Specialeafhandling: Pharmaceutical Reverse Payment Settlements - a European Perspective

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1. Setting the scene

Patent settlement agreements concluded by pharmaceutical companies have been under intensive competition law scrutiny in Europe for almost ten years now. Such agreements are intended to settle an actual or potential patent dispute and therefore lie in the intersection between competition law and patent protection. This intersection is complex, especially in the pharmaceutical sector for which patent protection is particularly important due to the expensive and time-consuming nature of the development of new medicines.

In 2008, the European Commission launched a sector inquiry into competition in the pharmaceutical sector. During this inquiry, these patent settlement agreements came into focus.

The Final Report, published in 2009, contains the results of the sector inquiry. It indicates that certain types of settlement agreements concluded by innovative pharmaceutical companies and generic pharmaceutical companies are designed to extend the exclusivity period granted by patent law. Such agreements result in delayed market entry of cheaper generic medicines to the detriment of European consumers whom will not benefit from the lower prices, which would have followed with generic entry.

In particular, settlement agreements that limit a generic company’s access to the market and include a value transfer from an innovative pharmaceutical company to the generic company have attracted a high degree of competition law scrutiny. Such settlement agreements are called reverse payment agreements. They are also

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1 See Part III, chapter 10 ‘Understanding Patent Settlements’
2 Hereinafter ‘the Commission’
5 See chapter Part II, chapter 5 ‘Main Stakeholders’
6 Final Report, para 1573
8 Payments in patent settlement agreements between originator and generic companies usually flow from the generic company. Hence, because of the unexpected direction of the payment,
called pay for delay agreements; indicating that the limitation on generic market entry is linked to the value transfer from the innovative pharmaceutical company.

The Commission has so far adopted three decisions regarding pay for delay agreements: the *Lundbeck (Citalopram)* decision from June 2013,\(^9\) the *Johnson&John-\(\text{son (Fentanyl)}\) decision from December 2013,\(^10\) and the *Servier (Perindopril)* decision from July 2014.\(^11\) In all three decisions, the Commission found that the pay for delay agreements were comparable to market sharing agreements and thus had the object to restrict competition.\(^12\) The Commission was therefore not required to demonstrate any actual or potential anticompetitive effects of the settlement agreements for the finding of an infringement of Article 101 of the Treaty on the Functioning of the European Union (TFEU).\(^13\)

In September 2016, the General Court of the European Union\(^14\) upheld the Commission’s *Lundbeck (Citalopram)* decision and held that agreed with the Commission that the correct analysis to be applied was the ‘by object’ analysis.\(^15\) This judgement is the General Court’s first and only judgement regarding pay for delay agreements.

The Commission has been criticised for applying the ‘by object’ analysis when assessing reverse payment agreements, especially in the light of the Court of Justice of the European Union’s\(^16\) recent judgement in *Groupement des cartes bancaires (CB)*\(^17\) in which it was held that the concept of ‘by object’ restrictions should be interpreted restrictively and applied in light of experience gained.

Taking this judgement and the fact that pay for delay agreements are new types of agreements, which have not yet been ruled on by any European court before, it is

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\(^9\) Decision of 19 June 2013, *Lundbeck*, COMP/AT.39226, hereinafter ‘*Lundbeck (Citalopram)*’

\(^10\) Decision of 10 December 2013, *Fentanyl*, COMP/AT.39685, hereinafter ‘*Johnson&Johnson (Fentanyl)*’

\(^11\) Decision of 9 July 2014, *Servier (Perindopril)*, COMP/AT.39612, hereinafter ‘*Servier (Perindopril)*’

\(^12\) See Part IV chapter 16 ‘The Commission’s Decisions on Pay For Delay Agreements’

\(^13\) Consolidated version of the Treaty on the Functioning of the European Union, OJ C 326, 26 October 2012, p. 47-390 (hereafter TFEU)

\(^14\) Hereinafter ‘the General Court’

\(^15\) Press Release MEMO/16/2994, ‘Antitrust: Commission welcomes General Court judgement upholding its Lundbeck decision in first pharma pay-for-delay case’, 8 September 2016. See Part V ‘The General Court’s Approach’

\(^16\) Hereinafter ‘the Court of Justice’

interesting to analyse how the General Court found these agreements to constitute ‘by object’ restrictions.
2. Purpose

This thesis presents the main characteristics of the pharmaceutical industry and examines the different types of patent settlement agreements concluded by originator and generic companies. In particular, this thesis investigates reverse payment agreements.

Fundamentally, the aim of this thesis is to clarify the application of European competition law on patent settlement agreements and to examine what types of such agreements the Commission considers as problematic from a competition law perspective. It also intends to analyse the approach taken by the Commission and the General Court when considering pay for delay agreements as ‘by object’ restrictions and what factors they take into account when assessing such agreements.

Finally, the Commission’s and the General Court’s finding of restrictions of competition by object is discussed in light of the Court of Justice’s interpretation of the concept of ‘by object’ and of the context in which patent settlement agreements are concluded in the pharmaceutical sector.

2.1. Research Question

This thesis gives an answer to the following research question:

What types of patent settlement agreements concluded by pharmaceutical companies are problematic from a European competition law perspective? How are these agreements analysed and to what extent is this analysis appropriate for the assessment of such settlement agreements?
3. Delimitation

This thesis focuses on patent settlement agreements concluded by pharmaceutical companies within the European Union. Such settlement agreements may be concluded between two or more originator companies and between originator and generic companies. This thesis only focuses on patent settlement agreements concluded by originator and generic companies.

Settlement agreements may violate both Article 101 and Article 102 TFEU, however, it is not the aim of this thesis to cover all competition law aspects of such agreements. This thesis focuses on violation of Article 101 TFEU.

Patent settlement agreements lie in the intersection between competition law and patent protection. This thesis focuses mainly on competition law but will give an overview of patent protection in the pharmaceutical sector in order to give an understanding of the context in which patent settlement agreements are concluded.
4. Methodology

The research question posed in this thesis is answered based on a traditional legal dogmatic method. The legal sources included are traditional sources in European law, such as primary legislation, including the TFEU, and secondary legislation of the EU, including relevant regulations, directives, Commission’s decisions and case law of the Court of Justice and the General Court. European soft law such as guidelines, reports, communications and press releases from the Commission is also included.

The Commission’s findings in its Final Report of the sector inquiry\(^\text{18}\) and European and US academic literature are used to describe the main characteristics of the pharmaceutical industry in Europe. This is done in order to give an understanding of the economic context in which patent settlement agreements are concluded. The specific context establishes the basis for understanding the benefits and effects of patent settlement agreements.

The legal dogmatic method is mainly used to describe, systematise and interpret the application of the relevant legal provisions on patent settlement agreements. The provisions are subject to a literal interpretation focusing on the ordinary meaning of the wording. However, the context in which the words are used and the context of the purpose underlying the provisions are taken into account in order to reveal the provisions’ correct normative content.\(^\text{19}\) This is done to identify the applicability of Article 101 TFEU to patent settlement agreements and to distinguish legal settlement agreements from anticompetitive settlement agreements.

The case law of the Court of Justice and decisions from the Commission are of primary relevance for specifying the scope of Article 101 TFEU, since the provisions of the TFEU establish a general legal framework. However, it is only recently that attention has been directed towards patent settlement agreements in the pharmaceutical sector and there is therefore a scarcity of European case law specifically dealing with the assessment of such agreements. The Commission has

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\(^{18}\) The information on which the Commission carried out its sector inquiry stems from, inter alia, surprise inspections at the premises of a number of originator and generic companies, requests for information sent to 46 originator companies and 39 generic companies, and submissions by stakeholders and specialised offices such as the European Patent Office. See the Annexes to Chapter A, Part II to the Final Report, para 1-12 \textit{http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part2.pdf} accessed 22 July 2017

adopted three decisions on pay for delay agreements, while the General Court has given only one judgement on these agreements. The lack of European judgements of specific relevance to the research question asked give the Commission’s guidelines and reports an important role. The relevant European judgements are analysed in order to establish the approach taken by the European authorities when assessing pay for delay agreements and to examine what factors are taken into account in the assessment.

US sources, including literature and articles, are also included in this thesis. Much of the literature on competition law and patent settlement agreements in the pharmaceutical sector is US centric, since the US directed attention to pay for delay agreements years before the European Union and the case law has developed more rapidly. However, it is not the purpose of this thesis to engage in an actual comparison of US and EU case law. Rather, the use of US sources serves to deduce the commercial and economic reasoning, which may be relevant to the interpretation of the application of Article 101 TFEU on patent settlement agreements.

This thesis makes use of the terminology and concepts employed by the stakeholders in the pharmaceutical industry when describing the different types of patents and medicines and related strategies. It thus includes terms and concepts not defined in competition law or patent law.
PART II - MARKET STRUCTURE OF THE PHARMACEUTICAL INDUSTRY

The structure of the pharmaceutical industry is characterised by a high degree of regulation20 and a great variety of stakeholders. The regulation of the industry aims at achieving different objectives. These objectives range from supporting innovation to ensuring a high degree of public health.21 The most important form of innovation in the industry is the research and development of new medicines that enable patients to benefit from treatments that were not available before.22 The significant research and development efforts of originator companies are thus of key importance for achieving innovation and ensuring a high level of public health.

The pharmaceutical industry is one of the most research-intensive industries and it has one of the largest investments in research and development compared to other industries.23 It is expensive and time-consuming to develop new medicines and continued innovation in the industry is thus only possible when the protection of intellectual property rights is adequately ensured.

This chapter describes the main characteristics of the pharmaceutical industry, including the role of the most important stakeholders and the life cycle of a medicine. It also describes the different types of intellectual property rights in the industry. The chapter intends to give an overview of the structure of the industry and the competitive environment in which the stakeholders operate. This is done in order to facilitate the understanding of the importance of patent protection in the industry and the understanding of the economic context in which patent settlement agreements are concluded.

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20 The most relevant areas of legislation for the pharmaceutical industry seem to be i) patent law and the enforcement system, ii) the marketing authorisation system and iii) the pricing and reimbursement system. See European Commission, 'Pharmaceutical Sector Inquiry: Final Report', para 1289
5. Main Stakeholders

The industry is characterised primarily by two types of pharmaceutical companies: originator companies and generic companies.

5.1. Originator Companies

Originator companies are research based pharmaceutical companies that carry out research into new medicines, develop them from the laboratory and launch them on the market after obtaining a marketing authorisation.\textsuperscript{24} They invest billions of dollars on research and development of new medicines. It is estimated that they invest over $30 billion each year in the search for new medicines.\textsuperscript{25} It is the development of the medicine consisting of carrying out clinical trials to prove safety and efficacy that constitutes the lion share of the time and costs incurred before the medicine is ready to be launched on the market. The development phase is associated with high risks since the success rate through this phase is extremely low.\textsuperscript{26} Originator companies are thus engaged in time-consuming, expensive and high-risk business.

5.2. Generic Companies

Generic companies are pharmaceutical companies that produce and sell generic medicines that are identical to original medicines in that sense that the generic medicines contain the same active ingredients and are used in the same doses to treat the same diseases.\textsuperscript{27} Generic companies do not need to carry out clinical trials as originator companies if they can prove that their medicine is equivalent to the

\textsuperscript{24} European Commission, ‘Pharmaceutical Sector Inquiry Final Report’, para 47
\textsuperscript{26} Between 1993 to 2003, the failure rate increased from 81 percent to 91 percent, meaning that the majority of discovered medicines never make it to the market because it is found not to work or to have serious side effects. See David Taylor, ‘The Pharmaceutical Industry and the Future of Drug Development’, Pharmaceuticals in the Environment (2015) 1-33, p. 8; and Timo Minssen, ‘Assessing the Inventiveness of Bio-Pharmaceuticals under European & US Patent Law - A comparative study with special emphasis on DNA & protein-related technology’ (2012), p. 5
\textsuperscript{27} European Commission, ‘Pharmaceutical Sector Inquiry Final Report’, para 48
original medicine, for which such trials have already been carried out.\textsuperscript{28} This saves generic companies high development costs and time. Additionally, the original medicines have already shown to be commercially successful in the market, and generic companies are thus low-cost and low-risk business compared to originator companies.\textsuperscript{29}

5.3. The Competitive Environment

In view of the above descriptions of originator and generic companies, the main difference between these two companies resides in the procedure to prove safety and efficacy of the medicine; originator companies must prove this through their own clinical trials, while generic companies can rely on results from such clinical trials if their medicine is equivalent to the original medicine.

This difference causes an asymmetry of risk in the industry; originator companies invest billions of dollars on research and development and rarely have a successful medicine, while generic companies are engaged in low-cost and low-risk business and rarely have an unsuccessful medicine.

Generic companies can thus launch generic medicines at a much lower price.\textsuperscript{30} Consequently, the vast majority of all medicines sold are generic medicines, while originator companies, however, represent a great part of the industry in terms of finance.\textsuperscript{31}

The asymmetry of risk in the industry is in some ways balanced through the patent system.\textsuperscript{32}


\textsuperscript{30} Since generic medicines are identical/equivalent to original medicines, the only way for generic companies to compete with originator companies is therefore on price. This is contrary to competition between originator companies which takes place mainly on quality and sales promotion. See European Commission, ‘Pharmaceutical Sector Inquiry Final Report’ (8 July 2009), para 209


\textsuperscript{32} See Part II, chapter 7 ‘The Importance of Patent Protection’
6. Product Life Cycle

The life cycle of a new medicine can be divided into three phases i) research, development and marketing authorisation, ii) launch, and iii) loss of exclusivity. In every phase, patent protection plays a crucial role for originator companies.\(^{33}\)

6.1. Research, Development and Marketing Authorisation

The first phase of the life cycle of a new medicine comprises “\([…]\) the initial discovery of a new molecule and its development as a new medicine up to market authorisation \([…]\)\(^{34}\)” Originator companies consider to filing patent applications already during the initial discovery if the new molecule is identified as a potential treatment for a disease.\(^{35}\) However, they can continue to file patent applications throughout the medicine’s entire life cycle.\(^{36}\)

In the development of a new medicine, originator companies carry out clinical trials in both animals and humans in order to demonstrate that the medical product is safe, effective and of good quality. The results of such clinical trials must be submitted in order to obtain a marketing authorisation for the medicine,\(^{37}\) which is needed before the medicine can be placed on the market within the European Union.\(^{38}\)

This first phase of the life cycle of a new medicine is a complex, expensive and time-consuming process for originator companies. The phase can take between two to ten years, with an average of five years.\(^{39}\)

\(^{33}\) European Commission, ‘Pharmaceutical Sector Inquiry Final Report’, para 129
\(^{34}\) European Commission, ‘Pharmaceutical Sector Inquiry Final Report’, para 133
\(^{36}\) See Part II, chapter 8 ‘Types of Patents’
\(^{37}\) Directive 2004/27/EC on the Community code relating to medical products for human use, Article 8(3)
\(^{38}\) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medical products for human use, Article 6. The European marketing authorisation system offers several procedures to obtain an authorisation; the centralised procedure, the mutual recognition procedure and the decentralised procedure. It is outside the scope of this thesis to describe the procedures for marketing authorisation in detail. See https://ec.europa.eu/health/authorisation-procedures_en for further information
6.2. Launch

During the second phase, originator companies launch their new medicine on the market. At this time, originator companies have obtained patent protection for their new medicines and thus have exclusive rights.

It is in this phase during which originator companies must generate sufficient revenues to cover their research and development investments and earn profit. It is worth mentioning that the full research and development costs for originator companies include costs for both medicines that make it to the market and those that fail along the way.40

6.3. Loss of Exclusivity

The third phase occurs when the medicine loses its exclusivity; meaning that the exclusive rights for the medicine expire.41

At this time, any company has the possibility to enter the market with a generic version of the original medicine. Occasionally, generic companies enter the market earlier; in cases where the generic company believes that the originator company’s patents are not valid or in cases where the generic company believes it has found a way to produce the medicine without infringing the originator company’s patent rights.42 This is called entering the market ‘at risk’.

The price at which generic companies enter the market is significantly lower than the price of the originator medicine. The Commission’s Final Report has shown that average prices dropped about 25 percent after two years in markets with generic entry.43 The launch of generic medicines thus confronts originator companies with challenges as a result of drastically falling revenues.

