "by object".¹⁹³ Quite the contrary, the Commission announced that whether it would deem certain patent settlement agreements as anti-competitive or not would require an in-depth case-by-case assessment.¹⁹⁴ Some critics mean that this suggested that the assessment of the agreements were to be made on the basis of an effect-analysis, something that was clearly wrong considering the outcome of the several hundred pages long decisions in *Lundbeck* and *Servier*.¹⁹⁵ Concern has however been raised contending that there is an absence in sufficiently clear guidelines of the competitive assessment made on patent settlements, which ultimately creates legal uncertainty.¹⁹⁶

In its decisions the Commission relied on mainly three cumulative conditions to establish that the agreements between the originators and the generic contenders constituted by object restrictions in the meaning of article 101 (1) TFEU. The Commission considers a settlement agreement restrictive of competition by object where; the undertakings to the agreement were (i) at least

¹⁹¹ Forrester, I.S., §2.02: *The Dangers of Settling Patent Litigation*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp. 67-76, 2016, p. 73 [cit. Forrester], see also Schröder, p. 511-512, and Perinetto, P.A., *The complexities of the EU competition law assessment of pharmaceutical pay-for-delay agreements*, European Competition Law Review, 39(2), pp. 70-76, 2018, p. 73-75 [cit. Perinetto].

¹⁹² Geradin, et al., p. 137.

¹⁹³ Final report of the Pharmaceutical sector inquiry, p. 15.

¹⁹⁴ Executive summary of the pharmaceutical sector inquiry report, p. 20.

¹⁹⁵ Bruzzone, G., & Capozzi, S., *The Procompetitive and Anticompetitive Impact of Patent Settlements*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp. 15-30, 2016, p. 18 [cit. Bruzzone & Capozzi].

¹⁹⁶ Bruzzone & Capozzi, p. 18, see the referenced work in note 10.

potential competitors, (ii) the generic undertaking committed itself in the agreement to restrict its entry and (iii) the agreement was related to a value transfer from the originator to the generic undertaking which substantially reduced the incentives of the generic undertaking to enter the market.¹⁹⁷ These three conditions will be analyzed in the following.

5.2.1 Potential competition

The prohibition in article 101 (1) TFEU is only applicable to sectors that are open to competition.¹⁹⁸ This means that the assessment of whether an agreement is restrictive of competition or not, must pay regard to not only existing competitors active on the market, but also whether the agreement restricts potential competition.¹⁹⁹ Since the agreements were concluded before any generic entry had occurred, the Commission and subsequently the GC considered in both *Lundbeck* and *Servier* the generic contenders to be at least potential competitors.

In the case law it has been established that to determine whether an undertaking qualify as a potential competitor the Commission must establish that there would have been “*real concrete possibilities*” for the undertaking to enter the market and compete with existing competitors absent the agreement.²⁰⁰ The undertaking will not be considered a potential competitor unless it has an “*economically viable strategy*” to enter the market.²⁰¹ The intention of an undertaking to enter the market can be of relevance for the Commission’s assessment, however the relevance of such intention must derive from the undertaking’s *ability* to fulfill its intention to enter the market.²⁰² For there to be an ability to enter the market, the Commission must show that there are not any *insurmountable barriers* that hinder the undertaking’s ability to enter the market.²⁰³ The time of the entry must also be taken into consideration when determining if an undertaking is a potential competitor. According to settled case law, the Commission must prove, by factual evidence or an analysis of the structures of the market that the undertaking in question could enter the market “*sufficiently quickly*”.²⁰⁴

¹⁹⁷ See e.g. Final report of the Pharmaceutical sector inquiry, p. 269; Commission decision, AT. 39226 – *Lundbeck*, para. 661 and Case AT.39612 – *Perindopril (Servier)*, para. 1154.

¹⁹⁸ T-360/09, *E.ON Rubrygas and E.ON v. Commission*, para. 84 and the cited case law.

¹⁹⁹ Case T-472/13, *Lundbeck v. Commission*, para. 99; Case C-234/89, *Delimitis*, para. 21; Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94 *European Night Services and Others v. Commission*, para. 137, and Case T-461/07, *Visa Europe Limited and Visa International Service v. Commission*, para. 68.

²⁰⁰ Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, paras. 166.

²⁰¹ *Ibid*, para. 167 and Case T-177/04, *easyJet v. Commission*, paras. 123-125.

²⁰² Case T-461/07, *Visa Europe Ltd and Visa International Service v European Commission*, para. 168.

²⁰³ T-519/09, *Toshiba Corp. v. Commission*, para. 230 and T-208/13, *Portugal Telecom v. Commission*, para. 181.

²⁰⁴ T-360/09, *E.ON Rubrygas and E.ON v. Commission*, paras. 106 and 114.

The GC held in its judgments in both *Lundbeck* and *Servier* that the Commission had been correct in finding that the generic undertakings were potential competitors.²⁰⁵ The Commission's analysis is largely based on the fact that the existing process patents were not insurmountable barriers for the generic companies ability to enter the market. However, considering that a patent confers an exclusive right and a presumption for patent validity applies in competition law cases, how "real and concrete" are the possibilities of generic undertakings to actually enter the market? This was some of the arguments posed by Servier and Lundbeck.

At the time when the settlement agreements were concluded, all substance patents covering the medicine had expired and the originators only had process patents protecting some of the production methods of the medicines. The Commission considered that despite these process patents, generic undertakings would still have the ability to launch a generic version of a drug by finding other production methods that would not infringe existing process patents.²⁰⁶ The Commission recognized the presumption for patent validity, but accentuated that this presumption does not prevent the Commission from establishing potential competition.²⁰⁷ The Commission held that the presumption for patent validity does not mean that there also is a presumption that the generic versions infringed the patents – it is for the patent holder to bring an infringement action and to prove such alleged infringements in court.²⁰⁸ The Commission argued that as long as the generic undertakings have the possibility of challenging the validity of the originators patents, these patents could not constitute insurmountable obstacles to entry.²⁰⁹ In both *Lundbeck* and *Servier* all the generic companies had in fact been involved in legal actions or disputes concerning the originators process patents, whether in the form of a defense against infringement allegations or counterclaims to invalidate such patents. The Commission held that this was an expression of potential competition from the generic companies intent to enter the markets.²¹⁰

The Commission also relied on the parties' own perceptions that the parties had expressed in its internal documentation. This revealed that there was genuine doubt from both the originators and the generic undertakings to

²⁰⁵ General Court of the European Union, press release No 194/18 regarding Judgment T-691/14, *Servier and others v. Commission*, 12 December 2018, and press release No 90/16 regarding Judgment T-472-13, *Lundbeck v. Commission*, 8 September 2016.

²⁰⁶ Case AT.39226 – *Lundbeck*, para. 621 and Case AT.39612 – *Perindopril (Servier)*, para. 1169.

²⁰⁷ Case AT.39612 – *Perindopril (Servier)*, para. 1168.

²⁰⁸ Case AT.39226 – *Lundbeck*, para. 629 and Case AT.39612 – *Perindopril (Servier)*, para. 1171 and 1176.

²⁰⁹ Case AT.39226 – *Lundbeck*, para. 628 and Case AT.39612 – *Perindopril (Servier)*, para. 117, according to the GC this was also expressed by the Commission in Servier, see T-691/14, *Servier and Others v. Commission*, para. 368.

²¹⁰ Case AT.39226 – *Lundbeck*, para. 633 and Case AT.39612 – *Perindopril (Servier)*, para. 1179.

whether the process patents were valid or infringed.²¹¹ Lundbeck had even considered that there was a 60 % risk of having a court rule that the process patents were invalid and Lundbeck's generic contenders had referred to the process patent as "high school chemistry".²¹² In *Lundbeck* it was also the generic companies' view that it did not infringe the patents or if this was the case that they could switch to another non-infringing production method.²¹³ Furthermore, both Lundbeck and Servier had acknowledged that there were in fact other possibilities of producing the medicines without infringing the process patents.²¹⁴ Thus, the Commission found that it was clear that the parties viewed each other as potential competitors.

