

TALLINN UNIVERSITY OF TECHNOLOGY
School of Business and Governance
Department of Law

Juhana Tuhkanen

**Development of Competition Law in the Pharmaceutical Sector in
Europe: The Lundbeck Judgment in Context**

Bachelor Thesis

Supervisor: Thomas Hoffmann, Associate Professor

Tallinn 2017

I hereby declare that I am the sole author
of this Bachelor Thesis and it has
not been presented to any other
university of examination.

Juhana Tuhkanen

“.....” 2017

The Bachelor Thesis meets the established requirements

Supervisor Thomas Hoffmann

“.....” 2017

Accepted for Examination “.....” 2017

Board of Examiners of Bachelor’s Theses

Table of Contents

Table of Contents.....	3
Introduction.....	4
1. The Legal and Analytical Framework for Patent Settlements in the EU.....	6
1.1 The Pharmaceutical Sector Inquiry.....	6
1.2 Other Legal Context for Analysis Regarding Pay-For-Delay Settlements.....	8
1.2.1 Annual Monitoring Reports on Patent Settlements.....	8
1.2.2 Recent Cases Other Than Lundbeck.....	9
2. Lundbeck Citalopram Case and the Commission’s Decision.....	12
2.1 Background.....	12
2.2 Competition Law Perspective According to the Commission’s Decision.....	15
2.3 The General Court Judgment.....	18
3. Application of the Proportionality Test to the Lundbeck Judgment.....	19
3.1 Suitability.....	20
3.1.1 The Notion of Potential Competition.....	21
3.1.3. Other “By Object” Restriction of Competition Considerations.....	27
3.1.4. Substantive Scope of an Intellectual Property Protection.....	31
3.1.5 Assessing the Counterfactual.....	33
3.2 Necessity.....	36
3.2.1 Actavis and the US Approach.....	36
3.3 Proportionality.....	39
Conclusions.....	40
Annex 1.....	44
Reference List.....	45
Academic Sources.....	45
Internet Sources.....	46
Other Sources.....	47

Introduction

On 19 June 2013 the European Commission gave its decision on the Lundbeck citalopram case, its very first decision concerning reverse patent settlement agreements within the European Union. Almost 500 pages in size, it is truly a landmark decision, showing for the first time the approach by the European Commission to these so-called “pay-for-delay” settlements in the European Union.¹ The Commission’s decision, or rather the legal basis for the decision was widely accused of using vague definitions as well as of disregarding some potentially relevant case law and other legal context.² This decision was nevertheless later confirmed by the General Court on 8 September 2016, a judgment that is merely months old at the time of writing of this thesis.³ As the first judgment to touch upon the subject of reverse payment patent settlements it will be of great significance in terms of it working as the first concrete policy guideline for European pharmaceutical companies. The judgment was both a confirmation of most of the content of the commission’s decision and an examination of and answer to the critique on the Commission’s decision.

The Lundbeck judgment represents the beginning of new area of case law on the EU level. There have been several cases on more or less similar circumstances, where there is a clear balancing test between an intellectual property right and competition law, where trademarks are concerned for instance, but never on patent settlements which include reverse payments. These are the types of agreements in which the pharmaceutical industry is at the forefront.⁴

The research question of this thesis is: Is the Lundbeck judgment a suitable, necessary and proportional instrument to protect competition law interests in Europe? The analysis, that utilizes the very standard European Union proportionality test, is centered especially around the critique that the Commission’s Lundbeck decision attracted after it was released in 2013 with regards to its potential incoherence with existing legal framework and to its use of a vague definition on especially one notion: Potential competition. Specifically, this paper will look at the ‘by object’ infringement approach of the commission and how the General Court has been able to take into account the critique on it and how it has, where necessary, elaborated the rationale behind some

¹ European Commission Press Release, Brussels, 19 June 2013, http://europa.eu/rapid/press-release_IP-13-563_en.htm (12.12.2016)

² Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. The Consistent Application of EU Competition Law: Substantive and Procedural Challenges. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 55.

³ GC judgment 08.09.2016, Case T-472/13, Lundbeck v Commission

⁴ Gallasch S. Activating Actavis in Europe - the proposal of a ‘structured effects-based’ analysis for pay-for-delay settlements. Legal Studies 2016 36 (4), pp. 683-705, p 683.

of the challenged arguments. This paper has a neutral stance as to the successful passing of the Lundbeck judgment of the proportionality test, which is the central tool of analysis of this thesis. This thesis therefore, does not have a hypothesis.

The problem for European pharmaceutical companies and national courts alike has been the absence of a meaningful legal framework for patent settlement agreements, in particular those with reverse payments. It has been known for quite a while, that reverse payment patent settlements lay on a legally gray area, but the criteria for determining whether a particular settlement fell into a legally black area has been less than concrete.⁵ Lundbeck has been, from the very start a big part of that conversation and the development of better European Union level guidelines for patent settlements has been the definitive factor in Lundbeck, really a point that makes the case so significant.⁶

For the sake of clarity, the purpose of this thesis is by no means to propose, or evaluate the need for further regulation in this area. Indeed, one might question the necessity of an European Union level uniform approach altogether, yet that is a conversation that goes beyond the Lundbeck judgment and the considerations in this paper and would need a re-evaluation of the scope of Article 101 and even 102 of the Treaty on the Functioning of the European Union, which are the applicable articles in practically all European Union competition law cases. Furthermore, this thesis does not make an attempt to dispute the facts that were established by either the Commission or the General Court. In analyzing Lundbeck as part of the legal framework it is more relevant to focus on what the judgment entails for the future of that legal framework than it is to focus on its accurateness as a separate case. The purpose of this thesis therefore, is to analyze the legal basis of an application of a legal norm, not to analyze the norm itself.

⁵ Clancy M. *et al.* Reverse-payment Patent Settlements in the pharmaceutical industry: An analysis of U.S. Antitrust Law and EU competition law, *The Antitrust Bulletin* 2014, 59 (1). pp. 153-172, p 164.

⁶ Ginsburg D. *et al.* Reverse Payment Patent Settlements in the European Union and the United States 2015. George Mason Legal Studies Research Paper No. LS 15-22, p 16-17.

1. The Legal and Analytical Framework for Patent Settlements in the EU

Before analyzing any particular case in detail, one has to first understand the legal framework, that is only just emerging in the European Union to enable such analysis, including the concepts and definitions on which no European case law exists yet. It is noteworthy that the Lundbeck citalopram case plays a big role in this emergence.

The concept of Reverse Payment Patent Settlements first came into existence in the USA, with the Hatch-Waxman Act of 1984 , which created the statutory framework for Reverse payment settlements.⁷ The concept of a reverse payment is altogether more well known in the United States, having been defined in *In Re Tamoxifen* (2006) as follows:

“Payments pursuant to the settlement of a patent suit such as those required under the Settlement Agreement are referred to as “reverse” payments because [...] here, the patent holder, which, if its patent is valid, has the right to prevent the alleged infringer from making commercial use of it, nonetheless pays that party not to do so⁸.”

A reverse payment is therefore, any payment in a settlement which reverses the traditional relationship between the plaintiff and the defendant. Applied to pharmaceutical patents, this means that the originator company who is also the patentee pays to the potentially infringing company a sum of money not to infringe. This circumvents the need to enforce a patent that is being infringed or challenged.

1.1 The Pharmaceutical Sector Inquiry

In 2003, the European Commission did a review with the Danish Competition Authority (DCA) on a number of patent settlements made between Lundbeck and multiple generic drug companies. These settlements all included reverse payments. The Commission, together with DCA saw these reviewed settlements as falling outside of any existing legal guidelines in the European Union and therefore problematic. This consideration prompted for its part the Commission to generate a more general investigation and analysis on such cases and settlements to create the guidelines for handling them.⁹ This goes to show, that Lundbeck was and is truly in the epicenter of official EU reasoning on the subject.

⁷ Schacht W. *et al.* The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents, CRS Report for Congress 2004, p 16

⁸ United States Court Of Appeals For The Second Circuit, *In Re: Tamoxifen Citrate Antitrust Litigation.*, 466 US (2006) 52

⁹ Clancy M. *et al.* Reverse-payment Patent Settlements in the pharmaceutical industry: An analysis of U.S. Antitrust Law and EU competition law, *The Antitrust Bulletin* 2014, 59 (1), p 164

In 2008 the Commission started its inquiry on the pharmaceutical sector, which attempted to concentrate on the practices with which companies may be able to block or delay generic competition. The inquiry focused especially on the competitive relationship between originators and generic companies.¹⁰ It was not before 2009 that European companies had any framework or case-law given by their European Union authorities on patent settlement agreements as the Final Report of the Pharmaceutical Inquiry was published.¹¹ The Inquiry is in total over 500 pages long. The Final Report of the inquiry defined patent settlement agreements as follows:

“Patent settlement agreements are commercial agreements to settle actual or potential patent-related disputes. Patent settlement agreements are concluded in order to resolve claims in patent disputes, opposition procedures or litigation where no final adjudication has been handed down or there has not yet been a court proceeding. The primary aim of a settlement agreement is to end the dispute, opposition procedure or litigation.”¹²

The most practical part of the Commissions inquiry was the categorization and analysis of the different kinds of patent settlements that had been included in the inquiry. This was the first guideline to European companies with regards to determining what kinds of settlements had the potential of being against the EU competition rules, and which kinds of settlements had the least potential. The categorization table is found in Annex 1 of this paper.¹³

Firstly, the patent settlements were broadly distinguished as falling into two categories, A and B. The settlement agreements that were categorized as belonging to category A were not explicitly limiting the entry into the markets by generic companies with their own competing products.¹⁴ Agreements categorized as belonging to category B then, were the complete opposite in that they explicitly limited, to at least some degree, the ability of generic companies to enter the market and compete. Category B was then cut down further into two sub-categories: B.I and B.II. The difference between these sub-categories is the inclusion in B.II, of a “value transfer” from the originator company to the generic company.¹⁵ This type of a value transfer is, by definition, a reverse payment as defined in *In Re Tamoxifen*, as it has the value transfer (payment) going from the originator (patentee) to the generic company (potential infringer). All pay-for-delay agreements therefore, that are also reverse payment patent settlements, belong to this sub-category of category B. The commission did underline, that even settlements that fall

¹⁰ European Commission Competition DG Pharmaceutical Sector Inquiry Final Report on 8 July 2009, para. 15

¹¹ Ginsburg D., Safty G., Geradin D. Reverse Payment Patent Settlements in the European Union and the United States 2015. George Mason Legal Studies Research Paper No. LS 15-22, p 18

¹² European Commission Competition DG Pharmaceutical Sector Inquiry Final Report on 8 July 2009, para. 704

¹³ *Ibid*, figure 106: Categorisation decision tree, p 270 (also see annex 1)

¹⁴ *Ibid*, para. 746

¹⁵ *Ibid*, para. 762

into category B.II would not be automatically deemed anticompetitive, even though that is quite clearly the area that raises concerns. An individual analysis would be required for each agreement.¹⁶ The final report of the pharmaceutical inquiry has an abundance of statistics as well as some very detailed analysis on the different kinds of patent settlement agreements. The analysis does work as a rough and implicit tool to expect real life application of competition law on similar agreements. It provided guidelines and principles that were highly superior to any materials previously published on the subject of pharmaceutical, in spite of which reverse patent settlement agreements remained, for the most part and especially in terms of actual practice, unexplored territory.¹⁷

1.2 Other Legal Context for Analysis Regarding Pay-For-Delay Settlements

1.2.1 Annual Monitoring Reports on Patent Settlements

The Pharmaceutical sector inquiry¹⁸, together with the Executive Summary of the Pharmaceutical Sector¹⁹ initiated an annual monitoring practice by the commission via their periodic reports on the Monitoring of Patent Settlements, the first of which was published on 5 July 2010.²⁰ The objective of these monitoring reports is to identify all patent settlement agreements capable of delaying or blocking generic entry, especially the ones including reverse payments. The Commission asks all relevant companies via formal requests, originators and generic alike, to put forward all patent settlement agreements that cover the European markets.²¹ David Hull and Michael Clancy argue in their article “The Application of EU Competition Law in the Pharmaceutical Sector”, that the discussion on the categories of patent settlements included in the monitoring reports each year are virtually the only truly relevant guidance in terms of practical application of Competition Law rules on these types of settlements and it is therefore used by companies as an informal guidance. By using nearly identical language in its consecutive monitoring reports the Commission seems to display an awareness of what Hull and

¹⁶ Ibid, para.763

¹⁷ Zulli A. *et al.* The Commission’s Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis? A review of the Commission’s assessment of reverse patent settlements in the Lundbeck citalopram case, Convington 2015 p 1

¹⁸ European Commission Competition DG Pharmaceutical Sector Inquiry Final Report on 8 July 2009, p 524, para. 1574

¹⁹ European Commission Communication From The Commission Executive Summary of the Pharmaceutical Sector Inquiry Report 2009 p 6

²⁰ European Commission Competition DG 1st Report on the Monitoring of Patent Settlements 2010 p 1

²¹ European Commission Competition DG 7th Report on the Monitoring of Patent Settlements 2016 p 1-2

Clancy are arguing in their article.²² Indeed, the wording between the first report and the latest, 7th report, is very similar.