41 See Part II, chapter 7.1. ‘Supplementary Protection Certificate (SPC)’
42 European Commission, ‘Pharmaceutical Sector Inquiry Final Report’, para 89
43 European Commission, ‘Pharmaceutical Sector Inquiry Final Report’, para 212
7. The Importance of Patent Protection

A patent is an exclusive right that protects an invention provided that it is "[...] new, involve an inventive step and are susceptible of industrial application." The exclusive rights conferred by a patent give the patent holder the right to prevent third parties from making, using, offering for sale, selling, or importing the product without the patent holder’s consent.

If the invention is a process, the exclusive rights are extended to the products directly obtained by such process.

The term of a European patent is 20 years from the date of filing the application.

In the pharmaceutical sector, this means that originator companies that have obtained patent protection for a new medicine retain exclusive rights for that medicine for 20 years. The rationales for such an exclusive right is to ensure originator companies compensation for their investments in developing the new medicines and to provide continued incentives for research and development of new medicines in general.

The asymmetry at risk in the pharmaceutical industry explained above makes it even more important to grant originator companies exclusive rights. As explained by the Commission, "[...] given the clear disparity between the high cost and risk of innovation in the pharmaceutical sector and the low cost and risk of imitation, it is self-evident that exclusivity and thus protection from imitation is needed if there is to be innovation."

44 Convention on the Grant of European Patents (European Patent Convention) 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 52
45 World Trade Organization (WHO), Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 28(1)
46 European Patent Convention, Article 64
47 European Patent Convention, Article 63(1)
In addition, the long life cycle of a medicine makes patent protection particularly important for the pharmaceutical industry.\textsuperscript{50} The criteria that an invention must be ‘new’ in order to be patent protected means that originator companies must apply for patent protection before any information about the new medicine reaches the public.\textsuperscript{51} This is why originator companies often apply for patents already in the initial discovery of a new molecule; several years before the originator companies can launch their new medicine on the market and recoup their investments. This means that the time from originator companies file patent applications to market launch can be lengthy with the consequence, that the time in which originator companies can cover their research and development investments is substantially less than the 20 years patent protection envisaged by the European Patent Convention.\textsuperscript{52}

The European legislature has acknowledged that the time from filing a patent application to market launch makes the period of effective protection under patent law insufficient to cover the investments put into research and development in the pharmaceutical industry. As a reaction hereto, a new regulation was adopted in 1992 which created a supplementary protection certificate (SPC) for medical products.\textsuperscript{53}

7.1. Supplementary Protection Certificate (SPC)

A supplementary protection certificate (SPC) is an intellectual property right that provides an additional patent-like protection to already patented medicines. It confers the patent holder the same rights as a patent.\textsuperscript{54}

\textsuperscript{50} EU Commission, ‘Pharmaceutical Sector Inquiry: Final Report’, para 9
\textsuperscript{51} The novelty criteria is only fulfilled if the invention “does not form part of the state of the art” which comprises everything that is public accessible. See European Patent Convention, Article 54(1) and (2)
\textsuperscript{53} Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medical products
\textsuperscript{54} Council Regulation No 1768/92 concerning the creating of a supplementary protection certificate for medical products, Article 5 and 6
The supplementary certificate takes effect at the end of the protection period of the patent and can prolong the patent protection with up to five years from patent expiry. A patent holder with both a patent protection and a supplementary protection certificate can enjoy a maximum period of 15 years protection from the time the medicine first obtains a marketing authorisation.

There is a third exclusive right in the pharmaceutical sector, which applies in parallel with the rules on patents and supplementary protection certificate. This exclusive right concerns data and marketing.

As described, the data collected through clinical trials required to obtain a marketing authorisation is associated with significant costs. The rules on data exclusivity give originator companies the benefit from an eight-year period of data exclusivity from the date of first marketing authorisation; meaning that generic companies cannot use an originator company’s data from clinical trials before eight years.

While the rules on marketing exclusivity give originator companies the benefit of a ten-year period of marketing exclusivity from the date of first marketing authorisation; meaning that generic medicines cannot be placed on the market until ten years have elapsed.

The third phase of the life cycle of a medicine; loss of exclusivity, when generic medicines can enter the market, occurs when patent protection, supplementary protection certificate and data and marketing exclusivity expire.

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55 See Council Regulation No 1768/92 concerning the creating of a supplementary protection certificate for medical products, Article 13(1) and (2)
56 The duration of the certificate is equal to the time between the date on filing patent application and the date of first marketing authorisation, reduced by a period of five years. Example: A company applies for a patent in 1985 and obtains first marketing authorisation in 1993 (8 years). The patent expires in 2005 (20 years later from patent application), making the period of effective protection 12 years (from 1993 to 2005). If the company obtains a supplementary protection certificate, the company can prolong the patent protection with 3 years (8 years between filing patent application and first marketing authorisation reduced by 5). The exclusive right is thus prolonged to 2008 (15 years from first marketing authorisation in 1993)
57 Directive 2004/27/EC on the Community code relating to medicinal products for human use, Article 10
8. Types of Patents

In its sector inquiry, the Commission found that the main types of inventions in the pharmaceutical sector relate to i) new molecules, ii) new formulations of already patent protected medicines, and iii) new processes for producing the medicine.59 All these inventions are patentable, given they meet the objective criteria for patentability in the European Patent Convention: ‘new’, ‘inventive step’ and ‘susceptible of industrial application’.60

Patents covering new molecules are often referred to as ‘primary patents’ or ‘original patents’, while patents covering new formulations or new processes are referred to as ‘secondary patents’.61

When a primary patent expires, the molecule of the medicine is no longer protected and the market is, in principle, open for any generic company. The criterion that an invention must be ‘susceptible of industrial application’ means that the new discovered molecule must be capable of exploitation in the industry. In other words, a patent application for a new molecule must describe the way in which it can be produced. The original patent therefore consists of both the molecule and the original production process; meaning that the exclusivity for both expires at the same time.

Secondary patents are often obtained during the development phase and after launch of the medicine. This means that patent protection of different aspects of a medicine expires at different times and, consequently, creates confusion as to the exact scope of the patent protection and to the exact exclusivity period.

In addition, the Commission found in its sector inquiry that the number of secondary patents has increased, especially close to the expiry of the original patent.62 This means that the exact scope of protection and the period of protection is not always easy to determine and that originator companies and generic companies thus may disagree upon the validity and/or scope of a patent protection.

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59 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 259
60 European Commission, Annexes to Chapter B, Part III to the Final Report, para 132
61 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’ (8 July 2009), para 260
62 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 461
9. Summary

The pharmaceutical industry is characterised by two main stakeholders: originator companies and generic companies. Originator companies are researching for and developing new medicines, which is a high-cost, high-risk and time-consuming business. On the contrary, generic companies are producing and selling generic medicines, which is a low-risk and low-cost business. Hence, an asymmetry of risk in the competitive environment in the industry exists.

This asymmetry in the industry is to some extent balanced by granting originator companies exclusive rights for a medicine for a limited period of time in which they can recoup their significant research and development investments. However, the long life cycle of a medicine means that the time in which originator companies can recoup their investments is substantially less than the 20 years patent protection envisaged by the European Patent Convention. This has led to the adoption of supplementary exclusive rights, including supplementary certificate protection and rules on data and marketing exclusivity. The rationale behind these exclusive rights is to support innovation in the pharmaceutical industry that is necessary in order to bring new medicines to the market.

It is clear that the pharmaceutical industry relies heavily on patent protection and other exclusive rights to ensure continued innovation in the industry.

Generic companies can, in principle, enter the market after the expiry of the original patent, Supplementary Protection Certificate and data and marketing exclusivity. However, they must respect any process patents. Generic medicines can be launched with a significantly lower price than original products and originator companies are thus confronted with challenges as a result of drastically falling revenues.
PART III - PATENT SETTLEMENTS AND COMPETITION LAW

During the sector inquiry, the Commission identified a number of strategies that originator companies may use to try to extend the commercial life of their medicines and to ensure continued revenue streams for their patented medicine by restricting generic entry to the market. Such strategies may be problematic from a competition law perspective as they delay market entry of cheaper generic medicines to the detriment of European consumers. These delays are important as the price at which generic companies enter the market is significant lower than the price of the original medicines.

The strategies observed include, inter alia, filing numerous patent applications in relation to a single medicine (‘patent clusters’), engaging in patent disputes and litigation with generic companies and concluding settlement agreements with generic companies. In particular, the Commission dealt with the strategy to conclude so-called patent settlement agreements with generic companies.

This chapter explains patent settlement agreements in general and the incentives to conclude them. This is done in order to give an understanding of the rationale behind such agreements. This chapter also explains the application of competition law on patent settlement agreements. In light of the purpose of this thesis, it presents Article 101 TFEU, including the concept of potential competition and the concept of ‘by object’ restrictions. The latter concept is examined in light of recent case law from the Court of Justice in order to give an understanding of the interpretation of the concept.

The different types of patent settlement agreements concluded by originator and generic companies are explained in Part IV, chapter 14.1. ‘Classification of Different Types of Settlement Agreements’

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63 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 1557
64 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, paras 167 and 1558
10. Understanding patent settlements

A patent dispute may arise in different ways. It may arise in connection with a generic company claiming that the originator company’s patent(s) is invalid; either by entering the market ‘at risk’ or by seeking a declaration of non-infringement in court. A patent dispute may also arise in connection with an originator company claiming that a generic medicine is infringing its patents.

A settlement is generally accepted as a legitimate way to end a patent dispute. The involved companies may settle their dispute before any legal proceedings have started, or in the case of litigation before a final judgement is given.

A patent settlement is a commercial agreement between the involved companies that settles a patent-related dispute. Generally, such settlements are concluded in order to resolve the companies’ claims and to end the dispute at issue. Since patent settlements are concluded in the context of the specific patent dispute, they are fact-specific and the content and terms of settlements therefore vary. In addition, it must be recalled that a medicine is often protected by several exclusive rights; such as original patent, process patents, Supplementary Certificate Protection and data and marketing exclusivity. This creates confusion as to the exact scope of patent protections.

According to statistics issued by the Commission, the number of patent settlements in the pharmaceutical industry has increased significantly since the year 2000. In the period 2000-2007 the average number of patent settlements were around 24 per year, while in the period 2008-2015 the average number was around 105 settlements per year.

However, the number of patents granted by the European Patent Office has also increased the last ten years. It is clear that the more patents granted, the more

disputes may arise, and consequently, more disputes have the potential to settle out of court.

10.1. Incentives for concluding patent settlements

There are various reasons why companies may wish to settle their dispute, rather than proceed to its final judgement.

Patent litigations are considered to be complex and very technical. Especially patent litigation cases in the pharmaceutical sector can be complex due to the high number of patents protecting the same medical product. The companies involved are therefore allocating many resources to solve the dispute and they may not be able to focus on other businesses. Both companies also risk being imposed considerable costs, since the losing company may be required to reimburse the winning company. Thus, the companies may prefer to discontinue the dispute or litigation because it proves to be costly and time-consuming to continue.\(^{70}\)

The complexity surrounding patent litigation means that the ultimate outcome of such litigation can never be foreseen, which leads to uncertainty for the involved companies;\(^{71}\) it is uncertain whether the patent will be declared invalid or not, and it will thus be uncertain for the generic company whether it can enter the market, while it will be uncertain for the originator company whether it will be exposed to generic competition.\(^{72}\)

This commercial uncertainty that the involved companies are facing is another important factor when deciding to settle a dispute. If the companies are able to find a solution to solve the dispute that benefits them both, they will most likely prefer to settle instead of continue the litigation.\(^{73}\)

Although the costs, time and commercial uncertainty associated with patent litigation give both companies incentives to settle the dispute, originator companies also consider another important factor. According to the Final Report, one of the key factors, which originator companies take into consideration, is the “strength of their position in the patent litigation (expected likelihood of winning).”\(^{74}\) If the originator company assesses its patent as weak and therefore risks losing the patent


\(^{71}\) European Commission, ‘Pharmaceutical Sector Inquiry: Final Report’, para 729


\(^{73}\) European Commission, ‘Pharmaceutical Sector Inquiry: Final Report’, para 729

\(^{74}\) European Commission, ‘Pharmaceutical Sector Inquiry: Final Report’, para 720
litigation, the company is more likely to settle the dispute than if it assesses its patent as strong.
11. The Relationship between Patents and Competition Law

It is well-established jurisprudence of the Court of Justice that the existence of a patent right is not affected by European competition law. However, the exercise of such rights may fall within the prohibitions contained in competition law; meaning that although patent rights grant exclusivity, the means used to achieve market exclusion can fall afoul of competition law.

The relationship between patent rights and competition law presents a paradox. Both fields of law share the same goal; promoting innovation to ensure consumer welfare. The paradox arises because the two fields of law seek to meet this goal in contrasting ways. Patent law promotes innovation by encouraging companies to invest in developing new medicines by granting the company a limited period of exclusivity, while competition law promotes innovation by protecting competition on the market and putting pressure on companies to innovate.

European competition law is developed from two central rules set out in the Treaty on the Functioning of the European Union (TFEU); Article 101 TFEU that prohibits agreements between two or more independent companies which restrict competition and Article 102 TFEU that prohibits companies that hold a dominant position to abuse that position. In light of the purpose of this thesis, only Article 101 TFEU will be further analysed.

The General Court has stated that Article 101 TFEU makes no distinction between agreements whose purpose is to end a litigation and those concluded with other aims in mind. This means that, although settlement agreements are a generally, legitimate way of ending patent disputes, such agreements are not immune from competition law simply because they relate to patent rights.

75 Case 15/74, Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc, para 7; and Case 24/67, Parke Davis v Probel, para 2
76 European Commission, ‘Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements’ (2014/C 89/03), para 7
77 See e.g. Case 65/86, Bayer AG and Maschinenfabrik Hennecke v Heinz Süßhöfer, para 15; and Case T-472/13, Lundbeck v Commission, para 486
12. Application of Article 101(1) TFEU

Article 101(1) TFEU prohibits “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 [...]”. Agreement explicitly prohibited by this article include, in particular, those which: “limit or control production, markets, technical development, or investment” and “share markets or sources of supply”. A general principle underlying Article 101(1) is that each economic operator must determine independently the policy, which he intends to adopt on the market. If an agreement is found to restrict competition within the meaning of Article 101(1), it is not necessarily unlawful. Article 101(3) acknowledges that some restrictions on competition may generate pro-competitive benefits that outweigh the negative effects and thus provides an exception to the prohibition in article 101(1). The assessment of whether the pro-competitive benefits outweigh the negative effects is conducted exclusively within the framework of Article 101(3).

Any type of agreements can be defended under Article 101(3); even an agreement that has as its object to restrict competition.

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78 In this thesis, the term ‘restriction’ is used as covering ‘prevention, restriction and distortion’
79 See Article 101(1)(a-c) TFEU
81 European Commission, ‘Guidelines on the applicability of Article 101 of the Treaty to horizontal co-operation agreements’ (2011/C 11/01), para 20
82 An agreement must fulfill four cumulative conditions in order to satisfy Article 101(3): i) it must contribute to improving the production or distribution of goods or to promoting technical or economic progress, ii) while allowing consumers a fair share of the resulting benefit, iii) it must not impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives, and iv) afford such undertakings the possibility of eliminating competition in a substantial part of the products in question. See European Commission, ‘Guidelines on the application of Article 81(3) of the Treaty’, (2004/C 101/08), para 33
An agreement which is prohibited by Article 101(1) and which does not satisfy the conditions in Article 101(3) is stated to be automatically void by virtue of Article 101(2), and the companies concerned may be imposed fines.\textsuperscript{84}

Many aspects of the prohibition in Article 101(1) TFEU require further explanation. However, in light of the purpose of this thesis, this chapter focuses on the concept of potential competitors, and on what is meant by agreements that ‘have as their object or effect’ the restriction of competition.\textsuperscript{85}

12.1. Potential competitors

Article 101(1) is concerned with agreements between actual or potential competitors; known as horizontal agreements,\textsuperscript{86} and with agreements between companies operating at different levels of the production or distribution chain; known as vertical agreements.\textsuperscript{87} This cannot be derived directly from the wording of Article 101(1) but has been established in case law.\textsuperscript{88}

Patent settlement agreements entered into between originator companies and generic companies that are active in the production of generic versions of the originator’s medicine are horizontal agreements because both of the companies are active in the same market.\textsuperscript{89}

In relation to horizontal agreements the term ”competitors” includes both actual and potential competitors. If two companies are active on the same market, they are treated as actual competitors; while a company is treated as a potential competitor of another company if it has ’real concrete possibilities’ to enter the market

\textsuperscript{84} See Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1, 4.1.2003, p. 1–25, Article 23(2)(a)
\textsuperscript{85} Article 101(1) TFEU sets up the conditions for when an agreement should be prohibited. An in-depth examinations of all the conditions in the article is not made in this thesis. It is, however, important to mention that all the conditions should be taken into consideration when assessing an agreement under Article 101(1) TFEU
\textsuperscript{86} European Commission, ‘Guidelines on the applicability of Article 101 TFEU to horizontal co-operation agreements’, para 1
\textsuperscript{88} See Joined Cases 56/64 and 58/64 Consten v Commission de la EEC, 1965
\textsuperscript{89} Agreements between originator companies and generic companies can also be of vertical nature; e.g. if the generic company is a distributor of the originator company’s product. See European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 1249
on which the other company is active.\textsuperscript{90} The assessment of whether a company is a potential competitor has to be based on reasonably objective grounds. This means that the mere theoretical possibility to enter a market is not sufficient.\textsuperscript{91}

The concept of potential competition in relation to patent settlement agreements concluded by originator companies and generic companies is analysed and discussed in connection with the analysis of the General Court’s judgement in \textit{Lundbeck v Commission}.\textsuperscript{92}

12.2. The ‘object or effect’ of restricting competition

Article 101(1) TFEU prohibits agreements “\textit{which have as their object or effect the prevention, restriction or distortion of competition [...]}”. The article distinguishes between those agreements that have a restriction of competition as their \textit{object} and those agreements that have a restriction of competition as their \textit{effect}.