As another line of defense, Servier and Lundbeck both asserted that the fact that the generic undertakings had not received Market Authorizations they could not be perceived as potential competitors because this constituted an insurmountable barrier to entry. The Commission rejected this argument and held that the requirement of a generic undertaking to have a "real and concrete possibility" to enter the market would still be achieved even in the absence of Market Authorizations, as long as the generic was pursuing efforts to obtain regulatory approvals.²¹⁵ This had been done in both *Lundbeck* and *Servier*. In addition, the Commission also suggested that given that the patents were process patents, the generic undertaking's had several possible routes to enter the market at the time when the agreements were concluded. Among those possible routes it was included that the generic undertaking could launch its product "at risk" of having to face proceedings by the originator company.²¹⁶

Conclusively, the GC found that the Commission had been correct in establishing that the generic contenders of Lundbeck and Servier respectively were potential competitors.²¹⁷

5.2.2 Limitation to entry

The Commission's second criterion relates to whether the agreements contained clauses by which the generic undertakings limited or restricted its efforts to launch its generic versions of the drugs. On the one hand, it is difficult to see that potential competition would be restricted where the agreements would not limit generic entry. On the other hand, as has been discussed in chapter 3.3, where the parties decide to end an ongoing patent dispute by the means of a genuine and legitimate settlement agreement, a

²¹¹ Case AT.39226 – *Lundbeck*, para. 634 and Case AT.39612 – *Perindopril (Servier)*, para. 1172.

²¹² Case AT.39226 – *Lundbeck*, para. 627.

²¹³ *Ibid*, para. 1038.

²¹⁴ Case AT.39226 – *Lundbeck*, para. 634 and Case AT.39612 – *Perindopril (Servier)*, para. 1169.

²¹⁵ Case AT.39226 – *Lundbeck*, para. 1038 and Case AT.39612 – *Perindopril (Servier)*, para. 1181.

²¹⁶ Case T-472/13, *Lundbeck v. Commission*, para. 128.

²¹⁷ General Court of the European Union, press release No 194/18 regarding Judgment T-691/14, *Servier and others v. Commission*, 12 December 2018, and press release No 90/16 regarding Judgment T-472-13, *Lundbeck v. Commission*, 8 September 2016.

common and moreover accepted outcome is that the alleged infringer refrains from entering the market as a result from the recognition of the patent's validity. Under such circumstances it is also an inherent outcome that settlement agreements include so called non-challenge clauses for the purpose of settling existing and/or avoid future disputes.²¹⁸

Even though the Commission acknowledges that both non-compete and non-challenge clauses may be legitimate in the context of settling patent disputes, the Commission has emphasized that the generic companies submission to such clauses must be based on the parties recognition of the disputed patent's validity and the infringing nature of the generic products of such patents.²¹⁹ It is also necessary that such clauses are limited to the patent's scope of protection i.e. the settlement agreement cannot go beyond what would have been possible to achieve from a court ruling on patent validity and infringement.²²⁰ Was this the case in *Servier* and *Lundbeck*? Furthermore, if the legality of settlement agreements is dependent on an assessment of the patents' scope of protection, does the Commission and the GC really have the competence to rule on such matter?

In its judgments in *Servier* and *Lundbeck*, the GC held that even though the Commission or the EU Courts do not have the competence to determine the scope of a patent or its validity, these institutions cannot refrain from assessing competition law infringements merely because the scope of protection is relevant for this assessment. It was accentuated that such assessments would nevertheless "in no way prejudice the assessments of the competent national courts relating to patent rights".²²¹ In its assessments, the Commission considered Lundbeck's and Servier's remaining process patents and its different scope of protections as significant elements of the legal and economic context of which the disputed agreements had been concluded in. If Lundbeck and Servier had successfully enforced its patents in court, the scope of protection conferred by those patents would only afford protection against generic versions produced using the very same process as disclosed by those patents. In *Servier* the non-compete clauses actually covered the scope of Servier's patents, i.e. the generic undertakings were only hindered from launching generic versions of perindopril that were produced using Servier's process patents.²²² However in *Lundbeck*, the settlement agreements included non-compete clauses that covered all generic versions of citalopram and not only those production methods protected by Lundbeck's patents.²²³ Furthermore, these agreements

²¹⁸ Guidelines to technology transfer agreements, para. 242.

²¹⁹ Case T-472/13, *Lundbeck v. Commission*, paras. 335-336, 539 and T-691/14, *Servier and Others v. Commission*, paras. 258 and 260-262.

²²⁰ Case T-472/13, *Lundbeck v. Commission*, para. 333 and T-691/14, *Servier and Others v Commission*, para. 260.

²²¹ Case T-472/13, *Lundbeck v. Commission*, para. 333 and T-691/14, *Servier and Others v Commission*, para. 234-245.

²²² Case AT.39612 – *Perindopril (Servier)*, paras. 5-8 and 1309.

²²³ Case AT.39226 – *Lundbeck*, p. 290, paras. 824, 962, 1013, 1087 and 1174.

did not finally resolve any patent disputes since the agreements did not allow for the immediate market entry of the generic companies after the agreement's expiry.²²⁴ Nevertheless, the GC held in both *Servier* and *Lundbeck*, that regardless of whether the restrictive clauses went beyond the material scope of the patents or not, the agreements still constituted infringements of article 101 (1). The reason for this was that the generic undertaking's submission to those clauses was not a result from the parties' de facto recognition of the validity of the patents nor the existence of an infringement. Rather it was apparent that the generic companies only submitted to those clauses because they were induced to do so by the financial incentives offered by the originator companies through the value transfers.²²⁵

5.2.3 Value transfer

The existence of a value transfer from the originators to the generic undertakings was considered to play a decisive role on the generic undertaking's commitments under the agreements in both *Lundbeck* and *Servier*. The Commission was of the view that the generic undertakings would not have accepted the non-challenge and non-compete clauses absent the value transfers that were made.²²⁶ But what do these value transfers really indicate? Furthermore, since a settlement is a *mutually* acceptable compromise between the parties, must not all settlements include some sort of value transfer made from the patent holder in one way or the other?

The Commission asserted in both *Lundbeck* and *Servier* that although a value transfer in itself is not a proof of an anti-competitive conduct, it is considered to be a "warning signal" when a reverse payment is made in combination with a limitation to entry.²²⁷ In *Servier* the GC held that the very nature of a patent is to allow the patent holder to reward a fair profit from the investments made. Thus, when the parties to a settlement assert that they recognize the validity of a disputed patent then the agreement must in principle allow a value transfer to the holder and not the other way around.²²⁸ Hence, when a reverse payment is made in the context of a patent settlement agreement it is an indication that the patent is invalid or not infringed.²²⁹

In *Lundbeck* the GC held that the Commission had established that the reverse payments made by Lundbeck constituted inducements for the generics limitation on entry because of the *size* of the payments.²³⁰ Based on the

²²⁴ Case T-472/13, *Lundbeck v. Commission*, para. 497.

²²⁵ Case T-472/13, *Lundbeck v. Commission*, para. 336 and T-691/14, *Servier and Others v Commission*, para. 263-264.

²²⁶ Case T-472/13, *Lundbeck v. Commission*, para. 431 and T-691/14, *Servier and Others v Commission*, para. 270.

²²⁷ Case AT.39226 – *Lundbeck*, para. 702 and T-691/14, *Servier and Others v Commission*, para. 264.

²²⁸ T-691/14, *Servier and Others v Commission*, ECLI:EU:T:2018:922, para. 264.

²²⁹ See also the Commission's similar argumentation in Case AT.39226 – *Lundbeck*, para. 640.

²³⁰ Case T-472/13, *Lundbeck v. Commission*, paras. 262 and 266.

Commission's findings of what the generic companies expected to make in profits upon successful market entry, it appeared that the size of the reverse payments corresponded to these expected profits.²³¹ Therefore, the GC found that the Commission had sufficiently established that the significant reverse payments were inducements for the generic undertakings to accept the restrictive clauses.²³²

The size of the payments made in *Servier* were also an important factor, but the GC emphasized in its judgment that the mere presence of a reverse payment cannot lead to a conclusion that there is a restriction by object.²³³ The GC found that in order to determine whether a reverse payment is to be considered as an inducement for the generic manufacturers to accept the restrictive clauses, it is relevant to examine the nature of the payments and whether they can be justified.²³⁴ The GC held that in the context of patent settlements, a reverse payment may be justified where such payments cover the costs inherent to the settlement or the dispute, including e.g. the litigation costs of the generic company. However, if the reverse payments cover costs that are external to the dispute or the settlement then the reverse payments are not linked to the settlement agreement. Rather such costs are incurred independently of the occurrence of the patent disputes.²³⁵ Thus, the compensation in *Servier* covering the production- or development costs of the generic versions, as well as the costs for terminating third-party contracts were not justified.²³⁶ Therefore, the GC held that the Commission had correctly found that the reverse payments were excessive and covered more costs than could be justified. The payments were therefore to be seen as inducements for the generic's submission to restrict its entry to the market.²³⁷

5.2.3.1 *Side deals as a concealed value transfer*

The Commission alleged in *Servier* that the reverse payments did not only take the form of direct monetary transfers to the generic undertakings, but also through "side-deals". The GC held that there is a risk that a settlement agreement which contains restrictive clauses is covered by side deals. By taking the form of complex contractual arrangements, these side deals may serve as a tool to conceal value transfer from the patent holder to the generic company.²³⁸ The GC defined side deals as "usual commercial agreements" that are connected to a patent settlement agreement, which include clauses of a restrictive nature.²³⁹ A connection between a side deal and the settlement

²³¹ Case T-472/13, *Lundbeck v. Commission*, para. 500 and Case AT.39226 – *Lundbeck*, p. 661-662.