The Monitoring reports have confirmed, with regards to the categories of patent settlements, what the Inquiry on the Pharmaceutical sector implied. The commission has concluded in multiple monitoring reports, that all category A agreements will be regarded as *prima facie* not problematic and therefore unlikely to attract competition law scrutiny.²³ Correspondingly, the Commission has stated that it will most likely scrutinize B.II settlements, having so far backed up this statement.²⁴ The Commission concludes in its latest monitoring report that only a small number of the patent settlements that exist and have been reported to the Commission, categorically have potential of raising competition law concerns and thus of attracting scrutiny. The percentage of such settlements has decreased and stabilized at a low level (10%).²⁵

1.2.2 Recent Cases Other Than Lundbeck

Servier is a case on which the Commission decided a year after the Lundbeck decision. It was different to Lundbeck in the sense that, while the commission analyzed the agreements in Lundbeck only through a “restrictive by object”- test, they included “restrictive by effect” considerations for *Servier*,²⁶ perhaps in part due to expectations on the content of the *Cartes Bancaires*- judgment, which came out from the European Court of Justice soon after the *Servier* decision. Those considerations contributed to its size of 805 pages in total. In that decision *Servier* was found to be in violation of both central competition law articles of the Treaty on the Functioning of the European Union, article 101 and article 102, not just 101 as was the case in Lundbeck.²⁷

Cartes Bancaires is a judgment, that came out from the European Court of Justice in September 2014. This case was extremely significant in its elaboration of “by object” restrictions of competition. In its judgment, the ECJ set aside the judgment of the General Court of 2012 and

²² Hull D. *et al.* Application of EU Competition Law in the Pharmaceutical Sector, Journal of European Competition Law & Practice, Oxford University Press, 2016, Vol. 7, No. 2 p 152

²³ European Commission Competition DG 1st Report on the Monitoring of Patent Settlements 2010 p 13 para. 38

²⁴ European Commission Competition DG 7th Report on the Monitoring of Patent Settlements 2016 p 13 para. 48

²⁵ *Ibid* p 13 para. 49-50

²⁶ Cole M. *et al.* European Commission Published Non-Confidential Version of *Servier* Decision, Inside EU Life Sciences, Covington 2015

www.insideeulifesciences.com/2015/07/17/european-commission-published-non-confidential-version-of-servier-decision/ (July 17, 2015)

²⁷ Hull D. *et al.* Application of EU Competition Law in the Pharmaceutical Sector, Journal of European Competition Law & Practice, Oxford University Press, 2016, Vol. 7, No. 2 p 151

referred it back to them.²⁸ The Court concluded that, when analyzing conduct using the “by object” restriction- principle, a ‘sufficient degree of harm’ has to be intrinsic to the conduct itself. This consideration, the Court further concludes, has to be based on some type of knowledge from past experiences with similar conduct. That would be the only way of taking all relevant aspects into account in the assessment.²⁹ This elaboration is an application of the Court’s idea, that one must first regard not only the content of conduct (for example making a certain type of settlement agreement) and the object, but also the whole economic and legal context, including market’s functioning and structure.³⁰ In *Lundbeck* for example, the Commission decision and later the General Court used the same rationale, that a ‘by effect restriction’ -test was not necessary and only constructed their arguments on the assumption that they were able to deem the agreements made by *Lundbeck* and the four generic companies as being restrictive of competition ‘by object’.

Novartis’ significance for this paper mainly lies in the fact that the case demonstrated the extent of the Commission’s definition of Pay-for-delay settlements. In its *Novartis Fentanyl* decision, the Commission regarded the patent settlement agreements as pay-for-delay settlements even though the settlements did not include a patent settlement, let alone reverse payments. This differentiated the Commission definitions between reverse payment patent settlements and pay-for-delay agreements - when most other legal sources had regarded them as the same thing. This description is, at least according to David Hull in “The Application of EU Competition Law in the Pharmaceutical Sector”, misleading, as it seems to create an equivalence between the two completely different types of agreements.³¹

AstraZeneca was a case where the European Commission found *AstraZeneca* in violation of article 102 TFEU for delaying the entry of generic companies to the market to compete with its brand drug called *Losec*.³² This was later (in 2012) confirmed in the European Court of Justice. The case was the first in the pharmaceutical sector, to include restrictions of competition by the originator via delaying generic entry to the market. Therefore it was highly influential to the way

²⁸ ECJ 11.09.2014, C- 67/13 P, *Cartes Bancaires*, para. 95-99

²⁹ Calzado J. *et al. Groupment des Cartes Bancaires v Commission*: Shedding Light on What Is not a ‘by object’ Restriction of Competition, *Journal of European Competition Law & Practice* 2015 Vol. 6 (7) p 495-498

³⁰ Schwarz D. Immovable objects The evolution of object restrictions after the *Cartes Bancaires* case 2016, Vol. 15 Issue 1 p 14-15

³¹ Hull D. *et al. Application of EU Competition Law in the Pharmaceutical Sector*, *Journal of European Competition Law & Practice*, Oxford University Press, 2016, Vol. 7, No. 2 p 154

³² Käseberg T. *Intellectual Property, Antitrust and Cumulative Innovation in the EU and the US*. Cornwall, Hart Publishing Ltd 2012, p 108-109.

companies structured their strategies to protect their brands after patent expiry. According to Nick Beckett, David Marks and John Markham in “AstraZeneca judgment: don’t game the system”, in this regard it was even more influential, than the Commission’s Pharmaceutical Sector Inquiry.³³ The other, perhaps even more significant feature of *AstraZeneca* was the general acknowledgment by the European Court of Justice of the legality and legitimacy of the strategies by originator companies that attempt to minimize losses that they expect will arise due to the generic competitors entering the market. The ECJ states in their judgment that:

“[...] the preparation by an undertaking, even in a dominant position, of a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.”³⁴

Through this statement in its judgment, the European Court of Justice renders these “Life cycle management” strategies as they are commonly known, as compliant with EU law.³⁵ If used purely within the context of follow-on patents that are made for already existing drugs in order to extend the market monopoly of the originator - or to delay generic entry, such strategies are also referred to as “evergreening”.

³³ Beckett N. *et al.* AstraZeneca judgment: don’t game the system. CMS Cameron McKenna, Lexology 2012. www.lexology.com/library/detail.aspx?g=6178aea4-40af-4f57-b629-b53402a909cf(07.01.2017)

³⁴ ECJ 06.12.2012, C- 457/10 P, AstraZeneca v Commission, para. 129

³⁵ Zulli A. *et al.* The Commission’s Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis? A review of the Commission’s assessment of reverse patent settlements in the Lundbeck citalopram case, Convington 2015 p 2.

2. Lundbeck Citalopram Case and the Commission's Decision

2.1 Background

The heart of the case lies in the agreements, which Lundbeck concluded between the years 2002 and 2003, with four different generic companies. In total, there were 6 problematic agreements and they all concerned Lundbeck A/S's bestselling drug, an antidepressant citalopram. The brand name for Lundbeck's own brand names for citalopram were Cipramil and Celexa, which the company considered to be, according to some internal documents, their "golden eggs".³⁶ The agreements were reverse payment patent settlements in the sense that has been outlined previously in this paper. The settlements were therefore, quite clearly also categorized as B.II in the context of the pharmaceutical sector inquiry and the Commission's monitoring reports. All of the problematic patent settlement agreements were concluded within the context of patent disputes, or rather, potential patent disputes. The only already ongoing litigation was between Alpharma and Lundbeck. All of the potential disputes had to do with citalopram and the generic companies either had intentions of producing or the intentions of marketing generic citalopram products. Lundbeck's problematic patent settlement agreements were the following;

1) Merck KGaA, or in the United Kingdom its subsidiary, Generic UK

Lundbeck had two agreements with Merck. The first of the agreements was about the United Kingdom. That agreement was valid between 24 January 2002 and 1 November 2003. During that time Merck agreed to withhold launching generic versions of citalopram and received in return from Lundbeck, the right to sell its citalopram brand Cipramil and a number of value transfers, that totaled 19,4 million euros. The other agreement was about the remaining European Economic Area of that time. That agreement was valid from 22 October 2002 through 22 October 2003. Its structure was more simplistic in that Merck agreed to withhold a generic launch for a year, receiving a value transfer in monthly installments in return, which totaled 12 million euros.

2) Two agreements with Arrow

³⁶ Zulli A. *et al.* The Commission's Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis? A review of the Commission's assessment of reverse patent settlements in the Lundbeck citalopram case, Convington 2015.

Lundbeck had two agreements with Arrow. Again, there was a UK agreement, valid from 24 January 2002 through 20 October 2003. During that time period Arrow, in exchange for multiple value transfer, totaling 10,4 million euros, agreed not to sell a generic version of citalopram. The second agreement was for Denmark, valid from 2 June 2002 through 1 April 2003. According to that agreement Arrow would not sell a generic version of citalopram within that time period, and would get monthly installments totaling 684 000 euros.³⁷

3) One agreement with Alpharma, that included the European Economic Area from 22 February 2002 until 30 June 2003; Alpharma would not sell a generic version of citalopram during that time, in exchange for a payment totaling 11,7 million euros.

4) One agreement with Ranbaxy on the European Economic Area, from 16 June 2002 until 31 December 2003; Ranbaxy would not sell a generic version of citalopram during that time, in exchange for a payment totaling 12,7 million euros.³⁸

It is noteworthy that these 6 agreements in each instance had in them a value transfer, that comprised of a sum that was similar to the sum that could have been expected to be the revenue of the generic company, had it entered the market with a citalopram product successfully. On top of that, to some Lundbeck had also promised certain revenues through distribution agreements.

It is also noteworthy, that the relevant patents for citalopram had expired prior to all the aforementioned patent settlement agreements. When nearing patent expiry however, Lundbeck had started acquiring more and more production process patents in order to cover as many possible production pathways for citalopram as possible. The most relevant of these new process patents was a crystallization patent. However, this patent on the process was deemed by the generic companies, simple and not in any way groundbreaking science. These types of life cycle strategies amount to what is commonly known as “evergreening”, whereby a company makes a multitude of patents on the same product to delay or block generic entry, and sometimes also to create a window of opportunity for a different kind of practice, where the originator company creates a new compound with a completely new patent protection that will then replace the

³⁷ Jourdan J. et al. The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test For Patent Settlement Agreement. White & Case, Brussels, Competition Policy International 2014, p 4.

³⁸ The European Commission Lundbeck Decision 2013 para. 1

original drug through a marketing exercise on both the patients and their doctors.³⁹ Despite holding a multitude of patents and therefore protection for multiple production pathways, with the critical compound patent missing, it should not have been possible for Lundbeck to impose a general ban for generic companies to market generic citalopram products within the European Economic Area. Not only was it still possible for generic producers to produce the compound in through some means, but it was also possible to import such generic citalopram products from elsewhere, namely, India.⁴⁰

The Commission took into account and reviewed several other internal documents from Lundbeck, which demonstrated Lundbeck's own lack of trust in their remaining process patents. Lundbeck did not seem to believe that the company would have been able to win a litigation in court against the generic companies. Lundbeck was able to completely avoid that route of litigation by bringing various parties to the negotiation table and concluding agreements with them, blocking them from entering the citalopram market in the process. In these agreements, the generic companies accepted terms that gave rise to a much extensive protection for Lundbeck's patents, than could have been achieved simply by enforcing those patents in all relevant courts combined. Through way of litigation and enforcement, it would not have been possible for Lundbeck, for example to completely prevent a generic company from selling generic citalopram. If Lundbeck was successful in enforcing its patents, it would have been able to only block or delay the usage of its crystallization method for manufacturing citalopram.⁴¹

The Commission concludes in its press release, that these agreements were restrictive of competition in violation of article 101(1) of the Treaty on the Functioning of the European Union, or TFEU. "*The European Commission has imposed a fine of € 93,8 million on Danish pharmaceutical company Lundbeck and fines totalling € 52,2 million on several producers of generic medicines*".⁴² Lundbeck and the four generic companies appealed the Commission's decision to the General Court.⁴³

³⁹ Burdon M. *et al.* Biogen insufficiency explained; Alendronate in Netherlands; Behaviour relevant to injunction; Perindopril evergreening criticised; ' Negative Term ' SPCs ' ; new dosage regimes. *Journal of Generic Medicines* 2008, 5 (4), pp. 341-352, p 348.