It is clear from the wording of the provision, in which the conjunction ‘or’ is used, that the terms ‘object’ and ‘effect’ are alternative and not cumulative. This means that if an agreement is considered as a restriction of competition ‘by object’, it is not necessary to demonstrate any actual or potential anticompetitive effects of the agreement for a finding of an infringement of Article 101(1) TFEU.\textsuperscript{93}

Arguably, two approaches can be applied in order to identify agreements that have anticompetitive effects.\textsuperscript{94}

The first approach is the effect analysis that involves a detailed and thorough examination of the actual and potential effects of the agreement. The negative effects


\textsuperscript{91} European Commission, ‘Guidelines on the applicability of Article 101 TFEU to horizontal co-operation agreements’, para 10

\textsuperscript{92} T-472/13, \textit{Lundbeck v Commission}. See Part V, chapter 17.2. ‘Potential Competition in the Pharmaceutical Sector’

\textsuperscript{93} See European Commission, ‘Guidelines on the applicability of Article 101 TFEU to horizontal co-operation agreements’, para 24; Case C-209/07 \textit{Beef Industry Development Society Ltd}, para 16; Case C-8/08 \textit{T-Mobile Netherlands} (2009), paras 28 and 30; Joined Cases C-501/06, C-515/06, C-519/06 \textit{GlaxoSmithKline Services and others v Commission} (2009), para 55; Case C-32/11 \textit{Allianz Hungária Biztosító Zrt} (2013), paras 33-34; and Case C-67/13 \textit{Groupe des Cartes Bancaires v Commission} (2014), para 49

\textsuperscript{94} Opinion of Advocate General Wahl delivered on 27 March 2014 in Case C-67/13P, \textit{Groupe des cares bancaires (CB) v European Commission}, para 27
must be assessed in comparison to the degree of competition that would have existed in the absence of the agreement.\textsuperscript{95} The agreement must "[…] have an actual or likely appreciable adverse impact on at least one of the parameters of competition […], such as price, output, product quality, product variety or innovation."\textsuperscript{96} This approach has the advantage of only finding a violation of Article 101(1) when the restriction clearly has negative effects on the market, but on the other hand, it involves significant resources for the competition authority that must carry out a detailed analysis of the agreements.\textsuperscript{97}

The second approach is the ‘by object’ analysis that is based on the categorisation of certain types of restrictions that are generally considered, by their very nature, to have anticompetitive effects on competition.\textsuperscript{98} Arguably, this approach is less tailored to individual cases, however "[…]it undoubtedly provides predictability, and therefore legal certainty, for undertakings in that it enables them to know the legal consequences […] of some of their actions […]" and "[…]it furthers procedural economy[…]"\textsuperscript{99} because it is unnecessary for the competition authorities to demonstrate any actual or potential negative effects on competition.

The Commission has been criticised for applying a too broad interpretation of the ‘by object’ category in order to achieve procedural efficiencies. The criticism is that it has become easier to establish a ‘by object’ restriction due to an expansion of the concept of ‘by object’.\textsuperscript{100}

The following sections describe those restrictions that are generally considered to constitute restrictions of competition ‘by object’ and examine which factors must be taken into consideration when determining whether an individual restriction constitutes a ‘by object’ restriction. In addition, the sections briefly analyses recent judgement from the Court of Justice regarding the concept of ‘by object’ in order to give an understanding for the development of this concept.

\begin{footnotesize}
\begin{itemize}
\item[\textsuperscript{95}] European Commission, ‘Guidelines on the applicability of Article 101 TFEU to horizontal co-operation agreements’, para 29
\item[\textsuperscript{96}] European Commission, ‘Guidelines on the applicability of Article 101 TFEU to horizontal co-operation agreements’, para 25
\item[\textsuperscript{97}] Opinion of Advocate General Wahl delivered on 27 March 2014 in Case C-67/13P, Groupement des caires bancaires (CB) v European Commission, para 28
\item[\textsuperscript{98}] See Case C-226/11 Expedia, para 36
\item[\textsuperscript{99}] Opinion of Advocate General Wahl delivered on 27 March 2014 in Case C-67/13P, Groupement des caires bancaires (CB) v European Commission, para 35
\end{itemize}
\end{footnotesize}
12.2.1. Categories of ‘by object’ restrictions
The classification of certain types of restrictions as ‘by object’ restrictions is based on the nature of the restriction and experience showing that such restrictions are most likely to have negative effects on competition. In 2014, the Commission adopted a revised De Minimis Notice. In this notice, the Commission states that it regards all “restrictions that are listed as hardcore restrictions in any current or future Commission block exemption regulation (...)” as ‘by object’ restrictions.

In addition to the revised De Minimis Notice, the Commission adopted a guidance providing an overview of what is so far considered to be ‘by object’ restrictions. The guidance is based on various regulations and soft-law from the Commission and examples taken from the case law of the Court of Justice and decisions from the Commission.

The types of ‘by object’ restrictions differ depending on whether the agreement is a horizontal or a vertical agreement. In the event of horizontal agreements, ‘by

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102 European Commission, ‘Notice on agreements of minor importance which do not appreciably restrict competition under Article 101(1) TFEU (De Minimis Notice)’, OJ C 291, (30 August 2014), p. 1-4. This notice provides a safe harbour for agreements which have non-appreciable effects on competition; meaning that Article 101 TFEU does not apply where the impact of the agreement on competition is not appreciable. This safe harbour applies if the market shares of the companies concluding those agreements do not exceed the market share thresholds set out in the De Minimis Notice. However, the safe harbour does not cover agreements which have as their object the restriction of competition.
103 Hardcore restrictions are restrictions which are generally considered to be particularly serious and do not produce any beneficial effects. The most prominent examples include price fixing and market sharing.
104 The Commission’s so-called block exemption regulations are regulations that exempt certain categories of agreements from the prohibition laid down in Article 101 TFEU; the Commission has adopted such regulations for, among others, vertical agreements, R&D agreements, specialisation agreements, technology transfer agreements and car distribution agreements. However, such block exemption regulations do not apply to hardcore (‘by object’) restrictions. See European Commission, ‘Annexes to Chapter A, Part II to the Final Report’, para 11
105 European Commission, ‘De Minimis Notice’, para 13
106 European Commission, ‘Guidance on restrictions of competition “by object” for the purpose of defining which agreements may benefit from the De Minimis Notice’, SWD(2014) 198 final, 26 June 2014, revised version of (3 June 2015). Hereafter ‘the By Object Guidance’
107 European Commission, ‘By Object Guidance’, page 5
object’ restrictions include, in particular, restrictions whereby competitors agree to fix prices of products (price fixing), agreements in which competitors agree to restrict the volume of their supply or production capacity (output restrictions) and agreements in which competitors allocate markets or customers (market sharing).108

As examples of market sharing agreements, the Commission’s By Object Guidance lists the Commission’s decision in Lundbeck (Citalopram) and Johnson&Johnson (Fentanyl). Both cases concern patent settlement agreements concluded by pharmaceutical companies. The settlement agreements including a commitment by the generic company not to enter the market and a payment from the originator company to the generic company. The agreements were considered as a form of market sharing agreements.109

These two cases are the first decisions regarding the so-called pay for delay agreements. The approach taken by the Commission when considering the settlement agreements as ‘by object’ restrictions is analysed in Part IV, chapter 15. ‘The Commission’s decisions on pay for delay agreements’.

Although the Commission’s By Object Guidance provides an overview of the different types of ‘by object’ restrictions, the question of which factors that must be taken into consideration when determining whether an individual restriction constitutes a ‘by object’ restriction still remains.

12.2.2. Factors that must be taken into account
First of all, the Court of Justice in Groupement des cartes bancaires (CB) stated that “[…] the essential legal criterion […] is the finding that (the agreement)[…] reveals in itself a sufficient degree of harm to competition.”110 It is the objective meaning and purpose of the agreement that is important.111 However, the Court of Justice has found that the companies subjective intentions are a relevant factor when assessing whether a restriction has as its object the restriction of competition.112

108 In the event of vertical agreements, restrictions by object are in particular fixing resale prices or restrictions that limit sales into particular territories or to particular customer groups. See European Commission, ‘By Object Guidance’, pages 5, 6, 7 and 10.
109 European Commission, ‘By Object Guidance’, page 8
110 Case C-67/13 P, Groupement des cartes bancaires (CB) v European Commission, para 57
It is well-established jurisprudence of the Court of Justice that, in order to determine whether an agreement is a ‘by object’ restriction, regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms part. It is evident that these factors do not constitute an exhaustive list.

In recent case law, the Court of Justice has stated that when determining the economic and legal context “[...]it is also necessary to take into consideration the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question[...]”.

Clearly, the analysis of whether an agreement constitutes a ‘by object’ restriction gives rise to the possibility of a detailed review of an agreement. It has been argued that the additional factors that the Court of Justice considers necessary in the economic and legal context represent a more or less quick effect analysis.

The next section examines the development of the ‘by object’ restriction, which has been a controversial topic in many years of European competition law, and it continues to be debated. This is done in the light of the Court of Justice’s recent judgement in Groupement des cartes bancaires (CB) which “[...] should put an end to what has been perceived as a creeping expansion of the concept of restriction by object [...].”

12.2.3. The concept of ‘by object’ restrictions
The Court of Justice has, through their case law, repeatedly ruled on the interpretation of the concept of ‘by object’ restrictions within the meaning of Article 101(1) TFEU. The topic is generating renewed discussion, not least because of a

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114 See also Case C-226/11 Expedia Inc. (2012), para 21; and Case C-32/11 Allianz Hungária Biztosító Zrt (2013), para 36


number of recent judgements from the Court. As Advocate General Wahl notes; “It is clear that the case-law of the [...] [the Court of Justice] and of the General Court, [...] could, to a certain extent, be a source of differing interpretations and even of confusion.”\(^{120}\)

The jurisprudence of the Court of Justice has been consistent for a long time in saying that an agreement must reveal a sufficient degree of harm to competition in order to be considered as a ‘by object’ restriction.\(^{121}\)

However, in the judgement in T-Mobile\(^{122}\) from 2009, the Court of Justice said that, in order to consider an agreement as a ‘by object’ restriction, “it is sufficient that it has the potential to have a negative impact on competition” (emphasis added).\(^{123}\) This judgement has been criticised for laying down a very wide test for considering restrictions as ‘by object’ restrictions and thus expanding the concept of such restrictions.\(^{124}\) The Court of Justice repeated the formulation in T-Mobile in its subsequent judgement in Allianz Hungária Biztosító Zrt\(^{125}\) from 2013, and the same did the General Court in its judgement in Groupement des cartes bancaires (CB)\(^{126}\) from 2014. In this judgement, the General Court also said, “the concept of infringement by object should not be given a strict interpretation.”\(^{127}\)

Whish and Bailey note that in the judgements in T-Mobile and Allianz Hungária Biztosító Zrt, the Commission’s practice of identifying new restrictions as ‘by object’ restrictions, such as the pay for delay agreements in its decisions in Lundbeck (Citalopram) and Johnson&Johnson (Fentanyl), and the Commission’s statement


\(^{120}\) Opinion of Advocate General Wahl delivered on 27 March 2014 in Case C-67/13 P, Groupement des Cartes Bancaires v. Commission, para 46

\(^{121}\) see Case C-209/07 Beef Industry Development Society (BIDS) [2008], para 15, C-519/06 P GlaxoSmithKline [2009], para 55, C-808 T-Mobile Netherlands BV [2009]

\(^{122}\) Case C-808 T-Mobile Netherlands BV [2009], para 31


\(^{124}\) Case C-32/11 Allianz Hungária Biztosító Zrt and Others [2013], para 38

\(^{125}\) T-491/07 CB v. Commission. See Case C-67/13 P, Groupement des cartes bancaires (CB) v European Commission, para 55 citing T-491/07 CB v. Commission, para 125

\(^{126}\) See Case C-67/13 P, Groupement des cartes bancaires (CB) v European Commission, para 55 citing T-491/07 CB v. Commission, para 124
that all hardcore restrictions are regarded as ‘by object’ restrictions gave the impression that the concept of ‘by object’ restrictions was steadily expanding.\textsuperscript{128}

For a period, it thus appeared that it was becoming easier to establish a ‘by object’ restriction. However, that trend appears to have ended, and arguably reversed by the Court of Justice’s judgement in \textit{Groupement des cartes bancaires (CB)} in September 2014.\textsuperscript{129}

\textbf{12.2.3.1. \textit{Groupement des Cartes Bancaires (CB)}}

In \textit{Groupement des cartes bancaires (CB)}, the Court of Justice annulled the finding of the General Court in the contested decision that the measures at issue constituted restrictions of competition ‘by object’.

The Court of Justice found that the General Court had erred in finding that the concept of ‘by object’ restrictions must not be interpreted ‘restrictively’.\textsuperscript{130} It said, “the concept of restriction of competition ‘by object’ can be applied only to certain types of coordination between undertakings which reveal a sufficient degree of harm to competition […]”.\textsuperscript{131}

Arguably, the Court of Justice therefore rejected the wider interpretation of the concept of ‘by object’ restrictions in \textit{T-Mobile} and in \textit{Allianz Hungária Biztosító Zrt}, which the General Court referred to in the contested decision. The Court of Justice thus reconfirmed the longstanding interpretation that a ‘by object’ restriction must reveal a sufficient degree of harm to competition.\textsuperscript{132}

In the contested decisions, the General Court in fact assessed the potential effects. However, the Court of Justice found that by assessing the potential effects, the General Court indicated itself that the measures in question could not be considered ‘by their very nature’ harmful to competition.\textsuperscript{133}

In its opinion, Advocate General Wahl advocated that “only conduct whose harmful nature is proven and easily identifiable, in light of experience and economics, should […] be regarded as a restriction of competition by object […]”.\textsuperscript{134}

\textsuperscript{129} Case C-67/13 P, \textit{Groupement des cartes bancaires (CB) v European Commission}
\textsuperscript{130} Case C-67/13 P, \textit{Groupement des cartes bancaires (CB) v European Commission}, para 58
\textsuperscript{131} Case C-67/13 P, \textit{Groupement des cartes bancaires (CB) v European Commission}, para 58
\textsuperscript{132} James Killick & Jeremie Jourdan, ‘Cartes Bancaires: A Revolution Or A Reminder of Old Principles We Should Never Have Forgotten?’, Competition Policy International (19 December 2014), p. 6
\textsuperscript{133} Case C-67/13 P, \textit{Groupement des cartes bancaires (CB) v European Commission}, para 82
\textsuperscript{134} Opinion of Advocate General Wahl delivered on 27 March 2014 in Case C-67/13 P, \textit{Groupement des cartes bancaires}, para 56
In fact, the Court of Justice itself explicitly refers to the notion of experience in the judgement.\textsuperscript{135} Even though this statement is made in relation to price fixing, it seems to be an endorsement of the relevance of experience when considering whether an agreement is a ‘by object’ restriction.\textsuperscript{136}

According to Advocate General Wahl, “‘experience’ must be understood to mean what can traditionally be seen to follow from economic analysis, as confirmed by the competition authorities and supported, if necessary, by case-law.”\textsuperscript{137}

In addition, Director-General for Competition Alexander Italianer, gave a speech\textsuperscript{138} in December 2014 in which he says that a lesson learned from the Court of Justice’s judgement in Groupement des cartes bancaires (CB) is that the Commission “must take particular care when [...] [it] find an agreement to be a restriction by object if it does not bear an obvious resemblance to past cases where a restriction by object was established.”\textsuperscript{139}

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\textsuperscript{135} Case C-67/13 P, Groupement des cartes bancaires (CB) v European Commission, para 51; “Experience shows that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers.”