²³² Case T-472/13, *Lundbeck v. Commission*, para. 500.

²³³ T-691/14, *Servier and Others v Commission*, para. 265.

²³⁴ *Ibid.*, para. 265.

²³⁵ *Ibid.*, paras. 277-280.

²³⁶ *Ibid.*

²³⁷ *Ibid.*, para. 680.

²³⁸ *Ibid.*, paras. 801-802.

²³⁹ *Ibid.*, 798.

agreement may be either temporal or legal and is an indication that the agreement is actually “part of the same package”.²⁴⁰ A temporal connection exists when the two different agreements are concluded on the same day, while the legal connection exist when the “side-deal” agreement is conditioned upon the conclusion of the settlement agreement.²⁴¹ The GC held that a third form of connection might also exist if the Commission is able to establish that the side-deal agreement in view of the context that it is concluded is inseparable from the settlement.²⁴²

In *Servier* the Commission took the view that the licensing agreement between Servier and Krka that was legally connected to the settlement agreement was a side deal that concealed a value transfer to Krka. The licensing agreement allowed Servier a 3 % royalty on Krka’s net sales, which the Commission considered to be an abnormally low royalty.²⁴³ The GC held that licensing agreements do not in principle fall under the category of “suspicious” side deals. In fact, it was considered common to grant licenses in the context of patent settlement agreements.²⁴⁴ Furthermore, the GC emphasized that under licensing agreements, value transfers occur both ways; from the originator to the generic company since the latter can enter the market without risk, and the other way around through the payment of a royalty.²⁴⁵ The GC held that the Commission must therefore establish that the royalty rate was abnormally low for the licensing agreement to be considered a concealed value transfer. To establish that the restrictive clauses in the settlement agreement in connection with an abnormally low royalty rate constituted a sufficient degree of harm to competition, the GC also emphasized that the abnormality of such rate must be “all more obvious” to qualify as a restriction by object.²⁴⁶ The GC found that the Commission had not established that the royalty rate was abnormally low and could therefore not be considered a reverse payment.²⁴⁷

The Commission also alleged that the assignment agreement where Krka assigned its technology to Servier in return for EUR 30 million was to be seen as a concealed value transfer for Krka’s submission to the restrictive clauses in the settlement agreement.²⁴⁸ The GC found that since the agreements had been concluded two months after the settlement agreement, there were no temporal link. Nor had the Commission established the existence of a legal link between the two agreements or that they were inseparable in another way.²⁴⁹ The GC also observed that the Commission itself had made clear that there in fact was

²⁴⁰ Ibid, 798-799.

²⁴¹ T-691/14, *Servier and Others v Commission*, para. 798.

²⁴² Ibid.

²⁴³ Ibid, paras. 907-911, p. 192-194.

²⁴⁴ Ibid, paras. 943-963.

²⁴⁵ Ibid, paras. 950-951.

²⁴⁶ Ibid, para. 953.

²⁴⁷ Ibid, paras. 975-985 and 1030-1032.

²⁴⁸ Case AT.39612 – *Perindopril (Servier)*, para. 1670.

²⁴⁹ T-691/14, *Servier and Others v Commission*, para. 1057.

no link between the licensing and settlement agreements in its decision.²⁵⁰ The Commission had therefore wrongly concluded the existence of a restriction by object also in respect of the assignment agreement between Servier and Krka.²⁵¹

In this regard it is to be noted that since the Commission had not established that the restrictive clauses in the agreements in combination with the alleged side deals constituted a restriction by object, the Commission moved on to construct an effect-analysis. The GC held however that the Commission had not been able to prove that absent the agreements, Krka would have probably entered the market with its generic products. The GC held that since Krka had recognized the patent's validity in the settlement agreement it was not likely that Krka would have entered the market even at risk.²⁵² Thus, the agreements between Servier and Krka did not either constitute any restriction of competition by effect.²⁵³

5.2.4 The conclusions of the GC

In its judgments in both *Lundbeck* and *Servier* the GC upheld the three cumulative criteria used by the Commission in order to determine if a patent settlement agreement reveals a sufficient degree of harm to competition that it amounts to a restriction by object within the meaning of article 101 TFEU. The GC held that the Commission had correctly established that the generic undertakings were potential competitors since the remaining patents of Lundbeck and Servier were only process patents. Therefore the patents did not constitute insurmountable obstacles for the generic undertaking's abilities to enter the market. The Commission had also found evidence, which showed that the parties' did not recognize neither the validity of those patents nor the infringing nature of the generic versions. The originators had even themselves stated that other non-infringing production methods existed to produce the drugs. Based on an overall assessment of these factors the GC held that the Commission had established that the generic undertakings would have had real concrete possibilities to enter the market absent the agreements.

The Commission had also correctly assessed the legal and economic context of which the agreements were concluded in. By taking account to the remaining process patents and its scope of protection the Commission made a correct assessment of the restrictive clauses in the settlement agreements. The Commission considered that non-challenge and non-compete clauses could be legitimate in the context of patent settlements only were such clauses did not go beyond the patent's scope of protection, which was not the case in *Lundbeck*.

²⁵⁰ Ibid, para. 1058 with reference to statements made by the Commission in Case AT.39612 – *Perindopril (Servier)*, para. 1678.

²⁵¹ T-691/14, *Servier and Others v Commission*, para. 1060.

²⁵² Ibid, paras. 1140-1213.

²⁵³ General Court of the European Union, press release No 194/18 regarding Judgment T-691/14, *Servier and others v. Commission*, 12 December 2018.

The GC held that even though the clauses would conform to the patent's scope of protection (as it did in *Servier*) the agreements are still to be considered having as their object to restrict competition when it is clear that the originator has induced the generic undertakings to submit to such clauses through reverse payments. This was the case in all agreements made in *Lundbeck* because the size of the payments made were excessive and corresponded to the expected profits of the generic undertakings in the case they would have entered the market. The Commission's findings in *Servier* were confirmed in all agreements except the agreements concluded between Servier and Krka. The GC annulled part of the decision in this regard because the Commission had not established the existence of an inducement by Servier in exchange for Krka's withdrawal from the market. Consequently, the settlement agreement between Servier and Krka was neither considered a restriction of competition by object nor by effect.

The GC concluded that when it is established that the exclusion of competition is a result from an inducement by the originator company in the form of a reverse payment, such exclusion must be considered an extreme form of market sharing and production limitation when the excluded competitors were generic companies and amounts to a restriction of competition by object.²⁵⁴ It is clear that both the Commission and the GC are reluctant to accept arrangements where competitors exploit generally accepted settlement agreements as a veil to cover its collusive deals on the expense of society. In my view, it is absolutely necessary to ensure that collusive arrangements like pay-for-delay is prohibited and prevented. But is the Commission's three-step analysis really the best way forward?

²⁵⁴ T-691/14, *Servier and Others v. Commission*, para. 1058, with reference to C-209/07, *Beef Industry Development and Barry Brothers (BIDS)*, paras. 8 and 31-34, and Case T-472/13, *Lundbeck v. Commission*, para. 435.

6 Possible problems with the Commission's assessment of pay-for-delay agreements

6.1 Should the Commission's "by object" analysis be justified?

As discussed in the previous chapter, when a certain type of agreement is considered a restriction of competition "by object" it must reveal by its very nature a sufficient degree of harm to competition. A classification of a certain type of agreement under the "by object" approach must be made on experience that this type of arrangement repeatedly has the same negative effects on competition that it deserves to be automatically condemned by the competition rules. It could be questioned whether the classification of pay-for-delay settlements is really based on such experience?