⁴⁰ GC judgment T-472/13 - Lundbeck v Commission, 08.09.2016 para. 700.

⁴¹ Zulli A. *et al.* The Commission's Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis? A review of the Commission's assessment of reverse patent settlements in the Lundbeck citalopram case, *Convington* 2015 p 6.

⁴² European Commission Press Release, Brussels, 19 June 2013, http://europa.eu/rapid/press-release_IP-13-563_en.htm (12.12.2016)

⁴³ GC judgment T-472/13 - Lundbeck v Commission, 08.09.2016.

2.2 Competition Law Perspective According to the Commission's Decision

The commission declared the reverse payment patent settlements in Lundbeck as restrictive “by object”. An agreement has to have the potential by its very nature to restrict competition, if it is to fall into the category of by object infringements. The Commission introduced in its decision, a test to determine, if an agreement has potential to restrict competition by its very nature. This test is covered in detail by Pascal Berghe and James Killick in their article Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason.⁴⁴ It is centered around three central points (which the aforementioned six agreements all fulfilled, according to the commission), namely;

- 1) Potential Competition
- 2) The generic company promises to withhold from entering the market
- 3) There is a value transfer from the originator to the generic company

On top of these three points, the commission did consider a “cocktail of factors” that were relevant as details to the present case, but in order to determine the usability of the Lundbeck decision as a precedent, the notion and definition, of a ‘by object’ infringement, which is largely centered around this test, is really the meat and bone of the commission’s analysis.⁴⁵ This test, along with some other considerations is the central tool, that the Commission attempts to formulate for reverse payment patent settlements in its Lundbeck decision. Not only was this test the central tool of argument for the commission in its decision, but it was also the reason for much of the critique that the decision later faced. More specifically, the notion of potential competition and the Commission’s legal basis for applying ‘by object’ restriction of competition to the reverse payment patent settlements in Lundbeck. The critique itself will be covered in greater detail in the next chapter.

Potential competition was loosely defined; If there was a possibility for the generic to challenge the patent freely, then that generic was a potential competitor. The commission states as follows: “*it cannot be excluded that the generic undertaking will remain a potential competitor as long as there is no final injunction and possibilities of legal challenge remain.*”⁴⁶

⁴⁴ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 22.

⁴⁵ Hull D. *et al.* Application of EU Competition Law in the Pharmaceutical Sector, *Journal of European Competition Law & Practice*, Oxford University Press, 2016, Vol. 7, No. 2, pp. 150-161, p 151

⁴⁶ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 624

On the principle of presumption of validity of an intellectual property right, the commission argued, against the view of Lundbeck and the generic companies, that when there is a possibility of challenging the patent of an originator, that fact alone can still establish a generic as a potential competitor, because presuming a patent in this instance does not make it impossible to take legal actions against the originator to challenge the validity of the patent - and the mere possibility of invalidating the patent constitutes a sufficient realistic ground to assess the generic as a potential competitor.⁴⁷ The commission's test therefore, does not differentiate between situations, where the rate of successful invalidation of a patent is different, namely, a patent dispute could very well have a success rate of 50/50, 10/90 or 90/10. In other words, there is no clear distinction between a settlement by the originator with a generic company that has an immediate readiness of entering the market and a settlement by the originator with a generic company which is at the beginning of its process of entering a market and which still has serious issues to overcome before it will have a concrete possibility of entering the market.⁴⁸

Regarding the 'value transfer', the reverse payment itself, from the originator to the generic company, the Commission's rationale is more straightforward. A payment from the originator to the generic company will undermine the incentive of the generic company to resist market exclusion, when concluding the patent settlement. Thereby, the originator can replace uncertainty of generic market entry with certainty of non-entry by the generic company; "*It is the uncertainty of possible generic market entry, including through patent litigation, which reflects potential competition. This potential competition is eliminated through the transfer of value and transformed into the certainty of no competition.*"⁴⁹ Furthermore, if the market exclusion is achieved without a value transfer from the originator to the generic company, it is far more probable that the settlement's conclusion was due to competing assessments of the patent strength.⁵⁰

The limitation of the generic company's right to enter the market is the most simple qualification in the commission's test. It focuses on the existence of a clause in the patent settlement, that explicitly requires the generic company to withhold from infringing the patent of the originator company. This type of a clause is an almost inevitable consequence of successful settlements in genuine patent disputes.⁵¹ Due to the high frequency of such non-challenge

⁴⁷ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 628

⁴⁸ Killick J. Patent Settlements as by Object Restrictions: a European Approach, but is it the right one? A Scot without Borders - Liber Amicorum, 2015, 2, p. 197

⁴⁹ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 603

⁵⁰ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 604-605

⁵¹ Killick J. Patent Settlements as by Object Restrictions: a European Approach, but is it the right one? A Scot without Borders - Liber Amicorum, 2015, 2, p. 197

clauses in patent settlements in general, it is necessary for such clauses to be accompanied by or linked to a considerable transfer of value from the originator to the generic company in order for such a clause to be categorized as a relevant part of the commission's test.⁵²

2.2.2 Other Important Factors in Determining 'By Object' Infringement

On top of the aforementioned considerations of the the aforementioned 'by object' test, the commission did take into account a multitude of other factors, that it deemed relevant in determining whether or not Lundbeck's patent agreements would fall into the category of by object infringement. James Killick identifies three additional factors in his article Patent Settlements as by Object Restrictions: a European Approach, but is it the right one?

Firstly, in the Commission's view the agreements were not merely a settlement on the disputed patents. This was due to the fact, that all of the agreements between Lundbeck and the generic producers did not only block the generic company from selling citalopram through the potentially infringing routes, but they prevented the generic companies from selling any citalopram altogether. This was considered to be a major additional factor for the commission in its attempt to categorize Lundbeck's settlement agreements as restrictive by object.⁵³

A second additional consideration other than the 'by object' test of the commission, was the fact the value transfer in each of the agreements was according to the commission roughly similar to what could have been expected from a successful entry to the market. The basis on the sizing of the value transfer, according to the commission, would have been the same in a court's consideration of compensation to the generic company after winning a litigation against the originator company Lundbeck.⁵⁴

The third major, yet additional factor in the commission's wide array of factors was the fact, that Lundbeck did not in the settlements commit itself into not starting infringement proceedings after the time period mentioned in the patent settlement had passed. The commission considered this to be a demonstration of the fact, that the object of the settlements between the generic companies and Lundbeck was not to settle a patent dispute or litigation, but indeed, the restriction of competition.

These three additional factors, as identified by James Killick, were by no means the only major considerations besides the central three points in determining an existence of an

⁵² Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 1144

⁵³ Jourdan J. *et al.* The Commission's Lundbeck Decision: A Critical Review of the Commission's Test For Patent Settlement Agreement. White & Case, Brussels, Competition Policy International 2014, p 4.

⁵⁴ *Ibid*, p 5.

infringement by object. In particular, the Commission considered inter alia the entirety of the commercial strategy of Lundbeck and internal documents of both Lundbeck and the generic companies.⁵⁵ This paper recognizes one factor especially compelling as to any conclusions on Lundbeck's incentives, which is apparent in the Lundbeck Decision paragraphs 131-132: the cipralext switch, an apparent evergreening strategy of Lundbeck whereby the window of opportunity for a successful market penetration for Lundbeck's own generic product was created by delayed generic entry. The strategy was apparent from an internal document of Lundbeck, which underlines the "value of delayed generic entry".⁵⁶

2.3 The General Court Judgment

The General Court's judgment on the commission's approach came out on 8th September 2016. How well it was able to answer the arguments raised by Lundbeck and the generic companies will be analyzed in chapter 3 of this thesis. What is central to the General Court's rationale, in the view of this paper, is the fact that it is close to an overhauled version the Commission's decision.

On potential competition, the Commission notably for the purposes of this thesis, confirmed two views of the commission: First, the fact that Lundbeck's process patents did not necessarily constitute insurmountable barriers for the generic undertakings to enter the citalopram market. Secondly, the General Court confirmed that the generic companies did have real concrete possibilities to enter the market, one of which is, the Court concludes, the possibility of launching the generic citalopram product 'at risk'. In other words, the Court held that potential competition can arise from non-certainty of patent infringement while launching a generic product.⁵⁷

On reverse payments (transfer of value from the originator to the generic company), the Court confirmed first, that reverse payments are only problematic, where they are accompanied by a delay of generic entry.⁵⁸ The Court then concluded that the very existence and size of the reverse payments were relevant in establishing a 'by object' restriction of competition.⁵⁹ Due to these considerations, it is the view of this thesis, that the General Court validated the most

⁵⁵ Zulli A. *et al.* The Commission's Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis? A review of the Commission's assessment of reverse patent settlements in the Lundbeck citalopram case, Convington 2015 p 6.

⁵⁶ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 131-132.

⁵⁷ GC judgment T-472/13 - Lundbeck v Commission, 08.09.2016 para. 124-128

⁵⁸ GC judgment T-472/13 - Lundbeck v Commission, 08.09.2016 para. 352

⁵⁹ *Ibid.* para. 355

central aspects of the Commission's test for patent settlements. Accordingly, the General Court concludes in its judgment:

*“Since none of the pleas in law relied on by the applicants in support of their application for annulment of the contested decision is well founded or effective and since the examination of the arguments put forward in support of their application for reduction of the amount of the fine has not revealed inappropriate elements in the Commission's calculation of the amount of that fine, the action must be dismissed in its entirety.”*⁶⁰

3. Application of the Proportionality Test to the Lundbeck Judgment

There are multiple ways of analyzing The Lundbeck Decision and its General Court judgment in order to determine how coherent an instrument it is to protect competition law interests.

A judgment has to be able to be sound case law in and of itself, but also help produce new case law that is favorable in light of the legal or moral principles it seeks to protect. By ‘sound case law in and of itself’ this research paper means specifically, that the judgment is required to pass the kind of legal test that will demonstrate that the judgment has a reasonable and logical legal basis. In order to analyze the Lundbeck judgment as a measure and within that specific legal regime, this paper will apply to it the Proportionality test that has been used rapidly in the European legal tradition and which is outlined as a three part test by Paul Craig and Grainne de Burca in their book EU Law: Text, Cases and Materials.⁶¹ The Proportionality test is outlined as follows;

“In any proportionality inquiry the relevant interests must be identified, and there will be some ascription of weight or value to those interests, since this is necessary condition precedent to any balancing operation. There will normally be three stages in a proportionality inquiry.

- i. Whether the measure was suitable to achieve the desired end.*
- ii. Whether it was necessary to achieve the desire end.*
- iii. Whether the measure imposed a burden on the individual that was excessive in relation to the objective sought to be achieved (proportionality stricto sensu)”*⁶²

⁶⁰ Ibid. para 845.

⁶¹ Craig P., de Burca G. EU Law: Text, Cases and Materials. Oxford, Oxford University Press 2011, p 526

This paper will discuss all of the points from the proportionality test in detail, adopting the test to the context of pharmaceutical industry. In analyzing Lundbeck, the focus of the vast majority of the analysis will be on aspects relative to the infringement ‘by object’ approach, which was introduced in the previous chapter, and which the commission chose to take with regards to reverse payment patent settlements. This is due to the fact that the approach in its entirety, and more specifically accompanied by the commission’s test concerning the three different notions in order to determine the availability of the ‘by object’ approach are the most important considerations in Lundbeck and where assessing the usability of all that the judgment entails is concerned, they also remain the most relevant factors.⁶³

3.1 Suitability

The Lundbeck- case, together with the pharmaceutical sector inquiry, from the very start have had two ‘desired ends’, as defined in EU Law: Text, Cases and Materials.⁶⁴ The first desired end is establishing for the first time, sound policy around article 101 of the Treaty on the Functioning of the European Union regarding reverse payment patent settlements⁶⁵ and the second desired end is the very basic principle and goal of competition law of being able to prohibit practices that restrict competition.⁶⁶

To determine the suitability of the Lundbeck judgment with regards to the desired ends of establishing sound policy and of prohibiting restrictive agreements, this paper will analyze the coherence of Lundbeck with the current legal framework and try to examine the development of the legal framework, of which it is part. It is relevant to discuss for example, whether or not Lundbeck has shed light on some previously unanswered questions and review some of the decisions or applications of competition law which have referred to the Lundbeck decision or the Lundbeck judgment in their considerations and see to what degree this judgment has had an effect in those applications. This analysis is done using cases of the aforementioned applications of competition law. Applying the proportionality test to Lundbeck, it seems clear that the best way of analyzing the judgments compatibility with existing competition law is by reviewing

⁶³ Jourdan J. *et al.* The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test For Patent Settlement Agreement. White & Case, Brussels, Competition Policy International 2014, p 5.

