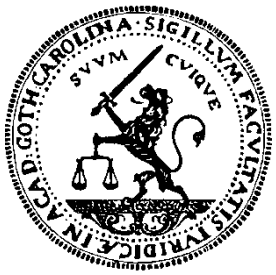

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Reverse payment settlements in the context of Article 102 TFEU:
Abusive or not? By object or not?

JAEM01 Master Thesis

European Business Law
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TABLE OF CONTENTS

SUMMARY

Pharmaceutical reverse payment settlements lie at the intersection of competition law and intellectual property law. In the recent years, these settlement agreements have increasingly attracted the attention of competition law authorities in the European Union. Generally, the focus of these cases, and of the literature concerning reverse payment settlements, has been on the collusive nature of the agreements. In 2014, however, the European Commission assessed such agreements as part of a unilateral strategy under Article 102 TFEU. The compatibility of reverse payment settlements has also been examined by the national competition authority in the United Kingdom.

There is still lot of ambiguity surrounding the treatment of reverse payment settlements under Article 102 TFEU, including whether such settlement agreements can constitute an abuse of a dominant position in themselves, when, and what would be the most suitable legal test for their competition law assessment.

This thesis will attempt to provide an answer to these questions. This will be done by first providing an overview of the complex legal framework in which these agreements operate, after which the Commission decision in *Servier* and the UK Competition and Markets Authority's decision in *Paroxetine* will be examined in an attempt to shed some light into the current approach of the competition authorities. It will be argued that reverse payment settlements, especially where pursued by an originator in a dominant position as a consistent strategy, justify competition law scrutiny under Article 102 TFEU.

Finally, the thesis will point out the unsuitability of the object-based analysis, as it effectively disregards the existence and relevance of patents and an argument will be put forward that reverse payment settlements should be assessed in accordance with the effects-based analysis, as it more effectively takes into account the complicated legal and economic analysis in which these agreements operate.

PREFACE

I am going to keep this short and sweet. First and foremost, I would like to express my gratitude to my thesis supervisor, Dr. Julian Nowag, for his support and invaluable input in my thesis. I would also like to thank my friends, classmates and the staff at the Juridicum for making this year as great and educational as it has been.

ABBREVIATIONS

API	Active pharmaceutical ingredient
CAT	Competition Appeal Tribunal
CJEU	Court of Justice of the European Union
CMA	Competition and Markets Authority
EPC	European Patent Convention
EU	European Union
GC	General Court of the European Union
GSK	GlaxoSmithKline
IP	Intellectual property
IPR	Intellectual property right
R&D	Research and Development
TFEU	Treaty on the Functioning of the European Union

1 INTRODUCTION

1.1 Background

Pharmaceutical reverse payment settlements, or pay-for-delay agreements, lie at the intersection of competition and patent laws. In essence, these agreements arise in the context of patent disputes, where, under a settlement agreement, an originator company transfers value to a generic company and in exchange, the generic agrees to delay its market entry, allowing the originator artificially to keep its profits high.[1] Originator companies, or originators, are those pharmaceutical companies which invest considerable resources in the research and development ('R&D'), manufacturing, and marketing of new medicinal products.[2] Generic companies, or generics, on the other hand, is used to refer to pharmaceutical companies which, instead of investing significant sums in the R&D of new drugs, develop and manufacture medicines that are identical or bioequivalent to economically successful brand-name drugs developed by originators.[3] The term reverse payment settlement stems from the fact that under these agreements, the direction of the payment is 'reverse', since normally, under a patent settlement agreement, the payment is made by the alleged infringer to the patent holder.

The economic interests involved in the pharmaceutical sector are exceptionally high and the importance of the sector to public health and welfare can hardly be underestimated. This is why finding the right balance between competition and patent law considerations is a crucial and difficult task.[4] While reverse payment settlements are legal under the national patent laws of the EU Member States, from an EU competition law point of view, these agreements appear, *prima facie*, to distort competition and to hinder the

[1] Richard Whish & David Bailey, *Competition Law* (8th edn, OUP 2015) 838.
[2] Commission, 'Pharmaceutical Sector Inquiry Final Report' of 8 July 2009, available at: <www.ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part 1.pdf> accessed 19 March 2018, para 51.
[3] Final Report (n2) para 89.
[4] Rainer Moufang, 'Patentability of pharmaceutical innovations: the European perspective' in Josef Drexl and Nari Lee (eds), *Pharmaceutical Innovation, Competition and Patent Law* (Edward Elgar Publishing Ltd 2013) 54.

effective functioning of the single market.[5] The Commission, which, through its role as the EU competition law watchdog, possesses a strong competition law competence which it uses to force pharmaceutical companies to act in accordance with its views of the optimal free movement of goods and effective competition for the benefit of the consumers. This, however, may give rise to various problems, including undermining the commercial value of an originator's patents, reducing the ability of pharmaceutical companies to settle their patent related disputes privately, and ultimately, it might have a detrimental effect on the incentives of the originator companies to innovate and invest in pharmaceutical R&D.