Prior to 2009, when the pharmaceutical inquiry was made, the Commission had never considered settlement agreements containing reverse payments as a competitive constraint, either under the object-approach or the effect-approach. It was not until the first decision in *Lundbeck*, quickly followed by the decision in *Servier*, that the Commission condemned settlement agreements with reverse payments as restrictions of competition by object. Thus, the automatic condemnation was done without having any prior cases where such agreements had been analyzed under the effect-approach. As has been discussed, such condemnation must be based on proper experience by which the agreements have repeatedly shown to have severe negative *effects* on competition that it is justified to penalize the agreement for the sake of procedural economy.²⁵⁵ It could therefore be questioned whether settlement agreements that includes a reverse payment really deserves to be automatically condemned as a restriction by object? Might there be a risk that the Commission condemns settlement agreements that might actually be genuine and legitimate from a competition law perspective?

As seen from the GC's judgment in *Servier*, the Commission had incorrectly alleged that the agreements between Servier and generic manufacturer Krka constituted a restriction by object, which was later proven to not even constitute a restriction by effect. Something that is worthy of note in regards to the effect analysis of Krka's ability to enter the market is the fact that the GC

²⁵⁵ See section 5.1.3.

welcomed the Commission's findings in the internal documentation where the parties' own perceptions appeared for establishing that Krka was a potential competitor. Despite this, the GC still did not consider that Krka would have been able to enter the market, even at risk. As recalled, the Commission had found statements where Servier had acknowledged that there were in fact other possibilities of producing perindopril without infringing Servier's process patents.²⁵⁶ This was a decisive factor for finding that Servier's process patents were not *insurmountable obstacles* for the generic undertaking's entry, including Krka. These statements did however not seem to matter under the effect-analysis, since the GC found that Krka probably could not even enter the market "at risk" absent the agreements. In my view this is a bit contradictory, because if there actually were other methods that could be used by the generic undertakings, would not Krka have been able to enter the market even if its current method was infringing the patent? This was apparently not something that the Commission was able to prove once it moved on to the effects-analysis. Based on this thought-experiment it could therefore also be questioned if there might not be a risk that the other agreements in *Servier* also would have been found not restrictive of competition by its effects if the Commission had carried out a full effects-analysis of these agreements as well?

As discussed in the previous chapter, the rationale behind automatically condemning certain types of anti-competitive arrangements is to create legal certainty. It is important that undertakings and its legal counsels are able to *ex-ante* foresee the legal consequences of its agreements so that they are able to modify their conduct accordingly.²⁵⁷ Critics have however condemned the Commission's three-criteria-test as being "too abstract and simplistic" to show whether a settlement agreement is anti-competitive by its very nature.²⁵⁸ Other critics have similarly held that there is a lack of sufficiently clear guidelines of the core illegality of settlement agreement's and that the "several hundred pages *too long*" decisions "sows confusion and uncertainty and makes daunting the tasks of judicial review".²⁵⁹ This criticism is understandable too some extent. It is reasonable that the legal community calls for clearer guidelines to enable undertakings to predict the legal consequences to clear out any competitive concern. However, just because a certain practice *may* amount to a restriction by object does not mean that every practice will ultimately be found to do so. This is to be decided from case to case. Furthermore, it is important to recall that in the context of complex patent rights, no undertaking will probably find any spot on previous case to use as a thumb stock. Nevertheless, there are some parts of the Commission's assessments in *Lundbeck* and *Servier* that has given rise to skepticism in the legal doctrine.

²⁵⁶ See section 5.2.1.

²⁵⁷ see section 5.1.3.

²⁵⁸ Killick, J., Jourdan, J., & Kickinson, J., *The Commission's Lundbeck Decision: A Critical Review of the Commission's Test For Patent Settlement Agreements*, Competition Policy International, 2014, p. 7.

²⁵⁹ Forrester, p. 18 and Schröder, p. 508.

6.1.1 Possible problems with the “potential competition”-criteria

In its decisions, the Commission sets out to establish a formal classification consisting of three cumulative conditions under which settlement agreements are to be considered to have as its object the restriction of competition. However, it has been criticized that it is apparent from the decisions and judgments in both *Lundbeck* and *Servier*, that other factors not part of the “test” have held significant weight on the outcome.²⁶⁰ One of these factors were the parties’ own perceptions that appeared in the internal documentation, which was relevant for the finding of potential competition. On the one hand, it is true that this factor is not explicitly part of the Commission’s test, which might be criticized from a legal certainty-perspective. On the other hand, it has been established in the Court’s previous case law that the subjective intent and perceptions can be of relevance to establish a restriction by object and might therefore in my view be superfluous to include in the test.

Another criticism that has been raised is that the Commission does not duly take patent law into consideration. These critics mean that the Commission’s finding of a potential competitor based on the uncertainty of patent validity jeopardizes the value of- and the presumption for validity of the originator’s patents.²⁶¹ Critics mean that by considering generic undertakings as potential competitors because they can launch their products “at risk” goes against the presumption for patent validity, which “instructs treating them [*the patents*] as valid until otherwise proven”.²⁶² The Commission and the GC has however held that the presumption for patent validity does not mean that there *also* is a presumption for infringement. In my view, it is clear that unless a competent court has ruled on the matter, it is equally certain or uncertain that a patent is valid or that the generic product infringes that patent. Furthermore, even though there might be different reasons to why the parties decide to settle ongoing disputes, the very fact that there even was something to dispute about (either patent validity or infringement) does in my view speak for that the parties are potential competitors. Why would a generic company contest the validity of a patent if it were not part of a plan to fulfill its intentions of entering the market? And the fact that there was a behavior from the generic undertaking that brought an infringement action from the patent holder must speak for that the holder thought of the generic company as a potentially competitive threat. It is of course possible that both parties genuinely consider a patent valid and might decide to settle a dispute merely to e.g. avoid legal costs or prolonged litigation. Nevertheless, the fact that the generic company will still be deemed as a potential competitor under the Commission’s test should not be problematic in such a case, because that settlement agreement

²⁶⁰ Perinetto, p. 75.

²⁶¹ Schröder, p. 508 and Friend, M., *Reverse patent settlements and EU competition law*, The Cambridge Law Journal, Cambridge, Vol. 76 (1), pp. 29-32, March 2017, p. 30-31.

²⁶² Schröder, p. 508

should under such circumstances logically not consist of a *reverse* payment. This is because, as the GC explained, the recognition of a valid patent should allow the holder to reward from its investments, not the other way around.²⁶³ Denying the competitive relationship between originators and generic companies would disregard the very core business of generic manufacturing that is based on producing the pharmaceutical innovations created by originators. The very fact that potential competition is a condition in the Commission's "by object" analysis does not mean that when this criterion is fulfilled, the settlement agreement is automatically condemned as a restriction by object. The condition is merely a necessary means for there to even be a competitive relationship to analyze.

What is notable is however the fact that for an undertaking to be considered a potential competitor, the ability of that undertaking to enter the market must, according to settled case law, be made "*sufficiently quickly*". It is for the Commission to provide factual evidence or an analysis of the structures of the market that such is the case.²⁶⁴ In my view this was not properly done in either *Lundbeck* or *Servier*. Even though the Commission considered it possible for the generic's to launch their products "at risk", the Commission's assessment also relied on the fact that there were other possibilities available for producing the drug. The Commission did however not provide any factual evidence for these "available possibilities" nor can it be said that an analysis of the market structures were made. Rather the Commission seemed to have taken the availability of these "other production methods" for granted by relying on the internal documentation where the originators merely had stated that there were other possibilities. This was not something that the GC considered problematic, but maybe should have? Should the Commission really be able to rely on statements made from the parties as "factual evidence", even when such evidence do not speak a word on the "quickness" of a possible switch? Ultimately it is the alleging party that holds the burden of proof to show that the parties to an agreement are actual or potential competitors by following the established rules in the Court's case law, not the other way around. Nevertheless, in the cases of *Lundbeck* and *Servier*, it was maybe enough to show that the generics asserted competitive pressure on the originators merely because the generics could launch its current product "at risk" of facing infringement actions. But would not then all generic undertakings be potential competitors absent a court ruling confirming infringement?

²⁶³ See section 5.2.3.