⁶⁴ Craig P., de Burca G. EU Law: Text, Cases and Materials. Oxford, Oxford University Press 2011, p 526

⁶⁵ Hull D. *et al.* Application of EU Competition Law in the Pharmaceutical Sector, Journal of European Competition Law & Practice, Oxford University Press, 2016, 7 (2), pp. 150-161, p 150.

⁶⁶ Van Bael, Ellis. Competition Law of the European Community. Kluwer Law International 2005, p 28-29

critique on it and seeing how it has been able to foresee that critique, and test whether or not the judgment is a credible measure, in light of that criticism.

3.1.1 The Notion of Potential Competition

In his article *Lundbeck v Commission: on patents and Schrödinger's cat*, Pablo Colomo makes some well aimed discussion on a multitude of legal issues that the General Court's judgment might have either left out when attempting to tackle the critique on the Commission's decision, or even arisen newly in the judgment itself. The fundamental question according to Colomo is centered around the concept of 'potential competition';

*"The fundamental question, against this background, is whether the generic producers were 'potential competitors' within the meaning of the case law. If these producers are indeed found to be potential competitors in the relevant economic and legal context, it is inevitable to conclude that the agreements are restrictive of competition by object. They would be cartel-like arrangements without a plausible explanation other than the restriction of competition.[...] My impression, however, is that the General Court may not have fully appreciated the complexity of the economic and legal context. Accordingly, the qualification of the agreements as restrictive by object seems controversial."*⁶⁷

The same exact point has been subsequently raised by Monckton Chamber's IPKat-team in its discussion in [Lundbeck v European Commission - a rotten decision or effective competition law enforcement?](#)⁶⁸, and by Sven Gallasch in "General Court's pay for delay judgment in Lundbeck – some guidance, but worries remain".⁶⁹ It is a relevant point, which should be discussed in great detail.⁷⁰

As Monckton Chambers points out, article 101, which Lundbeck was found by the Court to be in violation of, will not be triggered unless the agreements are made between either actual or

⁶⁷ Colomo P. GC Judgment in Case T-472/13, *Lundbeck v Commission: on patents and Schrödinger's cat* 2016. chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat/ (22.2.2017)

⁶⁷ Monckton Chambers 2016, [Lundbeck v European Commission - a rotten decision or effective competition law enforcement?](#) <http://ipkitten.blogspot.fi/2016/10/lundbeck-v-european-commission-rotten.html> (06.02.2017)

⁶⁸ Sven Gallasch 2016

<https://competitionpolicy.wordpress.com/2016/09/14/general-courts-pay-for-delay-judgment-in-lundbeck-some-guidance-but-worries-remain/>(06.02.2017)

⁶⁹ Hull D. *et al.* Application of EU Competition Law in the Pharmaceutical Sector, Journal of European Competition Law & Practice, Oxford University Press, 2016, 7 (2), pp. 150-161, p 151.

potential competitors. As has been established previously in this paper, there was no actual competition yet between the generic manufacturers and Lundbeck. The issue on the substance of potential competition therefore, is the threshold issue.⁷¹ The legal test for this issue as defined by the General Court is whether or not there would have been ‘real concrete possibilities’ for an entry by the generic companies.⁷² This was a step forward from the Commission’s decision on Lundbeck, as in the decision there was no reconciliation with the *Visa*- case, which was the case that gave birth to that definition.⁷³ The approach until then seemed to be that unless a party was able to demonstrate that it was impossible for it to enter the market within the foreseeable future, then that party was deemed as a potential competitor. It is a general feature for pay-for-delay cases, that they include an originator company that on paper enjoys the protection of an intellectual property right on their product, creating a legal monopoly for the benefit of the originator pharmaceutical company. This fact on its own could work as a deterrent on market entry for an otherwise potential competitor. The crystallization patent, as established earlier, was not on its own, groundbreaking science, but despite that, Lundbeck had successfully acquired one for that process.⁷⁴ In light of this, could the generic companies be regarded as potential competitors, in that they have real concrete possibilities of entering into the market?

As is pointed out by the discussion in *Lundbeck v European Commission - a rotten decision or effective competition law enforcement?* - There does not exist a principle of law, which grants a potential competitor the right to launch an infringing product. Indeed, in accordance with this idea, the generic companies had maintained, after the Commission’s decision that they were not potential competitors in the sense that they had real concrete possibilities for entry to the citalopram market due to the manufacturing process patents held by Lundbeck, particularly the crystallization patent.⁷⁵ This argument was considered in the General Court’s decision in a lengthy analysis on the subject of potential competition. The Court cites the Commission’s list of the pathways for the generic companies to the market;

“In recital 635 of the contested decision, the Commission identified eight possible routes to the market in the present case, namely:

– *first, launching the product ‘at risk’ and facing possible infringement actions brought by Lundbeck;*

⁷¹ Monckton Chambers 2016, *Lundbeck v European Commission - a rotten decision or effective competition law enforcement?* <http://ipkitten.blogspot.fi/2016/10/lundbeck-v-european-commission-rotten.html> (06.02.2017)

⁷² GC judgment T-472/13 - *Lundbeck v Commission*, 08.09.2016 para. 98-99.

⁷³ GC judgment T-461/07 - *Visa International Service v Commission*, 14.04.2011 para. 68.

⁷⁴ GC judgment T-472/13 - *Lundbeck v Commission*, 08.09.2016 para. 20

⁷⁵ Monckton Chambers 2016, *Lundbeck v European Commission - a rotten decision or effective competition law enforcement?* <http://ipkitten.blogspot.fi/2016/10/lundbeck-v-european-commission-rotten.html> (06.02.2017)

- *secondly, making efforts to ‘clear the way’ with the originator undertaking before entering the market, especially in the United Kingdom;*
- *thirdly, requesting a declaration of non-infringement from a national court before entering the market;*
- *fourthly, claiming patent invalidity before the national courts, as a counter-claim to a claim of patent infringement made by the originator undertaking;*
- *fifthly, opposing a patent before the competent national authorities or the EPO and requesting that the patent be revoked or narrowed;*
- *sixthly, working with the current API producer or its supplier — in the case of Merck (GUK), Schweizerhall Pharma International GmbH (‘Schweizerhall’) — to change the API producers’ process in such a way as to eliminate or reduce the risk of infringement of the originator undertaking’s process patents;*
- *seventhly, switching to another API producer within the existing supply contract;*
- *eighthly, switching to another API producer outside of the existing supply contract, either because the existing supply contract permits it or possibly because an exclusive supply contract could be invalidated if the supplied API were found to infringe Lundbeck’s process patents.”⁷⁶*

It is questionable in light of these acknowledged routes (all of which are not without their problems) to the market, that the Commission in its decision, as well as the Court in its judgment take the line that potential competition is always certain, when there is some, or any potential. The question that arises then - is one or more of these routes on its own concrete enough to define a generic company that has that route, a potential competitor. The biggest issue here is, that the Court seems to argue, that because there is no certainty of the problems and risks involved in these routes to the market, the generic companies facing these possible routes can be deemed to be potential competitors.⁷⁷ Putting that type of line more simply; If an undertaking has potential for potential competition, that undertaking can be regarded as a potential competitor. On this point, Colomo for example, uses in his article *Lundbeck v Commission: on patents and Schrödinger’s cat*, an allegory:

“the position taken by the General Court is tantamount to saying that Schrödinger’s cat is alive because it may be alive. A generic producer is a potential competitor, in other words, because it may successfully enter the market.”⁷⁸

⁷⁶ GC judgment T-472/13 - Lundbeck v Commission, 08.09.2016 para. 97

⁷⁷ Ibid. Para. 120-121

⁷⁸ Colomo P. GC Judgment in Case T-472/13, Lundbeck v Commission: on patents and Schrödinger’s cat 2016. chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodin-gers-cat/ (22.2.2017)

In the end, it seems based on the judgment's paragraphs 129 and 131, that whatever the argument is for denying the existence of real concrete possibilities of entry, if the generic company has demonstrated in the past, an explicit intent to enter the market, prior to entering into a reverse payment patent settlement with the originator, that company may be found to be a potential competitor based on that fact. The Court states the following:

“In addition, the steps taken and investments made by the generic undertakings in order to enter the citalopram market before concluding the agreements at issue, as set out by the Commission in the contested decision as regards each of the generic undertakings [...] — the existence of which has not been contested by the applicants — show that they were ready to enter the market and to accept the risks involved in such an entry.”⁷⁹

While this statement is not able to reconcile the line that the General Court took with regards to the notion of potential competition, it is successful in making that point a trivial legal issue relative to the facts (as it will not be definitive of the notion's application to the potential competitors relevant in this case), not one that will on its own demonstrate a relatively large incoherence for the Lundbeck judgment with existing competition law applications. Also, successful addressing of that detail does not seem explicitly definitive as to the judgment as a whole. Considering the Commission's test for patent settlements however, the line that the General Court has taken in confirming, inter alia, the notion that an “at risk” possibility of entry makes one a potential competitor does diminish the usability of the ‘by object’ test independent from additional factors. If potential competition is defined in this manner then, so as to make it less desirable for a patent holder to conclude patent settlements with generics that are now deemed potential competitors, it might ultimately end up being a burden on competition. If patent settlements are made more difficult, challenges to patents by generics also become more difficult.⁸⁰

⁷⁹ GC judgment T-472/13 - Lundbeck v Commission, 08.09.2016 para. 129.

⁸⁰ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 23.

3.1.2 Fallacies in Focusing on the Existence of a Reverse Payment

In his article “Further Thoughts on Pay for Delay Settlements”, Pierre Régibeau demonstrates the probabilistic nature of approaching reverse payment patent settlements by competition authorities, that shows the connection of value transfers and the potential of successful litigation against the originator using an analogy;

“To see what this implies, consider a house owned by Mr Fixit. Although Mr Fixit has the deed to the house, there is also a competing claim from the descendent of the previous owner, Mr Leavit. Mr Fixit would like to expand the house, which is something that his neighbours would not appreciate. Mr Leavit, who would like to preserve family history, wants to preserve the house as is. As a result of the legal dispute over the ownership of the house, an agreement is reached: Mr Fixit keeps the house and is free to do as he wants in exchange for a payment of 100,000 euros to Mr Leavit. Clearly this agreement leaves the neighbours worse off. If litigation had proceeded, there was at least a chance that Mr. Leavit would have won so that the extension would not have been built. Should this be a ground for blocking such an agreement?”⁸¹

Régibeau argues, that the situation on reverse payment patent settlements is very similar to that of his story. As there is uncertainty as to the validity of the patent, the final judgment might vary and the neighbours, that in his story represent the consumers, might be better, or worse off in accordance with the judgment. If the final judgment finds the patent invalid, consumers might benefit from the potential price competition that would follow such judgment. On the contrary if the companies settle the dispute via a patent settlement, then there is almost no chance, that that settlement would not include a reverse payment from the originator to the generic producer. Régibeau comes to this conclusion through a calculation-based “Shapiro” test, that shows the risk and reward of litigation from the perspective of the patent holder.⁸² Following the logic of the probabilistic approach, the settlement should be illegal if it leaves the consumers in a worse expected position, than a judgment, or continuing litigation would on average. When the dispute ends to a settlement, the patent holder should according to that theory, only settle when the patent holder has certainty of getting at least as much from that settlement due to continuing monopoly, as it would from continuing the litigation to an ultimate judgment.