\textsuperscript{136} James Killick & Jeremie Jourdan, ‘Cartes Bancaires: A Revolution Or A Reminder of Old Principles We Should Never Have Forgotten?’, Competition Policy International (19 December 2014), p. 6

\textsuperscript{137} Opinion of Advocate General Wahl delivered on 27 March 2014 in Case C-67/13 P, Groupement des cartes bancaires, para 79

\textsuperscript{138} Speech by Alexander Italianer, Director-General for Competition, European Commission, ‘The Object of Effects’, (10 December 2014)

\textsuperscript{139} Speech by Alexander Italianer, Director-General for Competition, European Commission, ‘The Object of Effects’, (10 December 2014), page 13
13. Summary

Patent disputes often occur in the pharmaceutical sector. However, patent litigation is very complex, time-consuming and uncertain which is why pharmaceutical companies often wish to settle their dispute instead of waiting until final judgment in the litigation case.

The existence of a patent right, which grants exclusivity, is not affected by European competition law, however, the exercise of such rights may fall within the prohibitions contained in competition law. This means that, although patent settlement agreements are a generally, legitimate way of ending patent disputes, such agreements are not immune from competition law simply because they relate to patent rights. This means that they may fall within the prohibition laid down in Article 101 TFEU.

Article 101 TFEU prohibits all agreements, which have as their object or effect the restriction of competition. The term “competitors” in relation to this article includes both actual and potential competitors. If two companies are active on the same market they are treated as actual competitors; while a company is treated as a potential competitor of another company, if it has ‘real concrete possibilities’ to enter the market on which the other company is active.

The article distinguishes between those agreements that have a restriction of competition as their object and those agreements that have a restriction of competition as their effect. Arguably, there are two approaches that can be applied in order to identify agreements, which have anticompetitive effects. If a restriction is considered to have as its object the restriction of competition, it is not necessary to demonstrate any actual or potential anticompetitive effects.

It is well-established jurisprudence of the Court of Justice that, in order to determine whether an agreement is a ‘by object’ restriction, regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms part. The analysis of whether an agreement constitutes a ‘by object’ restriction gives rise to the possibility of a detailed review of an agreement. Arguably, the analytical framework seems to require a more or less quick effects analysis in order to classify a restriction as a ‘by object’ restriction.

The European competition authorities have been criticised for applying a too wide interpretation of the concept of ‘by object’ restrictions with the consequence that it was becoming easier to establish a ‘by object’ restriction. However, that trend
appears to have ended, and arguably reversed, by the Court of Justice’s decision in *Groupement des cartes bancaires (CB)*.

First of all, the judgement reconfirms the consistent jurisprudence that the concept of ‘by object’ restrictions only applies to agreements that reveal a sufficient degree of harm to competition. Secondly, the Court of Justice’s statement that this concept should be interpreted restrictively is a very significant one; meaning that the concept should not expand unduly.

Thirdly, the opinion of Advocate General Wahl and the statement from Director-General for Competition Alexander Italianer suggest that the classification of a restriction as a ‘by object restriction’ should be based on experience from economic analysis confirmed by the Commission and case law showing that this type of restriction reveals a sufficient degree of harm to competition that it is unnecessary to demonstrate any actual or potential effects. Moreover, the concept must only be applied on restrictions whose harmful nature is easily identifiable.
PART IV - THE COMMISSION’S APPROACH

In its Final Report of the sector inquiry, the Commission identified a number of strategies used by originator companies to extend the commercial life of their medicines with the consequence of delaying market entry of generic medicines. Such delays are important from a competition law perspective as the price of generic medicines is significant lower than the price of original medicines.

In particular, the Commission dealt with the strategy to conclude so-called patent settlement agreements with generic companies. “To reduce the risk that settlements are concluded at the expense of consumers [...]”, the Commission decided to continue monitoring patent settlement agreements in the pharmaceutical sector.140

The Commission has so far published seven monitoring reports and adopted three decisions on patent settlement agreements in the pharmaceutical sector. All three decisions concern pay for delay agreements which were considered as ‘by object’ restrictions and therefore found to violate Article 101 TFEU.

This chapter examines the results of the Commission’s monitoring exercise of patent settlement agreements and explain the categorisation of such agreements proposed by the Commission. This is done in order to examine what types of patent settlement agreements that are considered problematic from a competition law perspective. In addition, this chapter analyses the three decisions regarding pay for delay agreements from the Commission in order to establish the approach taken by the Commission when assessing such agreements.

140 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 1574
14. Continued Monitoring of

The Commission launched its monitoring exercise of patent settlement agreements in the pharmaceutical sector in January 2010.\textsuperscript{141} The main objectives of the monitoring exercise are to better understand the use of patent settlement agreements within the pharmaceutical sector and to identify those agreements that delay generic entry in violation of European competition law.\textsuperscript{142}

The Commission has conducted the monitoring exercise annually since 2010. The Commission has currently published seven reports.\textsuperscript{143} The latest report was published in December 2016 and covers patent settlement agreements concluded between originator and generic companies in the period January to December 2015.\textsuperscript{144}

The monitoring exercise is based on patent settlement agreements submitted by both originator companies and generic companies on the basis of formal requests for information from the Commission.\textsuperscript{145} The Commission analyses the submitted settlement agreements and classify them; using the same categorisation of settlement agreements as proposed by the Commission in its Final Report of the sector

\textsuperscript{141} Press Release IP/10/12, ‘Antitrust: Commission launches monitoring of patent settlements concluded between pharmaceutical companies’ (12 January 2010)


\textsuperscript{144} European Commission, ‘7th Monitoring Report’, para 5

\textsuperscript{145} European Commission, ‘7th Monitoring Report’, para 5
inquiry. This classification “[...] is aimed at giving an indication on which kinds of settlements may merit further competition rules scrutiny [...]”.146

14.1. Classification of Different Types of Settlement Agreements

The proposed classification of patent settlement agreements in the Commission’s Final Report is based on 207 patent settlement agreements concluded between originator and generic companies.147

Overall, the settlement agreements are categorised on the basis of whether they limit the generic company’s ability to enter the market and whether it involves a value transfer from the originator company to the generic company.148 Settlement agreements that do not limit generic entry are classified as category A, whereas agreements limiting generic entry are classified as category B. The latter category is divided in two; settlement agreements that do not include a value transfer from the originator company to the generic company are classified as category B.I., while those that do include such a value transfer is classified as category B.II.

Category A agreements are not described further because such agreements are typically unproblematic from a competition law perspective, as they do not limit generic market entry.149

14.1.1. Limiting Generic Entry (Category B.I)

Generic market entry can be limited in several ways. If a settlement agreement contains a clause explicitly stating that the generic company refrains from entering the market because it recognises the validity of the originator company’s patent, it is clear that the agreement limits generic entry.150

The generic company’s ability to enter the market is also limited if the generic company agrees not to enter and, in exchange, obtains a license to certain patent rights from the originator company or becomes a distributor of the originator company’s medicine. The reason for this is that the generic company cannot enter the

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146 European Commission, ‘7th Monitoring Report’, para 7
147 For the purpose of the sector inquiry, the Commission requested originator companies and generic companies to submit copies of all patent settlements concluded between originator companies and generic companies for the period from January 2000 to June 2008. In total, 207 patent settlement agreements were submitted. See European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, paras 709-710
148 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, paras 741-742
149 European Commission, ‘7th Monitoring Report’, para 15
150 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, page 269
market with its own product and because the generic company’s entry is partly or wholly controlled through the terms of the agreement.¹⁵¹

According to the Commission, the main characteristic of B.I. settlement agreements seems to be that the originator company had won the patent dispute against the generic company. In such situations, the generic company is interested in settling the case before a court might order the generic company to pay damages and legal costs to the originator company for having infringed the originator’s patent. The generic company, therefore, agrees to recognise the full validity of the originator company’s patent and further agrees not to market its product until after expiry of the relevant patent.¹⁵²

### 14.1.2. Limiting Generic Entry and a Value Transfer (Category B.II)

In some situations B.I. settlement agreements also include a value transfer from the originator company to the generic company. Among the 207 settlement agreements submitted to the Commission, 45 settlement agreements fell within this category.¹⁵³

A value transfer is not limited to a pure cash payment, but can take various forms and an agreement can contain more than one type of value transfer.¹⁵⁴ A value transfer can for example take the form as a compensation for the generic company’s legal costs in the patent dispute or as the purchase of an asset such as the generic company’s stock of the generic medicine it had intended to launch. Other forms of value transfer include the granting of a licence to the generic company or a supply and/or distribution agreement.¹⁵⁵

Category B.II. settlement agreements are also called reverse payment agreements or pay for delay agreements.

### 14.2. Possibly problematic settlement agreements

The Final Report concludes that category B.II. settlement agreements are an example of possibly anticompetitive agreements, “[…] in particular where the mo-

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¹⁵¹ European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 758
¹⁵² European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 769
¹⁵³ European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 762
¹⁵⁴ European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 764
¹⁵⁵ European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 769
tive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets.”

According to the Commission’s seventh monitoring report, category B.II. settlement agreements are of particular interest.

In its classification of patent settlements, the Commission’s definitions on what constitute a ‘limitation on generic entry’ and a ‘value transfer’ are broad. This means that a large number of settlement agreements may fall within the possibly problematic category B.II.

Settlement agreements that contain restrictions beyond the scope of the underlying patent are another example of possibly problematic agreements. “Such agreements would not appear to be directly related to the IP rights granted by the patents concerned.”

Additionally, settlement agreements regarding a patent which the patent holder/originator company knows does not meet the patentability criteria are problematic agreements.

As described in chapter 11, the overall number of settlement agreements has increased in recent years. Hence, the Commission’s scrutiny and enforcement activities in this area have not discouraged pharmaceutical companies from settling their patent disputes.

In the period covered by the sector inquiry (1 January 2000 to 30 June 2008), B.II. settlement agreements represented 22% of all settlements reported. This percentage has decreased over the years to reach 10% in 2015. The number of B.II. settlement agreements has thus stabilised at a low level which also has been welcomed by the Commission.

It is worth mentioning that in the 6th monitoring report none of the B.II. settlements included a pure cash payment to the generic company. In the 7th moni-

156 European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 1573
157 European Commission, ‘7th Monitoring Report’, para 4
158 European Commission, ‘7th Monitoring Report’, para 4
159 European Commission, ‘7th Monitoring Report’, para 4
161 European Commission, ‘7th Monitoring Report’, para 49
162 See Press Release IP/13/1228, ‘Antitrust: Commission welcomes continued low level of potentially problematic patent settlements in EU pharma sector’
toring report only one of the B.II. settlements included a cash payment to the generic company to compensate for damages.\textsuperscript{164} This statistic indicates that pharmaceutical companies largely refrain from using cash payments when settling patent disputes but instead rely on other forms of value transfer to compensate a generic company; in reality, constructing ‘side-deals’.\textsuperscript{165}

14.3. Case-by-case approach

Although the Commission’s Final Report and monitoring reports indicate that settlement agreements limiting generic entry and include a value transfer from the originator company are likely to raise anticompetitive concerns under Article 101 TFEU, the Commission stated on several occasions that “[...]any enforcement actions will be initiated on a case-by-case basis and will include a thorough examination of the specifics of each case taking into account the legitimate objectives to protect innovation and the regulatory framework.”\textsuperscript{166} The approach is basically that B.II. settlement agreements are closely scrutinised by the Commission and that the assessment may vary in each case.\textsuperscript{167}

It also stated that the assessment of whether patent settlement agreements are compatible or incompatible with European competition law requires an in-depth analysis, taking into account the factual, economic and legal background.\textsuperscript{168}

It may seem remarkable that the seventh monitoring report offers no further guidance on the legality of B.II. settlement agreements. Despite years of monitoring and several hundred settlement agreements analysed, the Commission has not been able to narrow down the broad categories of patent settlement agreements or to give any further guidance on which factors that can assist in distinguishing B.II. settlement agreements that conform with Article 101 TFEU from those that are in violation.

Instead, the Commission promises an individual assessment of each case. This statement provides no legal certainty as regards the assessment of B.II. settlement agreements. The next chapter analyses the Commission’s three decisions regarding pay for delay agreements in order to establish further guidance on when B.II.

\textsuperscript{164} European Commission, ‘7th Monitoring Report’, para 46
\textsuperscript{166} European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, para 1575; and European Commission, ‘7th Monitoring Report’, para 7
\textsuperscript{167} See James Killick, ‘Patent settlements as by object restrictions: a European approach but is it the right one?’, ConcurrencesVolume II, (December 2015), p. 191
\textsuperscript{168} European Commission, ‘Pharmaceutical Sector Inquiry; Final Report’, paras 463, 763, 797, 1088 and 1245
settlement agreements are considered as ‘by object’ restrictions and therefore are in violation of Article 101 TFEU.
15. The Commission’s decisions on pay for delay agreements

The Commission has so far adopted three decisions on pay for delay agreements, and there is another investigation ongoing. The three decisions are the Lundbeck (Citalopram) decision from June 2013, the Johnson&Johnson (Fentanyl) decision from December 2013, and the Servier (Perindopril) decision from July 2014. All the agreements included a commitment from the generic company not to enter the market and a value transfer from the originator company to the generic company. The agreements thus fall within the problematic B.II. category.

As mentioned earlier, the Commission found that the settlement agreements in question in both Lundbeck (Citalopram) and Johnson&Johnson (Fentanyl) constituted ‘by object’ restrictions and thus infringed Article 101(1) TFEU. In its decision in Servier (Perindopril), the Commission also found that the settlement agreements in question infringed Article 101(1) TFEU by object. In addition, it also found that Servier’s overall strategy to delay generic entry amounted to an abuse of its dominant position, and constituted an infringement of Article 102 TFEU.

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169 Case COMP/AT.39686 Cephalon and Teva, opened on 19 April 2011. This case is also subject to anti-trust litigation in the US initiated by the FTC, and will not be discussed further in the thesis.
171 Case COMP/AT.39685 Fentanyl, Commission decision of December 10, 2013.
173 See Part III, chapter 12.2.1. ‘Categories of “by object” restrictions’
174 Commission Vice-President Joaquín Almunia said that Servier had an overall strategy to systematically buy out any competitive threats to make sure that they did not enter the market. See Press Release IP/14/799, “Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine” (2014).
175 Case AT.39612 Servier (Perindopril), paras 2960 and 2997. In the Lundbeck (Citalopram) decision, the Commission stated, “in order to understand the rationale behind Lundbeck’s agreements as covered in this Decision and to evaluate their legality under Union competition law it is important to realize how these agreements fitted into Lundbeck’s overall strategy against generic entry.” See Case AT.39226 Lundbeck, para 134. However, the Commission did not consider whether this overall strategy infringed Article 102 TFEU. This thesis focuses on the violation of Article 101 TFEU and Article 102 will not be further discussed.
Since the Commission has always considered pay for delay agreements as ‘by object’ restrictions so far, it has not been necessary to demonstrate any actual or potential anticompetitive effects of the agreements.

The Lundbeck (Citalopram) and Servier (Perindopril) decisions are both appealed to the General Court. The Johnson&Johnson (Fentanyl) decision was not appealed. The General Court gave its judgement in Lundbeck (Citalopram) in September 2016, while the appeals against the Servier (Perindopril) decision are still pending before the General Court.

This chapter does not include an analysis of each individual decision but intends to examine the approach taken by the Commission when considering pay for delay agreements as ‘by object’ restrictions in each decision. This is done in order to analyse whether the decisions give any further guidance on which B.II. settlement agreements violate Article 101 TFEU.

15.1. Factors taken into account

In all three decisions, the Commission stated, in accordance with well-established case-law, that when assessing whether an agreement is a ‘by object’ restriction, regard must be had to the content of its provisions, the objectives it seek to attain and the economic and legal context of which it forms a part. In addition, the Commission noted that there is nothing prohibiting it from taken the parties’ intentions into consideration.