²⁶⁴ See section 5.2.1.

6.1.2 Potential challenges with the “limitation to entry”-criteria

In the Commission’s assessment of whether the agreements included restrictive clauses that limited the generic undertaking’s commercial freedom, the disputed patent’s scope of protection was pivotal for determining the legality of these agreements. As recalled, restrictive clauses in a settlement agreement is only legal if they correspond to what would have been possible to achieve if the patents were enforced in court.²⁶⁵

Opponents of competition law intervention in the area of patent related agreements have claimed that the Commission’s assessment of patent settlement agreements amounts to a “second-guessing” of the legitimate boundaries of patent law which increases uncertainty and may lead to inconsistencies and unduly deter genuine patent settlements even when they do not entail a restriction of competition.²⁶⁶ In its assessment, the Commission and the GC recognizes that these institutions do not have the competence to determine the scope of a patent or its validity. But it was accentuated that this cannot mean that it must refrain from assessing competition law infringements when such factors are important for determining the legality of a possibly anti-competitive agreement.²⁶⁷ In my view, this statement is characterized by a high degree of logic and goes in line with the previously discussed “existence/exercise” dichotomy and “specific subject matter” doctrine.²⁶⁸ The very fact that an agreement relates to a patent right does not mean that competition law denies the existence of such right. Settling patent disputes is however not part of a patent’s specific subject matter and therefore is an exercise that must be scrutinized by the rules of competition.

However, what is likely to be problematic with having the Commission assessing whether or not the settlement agreement’s “four angles” has extended the patent’s scope of protection is the very fact that the Commission may not be the best suited to do so. Even though it is emphasized that such assessments “in no way prejudice the assessments of the competent national courts relating to patent rights”, it is still a matter of fact that such assessments might be a difficult task for the Commission to tackle. The legal literature rightly problematizes a number of difficulties that the Commission must unravel in order to be able to assess a patent’s scope of protection.²⁶⁹ First, to assess the patent’s scope of protection requires a detailed assessment of the patent claims.²⁷⁰ Second, since patents are governed by the territoriality principle, an evaluation should be made with regards to every relevant national patent and its different patent legislations. Some jurisdictions might include a “doctrine of

²⁶⁵ See section 5.2.2.

²⁶⁶ Bruzzone & Capozzi, p. 17.

²⁶⁷ See section 5.2.2.

²⁶⁸ See section 2.3.

²⁶⁹ Schröder, p. 510-511.

²⁷⁰ A patent claim defines the invention by describing its technical function and the structure.

equivalence” that the Commission must take into consideration. This doctrine means that the patent’s claims can under certain circumstances be extended to cover more than what the literal wording of the claims discloses, and thus extend its scope of protection.²⁷¹ Third, an analysis of a patent’s scope of protection is very demanding and highly technical, why it requires vast recourses and expertise, both legal and technical.²⁷² The Commission did not take any of these difficulties into consideration when it established that the settlement agreements in *Lundbeck* extended the scope of Lundbeck’s patent. In *Servier* this was not a problem since the non-compete in the settlement agreement were limited to generic versions covered by Servier’s process patents.²⁷³

However, irrespective of whether or not the Commission rightly concluded that restrictive clauses in the settlement agreements went beyond the scope of the patent or not, it is still a matter of fact that the generic undertakings (except Krka) were induced by the originators to submit to the clauses and limit its entry in exchange for a payment. Again, it is important to remember that the Commission’s three-condition test is cumulative; the second condition “limitation to entry” is dependent on the third “a value transfer from the originator which substantially reduced the incentives to enter the market”. Thus it is pointless to merely conclude whether the restrictive clauses went beyond the patent’s scope of protection to find a restriction by object, because neither one of the three conditions do not say anything about the restrictive object of an agreement merely by looking at them separately. Thus, it is therefore reasonable to conclude that by cumulatively linking the two latter criteria, the Commission successfully distinguishes between legitimate settlement agreements and between those that constitute pay-for-delay agreements. In legitimate settlement agreements there would naturally be a limitation to generic entry due to the parties’ legitimate recognition of the validity of the patent and not because they were paid to do so. Even if the generic undertakings in *Lundbeck* and *Servier* actually had thought that the patents were valid, it would not have made any difference once the payments covered more than it had to. Assuming that all undertakings are economically rational, why would originators pay an excessive sum of money to a competitor who willingly surrenders to the will of the originators?

6.1.3 Criticism against the “value transfer”-criteria

In the legal literature it has been asserted that a value transfer in a patent settlement does not reveal much about whether competition is affected or not. Instead, it is asserted that a value transfer in the form of a reverse payment

²⁷¹ Domeij, 2007, p. 107-108.

²⁷² Schröder, p. 510-511.

²⁷³ See section 4.2.2 and 5.2.2.

merely increases the other party's will to settle the dispute.²⁷⁴ As a matter of fact, this line of argumentation goes well in line with the Commission's reasoning. The Commission explained in both *Lundbeck* and *Servier* that a value transfer *in itself* is not a proof of an anti-competitive conduct. Rather, it is considered to be a "warning signal" when a reverse payment is made in combination with a limitation to entry.²⁷⁵ Indeed, a reverse payment may increase the generic undertaking's incentives to settle a dispute. This is not something that the Commission has anything against, as long as the reverse payment correlates to the costs inherent to the dispute. The payment cannot be so excessive that it can be seen as the ultimate reason to why the generic undertaking submits to settle the dispute and agrees to limit its commercial freedom. Again, it must be reiterated that a genuine settlement where the parties recognize the validity of the patent must in principle allow a value transfer to the patent holder and not the other way around.²⁷⁶ Thus, it must be reasonable to conclude that where i) a reverse payment is made, although the parties recognize the patent's validity and despite the fact that there might be other production methods possible, and ii) the generic company accepts a non-challenge and a non-compete clause, then such payments do in fact indicate that the purpose of the reverse payment was something other than to end a *de facto* patent dispute.

Critics also challenge the Commission's findings that the size of a reverse payment is an indicator of an anti-competitive conduct. Instead, it is asserted that the size of the payment only reveals how risk averse the patent holder is of moving forward with court proceedings. Considering that the originator company has "everything to lose" it is suggested that even if the patent holder is confident of winning, a small risk of losing will still always be likely. The price drop followed by generic entry makes it almost impossible for the originator to recoup its financial investments in the drug. It is therefore suggested that it might be economically more rational to settle and pay the generic undertaking, than taking the small risk of losing.²⁷⁷ This line of argumentation is in my view quite difficult to agree with. If a patent holder is so convinced of the patent's validity and that the generic undertaking infringed this, a court order would prevent the generic company from unlawfully entering the market and would also allow for any possible damages to be paid. On the one hand this could indeed entail a small risk of losing. On the other hand, reaching a successful public court order could also create a wide uncertainty among other generic

²⁷⁴ Schröder, p. 509, with reference to Schmid, M., *Pharmaceutical Reverse Payment Settlements: A European Perspective in the Wake of the Sector Inquiry*, *European Competition Law Review*, 33(8), pp. 367-379, 2012, p. 379 [cit. Schmid]; McDonald, *Patent Settlements That Flow the 'Wrong Way'*, 15, *Antitrust Healthcare Chronicle* 2, 2002, p. 12, and Treacy & Lawrence, *Intellectual Property Rights and Out of Court Settlements*, *Intellectual Property and Competition Law*, 2011, p. 295.

²⁷⁵ See section 5.2.3.

²⁷⁶ See section 5.2.3.