⁸¹ Régibeau P. Further Thoughts on “Pay-for-delay” Settlements. *Concurrences* 2014, 11 (2), p 18

⁸² *Ibid.* p 19

The reality is not so clean. It goes beyond Shapiro's conditions, in part due to more risk on the patent holder than on the potential infringer, as there might not be a judgment at all, and the pharmaceutical company might face lowered prices on its drug, as the ultimate outcome of litigation becomes irrelevant. This results in the originator companies being more inclined to pay an extra premium for the sake of getting rid of that uncertainty, a risk premium, as Regibeau calls it. This in turn leads to the conclusion (as the new risk factor is added to the calculation) that it is not possible to claim that even a large value transfer, that goes beyond litigation expenses would be a sufficient ground for finding the patent settlement agreement anticompetitive.⁸³ Therefore, the fact that in Lundbeck one of the more major points in the analysis of the judgment is the focus on the existence of reverse payment, makes the rationale as a whole more questionable on these grounds⁸⁴; *"So, even if one espouses the normative probabilistic view of patent protection, the logical basis for focusing on the importance of "reverse" payments in settlements is not compelling."* In Regibeau's view, this approach will result in falsehoods on both negative and positive ends, and concludes, that if a policy is not precise, there is no need for such policy. Regibeau further elaborates his line in another article: "Pay-for-Delay": What Do We Disagree On? In that article, he rejects the commission's argument, that a negative stance on reverse payment settlements does not make it more difficult for pharmaceutical companies to settle patent disputes, and also rejects the argument that a negative stance on such value transfers has been an effective force in combating anticompetitive reverse payment settlements.⁸⁵

Not only does this realization show a fallacy in focusing on the existence of a value transfer, and therefore the second part of the commission's test for 'by object' infringement - but it is also an argument against one of the additional factors that the commission considered in determining the existence of an infringement 'by object', which is the correspondence between the expected income of the generic company following a successful market entry and the sizing of the value transfer in the patent settlement's between Lundbeck and the generic companies. This factor was present in each of the patent settlements. As with other additional factors that the commission considered on top of its test for 'by object' restriction of competition, it is unclear how much weight is on this particular factor, but no matter the ultimate influence on the judgment, the focus on both the existence of a reverse payment as a part of the test and the sizing of the value transfer

⁸³ Ibid. p 20

⁸⁴ Killick J. Patent Settlements as by Object Restrictions: a European Approach, but is it the right one? *A Scot without Borders - Liber Amicorum*, 2015, 2, p 194.

⁸⁵ Régibeau P. "Pay-for-Delay": What Do We Disagree On? *Competition Policy International* 2013, 9 (2), p 124.

⁸⁵ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 639.

⁸⁵ GC judgment 08.09.2016, Case T-472/13, Lundbeck v Commission, para. 350-351

in such a fundamental way is questioned under the line of argument present in both of Regibeau's articles.

Indeed, the Lundbeck decision, and later the judgment themselves do consider a very similar value transfer in the Neolab settlement, a reverse payment from Lundbeck to Neolab based on the same pattern, yet both the Commission and the General Court found that that particular settlement was unproblematic.⁸⁶ This fact alone undermines greatly the legitimacy of using the existence of a reverse payment as such a fundamental part of the approach in the test for by object restriction of competition. The General Court acknowledged, that the number of agreements concluded between Lundbeck and Neolab within a relatively short period of time did include both a delay to Neolab's entry to the market, as well as a transfer value from Lundbeck to the generic company Neolab, but concluded that agreement not to have an object of restriction of competition, but an object of settling an actual patent dispute.⁸⁷ While the Court's rationale with regards to their view on the Neolab settlement is sensible, when taken into account the multitude of factors relevant to the circumstances of that particular settlement, it does not reconcile, in the view of the of this thesis, with the fact that the 'by object' approach does not seem precise enough a line to take. Indeed, the Court's line does the opposite, as an analysis using the three-prong test of the commission should on paper categorize the Neolab settlement as anticompetitive. For the purpose of analyzing the suitability as to what Lundbeck has to offer as part of the legal framework on article 101 TFEU, and as sound case law on the matter of reverse payment patent settlements, it is irrelevant that the Court is correct in its ultimate conclusion on Neolab. The fact that it has to use such a wide array of additional considerations in order to come to the right conclusion does not strengthen, but weakens the argument for the 'by object' approach, that it chooses to take.

3.1.3. Other "By Object" Restriction of Competition Considerations

Perhaps the most important consideration in analyzing Lundbeck appears to be the peculiarity in it that the Commission does not, in its decision, include an extensive analysis on the application of "by object" vs "by effect" restriction of competition in this case. This approach is verified by the General Court in the Lundbeck judgment:

⁸⁶ Ibid. Para. 335

“[...] even if the restrictions set out in the agreements at issue fell within the scope of the Lundbeck patents — that is to say that the agreements prevented only the market entry of generic citalopram deemed to potentially infringe those patents by the parties to the agreements and not that of every type of generic citalopram — they would nevertheless constitute restrictions on competition ‘by object’, since, inter alia, they prevented or rendered pointless any type of challenge to Lundbeck’s patents before the national courts, whereas, according to the Commission, that type of challenge is part of normal competition in relation to patents”⁸⁸

“It must be found, therefore, that the Commission did not err in considering, in the contested decision, that the very existence of reverse payments and the disproportionate nature of those payments were relevant factors in establishing whether the agreements at issue constituted restrictions of competition ‘by object’ for the purpose of Article 101 TFEU in that, by those payments, the originator undertaking provided an incentive to the generic undertakings not to continue their independent efforts to enter the market.”⁸⁹

This line is questionable, especially in light of the *Cartes Bancaires* case, which came out from the European Court of Justice in 2014 - over one year after the Commission’s Lundbeck Decision. That judgment was extremely significant in its elaboration of “by object” restrictions of competition. In its judgment, the ECJ set aside the judgment of the General Court of 2012 and referred it back to them. According to the opinion by the advocate general Wahl it is experience and economic theory, that tell us when a conduct should be viewed as a by object restriction of competition.⁹⁰ The Court concluded that, when analyzing conduct using the “by object” restriction- principle, a ‘sufficient degree of harm’ has to be intrinsic to the conduct itself. This consideration, the Court further concludes, has to be based on some type of knowledge from past experiences with similar conduct. The Court called for a restrictive interpretation of ‘by object’ restriction of competition. The European Court of Justice stated in *Cartes Bancaires*, inter alia the following:

“It must be held that, in so reasoning, the General Court in part failed to have regard to the case-law of the Court of Justice and, therefore, erred in law with regard to the definition of the relevant legal criteria in order to assess whether there was a restriction of competition by ‘object’ within the meaning of Article 81(1) EC.

⁸⁸ Ibid. Para 335

⁸⁹ GC judgment 08.09.2016, Case T-472/13, Lundbeck v Commission, para. 355

⁹⁰ Opinion of AG Wahl in Case C - 67/13 P, 27.03.2014 (*Cartes Bancaires*), para. 56.

First, in paragraph 125 of the judgment under appeal, when the General Court defined the concept of the restriction of competition ‘by object’ within the meaning of that provision, it did not refer to the settled case-law of the Court of Justice mentioned in paragraphs 49 to 52 of the present judgment, thereby failing to have regard to the fact that the essential legal criterion for ascertaining whether coordination between undertakings involves such a restriction of competition ‘by object’ is the finding that such coordination reveals in itself a sufficient degree of harm to competition.”⁹¹

According to James Killick, Jérémié Jourdan, and Jerome Dickinson in *The Commission’s Lundbeck decision: A critical review of the Commission’s test for patent settlement agreements*, The Commission simply does not have enough experience on the subject matter of reverse payment patent settlements to enable it to definitively call an agreement as restrictive by object and therefore implying that past experience and economic theory have enough data on them, that one can put them into that category even without declaring the basis for such rationale.⁹² The General Court does not establish facts on that issue any better in its Lundbeck Judgment, but it does state, that the Commission was not erroneous in calling the agreement to be restrictive by object as it was, according to the General Court’s judgment, not necessary for this instance, to have prior experience on similar situations due to acknowledging that the particulars of the types of reverse payment patent settlements present in Lundbeck were so clearly comparable with market exclusion agreements. Experience on market exclusion agreements according to the Court therefore, was enough to determine whether or not a reverse payment patent settlement was restrictive by object.⁹³ This discrepancy is further strengthened by the fact that Commission, together with the Danish Competition Authority, in reviewing them in 2003 had definitively considered these kinds of patent settlements as falling into a “legal grey zone”, which was the key reason in initiating the Pharmaceutical Sector Inquiry which should have developed, or helped develop a general standard for how to deal with reverse payment patent settlements. The inquiry in turn, was a key reason in attracting competition law scrutiny on Lundbeck. Furthermore, it has to be underlined that Lundbeck specifically was the company that was under the review of the Commission and the DCA in 2003.⁹⁴ The question that arises in this regard is:

⁹¹ ECJ, C-67/13 P judgment - *CB v Commission*, 11.09.2014 (*Cartes Bancaires*) para. 56 -57

⁹² Jourdan J. *et al.* *The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test For Patent Settlement Agreement*. White & Case, Brussels, Competition Policy International 2014, p 8.

⁹³ Cole M. *et al* A landmark judgment: The General Court has affirmed the Lundbeck pay-for-delay decision 2016, Vol. 15 Issue 10, p 13

⁹⁴ Clancy M. *et al.* *Reverse-payment Patent Settlements in the pharmaceutical industry: An analysis of U.S. Antitrust Law and EU competition law*, *The Antitrust Bulletin* 2014, 59 (1). p 10.

At which point of this process of creating the legal framework (or as the Commission calls it: “a general standard”) for reverse payment patent settlements, which Lundbeck has been a part of from the very beginning, was the general standard developed enough for it to be applied to Lundbeck - a case that is part of the creation of that same general standard. How can the agreements between Lundbeck and the four generic companies be regarded legally as, first a “grey zone” and later a definitive case of ‘by object’ -restriction of competition, that does not require any ‘by effect’ -analysis? This discrepancy is discussed by Sven Gallasch in the article *Activating Actavis in Europe - the proposal of a ‘structured effects-based’ analysis for pay-for-delay settlements*, where he calls for a ‘structured effects-based’ analysis on such cases, that would apply to them, principles similar to those developed by the US Supreme Court in its case *Actavis*.⁹⁵ That type of an consideration certainly does put Lundbeck in a bad light, when determining whether there might be a cleaner legal approach than has been demonstrated by the European courts.

Cartes Bancaires was in part an elaboration of an earlier case, *Allianz*, in which the categorical approach to by object restriction of competition was largely abandoned, and a case-by-case approach was adopted.⁹⁶ This was a departure from some long-standing distinctions. First, *Allianz* and *Cartes Bancaires* call for what Csongor Nagy calls in *The concept of Anticompetitive Object Under EU Competition Law: Comparative Perspectives and European Realities*, a perfunctory market-analysis. Agreements that are analyzed under a ‘by object’ investigation are centered around the idea, that restriction of competition happens by nature in such agreements, meaning, that an investigation of the context, that is, a market-analysis is not necessary. Secondly, it has been a long-standing practice and principle, that once it has been established, that a settlement is infringing of competition by object, there is no need to assess in the same approach, the effects of that settlement on competition, regardless of the effects being actual or potential.⁹⁷ The context should therefore be relevant to a ‘by object’ approach only in the sense that, the interpretation of the objective content of the agreement might require an established understanding of the context of which it is part. That examination should not include

⁹⁵ Gallasch S. *Activating Actavis in Europe - the proposal of a ‘structured effects-based’ analysis for pay-for-delay settlements*. *Legal Studies* 2016 36 (4), pp. 683-705, p 685.

⁹⁶ Nagy C.I. *The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities*. *The Consistent Application of EU Competition Law: Substantive and Procedural Challenges*. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 56.