In Lundbeck (Citalopram) and Servier (Perindopril), the Commission also stated that regard must be had to the nature of the goods or services affected, as well as the real conditions of the functioning and structure of the market or markets in question.

15.1.1. The ‘Three Step Test’

In all three decisions, the Commission stated that an analysis taking the factors mentioned above into account allow a conclusion on whether

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176 This judgement will be analysed in detail in Part V, chapter 17. ‘The General Court’s Approach’
178 Case AT.39226 Lundbeck, para 648; Case AT.39685 Fentanyl, para 221-223; and Case AT.39612 Servier (Perindopril), para 1113
179 Case AT.39226 Lundbeck, para 648; and Case AT.39612 Servier (Perindopril), para 1113
i) the originator company and the generic company were at least potential competitors.\textsuperscript{180}

ii) the generic company committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter the market, and

iii) the agreement was related to a transfer of value from the originator undertaking which substantially reduced the incentives of the generic company to independently pursue its efforts to enter the market.\textsuperscript{181}

The Commission concluded that these three factors were relevant "[i]n order to identify whether each agreement had the potential\textsuperscript{182} to restrict competition, by its very nature."\textsuperscript{183}

The Commission thus applied the ‘by object’ analysis in order to analyse whether the agreements fell within the problematic B.II. category which consists of agreements where the generic company’s market entry is limited and where the originator company transfers a value to the generic company. In addition, an analysis of the actual content and objectives of the agreement and the subjective intentions of the companies allowed the Commission to determine whether the value transfer from the originator company was linked to the generic companies’ commitment not to enter the market,\textsuperscript{184} and thereby constituted exclusion payments.\textsuperscript{185}

It can thus be concluded that when assessing B.II. settlement agreements it is not only decisive whether the agreements include a limitation on generic entry and a value transfer, but also "whether those limitations were paid for by the originator company. "\textsuperscript{186}

In addition, the Commission stated in all three decisions that “in the present case other important factors will also be taken into consideration."\textsuperscript{187}

\textsuperscript{180} This factor will not be analysed further in this chapter. See the General Court’s analysis of potential competition in the pharmaceutical sector in Part V, chapter 17.2: ‘Potential Competition in the Pharmaceutical Sector’

\textsuperscript{181} Case AT.39226 Lundbeck, para 661; Case AT.39685 Fentanyl, para 219; and Case AT.39612 Servier (Perindopril), para 1154

\textsuperscript{182} See Part IV, chapter 15.4: ‘The Legal Test Applied’

\textsuperscript{183} Case AT.39226 Lundbeck, para 661. See also Case AT.39685 Fentanyl, para 219; and Case AT.39612 Servier (Perindopril), para 1154

\textsuperscript{184} Case AT.39226 Lundbeck, para 735

\textsuperscript{185} Case AT.39226 Lundbeck, para 658

\textsuperscript{186} Case AT.39226 Lundbeck, para 660

\textsuperscript{187} Case AT.39226 Lundbeck, para 662; Case AT.39685 Fentanyl, para 220; and Case AT.39612 Servier (Perindopril), para 1155
15.1.2. Value Transfer Correspond to Generic Turnover
In all three decisions, the Commission found that the fact that the value transfer from the originator company to the generic company corresponded to the turnover or the profit that the generic company expected if it had successfully entered the market was an important factor to take into account.

According to the Commission, this factor is relevant for determining whether the value transfer substantially reduced the incentives of the generic company to independently pursue its efforts to enter the market.\(^\text{188}\)

15.1.3. No Guarantee of Market Access
In the Lundbeck (Citalopram) and Servier (Perindopril) decisions, the Commission also found that the fact that the settlement agreements contained no commitment from the originator company to refrain from infringement proceedings if the generic companies entered the market with generic medicines after the expiry of the agreements was an important factor to take into account. In such a situation, it is not guaranteed that the generic companies can enter the market after expiry of the settlement agreements because they risk being faced with infringement proceedings by the originator company claiming that its patent is being infringed.

According to the Commission, this indicates that the objective aim of the settlement agreements was not to solve or terminate any underlying patent dispute.\(^\text{189}\) It must be recalled that settlement agreements are, generally, concluded in order to resolve the companies’ claims and to end the patent dispute.

15.1.4. Restrictions beyond the Scope of the Patent
In the Lundbeck (Citalopram) and Servier (Perindopril) decisions, the Commission also found that the fact that the originator company could not have obtained the same limitations on generic market entry through enforcement of its patents as it obtained in the settlement agreements was a relevant factor to take into account. In other words, the limitations on generic market entry exceed the scope of the underlying patent.\(^\text{190}\)

According to the Commission, this indicates as well that the objective aim of the settlement agreements is not to solve the underlying patent dispute but instead to commit the generic companies to stay out of the market.\(^\text{191}\)

\(^{188}\) Case AT.39226 *Lundbeck*, para 675. See Part V, chapter 17.3.2. ‘The Size and Disproportionate Nature of a Reverse Payment’

\(^{189}\) Case AT.39226 *Lundbeck*, paras 6, 769 and 873

\(^{190}\) Case AT.39226 *Lundbeck*, para 6; and Case AT.39612 *Servier (Perindopril)*, para 1155

\(^{191}\) Case AT.39226 *Lundbeck*, para 642
It can thus be concluded that the Commission takes several factors into account when assessing pay for delay agreements. It appears as if the three step test mentioned in all three decisions remains at the core of the Commission’s analysis of whether a pay for delay agreement constitute a ‘by object’ restriction. The main factor to take into account is thus whether the value transfer from the originator company is linked to the generic company’s commitment not to enter the market. Arguably, the additional factors that the Commission also found important appear to be taken into account in order to determine whether such a link exists.

15.2. Comparable to Market Sharing Agreements

In all three decisions, the Commission found that the analysis of the factors above permitted the conclusion that the originator companies paid the generic companies to accept to give up its independent efforts to enter the market for the duration of the agreement, “[…]and thereby shared its monopoly rents with [the generic company] […]”. 192

The Commission thus compared the pay for delay agreements with market sharing agreements since the aim of the agreements was to keep the generic companies out of the market. It therefore concluded that the agreements constituted ‘by object’ restrictions. 193

This finding is in accordance with the Commission statement in its Final Report in which it stated that settlement agreements where the motive is the sharing of profits via payments from the originator company is, in particular, potentially anticompetitive. 194

According to well-established case-law, there is no need for the Commission to demonstrate any actual or potential negative effects of an agreement if the agreement constitutes a ‘by object’ restriction. However, in both the Lundbeck (Citalopram) and Servier (Perindopril) decisions, the Commission did, to a limited extent, analyse the likely negative effects of the settlement agreements.

15.3. Showing Likely Negative Effects

In the Servier (Perindopril) decision, the Commission explicitly said that it “will nonetheless, for the sake of completeness, show […] that the agreement was also

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192 Case AT.39226 Lundbeck, paras 802 and 1338; and Case AT.39612 Servier (Perindopril), paras 1609 and 1812
193 Case AT.39226 Lundbeck, para 735
194 See Part IV, chapter 14.2. ‘Possibly Problematic Settlement Agreements’
likely to cause restrictive effects on competition [...]” \(^{195}\) The Commission analysed the competitive situation in case of generic entry and found that the average prices of the medicine perindopril decreased substantially.\(^{196}\)

In the Landbeck (Citalopram) decision, the Commission did not explicitly state that it would demonstrate any likely negative effects. However, as Director General Alexander Italianer said in a speech in 2013, the Commission did “for the sake of completeness [...] analyse the situation in the [market] and found that one year after [expiry of the agreements] prices of generic citalopram dropped on average by 90 per cent compared to Lundbeck’s previous price level.”\(^{197}\)

It can be concluded that the Commission in fact complemented its ‘by object’ analysis with a limited effect analysis, and that the Commission on the basis of the facts in the cases was able to carry out an effect analysis. This analysis “has been referred to as a “dual object-effect approach” [...]”\(^{198}\)

15.4 The Legal Test Applied

In the three decisions on pay for delay agreements, the Commission said that, in order to consider an agreement as a ‘by object’ restriction, it is sufficient that it has the potential to have negative effects on the market.\(^{199}\) The Landbeck (Citalopram) decision directly cited the formulation from the Court of Justice judgement in Allianz Hungária Biztosító Zrt, while the Servier (Perindopril) decision referred to the judgements in Allianz Hungária Biztosító Zrt and T-Mobile.

It is important to notice that all three decisions on pay for delay agreements are adopted before the Court of Justice gave its important judgement in Groupement des cartes bancaires (CB), which reconfirmed the longstanding interpretation that a ‘by object’ restriction must reveal a sufficient degree of harm to competition. Arguably, the Court of Justice therefore rejected the wider interpretation of the concept of ‘by object’ restrictions in T-Mobile and in Allianz Hungária Biztosító Zrt.

\(^{195}\) Case AT.39612 Servier (Perindopril), para 1213

\(^{196}\) Case AT.39612 Servier (Perindopril), para 1239

\(^{197}\) Speech by Alexander Italianer, Director-General for Competition, European Commission, ‘Competitor agreements under EU competition law’. 40th Annual Conference on International Antitrust Law and Policy, Fordham Competition Law Institute New York, (26 September 2013), p. 10. See also Case AT.39226 Landbeck, para 726

\(^{198}\) Irene Fraile, Ankur Kapoor & Rosa Morales, ‘Drug Test: When are Pay-for-Delay Agreements Illegal?’, Global Competition Litigation Review (2014) Issue 4, p. 219. See Part VI, chapter 18.2.2. ‘Showing Likely Negative Effects’

\(^{199}\) Case AT.39226 Landbeck, para 648; Case AT.39685 Fentanyl, para 219; and Case AT.39612 Servier (Perindopril), para 1111
The Commission thus applied a legal test which the Court of Justice rejected. In view of this, it is interesting to analyse the General Court’s judgement in *Lundbeck (Citalopram)* in order to see how it understands the Court of Justice judgement in *Groupement des cartes bancaires (CB)* and whether it has an influence on how pay for delay agreements are assessed.
16. Summary

Since the Commission published its Final Report of its sector inquiry, it has continued to monitor patent settlement agreements in the pharmaceutical industry. It analyses patent settlement agreements submitted by pharmaceutical companies and categorises them.

Settlement agreements that do not limit generic entry are classified as category A, while settlement agreements that limit generic entry are classified as category B. The latter category is divided in two; settlement agreements that do not include a value transfer from the originator company to the generic company are classified as category B.I, while those that do include such a value transfer is classified as category B.II. The Commission found that B.II. settlement agreements are likely to be problematic from a competition law perspective. It therefore welcomes the decrease of such settlement agreements that have occurred the last few years.

Despite the years of investigation through the sector inquiry and the monitoring exercise, the Commission has not been able to give much guidance on how B.II. settlements will be assessed and found to infringe Article 101 TFEU. It stated that any enforcement actions on patent settlement agreements will include a thorough examination of the specific facts of each case. This did not create much legal certainty as to how such B.II. settlement agreements will be analysed.

The Commission has since then adopted three decisions on pay for delay agreements; the Lundbeck (Citalopram), the Johnson&Johnson (Fentanyl), and the Servier (Perindopril) decisions. In all three decisions, the Commission found that the settlement agreements were comparable to market sharing agreements and that they thus constituted ‘by object’ restrictions.

In finding that the pay for delay agreements constituted ‘by object’ restrictions, the Commission relied on three main factors; i) the originator and generic company were at least potential competitors, ii) the generic company committed itself to limit its efforts to enter the market and iii) the value transfer from the originator company reduced the incentives for the generic company to enter the market.

According to the Commission, the decisive factor when assessing B.II. settlement agreements is thus whether the limitations on generic entry are paid for by the originator company. In order to analyse whether there is such a link between the limitations and the value transfer, the Commission found it relevant to consider
whether the value transfer corresponded to the expected profit for the generic company, whether the settlement agreement guarantee generic market access after expiry of the agreement, and whether the limitations on generic entry exceed the scope of the patent.

The legal test applied by the Commission in finding a ‘by object’ restriction is similar to that applied in Allianz Hungária Biztosító Zrt and T-Mobile. It stated that in order to consider an agreement as a ‘by object’ restriction, it is sufficient that it has the potential to have negative effects on the market.

The legal test in Allianz Hungária Biztosító Zrt and T-Mobile was rejected by the Court of Justice in its judgement in Groupement des cartes bancaires (CB). This judgement reconfirmed that a ‘by object’ restriction must reveal a sufficient degree of harm to competition.

In view of this, the following chapter analyses the General Court’s judgement in Lundbeck (Citalopram) in order to analyse the General Court’s assessment of pay for delay agreements and to see whether the Groupement des cartes bancaires (CB) judgement had an influence on how those agreements are assessed.
17. Case T-472/13 Lundbeck v Commission

On 8 September 2016, the General Court delivered its judgement in Lundbeck v Commission.200 This judgment is the General Court’s first and only ruling on patent settlement agreements including reverse payments.201 The General Court dismissed all actions brought by Lundbeck and the generic companies and confirmed the Commission’s decision. Hence, the General Court confirmed that the settlement agreements concluded between the companies restricted competition ‘by object’ in violation of Article 101(1) TFEU. It also upheld the fine of €146 million that the Commission imposed on Lundbeck and the generic companies.202

This chapter does not give a full detailed analysis of all the General Court’s findings. It analyses the General Court’s findings regarding the concept of potential competition in the pharmaceutical sector and the role of the patent in the antitrust analysis. This is done in order to analyse when originator companies and generic companies are seen as potential competitors when the originator company has an exclusive right through its patent rights. This chapter also presents the General Court’s analysis and considerations that led to the finding of a restriction of competition by object. It intends to identify the factors which the General Court emphasised in its assessment of reverse payment agreements. This is done in order to examine whether the General Court’s judgement give further guidance on how such agreements are assessed and to what extent the Court of Justice’s judgement

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201 This judgement does not use the term pay for delay agreements. This chapter will thus call the agreements ‘reverse payment agreements’
202 Press Release No 90/16, ‘The General Court of the European Union confirms the fines of almost €150 million imposed on several undertakings in the context of an infringement intended to delay the marketing of generic versions of the antidepressant citalopram’, (September 2016)
in *Groupement des cartes bancaires (CB)* influenced the General Court’s assessment. 203

17.1. Facts of the Case

The *Lundbeck v Commission* judgement concerns six agreements between the originator company Lundbeck and four generic companies (Merck, Arrow, Alpharma, and Ranbaxy) which operated in the years 2002 and 2003.204 The agreements were concluded in relation to a patent dispute concerning one of Lundbeck’s process patents for the medicine Citalopram.

Lundbeck’s original patent covering the molecule of citalopram and two original production processes for citalopram expired in January 2002.205 The original patent had thus expired by the time the settlement agreements were concluded. In the period up to patent expiry, Lundbeck obtained a number of new process patents that were in force at the time the agreements operated.206

The sale of citalopram was essential for Lundbeck’s revenue in general,207 but the time in which Lundbeck could fully exploit citalopram commercially on the market was comparatively short.208 Close to expiry of the original patent, Lundbeck

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203 Some of the General Court’s findings that is not analysed in this thesis relate to: there was no exemption under Article 101(3) TFEU since Lundbeck did not demonstrate that the restrictions set out in the agreements were “objectively necessary” in order to protect its IP rights. Lundbeck could have protected those rights by bringing actions before the national courts in the event that its patents were infringed. The General Court further rejected the “scope of patent” test as the relevant test for the purposes of examining the agreements at issue. That test is based on a subjective assessment by the patent holder of the scope and the validity of its patents. These findings will not be analysed in this thesis.

204 Lundbeck concluded two agreements with Merck; one regarding the United Kingdom and one regarding the EEA. Lundbeck also concluded two agreements with Arrow; one regarding the United Kingdom and one regarding Denmark. Lundbeck concluded one agreement with Alpharma regarding the EEA, and one agreement with Ranbaxy regarding the EEA. See Case T-472/13, Lundbeck v Commission, paras 23–48.

205 Case T-472/13, Lundbeck v Commission, para 215

206 Lundbeck applied for 14 new process patents and related patents for citalopram. See Case AT.39226 *Lundbeck*, paras 144 and 147.

207 Internal documents seized by the Commission during the inspections of Lundbeck’s facilities show that citalopram was essential for Lundbeck’s revenue. In an internal report, Lundbeck stated that “[…] generic citalopram represents a serious risk to Lundbeck.” See Case AT.39226 *Lundbeck*, para 127.