²⁷⁷ Schmid, p. 371-373.

contenders ultimately resulting in their legal refrainment from entering the market. Furthermore, the competitive price pressure that generic undertakings pose on originators is a characteristic part of the pharmaceutical sector's structure.²⁷⁸ Therefore, launching a pharmaceutical product always entails great financial risks, which the originator is willing to take. This "risk" cannot be used to justify that the originator finds it more economically viable to pay of its competitors rather than facing that risk. Moreover, trying to justify large payments based on the originator being "risk averse" would not be found justified in accordance with the GC's judgment in *Servier*, since only costs inherent to the dispute are qualified for justification.²⁷⁹

What could potentially lead to problems with the Commission's value transfer-criteria from a legal certainty perspective is the very fact that *side deals*, i.e. usual commercial agreements, as the GC defines them, may be found to constitute a concealed value transfer if the Commission is in a position to prove that there is a link between the side deal and the settlement agreement.²⁸⁰ It is understandable that when there is a temporal or legal link between a settlement agreement and a commercial agreement that is beneficial to the generic company, undertakings ought not to be too surprised if a competition authority declares such as constituting a reverse payment when the first two conditions of the test also are fulfilled. However, the GC found that an agreement would be considered a concealed reverse payment also when the Commission is in a position to prove that the agreements are *inseparable*. This third possibility for linking side deals to settlements was however and unfortunately not further explained by the GC. Even though an assessment is to be made in each case, the "by object" classification still requires that a degree of legal certainty be created, certainly where this category of restraints are extended.²⁸¹ How are undertakings supposed to know *ex-ante* whether or not a commercial agreement, which neither has a temporal nor legal link to a settlement agreement, will be deemed "inseparable" from a settlement agreement when there is no guidance on this matter? This may cause a lot of damage to the undertakings *ex-post* the agreements are concluded. It is however in the interest of society that the use of complex commercial arrangements to possibly shield collusive deals are scrutinized by competition authorities and the Commission. Nevertheless, the lack of sufficiently clear guidelines in this regard also makes the Commission or the NCA's investigations more difficult.

Furthermore, in *Servier* the GC held that a licensing agreement in connection with a settlement agreement is to be considered as a restriction by object only where the Commission is able to establish that the royalty is "abnormally low" and therefore is to be considered a value transfer from the originator

²⁷⁸ See section 3.1.

²⁷⁹ See section 5.2.3.

²⁸⁰ See section 5.2.3.1.

²⁸¹ See section 5.1.3.

company.²⁸² Since licensing agreements in connection with patent settlements are generally considered not to cause any competition law concern²⁸³, it is reasonable that for an abnormally low royalty, in connection with restrictive clauses in a settlement, to reveal a sufficient degree of harm to competition must be “all more obvious” to qualify as an object restriction. In *Servier* a 3 % royalty was not considered abnormally low by the GC, however without any further explanation. It is questionable where the Court’s threshold level for this “abnormality” lies and what considerations that stands behind this threshold?

Lastly, what also raises questions is the very fact that where royalty rates are deemed normal, a licensing agreement from the originator to the generic undertaking does not raise any competitive concern because a value transfer occur both ways allowing the generic undertaking to enter the market without risk. But has the *generic* undertaking really entered the market under such circumstances? Is the generic undertaking not in fact, at least implicitly, controlled by the originator undertaking in regards to its pricing? Even though imposing fixed or minimum prices amounts to resale price maintenance, which is a restriction by object in itself, recommended prices is allowed.²⁸⁴ In my view it is a fair assumption to assert that the expected price drop resulting from generic entry is probably not likely to occur when the generic undertaking enters the market with a license from the originator company. Thus, the important effects of generic entry to society will be delayed. Nevertheless, these possible societal effects and expected price drop does not say anything about whether the agreement in question had an anti-competitive object or effect, but are rather an ethical reflection. It needs to be remembered that when an agreement is not considered to be restrictive by its object, it is for the Commission to prove the actual or likely negative effects that the agreement has on competition, which apparently was not provable in *Servier*.²⁸⁵

6.2 The United States’ “Rule of Reason” – a better approach in the name of legal certainty?

In several legal articles where critics condemns the Commission’s approach to tackle pay-for-delay settlements in the EU, it has been suggested that the United States’ approach to restrain these collusive arrangements is better and should be applied in EU.²⁸⁶

Under the antitrust laws of the United States, a distinction between certain types of anti-competitive agreements has been made similar to the “by object”

²⁸² See section 5.2.3.1.

²⁸³ See section 3.3.

²⁸⁴ C-161/84, *Pronuptia*, para. 25 and C-243/83, *Binon v. AMP*, para. 44.

²⁸⁵ See section 5.2.3.1.

²⁸⁶ See e.g. Geradin, et al.; Schröder and Schmid.

and “by effect” categories of restraints under article 101 TFEU. In the US certain types of agreements that are considered seriously harmful to competition are directly prohibited under the so-called “*per se*” approach, while less serious anti-competitive constraints are treated under a “*rule of reason*”.²⁸⁷ The legality of patent settlements containing reverse payments under the US antitrust laws is governed by the rule of reason.²⁸⁸

Under the rule of reason the US courts’ assessment of an agreement has to be made *in casu* by weighing the positive and negative effects of that agreement to establish if the agreement complies with the antitrust laws.²⁸⁹ This resembles the possibility of an individual exemption under article 101 (3) under EU competition law where an agreement may be exempted from being prohibited if the positive effects outweigh its negative effects.²⁹⁰ There is however an important difference between the rule of reason and the efficiency defense under article 101 (3). The latter is constrained to only allow for an efficiency defense based on the pre-defined and closed list of efficiencies in article 101 (3), while any such rigid framework does not exist for the US courts under the rule of reason.²⁹¹ Another difference is that in the EU, as discussed in the previous chapter, when an agreement is considered as an object restriction it is presumed unlikely of having any outweighing positive effects on competition and therefore unlikely to produce the required efficiencies.²⁹² Thus, the “by object” category of agreements in the EU resembles the *per se* abuses under US antitrust law. Even though the US considers pay-for-delay settlements under the rule of reason and not as *per se* abuses, is the US assessment really that different from the EU Commission’s “by object” approach?

In the judgment from the US Supreme Court in *FTC v. Actavis*²⁹³ the Court held that a reverse payment patent settlement can “sometimes unreasonably diminish competition in violation of the antitrust laws”. The Court also established that “a large and unjustified reverse payment can bring in the risk of significant anticompetitive effects”.²⁹⁴ The Court however rejected that patent settlements containing reverse payments should be deemed “presumptively unlawful”. Instead the Court established that these settlements agreements are neither presumptively lawful nor unlawful and must therefore be evaluated on a case-by-case basis under a rule of reason.²⁹⁵ The Court did however not establish how this rule of reason was to be constructed or which factors to be considered in determining the legality of these agreements. What the Court however held was that the likelihood of a reverse payment being anti-

²⁸⁷ Bernitz, 2005, p. 63.

²⁸⁸ Geradin, et al., p. 128.

²⁸⁹ Bernitz, 2005, p. 63.

²⁹⁰ See section 5.1.

²⁹¹ Bernitz, 2005, p. 127.

²⁹² See section 5.1.3.

²⁹³ *FTC v. Actavis, Inc.*, 570 U.S. (2013).

²⁹⁴ Geradin, et al., p. 128, with reference to *FTC v. Actavis*.

²⁹⁵ *Ibid.*

competitive depends on “its *size*, its scale in relation to the payer’s *anticipated future litigation costs*, its *independence from other services* for which it might represent payment, and the *lack of any other convincing justification*”.²⁹⁶

As seen in *Lundbeck* and *Servier*, the above-mentioned determinant factors as held by the Supreme Court in *FTC v. Actavis* are in my view however not that different from those to be assessed under the established approach from the Commission and the GC.²⁹⁷ Even though the assessment to be made under the “by object” approach cannot be said to entail a full-blown rule of reason or an efficiency defense under article 101 (3) TFEU, the Commission’s “by object” approach still allow for a possibility for undertakings to show the legitimacy of their patent settlement agreements even when they include reverse payments. This ought to be the reality since the Commission reported that 45 patent settlement agreements containing reverse payments had been assessed in the pharmaceutical sector inquiry.²⁹⁸ Still only two decisions has been delivered, namely *Lundbeck* and *Servier*. This speaks for that the Commission’s test is in fact efficient in distinguishing legitimate settlements from those that have an anti-competitive object.

²⁹⁶ Geradin, et al., p. 128, with reference to *FTC v. Actavis* (emphasis added).

²⁹⁷ See sections 5.2.1-5.2.3.1.

²⁹⁸ See section 4.1.

Conclusions

An agreement that restricts competition by object is considered to be a hardcore restriction because it reveals a sufficient degree of harm to competition that its anti-competitive effects are presumed. When assessing whether an agreement has as its object the restriction of competition regard must be made to the agreement's content, its objectives and the economic and legal context of which it forms a part. A "by object" classification of a certain type of agreement such as reverse payment patent settlements must be made on experience that this certain type of arrangement repeatedly has the same negative effects on competition that it deserves to be automatically condemned by the competition rules. Prior to 2009, when the pharmaceutical sector inquiry was made, there were no decisions or judgments where it was established that settlement agreements containing reverse payments had the same negative effects on competition as those found in *Lundbeck* and *Servier*. Despite this, the Commission's classification of these agreements as "by object" restrictions should however still be deemed justified. The reason behind this is that these pay-for-delay agreements amount to an extreme form of market sharing and production limitation, which are restrictions of competition by object that are *in particular* harmful to competition as stated in article 101 (1) (b-c). Even for a short period of time, the foreclosure of generic medicines is sufficient to deter competition on the market to the detriment of the European health care systems and citizens dependent on affordable medicines. The benefits made by the colluding parties are therefore at the expense of society.