⁹⁷ Collins A.M., *Of Cattle, Crashes & Cards - Recent Case-Law of the Court of Justice on Restrictions by Object*. *The Consistent Application of EU Competition Law: Substantive and Procedural Challenges*. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 43-54, p 47.

an analysis of the actual and potential effects the agreement may entail.⁹⁸ This is where *Allianz* and later *Cartes Bancaires* met with a lot of critique by legal scholars, as it discredited the merits on clarity and foreseeability of the “pre-Allianz” ‘by object’ approach⁹⁹. This discrepancy is analyzed further in the next stage of the proportionality test, as the comparative aspects are more relevant in determining necessity. What is specifically important to consider for suitability in this regard however, is that a considerable part of the critique that *Cartes Bancaires* received was relative to the fact that the newly induced effects analysis of the ‘by object’ approach did not require a deep enough analysis on the effects. As the repercussions are the largest in infringements by object, it is not logical that the analysis then be lighter in that approach, than if an effects-based approach was taken.¹⁰⁰ The connection to the analysis of this thesis on suitability lies ultimately with the fact that Lundbeck was arguably not able to sufficiently fulfill the requirement of an effects-based analysis of the aforementioned cases, a requirement which was widely criticized for its incapability to entail a full examination on anticompetitive effects.¹⁰¹ Indeed, the General Court did not cite *Cartes Bancaires* at all in its judgment. This means that the rationale in Lundbeck is further weakened, not strengthened by the fact that *Cartes Bancaires* for example received such a large amount of criticism, though it would seem counter-intuitive.

3.1.4. Substantive Scope of an Intellectual Property Protection

As was established in part 2.3 of this thesis regarding the General Courts judgment, potential competition can arise on the basis of a possible ‘at risk’ launch of a generic product. Taken out of context, this line is a big departure from the principle, that an agreement cannot be deemed restrictive by object, when it remains within the substantive scope of the intellectual property right. This sets a precedent, according to which a patent holder, even though it is the beneficiary to an intellectual property right which makes it possible for it to sue the infringer, cannot by definition settle with the infringer due to a loosened notion of potential competition and its influence on the determination of the existence of restriction of competition. As Pablo Colomo explains, the aforementioned right is based on a fundamental legal doctrine: *qui peut le plus, peut*

⁹⁸ Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. The Consistent Application of EU Competition Law: Substantive and Procedural Challenges. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 57.

⁹⁹ Ibid. p 56.

¹⁰⁰ Ibid. p 68.

¹⁰¹ Ibid. p 68-69.

le moins, which means that there should exist a by definition possibility for the holder of the right to settle with the infringing party.¹⁰²

It was mentioned in this paper previously, that in the commission's view, all of the agreements between Lundbeck and the generic companies went further than any particular production process or other patent in a way that ultimately blocked in its entirety, entry to the market by the generics, with which Lundbeck had made the reverse payment patent settlements. If this claim were to be true, the generic companies were effectively prevented from selling any citalopram at all. On the same note, the agreements gave certainty to Lundbeck, that went beyond the substantive scope of the patent, or more generally speaking, the substantive scope of an intellectual property protection provided by the patent. The Court mentioned the following on the Merck agreement:

*“Merck (GUK) committed not to sell and not to supply any generic citalopram in the EEA excluding the United Kingdom during the term of the agreement, including to other Merck Generics subsidiaries and to NM Pharma. The broad scope of this commitment clearly exceeded the substantive scope of Lundbeck's process patents since it also necessarily included citalopram that would not infringe those patents.”*¹⁰³

This logic was disputed by both Lundbeck and the generic companies on every level of the case. Lundbeck and the other parties then, held that the agreement on not selling citalopram was indeed limited to citalopram that would have by the very least had a risk of infringing the patents of the patent holder. Therefore, the substantive scope of the patent, or the intellectual property protection was not broken.¹⁰⁴ The Court acknowledged, that while there was an exclusion of Merck from selling its own finished products, there also existed a distribution service agreement in the patent settlement.¹⁰⁵ Pierre Regibeau argues in his article “Pay-for-Delay”: What Do We Disagree On? that when the generic entry happens at short notice, given that such a distribution agreement is categorized as generic entry, and there exists an obligation on the generic company to purchase its product from the patent holder, even where there exists a value transfer from the originator company to the generic company in that agreement, which exceeds in a considerable manner, the expected costs related to continuing litigation to the very end, such an agreement

¹⁰² Colomo P. GC Judgment in Case T-472/13, Lundbeck v Commission: on patents and Schrödinger's cat 2016. chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodin-gers-cat/ (22.2.2017)

¹⁰³ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 846.

¹⁰⁴ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 484.

¹⁰⁵ Commission Decision 19.06.2013 Case 80/13, Lundbeck, para. 790.

cannot be presumed to have a negative effect on competition or on consumer welfare, which is the ultimate goal of competition law. This is in accordance with what was mentioned earlier in this chapter on the questionable basis of keeping focus on the existence or size of a reverse payment.¹⁰⁶

The argument on the substantive scope of the intellectual property protection is not completely a separate one, as the pattern here suggests. At least one more issue on the notion of potential competition can arise here, should Lundbeck and other parties to the patent settlements be correct; If a route other than a patent protected process, was allowed to a generic company in its attempts to produce citalopram, but that company was also able to produce citalopram, in accordance with the contract, through the patented process that it first agreed not to infringe after the short period of time that the patent settlement agreement was concerned with, how would it be possible for that generic company to be deemed a potential competitor, as it would have only had a short period of time to develop or utilize an alternative process in order to produce citalopram. This argument is strengthened, if the pattern is taken out of context and applied for the hypothetical situation of a generic, that only has one product, the one that the parties have agreed upon, so that for the duration of one year, the generic company will not produce the product through the potentially infringing means. If that generic company had only prepared for market entry through utilizing that particular successfully patented process, is it then not logically impossible to declare that company a potential competitor that had realistic ability to utilize a different process for the sake of one year (a relatively short period of time), even given the fact, that it had the freedom to do so?

3.1.5 Assessing the Counterfactual

Lundbeck and all of the generic companies maintained, that in order to determine a restriction of competition, the Court must consider the counterfactual¹⁰⁷. It is a peculiarity, that the General Court did not, in its judgment assess the counterfactual, Instead the Court considered, that it was impracticable in the present case; “Such an examination [of a hypothetical counterfactual scenario]of effects is not required in the context of an analysis based on the existence of a restriction of competition by object”.

Pablo Colomo and Alfonso Lamadrid de Pablo disagree in their article “On the Notion of Restriction of Competition: What we know and what we don’t know we know.” They argue that

¹⁰⁶ Régibeau P. “Pay-for-Delay”: What Do We Disagree On? *Competition Policy International* 2013, 9 (2), p 120.

¹⁰⁷ GC judgment 08.09.2016, Case T-472/13, *Lundbeck v Commission*, para. 466.

taking into consideration the counterfactual, has quickly become a venerable part of establishing the existence restriction of competition. It means that one has to evaluate the “conditions of competition that would have prevailed in the absence of the practice.”¹⁰⁸ Indeed, in the case *Société Technique Minière*, the European Court of Justice states, that when one is to consider whether an agreement has as its object the interference with the competition, it is necessary to consider the precise purpose of the agreement in the economic context in which it is to be applied.¹⁰⁹ Colomo and Lamarid de Pablo elaborate; *“The analysis of the counterfactual amounts in essence to asking whether the alleged restriction of competition is, or would be, attributable to the practice. The question, in other words is whether there is a causal link between the behaviour and the alleged restriction.”* The Court of Justice has been careful in its application of this legal standard, and in some cases, has held that the Commission had erred in establishing restriction of competition, due to not being able to take this requisite legal standard into account.

Where Lundbeck is concerned, the question in this regard is not in whether or not applying an assessment of the counterfactual would fundamentally change the established facts or the basis upon which restriction of competition is established. The question then becomes: Is the commission is applying different standards to comparable contexts? This is a question which is asked, and which calls for further research in the article “Lundbeck v European Commission - a rotten decision or effective competition law enforcement?”¹¹⁰ In light of the preciseness of the European Court of Justices application of the principle, the fact that the General Court so blatantly discredited the applicability of the principle, it may be regarded as another factor to question the Lundbeck judgment as a whole.

To conclude the first and most important stage of the proportionality test on suitability (3.1), this paper acknowledges, that there is a wide variety of well directed criticism on Lundbeck. That criticism is not aimed at the capability of the Commission or the General Court of establishing the correct relevant facts of the case or the context for that case. Indeed, as has been previously stated, if one truly has regard to all of the facts in Lundbeck and lays eyes inter alia to the internal documents of Lundbeck and the Generic companies, there is objectively speaking very

¹⁰⁸ Lamadrid de Pablo A., Colomo P. On the Notion of Restriction of Competition: What We Know and What We Don't Know We Know. Forthcoming in Damien Gerard, Massimo Merola and Bernd Meyring (eds), *The Notion of Restriction of Competition: Revisiting the Foundations of Antitrust Enforcement in Europe* (Bruylant 2017), p 8

¹⁰⁹ ECJ judgment 30.06.1966, Case 56/65, *Société Technique Minière*, para. 8

¹¹⁰ Monckton Chambers 2016, *Lundbeck v European Commission - a rotten decision or effective competition law enforcement?* <http://ipkitten.blogspot.fi/2016/10/lundbeck-v-european-commission-rotten.html> (06.02.2017)

little chance, in the view of this paper, that one would be able to consider, that the reverse payment patent settlements in question are anything short of restrictive of competition. Therefore it is impossible to definitively state, that when applied strictly to very similar cases Lundbeck would be unsuitable as to achieve the desired end of being able to prohibit those exact kinds of agreements.

However, as the criticism is directed at the general principles that Lundbeck appears to set, steering future development of the legal framework of which it is part, one has to look past the individual case and assess what is left of the analysis of the General Court and the Commission, when the cocktail of factors of Lundbeck is taken out of the picture and suitability is measured only based on the merits of the approach taken and the precedent that Lundbeck sets in general. On that notion this research paper finds Lundbeck too problematic of a case for it to be determined as a suitable general measure and part of the legal framework. This is due to many inconsistencies relative to the already existing legal framework, in part which seem to pave the way for application of different standards in comparable contexts. In particular this paper finds the ‘by object’ approach an incoherent way of analyzing restriction of competition in the case-by-case manner that is done in Lundbeck as it seems to have inconsistencies with both the “century-long” wisdom of competition law and the newer effects-inclusive approach that has been established in cases like *Allianz* and *Cartes Bancaires*.¹¹¹ It is not just the approach in itself that brings this research to this conclusion on suitability, indeed the problems that arise from the criteria within the approach in the form of the ‘by object’ test are even more important, perhaps most notably the notion of potential competition and the focus on the sizing of the reverse payment. The line, where there is enough information and factors to determine restriction of competition ‘by object’, and where there is not enough information i also, as it stands, too blurred - and that makes it impossible to consider Lundbeck a suitable measure to that end.

¹¹¹ Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. *The Consistent Application of EU Competition Law: Substantive and Procedural Challenges*. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 55.

3.2 Necessity

As mentioned earlier in this paper, the calls for effect-based, rather than object-based analysis for determining the restrictiveness of reverse payment patent settlements might prove to be a hard argument to tackle, as an effect-based approach may very well be considered a less onerous way of assuring both a meaningful policy on reverse payment patent settlements and the prohibition of restrictive settlements.¹¹² In its analysis regarding necessity, this paper focuses on that question exactly: In light of the criticism targeted at Lundbeck and the precedent it establishes on the European legal tradition on reverse payment patent settlements, is there an alternative route, which would be both as suitable, and a less burdensome, and which at the same time would successfully weed out anticompetitive agreements and raise less concerns than the established European approach among legal scholars? In particular, many articles written since Lundbeck have compared the approach taken by the Commission and the General Court to the approach taken by the US Supreme Court.

3.2.1 Actavis and the US Approach

The Commission, while adopting its decision on Lundbeck in 2013, made a reference to the US Supreme Court's ruling in the case *Actavis*, asserting that the approach which the Lundbeck Decision entails is very similar to that of the Supreme Court in the United States and has held this view up to date. This is, according to many, a misconception.¹¹³

The Hatch-Waxman Act was what originally created the framework, which allowed the Federal Trade Commission, or FTC to litigate potentially anticompetitive patent settlements. However, the US Courts have strongly held onto the view, that patent settlements are a completely sound life-management strategy for patents so long as the settlement stays within the scope of the patent protection.¹¹⁴ That fact alone distinguishes between the United States approach and the European Union approach. There are no examples similar to that of Lundbeck, whereby it can be considered in even those cases, where there is only some competitive pressure from a generic on a patent protected production process, the potential patent agreements are

¹¹² Killick J. Patent Settlements as by Object Restrictions: a European Approach, but is it the right one? *A Scot without Borders - Liber Amicorum*, 2015, 2, p. 185-200

¹¹³ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 21.