208 Case T-472/13, Lundbeck v Commission, para 123.
thus developed several policies as part of its strategic defence against entry of generic citalopram.\textsuperscript{209}

One of the policies was to persuade generic companies to stop their effort to enter the citalopram market. The four generic companies at issue in this case were all preparing to launch generic citalopram. Lundbeck thus decided to enter into discussions with them regarding patent infringement; claiming infringement of one or more of its new process patents. The generic companies claimed non-infringement or invalidity of the process patents Lundbeck invoked.\textsuperscript{210} The companies were thus in dispute over whether Lundbeck’s process patents were sufficiently strong to prevent the market entry of generic citalopram.

Lundbeck and the four generic companies concluded the six settlement agreements at issue in this case before a court ruling on these issues were given.\textsuperscript{211} Each of the agreements was characterised by the generic company’s commitment not to enter the citalopram market for the duration of the agreements and a value transfer from Lundbeck to the generic companies. The value transfers included, in particular, pure cash payments, purchasing stocks of generic medicines and distribution agreements.\textsuperscript{212}

The following section presents the General Court’s analysis of potential competition in the pharmaceutical sector. As analysed earlier, it is a part of the Commission’s three step test to assess whether the originator company and the generic company are at least potential competitors.

17.2. Potential Competition in the Pharmaceutical Sector

First, it must be recalled that, according to well-established case law, a company is a potential competitor of another company if it has ‘real concrete possibilities’ to enter the market on which the other company is active.\textsuperscript{213}

\textsuperscript{209} These policies were i) creating a window of opportunity for escitalopram (a successor product for citalopram which created a “window of opportunity” for Lundbeck to switch a maximum of new patients to escitalopram before entry of generic citalopram), ii) patenting processes to manufacture citalopram, iii) intervening in marketing authorisation procedures for generic citalopram, iv) eliminating the competitive threat of upcoming citalopram API producers and, v) persuading generic suppliers to stop their efforts to enter the citalopram market. See Case AT.39226 Lundbeck, para 134

\textsuperscript{210} Case AT.39226 Lundbeck, para 4

\textsuperscript{211} In fact, the validity of Lundbeck’s process patents had not been decided by any court. See Case AT.39226 Lundbeck, paras 2, 4 and 165

\textsuperscript{212} Case T-472/13, Lundbeck v Commission, paras 26, 35 and 42

\textsuperscript{213} The assessment of whether a company is a potential competitor has to be based on reasonably objective grounds. This means that the mere theoretical possibility to enter a market
The General Court acknowledged that Lundbeck’s original patents had expired before the conclusion of the agreements, but that it held a number of process patents. The General Court found that although the existence of a patent right is not affected by Article 101(1) TFEU, an agreement concerning a patent dispute is not exempt from competition law. It also acknowledged that patents are indeed presumed valid until they are expressly revoked or invalidated by a court.

17.2.1. No Court Ruling

The General Court emphasised that the settlement agreements were concluded before any court had found that the generic companies’ medicines infringed Lundbeck’s process patents. It noted that it “[...] was uncertainty as to whether [the generic companies’ medicines] would have eventually been declared infringing by a competent court.”

In other words, at the time the settlement agreements were concluded, it was uncertain whether the generic companies could enter the market without being subject to infringement proceedings brought by Lundbeck or whether they could successfully challenge the validity of Lundbeck’s patents. It was thus uncertain whether the generic companies could enter the market.

On this basis, the General Court found that the presumption of patent validity cannot be equated with a presumption of patent infringement in case of generic entry if no court ruling has been given on the patent’s validity. It stressed that the subject matter of a patent cannot be interpreted as affording protection against challenges of the patent’s validity. The point is that as long as a court has not given any judgement on whether a patent is valid and has been infringed, generic medicines placed on the market can only be considered as potentially infringing that patent.

It can thus be concluded that, according to the General Court the possibility of challenging the validity of a patent, either by claiming patent invalidity before a

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is not sufficient. This is also stated by the General Court, see Case T-472/13, Lundbeck v Commission, paras 99-100 and 123

214 Case T-472/13, Lundbeck v Commission, para 129

215 Case T-472/13, Lundbeck v Commission, paras 118, 427 and 459. This is in accordance with well-established case law from the Court of Justice

216 Case T-472/13, Lundbeck v Commission, para 121

217 Judgement para 363

218 As described in chapter X, this uncertainty is part of normal competition in the pharmaceutical industry and represents the expression of potential competition.

219 Case T-472/13, Lundbeck v Commission, para 121

220 The General Court found that it was for Lundbeck “[...] to prove before the national court, in the event that generics entered the market, that those generics infringed one of their process patents [...]”. See Case T-472/13, Lundbeck v Commission, paras 119 and 122
court or by entering the market ‘at risk’ is an expression of potential competition in the pharmaceutical sector. However, it appears that the General Court found that this is only an expression of a theoretical possibility to enter the market and that it does not “[...] suffice to establish the existence of potential competition.”

The General Court therefore took several other factors into consideration in order to establish that the generic companies had real concrete possibilities to enter the market, and that it was not merely theoretical.

17.2.2. Process Patents
The General Court emphasised that Lundbeck’s original patent had expired and that it only held a number of process patents at the time the agreements were concluded. It must be recalled that when an original patent expires, the molecule of the medicine and the original production process are no longer protected and the market is, in principle, open for any generic company.

The General Court found that Lundbeck’s process patents were not capable of blocking all possibilities for generic companies to enter the market because the generic companies could “[...] have produced generic citalopram by using the procedures described in its original patents [...] or by inventing a new type of process [...]”.¹²²

The General Court stated that the possibility for generic companies to enter the market ‘at risk’, with the possibility of having to face infringement proceedings brought by the originator company, represent the expression of potential competition, in a situation where i) the originator company’s original patent has expired and ii) where there are other procedures allowing the production of generic medicines that have not been found to infringe any patents.²²³

The General Court also relied on the fact that the generic companies had made significant investments and efforts in order to prepare their market entry.²²⁴

In addition, the General Court found the fact that “[...] there was a non-negligible possibility that some of Lundbeck’s process patents might be declared invalid [...]” important. The General Court relied on the general fact that patent litigation

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¹²¹ Case T-472/13, Lundbeck v Commission, para 157
¹²² Case T-472/13, Lundbeck v Commission, para 190
²²³ The General Court also found that that the very fact that Lundbeck concluded the agreements with the generic companies and decided to pay significant amounts to them in order to delay their entry to the market showed that the generic companies were potential competitors, “[...]since they were perceived by [Lundbeck]as a threat exerting competitive pressure on their position on the market.” See Case T-472/13, Lundbeck v Commission, paras 142-144 and 157
regarding process patents, in numerous cases, lead to a declaration of invalidity of those patents,225 and that the generic companies therefore had a real chance of succeeding in the event of litigation of the patent dispute.226 Moreover, the General Court relied on the subjective evidence that Lundbeck itself estimated that there was 50-60% chance that its process patents would be held invalid.227

17.2.3. Summary
It is clear from the General Court’s judgement that the possibility for generic companies to challenge an originator company’s patent(s) is an expression of potential competition in the pharmaceutical sector. This means that, according to the General Court, the exclusive right granted by patents is subject to challenge through the courts. This has been expressed as if a patent right “[…] in reality [is] only a right to try to exclude”.228

However, this possibility is only a mere theoretical possibility to enter the market, and the General Court therefore relied on several other factors in order to establish that the generic companies had real concrete possibilities to enter the market.

It can be concluded that the General Court found the following factors relevant in establishing that the generic companies had real concrete possibilities to enter the market: i) no court had found the generic medicines to infringe Lundbeck’s process patents, ii) Lundbeck’s original patent had expired and there were thus possibilities for the generic companies to enter the market, iii) the generic companies had made significant investments and efforts in order to prepare market entry and iv) there was a non-negligible possibility that Lundbeck’s process patent would be declared invalid.

On this basis, the General Court agreed with the Commission that the generic companies had real concrete possibilities to enter the market at the time the agreements were concluded and found that the Commission did not error in establishing that Lundbeck and the four generic companies were at least potential competitors.229

It is important to mention that the uncertainty whether the generic companies could enter the market was not only an important element in the analysis of potential competitor but also in the analysis of ‘by object’ restrictions. As will be analysed

225 Case T-472/13, Lundbeck v Commission, paras 122 and 363. The General Court referred to the contested decision in which the Commission referred to the Final Report which found (for the period between 2000 and 2007) that generic companies won 74% of all patent litigation cases regarding process patents. See Case AT.39226 Lundbeck, para 75.
227 Case T-472/13, Lundbeck v Commission, paras 122 and 363.
229 Case T-472/13, Lundbeck v Commission, paras 128 and 142.
in the following sections, the settlement agreements were designed to replace this uncertainty with the certainty of the settlement agreements.

17.3. Relevant Factors in the ‘By Object’ Analysis

This section intends to identify the factors which the General Court emphasised in its assessment of reverse payment agreements.

17.3.1. Legitimate Value Transfers from the Originator Company

The General Court agreed with the Commission that it was an important factor in finding a ‘by object’ restriction that the settlement agreements contained a value transfer from Lundbeck to the generic companies.230

However, it stressed that a settlement agreement including a reverse payment is not always problematic, “[...] particularly when (i) that payment is linked to the strength of the patent, as perceived by each of the parties, (ii) it is necessary in order to find an acceptable and legitimate solution [...] and (iii) it is not accompanied by restrictions intended to delay the market entry of generic [...].”231

The General Court agreed with the Commission that the settlement between Lundbeck and Neolab is an example of an unproblematic reverse payment agreement.232 In this settlement, Lundbeck agreed to pay the damages for the year that Neolab was prevented from selling generic citalopram because of voluntary injunctions. Lundbeck also agreed not to make any patent claims in the event that Neolab entered the market in exchange for Neolab’s commitment not to seek damages before a court.233

The General Court found that Lundbeck’s commitment not to bring any infringement proceedings against Neolab in the event it entered the market was crucial; “ [...] the payment made by Lundbeck was not made in exchange for an exclusion

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230 Case T-472/13, Lundbeck v Commission, para 354
231 Case T-472/13, Lundbeck v Commission, para 350
232 In October 2002, Neolab entered the United Kingdom market with generic citalopram. After this entry, Lundbeck started infringement proceedings against another generic company, Lagap. Neolab accepted voluntary injunctions until judgement on the invalidity of Lundbeck’s process patents was given in the Lagap litigation. Lundbeck settled with Lagap; meaning that no court ruling on the patents’ validity was given. Following Lundbeck’s settlement with Lagap, Lundbeck released Neolab from its injunctions. However, Neolab still had an interest in obtaining damages from Lundbeck. Lundbeck preferred to settle with Neolab. See Case T-472/13, Lundbeck v Commission, para 351; and Case AT.39226 Lundbeck, para 351
233 Case T-472/13, Lundbeck v Commission, paras 350-351
from the market, but was accompanied [...] by an acceptance of non-infringement and a commitment not to hinder the market entry of Neolab. “234

The General Court stressed that, in this case, the actual object of the reverse payment was to settle the patent dispute between Lundbeck and Neolab and not to achieve market exclusion.235 It can thus be concluded that, according to the General Court, a value transfer from an originator company may be legitimate if the settlement agreement includes no limitation on generic entry.

In continuation hereof, the General Court took the view that when a reverse payment is combined with an exclusion from the market, “[...] such limitation [may] not arise exclusively from the parties’ assessment of the strength of the patents but rather [is] obtained by means of that payment, constituting, therefore, a buy-off of competition.”236

This means that the General Court agreed with the Commission that it is relevant to assess whether the limitations on generic entry in a patent settlement agreement are paid for by the originator company. It was thus up to the General Court to assess whether the factors taken into account by the Commission in the contested decision were sufficient in order to establish whether the payments from Lundbeck substantially reduced the generic companies’ incentives to enter the market.

17.3.2. The Size and Disproportionate Nature of a Reverse Payment
First, the General Court stated that the “[t]he size of a reverse payment may constitute an indicator of the strength or weakness of a patent, as perceived by the parties to the agreements [...] and of the fact that originator undertaking was not initially convinced of its chances of succeeding in the event of litigation.”237

The General Court was, to a great extent, influenced by the judgement of the Supreme Court of the United States in Federal Trade Commission v. Actavis (‘the Actavis judgement’).238 Referring to this judgement, the General Court commented that a significant reverse payment “[...] can provide a workable surrogate for the weakness of a patent, without having to carry out a detailed analysis of the validity of that patent.”239

234 Case T-472/13, Lundbeck v Commission, para 351
235 Case T-472/13, Lundbeck v Commission, para 350
236 Case T-472/13, Lundbeck v Commission, para 352
237 Case T-472/13, Lundbeck v Commission, para 353
239 Case T-472/13, Lundbeck v Commission, para 353
It also stressed that Lundbeck seemed to acknowledged that the higher it estimates the chances of its patent being found invalid or not infringed, and the higher damages resulting from generic market entry, the more money is it willing to pay the generic company to avoid that risk.  

In other words, a significant reverse payment indicate that the originator company’s patent is weak; and if the originator company’s patent is weak, it is not very likely that the incentives for the generic companies to accept limitation on its possibilities to enter the market is based on the strength of the patent but rather on that significant payment, and therefore constitute a ‘buying-off’ of competition.

The General Court therefore found that “[...] the very existence of reverse payments and the disproportionate nature of those payments [...]” were relevant factors in establishing whether the settlement agreements constituted a ‘by object’ restriction.

It must be noted that the General Court relied on subjective evidence in establishing whether the payments from Lundbeck constituted the decisive basis of the generic companies’ commitment not to enter the market. It relied on isolated statements of Lundbeck and the four generic companies showing that Lundbeck estimated that its patents had 50-60% chance of being invalid or not infringed and that the generic companies were confident of their chances of being able to enter the market.

On this basis, the General Court concluded that Lundbeck’s process patent “[...] cannot have constituted the decisive basis of the generic undertaking’s commitment not to enter the market [...]” and that the payments from Lundbeck “[...] provided an incentive to the generic undertakings not to continue their independent efforts to enter the market.”

It can thus be concluded that a patent settlement agreement including a disproportionately high payment from an originator company and a commitment by the generic company not to enter the market may constitute a restriction of competition ‘by object’.

The General Court noted that the disproportionate nature of the settlement agreements combined with several other factors allowed the Commission to conclude that the agreements had as their object the restriction of competition.

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240 Case T-472/13, Lundbeck v Commission, para 353
241 Case T-472/13, Lundbeck v Commission, para 355
242 Case T-472/13, Lundbeck v Commission, paras 358, 363 and 369
243 Case T-472/13, Lundbeck v Commission, para 361
244 Case T-472/13, Lundbeck v Commission, para 355
245 Case T-472/13, Lundbeck v Commission, para 354
other factors were: i) the payments seemed to correspond to the expected profit by the generic companies if they had entered the market, ii) the absence of provisions allowing the generic companies to launch their medicines after expiry of the agreements and iii) the agreements contained restrictions going beyond the scope of the patents.\textsuperscript{246}

17.3.2.1. Value Transfer Corresponds to Expected Generic Profit
The General Court found that the fact that the payments from Lundbeck corresponded to the generic companies’ expected profit or turnover in case of market entry was a significant factor in the ‘by object’ analysis.\textsuperscript{247}

However, it noted that “[e]ven if those payments were less than the expected profits, they nevertheless constituted a certain and immediate profit, without necessitating the risks that market entry would have entailed.”\textsuperscript{248} This means that the payment may still provide incentives for a generic company to commit itself not to enter the market.

It can thus be concluded that this factor is a relevant but not decisive factor in establishing a ‘by object’ restriction.

17.3.2.2. Not Solving the Underlying Patent Dispute
The General Court agreed with the Commission that it was a relevant factor that the agreements did not contain any commitment from Lundbeck to refrain from bringing infringement proceedings against the generic companies if they entered the market after the expiry of the agreements. The agreements did therefore not solve the patent dispute but “merely allowed Lundbeck to gain time by denying the entry of generics [...]”.\textsuperscript{249}

This is contrary to the settlement between Lundbeck and Neolab which the General Court found to be an example of a legitimate reverse payment agreement.