When a settlement agreement is concluded between competitors on a given market, there is always a risk for competitive concern. These concerns are further increased where the agreement is conveniently concluded at the time of expected market entry of one of the agreeing parties, and that market entry is restricted or even suspended due to the agreement. Where the settlement agreement involves some form of payment being made from the market incumbent to the party that agrees to stay out of the market the warning signals are loud and clear. This gives reasons to scrutinize the real purpose behind those payments being made. When the primary reason to why the excluded party has agreed to stay out of the market is because that party deemed it more lucrative to share the monopolistic profits of the market incumbent, rather than pursuing its own intentions of market entry, the agreement does in fact have as its object the restriction of competition.

A lot of criticism has been raised against the decisions and following judgments in *Lundbeck* and *Servier* asserting that the Commission's approach is inadequate to inter alia distinguish legitimate settlements from anti-competitive settlements and therefore should not be justified. Some criticism is in my view legitimate and some are not. However, the legitimate criticism mostly relates to the assessments made in regards to the specific circumstances of the two cases and not the Commission's cumulative three-condition test as a whole. The clarifications made by the GC relating to how the three conditions should be assessed and what the Commission must prove supplements the test and contributes to both foreseeability and legal certainty of the competitive assessment of patent settlements. Both judgments have been appealed to the ECJ, and further clarification is expected. In my view, there are however no reason to believe that the ECJ will annul the GC:s judgments.

Conclusively, the cumulative three-condition assessment of patent settlement agreement containing reverse payments promotes both competition and innovation. By distinguishing between settlements that are legitimate from those that are not, the competitive structure of the pharmaceutical sector remains intact which ultimately benefits the consumer welfare and safeguarding of human health. Likewise can it be said that innovation is promoted by removing collusive arrangements that reduce the incentives for undertakings to innovate and compete on their own merits, thus promoting development in the pharmaceutical industry.

Bibliography

Legislation

Convention on the Grant of European Patents, of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

Directive 2004/27/EC of the European parliament and of the council of 31 march 2004 amending Directive 2001/83/EC on the community code relating to medicinal products for human use.

Consolidated version of the Treaty on European Union, Protocol (No 27) on the internal market and competition, 12008M/PRO/27, 2008.

Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

Consolidated Version of the Treaty on the Functioning of the European Union, OJ 2012, C 326/49 [cit. TFEU].

Swedish Patents Act, Swedish Statute Book, SFS, 1967:837, in the version in force from July 1, 2014.

Official documents of the European Union

Commission Notice: Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, C 101/81, 27 April, 2004 [cit. Guidelines on the effect on trade concept].

Communication from the Commission Notice – Guidelines on the application of Article 81(3) of the Treaty (2004/C 101/08).

European Commission, Pharmaceutical Sector Inquiry Final Report, 8 July 2009 [cit. Final report of the Pharmaceutical sector inquiry].

European Commission, Executive Summary of the Pharmaceutical Sector Inquiry Report, 2009 [cit. Executive summary of the pharmaceutical sector inquiry report].

General Court of the European Union, press release No 90/16 regarding Judgment T-472-13, *Lundbeck v. Commission*, 8 September 2016. Available at:

["https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-09/cp160090en.pdf"](https://curia.europa.eu/jcms/upload/docs/application/pdf/2016-09/cp160090en.pdf) (Retrieved 2019-05-10).

Communication from the Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements (2017/C 89/03) [cit. Guidelines to technology transfer agreements].

General Court of the European Union, press release No 194/18 regarding Judgment T-691/14, *Servier and others v. Commission*, 12 December 2018. Available at: ["https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-12/cp180194en.pdf"](https://curia.europa.eu/jcms/upload/docs/application/pdf/2018-12/cp180194en.pdf) (Retrieved 2019-05-10).

European Commission, Competition Enforcement in the Pharmaceutical Sector (2009-2017), COM (2019) 17 final, Brussels, 28 January 2019 [cit. Competition Enforcement in the Pharmaceutical Sector (2009-2017)].

Commission decisions

Case AT. 39226 – Lundbeck, C (2013) 3803 final. Available at: ["http://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_8310_11.pdf"](http://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_8310_11.pdf) (Retrieved 25 February 2019).

Case AT.39685 – Fentanyl, C (2013) 8870 final. Available at: ["http://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf"](http://ec.europa.eu/competition/antitrust/cases/dec_docs/39685/39685_1976_7.pdf) (Retrieved 20 February, 2019).

Case law

C-56/64, *Consten and Grundig v. Commission*, ECLI:EU:C:1966:41

C-56/65, *Societe Technique Miniere (STM) v. Maschinenbau*, ECLI:EU:C:1966:38

C-24/67, *Parke, Davis v. Centrafarm*, ECLI:EU:C:1968:11

C-41/69, *ACF Chemiefarma v. Commission*, ECLI:EU:C:1970:71

C-6/72, *Continental Can*, ECLI:EU:C:1975:50

C-15/74, *Centrafarm v. Sterling Drug*, ECLI:EU:C:1974:114

Joined Cases C-209/78 to 215/78 and 218/78, *Van Landenyeck and Others v. Commission*, ECLI:EU:C:1980:248

C-187/80, *Merck v. Stephar*, ECLI:EU:C:1981:180

C-15/81, *Schul*, ECLI:EU:C:1982:135

C-193/83, *Windsurfing International v. Commission*, ECLI:EU:C:1986:75

C-243/83, *Binon v. AMP*, ECLI:EU:C:1985:284

C-161/84, *Pronuptia*, ECLI:EU:C:1986:41

C-65/86, *Bayer AG and Maschinenfabrik Hennecke v. Heinz Süllhöfer*, ECLI:EU:C:1988:448

C-234/89, *Delimitis*, ECLI:EU:C:1991:91

C-10/89, *CNL-SUCAL v. HAG*, ECLI:EU:C:1990:359

T-7/89, *Hercules Chemicals v. Commission*, ECLI:EU:T:1991:75

T-17/93, *Matra Hachette v. Commission*, ECLI:EU:T:1994:89

C-232/94, *MPA Pharma v. Rhône-Poulenc Pharma*, ECLI:EU:C:1996:289

Joined Cases T-374/94, T-375/94, T-384/94 and T-388/94 *European Night Services and Others v. Commission*, ECLI:EU:T:1998:198

T-111/96, *ITT Promedia v. Commission*, ECR, EU:T:1998:183

T-41/96, *Bayer AG v. Commission*, ECLI:EU:T:2000:242

T-177/04, *easyJet v. Commission*, ECLI:EU:T:2006:187

C-238/05, *ASNEF-EQUIFAX*, ECLI:EU:C:2006:734

T-321/05, *AstraZeneca v. Commission*, ECLI:EU:T:2010:266

C-501/06 P, *GlaxoSmithKline Services and Others v. Commission and Others*, ECLI:EU:C:2009:610

C-209/07, *Beef Industry Development and Barry Brothers (BIDS)*, ECLI:EU:C:2008:643

T-461/07, *Visa Europe Ltd and Visa International Service v. European Commission*, ECR, EU:T:2011:181

C-8/08, *T-mobile Netherlands and Others*, ECLI:EU:C:2009:343

C-52/09, *Konkurrensverket v. TeliaSonera Sverige AB*, ECLI:EU:C:2011:83

T-360/09, *E.ON Rubrgas and E.ON v. Commission*, ECLI:EU:T:2012:332

T-119/09, *Protégé International v. Commission*, ECR, EU:T:2012:421

T-519/09, *Toshiba Corp. v. Commission*, ECLI:EU:T:2014:263

C-32/11, *Allianz Hungária Biztosító and Others*, ECLI:EU:C:2013:160

Joined Cases C-274/11 and C-295/11, *Spain and Italy v. Council*, ECLI:EU:C:1996:289

C-1/12, *Ordem dos Técnicos Oficiais de Contas*, ECLI:EU:C:2013:127

C-67/13 P, *Groupement des Cartes Bancaires v. Commission*, ECLI:EU:C:2014:2204

C-170/13, *Huawei Technologies*, ECLI:EU:C:2015:477

T-208/13, *Portugal Telecom v. Commission*, ECLI:EU:T:2016:368

T-472/13, *Lundbeck v. Commission*, ECLI:EU:T:2016:449

T-691/14, *Servier and Others v. Commission*, ECLI:EU:T:2018:922

National case law

FTC v. Actavis, Inc., 570 U.S. (2013).