¹¹⁴ Frank J. *et al.* Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective. Dewenter, Haucap, Kehder (eds.), *Wettbewerb und Regulierung in Medien, Politik und Märkten, Festschrift zum 65. Geburtstag von Jörn Kruse*, Baden-Baden, Nomos, 2013, pp. 385-413

presumed to be illegal, should they include a reverse payment, due to the loose definition of potential competition.

Two days prior to the announcement of the Lundbeck decision by the European Commission, the US Supreme Court gave a judgment in *FTC v. Actavis* on 17 June 2013. In the judgment, the Supreme Court established a “Rule of Reason” approach, which by definition means a ‘by effect’ restriction of competition analysis on wherever the rule of reason is applied to.¹¹⁵ This approach entails the need to assess, inter alia, the validity of the relevant patent and an analysis of the relevant market or context. A restriction ‘by effect’ means that the agreement: “*must affect actual or potential competition to such an extent that on the relevant market negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability*”.¹¹⁶ This stance therefore, as it takes into account all pro-competitive and anticompetitive effects, seem much more to the contrary of the General Court’s approach whereby patent settlement agreements are assessed strictly as ‘by object’ infringements, which is exactly the idea that the US Supreme Court rejected in *Actavis*.¹¹⁷

The General Court rejected an idea, which was very similar to what has now been endorsed by the General Court of the European Union, the “quick look” method, which was considered to be categorically insufficient in determining restriction of competition. Instead, the Supreme Court expressly called for a full Rule of Reason analysis, which it deemed necessary for “pay-for-delay” (reverse payment patent settlements) patent settlements.¹¹⁸ This approach is endorsed by many: namely this type of an effects based analysis seems to be preferable according to but not limited to, Gallasch¹¹⁹, Berghe¹²⁰, Killick¹²¹, and Geradin.¹²² It appears, that there is a lot of consensus in the scholarship with regards to what could be the route to take instead of the current infringement ‘by object’ approach taken by the Commission and the General Court as the less onerous way of establishing restriction of competition in reverse payment patent settlement.

¹¹⁵ Gallasch S. Activating Actavis in Europe - the proposal of a ‘structured effects-based’ analysis for pay-for-delay settlements. *Legal Studies* 2016 36 (4), pp. 683-705, p 684.

¹¹⁶ *Ibid.* p 693.

¹¹⁷ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 21.

¹¹⁸ Gallasch S. Activating Actavis in Europe - the proposal of a ‘structured effects-based’ analysis for pay-for-delay settlements. *Legal Studies* 2016 36 (4), pp. 683-705, p 695-696.

¹¹⁹ *Ibid.* p 705.

¹²⁰ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 24.

¹²¹ Killick J. Patent Settlements as by Object Restrictions: a European Approach, but is it the right one? *A Scot without Borders - Liber Amicorum*, *Concurrences* 2015, 2, pp. 185-200, p 200.

¹²² Ginsburg D. *et al.* Reverse Payment Patent Settlements in the European Union and the United States 2015. *George Mason Legal Studies Research Paper No. LS 15-22*, p 24.

Furthermore, as mentioned earlier in this chapter, there seems to be some confusion between two fundamentally different legal concepts. The confusion is by no means just the fault of the relevant authorities in Lundbeck. *Allianz* and *Cartes bancaires* and the Court of Justice of the European Union applied to the ‘by object’ infringement approach, some elements that had prior to those cases, been clearly a part of the ‘by effect’ analysis. Predictability was abolished from the determination of a restriction of competition by object, while the consequences, which are large in comparison to determination of a restriction of competition by effect.¹²³ This happened via the inclusion of a concept of what was rejected in the United States in *Actavis* - the “quick look”-method, or as it stands in Europe, a case-by-case analysis of ‘by object’ infringements, which includes a perfunctory analysis of the legal and economic context, that is, the effects-based analysis on competition of the patent settlement agreement, while object type agreements should always be restrictive of competition by nature, and on that note, by definition should not facilitate an investigation into the context of the arrangement. A restriction of competition ‘by object’ should entail, that the agreement reveals in itself some degree of harm, or the potential of harm on competition. If an arrangement is by its very nature and content anticompetitive, there should be no need for an analysis of the context. Moreover, there is a legitimate fear that, if this route is retained, procedural convenience might start to, unjustly, favor the ‘by object’ analysis in general, due to the fact that a full effects-based analysis takes far more resources to complete than does a perfunctory analysis, that has been induced into the object-based analysis.¹²⁴

The discrepancy does not have to be the standard. As described by Pablo Colomo in Article 101 TFEU and Market Integration, the tradition has been centered first around “Making sense of the rationale behind the approach”.¹²⁵ Csongor Nagy supports this thought in stating that the approach of the US, that is, a category-building doctrine of ‘by object’ restriction of competition is what the ‘old concept’ of anticompetitive object used to work in Europe as well.¹²⁶ Therefore, there does not have to exist a direct comparison between the US and the EU with regards to finding a less onerous way of analyzing reverse payment patent settlements, as those two

¹²³ Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. The Consistent Application of EU Competition Law: Substantive and Procedural Challenges. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 68.

¹²⁴ Ibid. p 58-70.

¹²⁵ Colomo P. Article 101 TFEU and Market Integration, 2016, Journal of Competition Law & Economics (2016) 12 (4), pp 749-779, p 775.

¹²⁶ Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. The Consistent Application of EU Competition Law: Substantive and Procedural Challenges. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 65.

regimes are not directly comparable anyway.¹²⁷ A clearer distinction between the concepts of ‘by object’ and ‘by effect’ restrictions of competition might, it itself bring about less contradictory cases and policy.

In conclusion, the Commission’s test, as confirmed by the General Court, with its ‘by object’ infringement of competition approach in the view of this paper, cannot be considered a necessary measure in light of the consensus among legal scholars, that there is a less burdensome general approach to analyzing the existence of a restriction of competition.. This time if Lundbeck were to be applied strictly to cases, that are exactly the same structurally and factually, one might be inclined to also deem Lundbeck to lack the necessity as to the desired end of being able to prohibit anticompetitive patent settlements, due to the fact that an effects-based analysis establishes more duly the context and actual effects of an agreement, and is as such a less onerous than the “automatic condemnation” that an object-based analysis entails.

3.3 Proportionality

Assessing proportionality *stricto sensu* is the third and final stage of the proportionality test, as defined in EU Law: Text, Cases and Materials. This part, when applied to Lundbeck asks therefore, whether the burden on the pharmaceutical companies was excessive in relation to the desired ends of prohibiting anticompetitive reverse payment patent settlements and establishing sound policy and case law around such settlements in relation to article 101 TFEU. It has been held that this stage of the test is not necessary where the question on proportionality has been answered in earlier stages, namely suitability and necessity.¹²⁸ This paper will apply that principle to its analysis, due to the lack of a *stricto sensu* consideration raising new specific arguments for the analysis in a whole. As this paper has established earlier in this chapter, with regards to development of the legal framework, Lundbeck, when all that it entails as a precedent are taken into account is neither a suitable, nor a necessary measure as a part of the legal framework of reverse payment patent settlements. To that end it is not necessary to consider the *stricto sensu* proportionality of Lundbeck as a measure. With regards to prohibiting anticompetitive patent settlements, if regard is had for all of the facts that were present in the General Courts analysis in Lundbeck, this paper will deem the burdens on the pharmaceutical

¹²⁷ Frank J. *et al.* Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective. Dewenter, Haucap, Kehder (eds.), Wettbewerb und Regulierung in Medien, Politik und Märkten, Festschrift zum 65. Geburtstag von Jörn Kruse, Baden-Baden, Nomos, 2013, pp. 385-413

¹²⁸ Craig P., de Burca G. EU Law: Text, Cases and Materials Fifth Edition. Oxford, Oxford University Press 2011, p 526

companies as proportional, if by ‘burdens’ one strictly means the repercussions that Lundbeck and the generic companies had to face after the decision, as confirmed by the judgment, in the form of fines- and if by proportionality one strictly means the *stricto sensu* proportionality of those fines relative to the severeness of the infringement, based on all of the considered facts. To that end, the General Court addressed sufficiently the calls for reduction of the fine by the relevant parties on multiple instances, namely paragraphs 71, 74, 830, 837 and 841 of the judgment.¹²⁹ Taken the aforementioned paragraphs into account, this paper concludes, that there is no doubt as to the proportionality of the burdens.

Conclusions

The biggest challenges that Lundbeck faces with regards to its usability as a first court-confirmed European Union case on reverse payment settlements concern its usage of such a huge amount of case-specific facts that go beyond any precise test. As this paper has established, the most central tool, that the commission attempted to formulate in Lundbeck was its test on “by object” infringement. So long as the Court considers in its rationale on that notion, such a variety of facts that are not specific to that test, how much relevancy can such a test have in later cases, when an authority or a court is supposed to utilize the test in its own analysis? If the application of the notion of “by object” infringement is dependent on yet more circumstances, it might quickly become too vague of a test. As the line cannot be drawn using a test then, which are the factors on top of that test, that ultimately make a settlement cross that line? It is not clear from the Lundbeck judgment, whether or not an absence of one important factor would have impacted the full conclusion.¹³⁰

In essence, as it currently stands, Lundbeck seems to be based on a concept of a ‘by object’ test, which has been developed not fully in accordance with the newest relevant legislation, namely the stance taken by the European Court of Justice in *Allianz* and *Cartes Bancaires*, in that it does not utilize sufficiently the required effects-based considerations, in accordance with those two judgments when determining the existence of a restriction of competition by object. That insufficiency is further strengthened if one takes into account how little support in terms of scholarship those two judgments had in part due to the requirement for analyzing the effects on

¹²⁹ GC judgment 08.09.2016, Case T-472/13, Lundbeck v Commission, para. 71-841.

¹³⁰ Jourdan J. *et al.* The Commission’s Lundbeck Decision: A Critical Review of the Commission’s Test For Patent Settlement Agreement. White & Case, Brussels, Competition Policy International 2014, p 5.

competition being too modest.¹³¹ An agreement which is declared as having an anticompetitive object has by far the biggest consequences and repercussions, and should therefore include the most careful analysis, not a simpler perfunctory analysis.

Based on that central notion, and multiple other problems and inconsistencies in the line that the Commission and the General Court took, as analyzed earlier in this paper, it has to be concluded that the Lundbeck judgment, as a fundamental part of the legal framework on reverse payment patent settlements is not a suitable instrument as to the desired end of establishing for the first time, sound policy around article 101 of the Treaty on the Functioning of the European Union regarding reverse payment patent settlements. As this paper did not attempt to dispute the facts that were established by the General Court however, this paper has to conclude that the Lundbeck judgment is a suitable instrument, as to the desired end of being able to prohibit anticompetitive agreements.

In addition to the analysis on suitability, the considerations on necessity focus even more greatly on the approach taken by the commission and the General Court in their utilization of ‘by object’ infringement. The challenge on necessity of Lundbeck as an instrument is the same with regards to both of the desired ends: Is there a less onerous way of achieving the desired end? The easiest comparison to the European Union’s ‘by object’ infringement approach is to the approach in the United States via their rule of reason. The conclusion on that front seems to be similar throughout the large field of articles written on the differences of the US approach in *Actavis* and the ‘by object’ approach established by Lundbeck in Europe - the US approach is the more coherent one, undermining the necessity of the approach in Lundbeck. The commission has later somewhat corrected its stance, as in *Servier* it included a more sufficient effects-based analysis with regards to restriction of competition of an agreement, which does bring the European approach closer to that of the United States.¹³² That inclusion alone however, does not reconcile with the fact that as it stands, the US approach seems the cleaner route to take. There is little consensus on the notion, that the authorities and courts should so strictly hold on to a restriction by object analysis, instead of a restriction by effect analysis in general. Therefore it must be concluded that Lundbeck, with its ‘by object’ test is not a necessary measure to achieve the desired ends.

¹³¹ Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. The Consistent Application of EU Competition Law: Substantive and Procedural Challenges. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 55-60.

¹³² ECJ judgment 26.02.2015, Case C691-13, *Servier*

The size and depth of both the decision and judgment on Lundbeck seem to demonstrate, not that the authority has in the best possible manner been able to bring to the table and consider all of the relevant facts, but instead that the authority has lacked the ability to coherently and sharply justify its utilization of the ‘by object’ restriction of competition approach in the first place. Neither does it demonstrate that the Commission had initially followed a rule of reason, regardless of what has been the stance of Commission official’s after adoption of the their decision.¹³³ As Régibeau stated in Further Thoughts on “Pay-for-delay” Settlements, if the policy is not precise enough, one might as well do without the policy.¹³⁴ If there is a lack of preciseness in applying a by object qualification to reverse payment settlements, it does not seem very logical to use that approach in general.