On this basis, the General Court said that patent settlement agreements are particular problematic when they are intended to pay potential competitors to stay out of the market without, however, resolving the underlying patent dispute.\textsuperscript{250}

17.3.2.3. Restrictions beyond the Scope of the Patents
The General Court also agreed with the Commission that the fact that limitations in the agreements went beyond the scope of Lundbeck’s process patents was a

\textsuperscript{246} Case T-472/13, Lundbeck v Commission, para 354
\textsuperscript{247} Case T-472/13, Lundbeck v Commission, para 362
\textsuperscript{248} Case T-472/13, Lundbeck v Commission, para 399
\textsuperscript{249} Case T-472/13, Lundbeck v Commission, para 717
\textsuperscript{250} Case T-472/13, Lundbeck v Commission, para 475
relevant factor in establishing a ‘by object’ restriction.\textsuperscript{251} As pointed out by the Commission in the contested decision; when the restrictions fall outside the scope of the patent, then it becomes even clearer that the generic companies’ commitment to give up its efforts to seek market entry is not based on the strength of the patent, but on the payment from the originator company.\textsuperscript{252}

However, the General Court found that even if the limitations in the agreements had not gone beyond the scope of Lundbeck’s process patents, “[…] those agreements went beyond the specific subject matter of their intellectual property rights, which indeed included the right to oppose infringements, but not the right to conclude agreements by which actual or potential competitors were paid not to enter the market.”\textsuperscript{253}

According to the General Court, a reverse payment does not constitute a legitimate means of reaching market exclusion.\textsuperscript{254} Instead of paying the generic companies in order to achieve market exclusion, the General Court stressed several times that Lundbeck “[…] could have obtained orders to prevent market entry before the competent national courts, or, in the event that the generic undertakings unlawfully entered the market, obtained damages from them.”\textsuperscript{255}

It can thus be concluded that paying potential competitors for not trying to enter the market is not based on any rights granted by patent law. The fact that the restrictions went beyond the scope of Lundbeck’s process patents was a relevant but not decisive factor in establishing the existence of a restriction of competition by object.\textsuperscript{256}

17.3.2.4. Summary

On the basis of the above analysis, it can be concluded that it is essential for the finding of a ‘by object’ restriction that the value transfer from the originator company is linked to the commitment by the generic companies not to enter the market.

In establishing such a link, the General Court emphasises the following factors:

i) the disproportionate size of the reverse payment; it is a relevant but not decisive factor that the payment corresponds to the profits that the generic companies expected in case of successful entry

\textsuperscript{251} Case T-472/13, Lundbeck v Commission, para 515
\textsuperscript{252} See Case T-472/13, Lundbeck v Commission, para 335, referring to Case AT.39226
\textsuperscript{253} Case T-472/13, Lundbeck v Commission, para 495
\textsuperscript{254} Case T-472/13, Lundbeck v Commission, para 383
\textsuperscript{255} Case T-472/13, Lundbeck v Commission, paras 122 and 384
\textsuperscript{256} Case T-472/13, Lundbeck v Commission, para 515
ii) the absence of provisions allowing the generic company to launch after expiry of settlement agreements; this is likely to indicate that the objective aim was not to solve the underlying patent dispute

iii) the presence of restrictions going beyond the scope of the patent; this is likely to indicate that the generic companies’ commitment to give up their efforts to seek market entry is not based on the strength of the patent, but on the payment from the originator company

The General Court thus took several factors into account when establishing a ‘by object’ restriction. It did not explicitly refer to the ‘three step test’ applied by the Commission in its three decision regarding pay for delay agreements. However, all the above mentioned factors were all factors that the Commission also took into account.

**17.3.3. Replacing Uncertainty with Certainty**

The General Court stressed several times that the settlement agreements between Lundbeck and the four generic companies replaced the significant uncertainty regarding the validity or non-infringement of Lundbeck’s process patents that existed at the time the agreements were concluded with the certainty that the generic companies would not enter the market. 257

It acknowledged that patent settlement agreements are often intended to reduce the uncertainty inherent in litigation.258 However, it stressed, “[w]hat matters is that there was uncertainty, at the time the agreements at issue were concluded, [...] and that those agreements had replaced that uncertainty, by means of significant reverse payments, with the certainty that the generic undertakings would not enter the market [...]”(emphasis added).259 The General Court reiterated this on several occasions in its judgement and it appears to be the key statement.

It also found that replacing that uncertainty with the certainty of the agreements “[…] constitutes, as such, a restriction on competition by object in the present case, since that result was obtained through a reverse payment.”260

**17.3.3.1. Comparable to Market Exclusion Agreements**

It must be recalled that, according to the General Court, this uncertainty consists of the generic companies’ possibility to challenge the originator company’s pa-

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257 Case T-472/13, Lundbeck v Commission, paras 336, 363, 369, 382, 401 and more
258 Case T-472/13, Lundbeck v Commission, para 475
259 Case T-472/13, Lundbeck v Commission, para 369
260 Case T-472/13, Lundbeck v Commission, para 401
tents, and that this possibility is the expression of potential competition in the pharmaceutical sector. Accordingly, the General Court found that, by concluding the settlement agreements, Lundbeck and the four generic companies had eliminated all competition, even potential, on the market, during the term of the agreements.

The General Court observed that the Commission had taken account of Lundbeck’s process patents, but that it “[...] took the view that, even if those patents were presumed to be valid, they did not allow the exclusion of all competition [...]”.

The General Court thus found that the settlement agreements were comparable to market exclusion agreements and that “[...] the [companies] were able to share a part of the profits that Lundbeck continued to enjoy, to the detriment of consumers who continued to pay higher prices than those they would have paid if the generics had entered the market.”

It stressed that “[...]he exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production.”

It can thus be concluded that a patent settlement agreement including a reverse payment constitutes a market exclusion agreement and thereby also a ‘by object’ restriction if: i) the payment is significant, ii) the generic company’s commitment not to enter the market is achieved on the basis of that payment and iii) the agreement eliminates all competition on the market.

The following section presents the legal test applied by the General Court in finding a ‘by object’ restriction and its interpretation of the Court of Justice’s judgement in Groupement des cartes bancaires (CB).

17.3.4. Groupement des Cartes Bancaires (CB)

The General Court recalled that “[...] certain forms of coordination between undertakings can be regarded, by their very nature, as being injurious to the proper

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261 Case T-472/13, Lundbeck v Commission, para 335. See chapter X for an analysis of the General Court’s findings regarding potential competition in the pharmaceutical sector.
262 Case T-472/13, Lundbeck v Commission, para 363.
263 Case T-472/13, Lundbeck v Commission, para 435.
265 Case T-472/13, Lundbeck v Commission, para 429.
266 Case T-472/13, Lundbeck v Commission, para 435.
267 Case T-472/13, Lundbeck v Commission, para 434.
functioning of normal competition” and that an agreement must “reveal a sufficient degree of harm to competition” in order for it to be considered as an ‘by object’ restriction.

It can thus be concluded that the General Court applied a different legal test than the Commission did in the contested decision; it applied the longstanding interpretation that a ‘by object’ restriction must reveal a sufficient degree of harm to competition which the Court of Justice reconfirmed in Groupement des cartes bancaires (CB).

Despite the different legal test applied by the General Court, it still confirmed the Commission’s finding of ‘by object’ restrictions and found “[...] that the Commission correctly applied the case-law [...]”.

The General Court stressed that it is not necessary that the same type of agreement has been considered as a ‘by object’ restriction in order for the Commission to classify it as such a restriction. It therefore found that the Commission is not prevented from classifying new types of restrictions as ‘by object’ restrictions, following an individual and detailed examination of the agreements having regard to their content, purpose and context.

In this respect, the General Court stated that the role of experience mentioned in Groupement des cartes bancaires (CB) does not refer to the specific category of agreements in a particular sector “[...] but rather refers to the fact that it is established that certain forms of collusion are, in general and in the view of the experience gained, so likely to have negative effects on competition [...]”.

It can thus be concluded that the General Court took account of the judgement in Groupement des cartes bancaires (CB), but found that the role of experience does not prevent the European competition authorities to apply a ‘by object’ analysis on new types of agreements that have never been ruled on before, such as reverse payment/pay for delay agreements. New types of agreements can thus be regarded, by their very nature, as being injurious to competition, although no experience is gained regarding that specific category of agreements.

268 Case T-472/13, Lundbeck v Commission, para 340
269 Case T-472/13, Lundbeck v Commission, paras 339, 342 and 343. The General Court also said that in order to consider an agreement a ‘by object’ restriction, “[... ]regard must be had to the content of its provisions, its objectives and the economic and legal context of which it forms a part.” Moreover, it said that it is necessary to take into consideration the nature of the goods, as well as the functioning and structure of the market. Finally, it stated that the parties’ intentions are not a necessary factor, but it may be taken into account
270 Case T-472/13, Lundbeck v Commission, para 436
271 Case T-472/13, Lundbeck v Commission, para 438
272 Case T-472/13, Lundbeck v Commission, para 438
It is not evident from the General Court’s reasoning whether it found the role of experience irrelevant for reverse payment agreements because the agreements at issue were comparable to market exclusion agreements, which are obviously, in view of experience gained, ‘by object’ restrictions.
18. Summary

The General Court’s judgement in *Lundbeck v Commission* is the first and only European judgement on pay for delay agreements. The General Court upheld the Commission’s decision and found that the settlement agreements including a reverse payment from Lundbeck to four generic companies constituted restrictions of competition ‘by object’.

The decisive element in the judgement appears to be that, at the time the settlement agreements were concluded, a considerable uncertainty existed as regards the possibility for the generic companies to successfully enter the market without being subject to infringement actions and to successfully challenge the validity of Lundbeck’s process patents.

First, the General Court stated that this uncertainty allowed the generic companies to enter the market ‘at risk’. This possibility is the expression of potential competition in a situation where the originator company’s original patent has expired and where other procedures allow the production of generic medicines that have not been found to infringe any patents. This means that although patents are presumed valid, they don't prevent companies from challenging that validity. A patent right is thus merely a right to try to exclude.

Secondly, the General Court stressed several times that by concluding the settlement agreements, Lundbeck and the four generic companies replaced that uncertainty with the certainty that the generic companies would not enter the market. It held that such agreements constitute ‘by object’ restrictions as such, if the exclusion of the generic companies is achieved on the basis of the reverse payment from the originator company.

In establishing whether the generic companies’ commitment not to enter the market was achieved on the basis of the reverse payment from Lundbeck, the General Court relied, in particular, on the size of the reverse payment. It held that a significant reverse payment may work as a surrogate for a weak patent; meaning that the size of the reverse payment may indicate whether the exclusion of generic companies is achieved based on that payment or on the strength of the patent.

The General Court also found that the fact that the payment corresponds to the expected generic profit is a significant factor. However, it is not decisive for establishing a ‘by object’. Moreover, it found that the fact that the generic companies are not guaranteed market access after the expiry of the agreements and the fact
that the agreements contain limitations on generic entry going beyond the scope of the patent indicate that the objective aim of the agreements is not to solve the underlying patent dispute but rather to exclude generic companies from the market.

On the basis of these factors, the General Court upheld the Commission’s finding of a ‘by object’ restriction. In addition, the General Court agreed with the Commission that the settlement agreements were comparable to market exclusion agreements since they eliminated all competition, even potential, from the market.

Finally, the Court of Justice took account of the Court of Justice judgement in Groupement des cartes bancaires (CB) that calls for a more restrictive interpretation of the concept of ‘by object’. Although, the General Court applied a more restrictive interpretation than the one applied by the Commission in the contested decision, it found that the Commission had applied the case law correct. It held that the role of experience in Groupement des cartes bancaires (CB) does not prevent the finding of a ‘by object’ restriction even if it’s a new type of agreement.

After having read both the Commission’s decision and the General Court’s judgement, it can be concluded that the case is very fact specific and the context in which the settlement agreements are concluded is surrounded by several complexities. The General Court stated several times: ‘in the particular case at hand’ and ‘in the present case’.273 It can thus be concluded that the General Court’s approach when analysing patent settlement agreements is in accordance with the Commission’s statement that such agreements will be assessed on the basis of the circumstances of each individual case.

However, the Lundbeck v Commission judgement still gives some guidance on which factors the General Court find to be relevant in establishing a ‘by object’ restriction in case of a reverse payment agreement.

At least it can be concluded that if the reverse payment in a patent settlement agreement is not linked to an exclusion of generic entry and if it is intended to solve the underlying patent settlement, the settlement agreement will most likely not be incompatible with Article 101 TFEU.

Lundbeck and the generic companies have appealed the General Court’s judgement to the Court of Justice.274 This appeal will most likely focus on the correct legal test to be applied to reverse payment agreements.

The following chapter intends to discuss the approach taken by the General Court when assessing reverse payment agreements in the pharmaceutical sector. It focuses on the General Court’s finding of a considerable uncertainty as regards the

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273 E.g. judgement paras 95, 96, 102 and 438
274 Case C-591/16P, Lundbeck v Commission, (case in progress).
generic companies’ possibilities to enter the market and the factors which it took into account in establishing a ‘by object’ restriction. It also discusses the legal test applied by the General Court. The discussion takes the specific characteristics of the pharmaceutical sector and the Court of Justice’s recent judgement in *Groupement des cartes bancaires (CB)* into consideration.
PART VI - OPEN QUESTIONS AND POINTS FOR DEBATE

In general, this chapter intends to discuss whether the ‘by object’ analysis is appropriate to assess patent settlement agreements in the pharmaceutical sector. It discusses whether the Commission should have applied a full effect analysis in the Lundbeck (Citalopram) case in the first place, and whether the General Court was right in upholding the Commission’s ‘by object’ analysis, especially in light of the judgement in Groupement des cartes bancaires (CB).

This chapter also discusses the General Court’s analysis in Lundbeck v Commission. It intends to discuss the implications of the judgement and to present some general points for debate regarding the factors that the General Court took into account in its assessment of reverse payment agreements.
19. Why Not an Effect Analysis?

In light of the critic of the European Commission in having applied a too broad interpretation of the concept of ‘by object’ restriction in general, and the new Court of Justice judgement in *Groupement des cartes bancaires* giving a call for a restrictive interpretation of the concept, it can be discussed whether it would have been more correct with an effect analysis when assessing patent settlement agreements including a reverse payment.

19.1. Complex Agreements

Patent settlement agreements are commercial agreements related to an underlying patent dispute. Such settlement agreements thus lie in the intersection between competition law and patent law. These two systems of law share the same goal: promoting innovation in order to ensure consumer welfare.

It is clear that patent settlement agreements that delay market entry of generic medicines have a significant impact on the price for which the medicine is sold. This has as a consequence that consumers do not benefit from the lower prices that would have existed if generic entry had happened. Such settlement agreements thus have a negative impact on consumer welfare.

However, this short-term interest of consumers must be seen in context with the long-term interest of consumers that consists in benefitting from the development of new medicines. The development of new medicines is encouraged by patent protection which is especially important in the pharmaceutical sector due to the high investments in research and development and the long life cycle of a medicine. It can thus be argued that it is no simple task to assess the negative effects and overall benefits of patent settlement agreements.

In addition, each patent right is different in scope and each patent dispute is therefore also different. Since patent settlement agreements are concluded in the context of the specific patent dispute, they are fact-specific and the content and terms of such settlements therefore vary.

It can thus be concluded that several complexities surround patent settlement agreements.
19.2. Lack of Experience

19.2.1. Years of Investigation
The Commission initiated the inquiry into the pharmaceutical industry in 2008, and adopted its results in a communication in 2009. Since then it found it necessary to continue to monitor patent settlement agreements concluded by pharmaceutical companies.

The mere fact that the Commission found it necessary to open a sector inquiry into the pharmaceutical sector and, in addition, continue to monitor patent settlement agreements in order to better understand the use of such agreements and to identify those agreements that delay generic entry in violation of European competition law indicate that this was a new area and that no previous experience existed.

There is no doubt that the Final Report of the sector inquiry presents a thorough analysis and examination of the market structure of the pharmaceutical industry, the competitive environment between pharmaceutical companies and the strategies developed by originator companies to delay market entry of generic medicines. The Commission’s categorisation of patent settlement agreements was broad and indicated merely that patent settlement agreements that include a commitment from a generic company not to enter the market and a value transfer from the originator company were likely to be incompatible with European competition law.

Since then, the Commission has monitored hundreds of patent settlement agreements through its annually monitoring exercise. However, the monitoring reports have not given much further guidance than the Final Report so far; only that settlement agreements that impose limitation on the generic companies that exceed the scope of the patent and settlement agreements where the patent holder knows that the underlying patent does not meet the patentability criteria are potentially problematic from a competition law perspective.