Opinions of Advocate Generals

Opinion of Advocate General Wahl in case C-67/13 P, *Groupement des cartes bancaires v. Commission*, ECLI:EU:C:2014:1958 [cit. AG Wahl opinion in C-67/13 P].

Literature and articles

Anderman, S., & Schmidt, H., *EU Competition Law and Intellectual Property Rights - the Regulation of Innovation*, 2nd ed., Oxford University Press, 2011.

Bernitz, U., *svenskt och europeiskt marknadsrätt 1*, 2005, Nordstedt Juridik [cit. Bernitz, 2005].

Bernitz U., Karnell, G., Pehrson, L., & Sandgren, C., *Immaterialrätt och otillbörlig konkurrens*, 13th ed., Jure bokhandel, Stockholm, 2013 [cit. Bernitz, et al.].

Bernitz U., & Kjellgren A., *Europarättens grunder*, 5th ed., Nordstedts Juridik, Stockholm, 2014 [cit. Bernitz & Kjellgren].

Bruzzone, G., & Capozzi, S., *The Procompetitive and Anticompetitive Impact of Patent Settlements*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp. 15–30, 2016 [cit. Bruzzone & Capozzi].

Castanheira, M., Oranghi, C., Siotis, G., & de Frutos, M.A., *The consequences of generic entry: price, promotional effort and market share*, July 5 2016. Available at: <http://www2.aueb.gr/conferences/Crete2016/Papers/Siotis.pdf> (Retrieved 25 february, 2019).

Chowdhury A., & Gaigl A., § 1.01: *The Economics of Competition Law and of Pharmaceutical Patents*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law*

in the Pharmaceutical Sector: An International Perspective, International Competition Law Series, Volume 65, Kluwer Law International, pp.5-14, 2016 [cit. Chowdhury & Gaigl].

Domeij, B., *Läkemedelspatent – Patent på läkemedel i Europa ur ett rättsvetenskapligt och ruttsekononiskt perspektiv*, Jure AB, Stockholm, 1998 [cit. Domeij, 1998].

Domeij, B., *Patenträtt*, Justus Förlag AB, Stockholm, 2007 [cit. Domeij, 2007].

Ezrachi A., *EU Competition Law – An Analytical Guide to the Leading Cases*, 6th ed., Hart Publishing, Oxford, 2018.

Forrester, I.S., §2.02: *The Dangers of Settling Patent Litigation*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp. 67-76, 2016 [cit. Forrester].

Friend, M., *Reverse patent settlements and EU competition law*, The Cambridge Law Journal, Cambridge, Vol. 76 (1), pp. 29-32, March 2017.

Geradin, D., Ginsburg, D.H., & Safty, G., §2.07: *Reverse Settlements in the European Union and the United States*, in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective*, International Competition Law Series, Volume 65, Kluwer Law International, pp. 125-146, 2016 [cit. Geradin, et al.].

Hettne J., & Otken Eriksson I., *EU-rättslig metod – teori och genomslag i svensk ruttstillämpning*, 2nd ed., Norstedts Juridik AB, Stockholm, 2011 [cit. Hettne & Otken Eriksson].

Jones A., & Sufirin B., *EU Competition Law*, 6th ed., Oxford University Press, Oxford, 2016 [cit. Jones & Sufirin].

Killick, J., Jourdan, J., & Kickinson, J., *The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test For Patent Settlement Agreements*, Competition Policy International, 2014. Available at:

“<https://www.competitionpolicyinternational.com/assets/The-Commissions-Lundbeck-decision-A-critical-review-of-the-Commissions-test-for-patent-settlement-agreements.pdf>” (Retrieved 14 May, 2019).

Kleineman, J., in Korling F., & Zamboni M., (red.), *Juridisk metodlära*, 1st ed., Studentlitteratur, Lund, 2013 [cit. Kleineman].

Kolstad. O., Report from the Swedish Competition Authority (report 2009:3), *Object contra effect in Swedish and European competition law*, 2009. Available at:

<http://www.konkurrensverket.se/globalassets/publikationer/uppdragsforskning/objekt-contradict-in-swedish-and-european-competition-law.pdf> (Retrieved 11 May, 2019).

McDonald, *Patent Settlements That Flow the Wrong Way*, (2002) 15, *Antitrust Healthcare Chronicle* 2, 2002.

De Mello-Sampayo, F., de Sousa-Vale, S., & Camões, F., *Substitutability Between Drugs, Innovation, and Fiscal Policy in the Pharmaceutical Industry*, *Annals of economics and finance* 16-2, p. 273–289, 2015. Available at: ["http://aeconf.com/Articles/Nov2015/aef160202.pdf"](http://aeconf.com/Articles/Nov2015/aef160202.pdf) (Retrieved 11 April, 2019).

Mestre-Ferrandiz, J., Sussex, J. and Towse, A., *The R&D cost of a new medicine*, Office of Health and Economics, December 2012. Available at: ["https://www.ohe.org/publications/rd-cost-new-medicine"](https://www.ohe.org/publications/rd-cost-new-medicine) (Retrieved 4 February, 2019).

Murray, G., *In search of the obvious: Groupement des cartes bancaires and "by object" infringements under EU competition law*, *European Competition Law Review*, 36(2), 2015 [cit. Murray].

Nagy, C. I., *The Distinction between Anti-competitive Object and Effect after Allianz: The End of Coherence in Competition Analysis?*, *Law and Economics Review*, Kluwer Law International, The Netherlands, 2013 [cit. Nagy].

Peczenik, A., *Juridikens allmänna läror*, *Svensk Juristtidning (SvJt)*, no. 3, pp. 249-272. Available at: ["https://svjt.se/svjt/2005/249"](https://svjt.se/svjt/2005/249) (Retrieved 23 December, 2018) [cit. Peczenik].

Perinnetto, P.A., *The complexities of the EU competition law assessment of pharmaceutical pay-for-delay agreements*, *European Competition Law Review*, 39(2), pp. 70-76, 2018 [cit. Perinnetto].

Reichel, in Korling F., & Zamboni M., (red.), *Juridisk metodlära*, 1st ed., Studentlitteratur, Lund, 2013.

Schmid, M., *Pharmaceutical Reverse Payment Settlements: A European Perspective in the Wake of the Sector Inquiry*, *European Competition Law Review*, 33(8), pp. 367-379, 2012 [cit. Schmid].

Schröder, V., *Pay-for-delay settlements in the EU: did the Commission go too far?*, *European Competition Law Review*, 37(12), pp. 506-512, 2016 [cit. Schröder].

Treacy & Lawrence, *Intellectual Property Rights and Out of Court Settlements*, *Intellectual Property and Competition Law*, 2011.

Turner, J., *Intellectual Property and EU Competition Law*, 2nd ed., Oxford University Press, Oxford, 2015 [cit. Turner].

Van Cleynenbreugel, P., *Article 101 TFEU and the EU Courts: Adapting legal form to the realities of modernization?*, *Common Market Law Review*, 51, United Kingdom, pp. 1381–1436, 2014.

Vinje T., *The Intellectual Property and Antitrust Review*, 2nd ed., Law Business Research Ltd, London, 2017.

Other

World Health Organization, Cancer prevention. Available at:
“www.who.int/cancer/en/” (Retrieved 2019-02-03).

The Swedish medical products agency, Det här är ett läkemedel. Available at:
“www.lakemedelsverket.se/malgrupp/Allmanhet/Vad-ar-ett-lakemedel/” (Retrieved 2019-02-03).

WIPO Intellectual Property Handbook: *Policy, Law and Use*. Available at:
www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch2.pdf. (Retrieved 2019-02-06) [cit. WIPO Intellectual Property Handbook].

European Commission, *Patent protection in the EU*. Available at:
“www.ec.europa.eu/growth/industry/intellectual-property/patents_fr” (Retrieved 2019-02-06)