The most important examination of this thesis, was the assessment of the proportionality of the Lundbeck judgment in its entirety with regards to the desired end of establishing a meaningful and legally sound instrument for the legal framework on reverse payment patent settlements in the European Union. That entails, that Lundbeck should be able to help better assess reverse payment patent settlements in the future, utilizing what has been established in the case. To that end, this thesis finds Lundbeck categorically not a proportional measure. More specifically, Lundbeck failed the proportionality test on both of the most relevant stages, suitability and necessity, due to both, the inconsistency of Lundbeck’s approach with other relevant legal framework and the possibilities of approaches that are explicitly rejected in Lundbeck. There is widespread consensus within the legal scholarship on the problems of the approach that Lundbeck uses.¹³⁵ It is a reasonable expectation that competition might be deteriorated by Lundbeck because, so long as it is made more difficult to conclude patent settlements the generic challenges also becomes more difficult and therefore fewer.¹³⁶ The third stage of the proportionality, *stricto sensu* proportionality was not necessary to be examined in-depth as the proportionality test was, where this end is concerned, resolved in the earlier stages.¹³⁷ These conclusions are the most important finding of this thesis. As it stands, the

¹³³ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 21.

¹³⁴ Régibeau P. Further Thoughts on “Pay-for-delay” Settlements. *Concurrences* 2014, 11 (2), pp 18-20, p 20.

¹³⁵ Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. *The Consistent Application of EU Competition Law: Substantive and Procedural Challenges.* Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70, p 55.

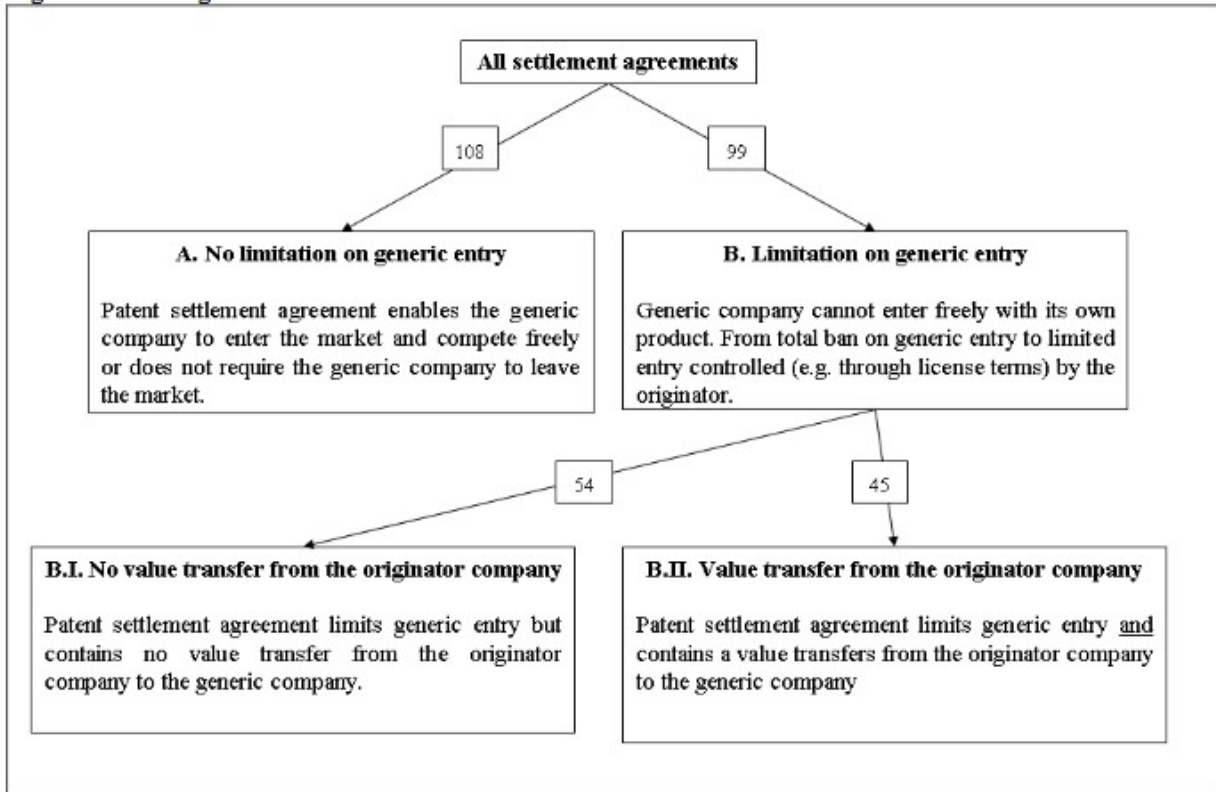
¹³⁶ Berghe P. *et al.* Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24, p 23.

¹³⁷ Craig P., de Burca G. *EU Law: Text, Cases and Materials Fifth Edition.* Oxford, Oxford University Press 2011, p 526.

European Union level approach to reverse payment patent settlements remains a peculiarity. The Lundbeck judgment seems to augment, not alleviate that perplexity.

Annex 1

Figure 106: Categorisation decision tree



Source: Pharmaceutical Sector Inquiry

Reference List

Academic Sources

1. Clancy M., Geradin D., Lazerow A. Reverse-payment Patent Settlements in the pharmaceutical industry: An analysis of U.S. Antitrust Law and EU competition law, *The Antitrust Bulletin* 2014, 59 (1). pp. 153-172.
2. Ginsburg D., Safty G., Geradin D. Reverse Payment Patent Settlements in the European Union and the United States 2015. George Mason Legal Studies Research Paper No. LS 15-22.
3. Zulli A., Robert A., Burton C., Bogaert P. The Commission's Lundbeck Decision: A Compass to Navigate Between Scylla and Charybdis? A review of the Commission's assessment of reverse patent settlements in the Lundbeck citalopram case, *Convington* 2015.
4. Hull D., Clancy M. Application of EU Competition Law in the Pharmaceutical Sector, *Journal of European Competition Law & Practice*, Oxford University Press, 2016, 7 (2), pp. 150-161
5. Calzado J., Scordamaglia-Tousis A. Groupment des Cartes Bancaires v Commission: Shedding Light on What Is not a 'by object' Restriction of Competition, *Journal of European Competition Law & Practice* 2015, 6 (7). pp. 495-498.
6. Schwarz D. Immovable objects The evolution of object restrictions after the Cartes Bancaires case 2016, Vol. 15 Issue 1.
7. Käseberg T. Intellectual Property, Antitrust and Cumulative Innovation in the EU and the US. Cornwall, Hart Publishing Ltd 2012.
8. Frank J., Kerber W. Patent Settlements in the Pharmaceutical Industry: An Antitrust Perspective. Dewenter, Haucap, Kehder (eds.), *Wettbewerb und Regulierung in Medien, Politik und Märkten*, Festschrift zum 65. Geburtstag von Jörn Kruse, Baden-Baden, Nomos, 2013, pp. 385-413
9. Cole M., A. Robert. A landmark judgment: The General Court has affirmed the Lundbeck pay-for-delay decision, *Competition Law Insight* 2016, 15 (10), pp 12-13.
10. Killick J. Patent Settlements as by Object Restrictions: a European Approach, but is it the right one? *A Scot without Borders - Liber Amicorum*, *Concurrences* 2015, 2, pp. 185-200.
11. Lamadrid de Pablo A., Colomo P. On the Notion of Restriction of Competition: What We Know and What We Don't Know We Know. Forthcoming in Damien Gerard, Massimo Merola and Bernd Meyring (eds), *The Notion of Restriction of Competition: Revisiting the Foundations of Antitrust Enforcement in Europe* (Bruylant 2017).
12. Craig P., de Burca G. *EU Law: Text, Cases and Materials Fifth Edition*. Oxford, Oxford University Press 2011.

13. Jourdan J., Kickinson J., Killick J., The Commission's Lundbeck Decision: A Critical Review of the Commission's Test For Patent Settlement Agreement. White & Case, Brussels, Competition Policy International 2014.
14. Burdon M. *et al.* Biogen insufficiency explained; Alendronate in Netherlands; Behaviour relevant to injunction; Perindopril evergreening criticised; ' Negative Term ' SPCs ' ; new dosage regimes. *Journal of Generic Medicines* 2008, 5 (4), pp. 341-352.
15. Gallasch S. Activating Actavis in Europe - the proposal of a 'structured effects-based' analysis for pay-for-delay settlements. *Legal Studies* 2016 36 (4), pp. 683-705
16. Colomo P. Article 101 TFEU and Market Integration, 2016, *Journal of Competition Law & Economics* (2016) 12 (4), pp 749-779.
17. Régibeau P. Further Thoughts on "Pay-for-delay" Settlements. *Concurrences* 2014, 11 (2), pp 18-20.
18. Régibeau P. "Pay-for-Delay": What Do We Disagree On? *Competition Policy International* 2013, 9 (2), pp 116-127.
19. Berghe P., Killick J. Applying a By Object Test to Patent Settlements is Very Different From the Rule of Reason. *Concurrences* 2014, 11 (2), pp 21-24.
20. Van Bael, Ellis. *Competition Law of the European Community*. Kluwer Law International 2005.
21. Nagy C.I. The Concept of Anti-Competitive Object Under EU Competition Law: Comparative Perspectives and European Realities. *The Consistent Application of EU Competition Law: Substantive and Procedural Challenges*. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 55-70.
22. Collins A.M., Of Cattle, Crashes & Cards - Recent Case-Law of the Court of Justice on Restrictions by Object. *The Consistent Application of EU Competition Law: Substantive and Procedural Challenges*. Almășan A., Whelan P. (Eds.). Springer International Publishing AG 2017, pp 43-54.

Internet Sources

1. Beckett N., Marks D., Markham J. AstraZeneca judgment: don't game the system. CMS Cameron McKenna, Lexology 2012. [www.lexology.com/library/detail.aspx?g=6178aea4-40af-4f57-b629-b53402a909cf\(07.01.2017\)](http://www.lexology.com/library/detail.aspx?g=6178aea4-40af-4f57-b629-b53402a909cf(07.01.2017)).
2. Cole M., Boudet J., Robert A. European Commission Published Non-Confidential Version of Servier Decision, Inside EU Life Sciences, Covington 2015. www.insideeulifesciences.com/2015/07/17/european-commission-published-non-confidential-version-of-servier-decision/ (July 17, 2015).

3. Colomo P. GC Judgment in Case T-472/13, Lundbeck v Commission: on patents and Schrödinger's cat 2016. chillingcompetition.com/2016/09/13/gc-judgment-in-case-t-47213-lundbeck-v-commission-on-patents-and-schrodingers-cat/ (22.2.2017)

4. European Commission Press Release, Brussels, 19 June 2013, http://europa.eu/rapid/press-release_IP-13-563_en.htm (12.12.2016)

Other Sources

1. European Commission Competition DG Pharmaceutical Sector Inquiry Final Report on 8 July 2009.

2. European Commission Communication From The Commission Executive Summary of the Pharmaceutical Sector Inquiry Report 2009.

3. European Commission Competition DG 1st Report on the Monitoring of Patent Settlements 2010.

4. European Commission Competition DG 7th Report on the Monitoring of Patent Settlements 2016.

5. ECJ judgment 11.09.2014, Case C-67/13 P, Cartes Bancaires

6. ECJ, C-67/13 P - CB v Commission, 11.09.2014 (Cartes Bancaires)

7. ECJ 06.12.2012, C-457/10 P, AstraZeneca v Commission.

8. Commission Decision 19.06.2013, Case 80/13, Lundbeck

9. GC judgment 08.09.2016, Case T-472/13, Lundbeck v Commission

10. ECJ judgment 30.06.1966, Case 56/65, Société Technique Minière

11. Schacht W., Thomas R. The Hatch-Waxman Act: Legislative Changes in the 108th Congress Affecting Pharmaceutical Patents, CRS Report for Congress 2004.

12. United States Court Of Appeals For The Second Circuit judgment, *In Re: Tamoxifen Citrate Antitrust Litigation.*, 466 US (2006) 52.

13. GC judgment T-461/07 - Visa International Service v Commission, 14.04.2011

14. Opinion of AG Wahl in Case C - 67/13 P, 27.03.2014 (Cartes Bancaires)

15. ECJ judgment 26.02.2015, Case C691-13, Servier