The Commission stated that any enforcement actions will be initiated on a case-by-case basis and will include a thorough examination of each specific case. It can thus be concluded that neither the Commission’s Final Report nor monitoring reports provided much guidance on the illegality of reverse payment agreements.

It does therefore not seem as if the Commission was sure about the anticompetitive aspect of such agreements at the time it opened antitrust proceedings against Lundbeck.

19.2.2. Showing Likely Negative Effects
As analysed earlier, the Commission did in both the Lundbeck (Citalopram) and Servier (Perindopril) decisions complement their ‘by object’ analysis with an additional analysis of the likely negative effects of the agreements.
Arguably, the fact that the Commission found it necessary ‘for the sake of completeness’ to demonstrate likely negative effects of the agreements indicates itself that the Commission was not convinced of the harmful nature of those agreements. It thus appears as if the Commission made a quick effect analysis in order to support its finding of ‘by object’ restrictions.

By doing so, the Commission nevertheless did not benefit from the advantage of a ‘by object’ analysis that consists in procedural efficiencies and economy since such an analysis allows the competition authorities to establish a violation of competition law without any need for them to demonstrate any potential or actual effects.

In light of the fact that several complexities surround patent settlement agreements, that the Commission has not been able to give much guidance regarding the anticompetitive aspects of reverse payment agreements and that it found it necessary to complement its ‘by object’ analysis with a limited effect analysis, it can be argued that no experience regarding the harmful nature of such patent settlement agreements existed, and that the Commission should have carried out a full effect analysis instead of applying a ‘by object’ analysis.
20. General Court Upheld ‘By Object’ Approach

The Commission’s decision to assess the agreements in Lundbeck (Citalopram) using a ‘by object’ analysis seems even more questionable after the Court of Justice judgement in Groupement des cartes bancaires (CB).

In this judgement, the Court of Justice held that the concept of ‘by object’ restrictions must be interpreted restrictively and applied only to conduct whose harmful nature is proven and easily identifiable in light of experience. Despite this judgement, the General Court upheld the Commission’s decision and found that the correct legal test to be applied was the ‘by object’ analysis.

The General Court stressed that it is not necessary that the same type of agreement has been considered as a ‘by object’ restriction in order for the Commission to classify it as such a restriction, because the role of experience does not refer to the specific category of agreements in a particular sector but to the fact that certain forms of conduct are, in general and in the view of experience, likely to have negative effects.

The General Court compared the reverse payment agreements in Lundbeck v Commission to market exclusion agreements that are, in general and in the view of experience, so likely to have negative effects on competition. It can thus be argued that the correct legal test nevertheless is the ‘by object’ analysis.

However, it must be recalled that the Court of Justice in Groupement des cartes bancaires (CB) argued that by assessing the potential effects of the agreements, the competition authority itself indicate that the agreements in question could not be considered ‘by their very nature’ harmful to competition. It is thus obviously wrong to actually assess the effects of an agreement in order to identify it as a ‘by object’ restriction since that would defy the purpose of having the category of ‘by object’ restrictions.

In this respect, it is questionable whether the General Court should have upheld the Commission’s decision. Arguably, it would have seem more appropriate that the Commission had applied a full effect analysis on reverse payment agreements until enough experience had been gained to classify them as ‘by object’ restrictions.
As the General Court’s judgement has been appealed, it is up to the Court of Justice to give the final judgement in this case. It will thus be interesting to see whether it agrees with the General Court’s interpretation of the role of experience and whether it upholds the judgement.
21. Future Implications

It is clear from the analysis of Lundbeck v Commission above, that the General Court emphasised that Lundbeck’s original patent had expired and only held a number of process patents when it established that there existed potential competition between Lundbeck and the four generic companies.

It must be recalled, that the market is in principle open when the original patent has expired as it allows generic companies to launch generic medicines that have been produced using the original processes that were covered by the original patent. The General Court therefore held that although Lundbeck’s process patents were presumed valid, they were simply not capable of blocking all competition.

In addition, the General Court emphasised the fact that patent litigation cases regarding process patents often lead to a declaration of invalidity of those patents.

Arguably, it seems as if a greater uncertainty whether generic companies can enter the market exists in a situation where the underlying patent of the settlement agreement is a process patent and not an original patent; meaning that it seems easier to establish potential competition where the underlying patent is a process patent.

In this respect, it is worth to mention that the patent settlement agreements in the Johnson & Johnson (Fentanyl) and Servier (Perindopril) decisions from the Commission also concerned process patents. This leaves the question of whether the establishment of potential competition will be different, if the underlying patent is not a process patent unanswered.

In addition, it has been argued that the Lundbeck v Commission is a special case because the underlying patent was a ‘weak’ process patent. It was clear from subjective evidence that Lundbeck itself estimated that there was 50-60% chance that its process patents would be held invalid and that the generic companies were confident in their chances of entering the market.

Arguably, it seems that the specific facts and circumstance of the case in Lundbeck v Commission led to the finding of potential competition. Thus, the questions remain: how to analyse potential competition in a situation where the underlying

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275 Sven Gallasch, ‘General Court’s pay for delay judgement in Lundbeck - some guidance, but worries remain’, (14 September 2016), Competition Policy Blog, University of East Anglia (UEA)
Patent is not ‘weak’ but rather ‘strong’ and how likely must it be that a patent would be found invalid for a generic company to be considered as a potential competitor?

It can be concluded that the *Lundbeck v Commission* is a special case and it is questionable whether the establishment of potential competition in other cases will be the same.

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22. Second Guessing Litigation Outcome

It is clear that it was essential for the judgement in *Lundbeck v Commission* that there was considerable uncertainty as regards the generic companies’ possibilities to enter the market at the time the patent settlement agreements were concluded and that this uncertainty was exchanged into certainty by means of a significant payment and not by the strength of the patent.

It was thus necessary for the General Court to establish a link between the reverse payment and the commitment by the generic companies not to enter the market. In establishing such a link the General Court relied on the subjective evidence that both Lundbeck and the generic companies assessed Lundbeck’s process patents as weak.

It can be argued that the companies own assessments of the strength of the patent are important to establish a link between payment and the generic companies’ commitment not to enter the market; if the generic companies assess the patent as weak, but still agree not to enter the market, it may indicate that such commitment is not achieved on the basis of the strength of the patent but on the reverse payment. It can thus be argued that it was essential for establishing a link between payment and generic commitment in *Lundbeck v Commission* that the companies were being so explicit regarding their own assessment of the strength of the patent.

However, it may be more complicated to establish such a link in cases where the companies are not being so explicit in their own assessment of the strength of the patent. According to the General Court, a significant payment may work as a surrogate for a weak patent. This indicates that in cases where the companies are not being as explicit in their assessment of the patent, the General Court may rely on the fact that the size of the payment is significant.

The General Court has been criticised for relying on the size of the reverse payment as an indicator of a weak patent. The criticism is that the General Court, in reality, is second-guessing the outcome of a patent litigation case.\(^\text{277}\) It must be recalled that patent litigation in the pharmaceutical sector is very complex and that

the outcome can almost never be predicted. Patent litigation cases are even more complex in the pharmaceutical sector as one medicine can be protected by several patents, supplementary protection certificate and/or data and marketing exclusivity. Even experts can have grave difficulty in predicting the outcome of such cases. Arguably, the General Court should be cautious in relying on the size of the payment.  

Furthermore, it can be discussed whether the size of the payment in reality says anything about the originator company’s assessment of the strength or weakness of a patent. It must be recalled that the competitive environment in the pharmaceutical industry between originator companies and generic companies consists of an asymmetry of risk. Originator companies invest many billion dollars in research and development which has to be recouped in the exclusivity period, while generic companies make minimal investments.

It can thus be argued that the originator companies are at greater risk in a patent dispute and have more at stake and therefore may wish to settle the dispute at some costs to protect their exclusive rights, rather than risk the loss of the possibility to recoup their investments. It can thus from a commercial perspective make sense for the originator company to pay the generic company in order to prevent market entry.

It can be concluded that a considerable payment may not always be an indicator of a weak patent but just as much an expression of high risks related to patent litigation. It is thus questionable whether it is appropriate to rely on the size of the payment.

In addition, it must be recalled that the value transfers from Lundbeck to the four generic companies took various forms; pure cash payments, purchasing stocks of generic medicines and distribution agreements. As described earlier, it appears as if originator companies are largely refraining from using pure cash payment in recent patent settlement agreements but instead rely on the construction of ‘side-deals’. In such a context, it might not be easy to determine the exact size of a reverse payment, and it has been argued that competition authorities will have to

279 Joseph Straus, “Pay for Delay” - A Subtly Hidden, Overlooked or Ignored Transatlantic Divide: Exemplified on the Actavis decision of the US Supreme Court and the Servier decision of the EU Commission, Zbornik znanstvenih razprav, Volume 76 (2016), page 223
281 See Part V, chapter 17.1. ‘Facts of the Case’
282 See Part IV, chapter 14.2. ‘Possibly Problematic Settlement Agreements’
look deeply into the economic rationale of the patent settlement agreement for assessing the reverse payment.\textsuperscript{282} Arguably, it seems too simplistic to rely on the size of the payment.

However, it must be mentioned that the General Court did not find that the existence of a significant payment was sufficient in itself to establish a ‘by object’ restriction. It found that it was the size of the payment combined with three other factors which led to that conclusion: i) the amount of the payment corresponded to the generic companies’ expected profits, ii) there was no commitment from Lundbeck to not bring infringement proceedings against the generic companies in case of market entry after the expiry of the agreements and iii) the limitations on generic entry went beyond the scope of Lundbeck’s process patents.

It can be argued that these additional factors can give the competition authority an indication on whether the object of the agreement was to delay generic entry or whether it was to solve the underlying patent dispute. However, the finding of a ‘by object’ restriction in \textit{Lundbeck v Commission} is characterised by the special facts and circumstance of the case which clearly showed that the object of the agreements was to delay the market entry of the generic companies and share a higher profit.

Arguably, it can be concluded that the General Court was right in establishing a ‘by object’ restriction. However, it seems remarkable that the General Court was not being more explicit about that this was a special case and that the specific facts and circumstances of the case led to the conclusion of a ‘by object’ restriction.

It has thus been argued that “[…] one conclusion that should not be drawn from the European decisions is that pay-for-delay deals will inevitably be treated as ‘by object’ infringements.”\textsuperscript{283}


\textsuperscript{283} Irene Fraile, Ankur Kapoor & Rosa Morales, ‘Drug Test: When are Pay-for-Delay Agreements Illegal?’ Global Competition Litigation Review (2014), p. 220
PART VII - CONCLUSION

This thesis has described the main characteristics of the pharmaceutical sector and analysed patent settlement agreements concluded by pharmaceutical companies within the European Union. It has analysed how pay for delay agreements are analysed under European competition law by analysing the Commission’s and the General Court’s assessment of such agreements. It has also discussed whether the ‘by object’ analysis is the most appropriate for assessing pay for delay agreements.

Patent settlement agreements are commercial agreements that are concluded in the context of a patent dispute. Patent disputes often occur in the pharmaceutical sector. However, patent litigation is very complex, time-consuming and uncertain which is why pharmaceutical companies often wish to settle their dispute instead of waiting until final judgement in the litigation case.

In its Final Report of the sector inquiry of the pharmaceutical sector, the Commission identified a number of strategies used by originator companies to delay generic market entry. It found that certain settlement agreements concluded by originator and generic companies are designed to exclude generic competitors from the market. Such agreements result in delayed market entry of cheaper generic medicines to the detriment of European consumers whom will not benefit from the lower prices, which would have followed with generic entry.

It can be concluded that the existence of a patent right is not affected by European competition law; however, the exercise of such rights may fall within the prohibitions contained in competition law. This means that patent settlement agreements may fall within the prohibition laid down in Article 101 TFEU. This article distinguishes between those agreements that have a restriction of competition as their object and those agreements that have a restriction of competition as their effect. If a agreement is considered to have as its object the restriction of competition, it is not necessary to demonstrate any actual or potential anticompetitive effects. The European competition authorities have been criticised for applying a too wide interpretation of the concept of ‘by object’ restrictions with the consequence that it was becoming easier to establish a ‘by object’ restriction.

During the sector inquiry and the following monitoring exercise of patent settlement agreements, the Commission found that patent settlement agreements that include a value transfer from the originator company to the generic company and a commitment from the generic company not to enter the market (B.II. agreements), so-called reverse payment agreements, are likely to be problematic from a competition law perspective. It also stated that any enforcement actions on patent
settlement agreements will include a thorough examination of the specific facts of each case.

The Commission has since then adopted three decisions on pay for delay agreements; the Lundbeck (Citalopram), the Johnson&Johnson (Fentanyl), and the Servier (Perindopril) decisions. In all three decisions, the Commission found that the settlement agreements were comparable to market sharing agreements and that they thus constituted ‘by object’ restrictions. It can be concluded that the decisive factor when assessing B.II. agreements is whether there exists a link between the commitment from the generic company not to enter the market and the value transfer from the originator company.

In two of the decisions the Commission demonstrated likely negative effects even though it applied a ‘by object’ analysis and found that in order to establish a ‘by object’ restriction, it was sufficient that the agreements had the potential to restrict competition.

After these three decisions were adopted, the Court of Justice gave its judgement in Groupement des cartes bancaires (CB) that stated that the concept of ‘by object’ restrictions should be interpreted restrictively and that it only applied to agreements that reveal a sufficient degree of harm to competition. The Advocate General Wahl also suggests that the classification of a restriction as a ‘by object restriction’ should be based on experience gained.

In light of the facts that the wide legal test applied by the Commission was similar to that the Court of Justice rejected in Groupement des cartes bancaires (CB), that the Commission had not been able to give much guidance regarding the anticompetitive aspects of reverse payment agreements before its decisions and that it found it necessary to complement its ‘by object’ analysis with a limited effect analysis, it can be concluded that no experience regarding the harmful nature of such patent settlement agreements existed at the time the Commission decided to apply a ‘by object’ analysis.

It must therefore be concluded that it would have been more appropriate that the Commission had carried out a full effect analysis instead of applying a ‘by object’ analysis.

However, the General Court upheld the Commission’s decisions in Lundbeck (Citalopram) and found that the correct legal test for analysing the reverse payment agreements in question was the ‘by object’ analysis. It held that the role of experience in Groupement des cartes bancaires (CB) does not prevent the finding of a ‘by object’ restriction even if it is a new type of agreement.
It can be concluded that it is questionable whether the General Court should have uphold the Commission’s decision. As the General Court’s judgement has been appealed, it is up to the Court of Justice to give the final judgement in this case. It will thus be interesting to see whether it agrees with the General Court’s interpretation of the role of experience and whether it upholds the judgement.

Although it is questionable whether the General Court should have uphold the Commission’s decision in *Lundbeck (Citalopram)*, the General Court’s judgement *Lundbeck v Commission* give some guidance on what types of reverse payment agreements that are incompatible with European competition law and that have the object of restricting competition.

First of all, it can be concluded that the General Court carries out a thorough examination of the reverse payment agreement. It agreed with the Commission that a significant reverse payment may indicate that the limitation on generic entry is not achieved on the basis of the strength of the patent but on the reverse payment. It can thus be concluded that the General Court agrees with the Commission in that the decisive factor when assessing reverse payment agreements is whether there exists a link between the limitations on generic entry and the value transfer.

It can be concluded that a reverse payment agreement constitutes a ‘by object’ restriction and is thus incompatible with Article 101 TFEU if the exclusion of the generic company is achieved on the basis of the reverse payment from the originator company. The General Court found that the following factors are relevant when establishing a link between the limitations on generic entry and the value transfer:

i) a disproportionate size of the reverse payment; it is a relevant but not decisive factor that the payment corresponds to the profits that the generic companies expected in case of successful entry

ii) the absence of provisions allowing the generic company to enter the market after expiry of the settlement agreement

iii) the presence of restrictions going beyond the scope of the patent

It can be concluded that a decisive element in the *Lundbeck v Commission* judgement was that, at the time the settlement agreements were concluded, a considerable uncertainty existed as regards the possibility for the generic companies to successfully enter the market and that this uncertainty was exchanged into the certainty by means of a significant payment.

It can also be concluded that the *Lundbeck v Commission* is a very fact specific and special case concerning a ‘weak’ process patent and where the companies were being quite explicit in their statements regarding the objective aim of the
settlement agreements. The agreements were therefore comparable to market exclusion agreements which may have influenced the General Court’s finding of a ‘by object’ restriction.

It can thus be concluded that it is questionable whether reverse payment agreements always will be treated as ‘by object’ restrictions.
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