1.2 Purpose & Research Question

Reverse payment settlements have been under increased scrutiny from EU competition authorities for almost a decade and the legal questions surrounding pharmaceutical reverse payment settlements are numerous. Typically, the focus in the case law and in the vivid academic debate has been on the collusive nature of the agreements.[6] However, reverse payment settlements might also raise competition concerns under Article 102 Treaty on the Functioning of the European Union ('TFEU'), insofar as they result from a dominant originator's unilateral conduct. In *Perindopril (Servier)*, the European Commission, in addition to finding an infringement of Article 101 TFEU, examined the compatibility of the reverse payment settlements with Article 102 TFEU for the first time.[7] The national competition authority in the United Kingdom, the Competition and Markets Authority ('CMA'), has

[5] The establishment and proper functioning of the internal market is one of the main objectives of the EU and a system of undistorted competition is an important part of the internal market. See, Consolidated Version of the Treaty on European Union [2016] OJ C202/13, Article 3(3); Protocol (No 27) on the Internal Market and Competition to the Consolidated Version of the Treaty on European Union [2016] OJ C202/308.

[6] See, e.g. Vilhelm Schröder, 'Pay-for-delay settlements in the EU: did the Commission go too far?' (2016) E.C.L.R. 506; Andrea Zulli and others, 'The European Commission's *Lundbeck* Decision: A Compass to Navigate between Scylla and Charybdis?' (2015) I.P. & I.T. Law 27(6) 3; Bill Batchelor and others, 'Lundbeck raises more questions than answers on "pay-for-delay" settlements; creates damaging divergence from US law' (2017) E.C.L.R. 3.

[7] *Perindopril (Servier)* (Case AT.39612) Commission decision of 9.7.2014 C(2014) 4955 final, para 62. Summary of Commission Decision of 9 July 2014 relating to a proceeding under Articles 101 and 102 of the Treaty on the Functioning of the European Union (Case AT.39612 — Perindopril (Servier)) (2016/C 393/05) [2016] OJ C 393/7.

also considered the question whether reverse payment settlements amount to an abuse of a dominant position.[8] However, there is still a lot of uncertainty concerning the assessment of pharmaceutical reverse payment settlements under EU competition law rules.

The purpose of this thesis is to examine the current approach adopted by the competition authorities in the EU towards the assessment of reverse payment settlements under Article 102 TFEU, and to consider whether and under which circumstances these settlements should fall within the scope of Article 102 TFEU. The thesis will also contemplate on what would be the most suitable legal test for the competition law assessment of such agreements, an object-based or effects-based analysis.

1.3 Methodology & Materials

The methodology adopted in this thesis is the legal doctrinal method. More precisely, since this thesis considers the current treatment of reverse payment settlements under Article 102 TFEU, whether that approach is optimal, and what the law should be, both *de lege lata*[9] and *de lege ferenda*[10] argumentation will be used.

Existing case law from the Commission and the EU Courts regarding reverse payment settlements and the interpretation of Articles 101 and 102 TFEU is in a central role in this thesis. In addition, the author has used academic texts and articles from various authors and scholars, as well as traditional sources of EU law, soft law instruments, and other materials from the Commission, to form a firm background and basis to support the arguments put forward in this thesis.

1.4 Delimitations & Research limitations

The scope of this thesis is limited to examining the treatment of reverse payment settlements under Article 102 TFEU. More specifically, this thesis will only discuss whether and in which situations reverse payment

[8] *Paroxetine* (Case CE-9531/11) Decision of the Competition and Markets Authority of 12 February 2016.
[9] Law as it stands.
[10] Law as it should be.

settlements amount to an abuse and what the most appropriate legal test would be for the assessment. No consideration will be given to the other elements relevant to Article 102 TFEU assessment, i.e. the finding of dominance and the effect on inter-State trade.

Pharmaceutical reverse payment settlements have only relatively recently begun to attract the attention of the EU competition law authorities, and therefore, the number of cases concerning reverse payment settlements is quite small. So far, there are only three EU cases and at least one national case, of which the author is aware, concerning pharmaceutical reverse payment settlements.[11] However, as mentioned above, the focus in the Commission case law has been on the assessment of these agreements under Article 101 TFEU and while the amount of literature regarding reverse payment settlements is immense, the number of cases and literature analysing reverse payment settlements from the perspective of Article 102 TFEU is fairly limited.

In addition, neither of the cases which deal with reverse payment settlements in the context of Article 102 TFEU are final judgments. The Commission decision in *Servier* has been appealed to the General Court ('GC'), and irrespective of the outcome of the appeal, it will most likely be appealed to the Court of Justice of the European Union ('CJEU').[12] The *Paroxetine* decision was also appealed by the defendants to the UK Competition Appeal Tribunal ('CAT') which referred the case to the CJEU for preliminary reference.[13] It will, therefore, take several years before the CJEU will give its final say on the matter.

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[11] See section 3.1 for more details.

[12] Case T-691/14 *Servier and Others v Commission* [2014] OJ C 462/25. Information relating to the case is available at: Court of Justice of the European Union, 'Case Information: Case T-691/14 *Servier and Others v Commission*' (*CURIA*) <www.curia.europa.eu/juris/fiche.jsf?id=T%3B691%3B14%3BRD%3B1%3BP%3B1%3BT2014%2F0691%2FP&pro=&lgrec=en&nat=or&oqp=&dates=&lg=&language=en&jur=C%2CT%2CF&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse&num=T-691%252F14&td=%3BALL&pcs=Oor&avg=&mat=or&jge=&for=&cid=875910> accessed 19 May 2018.

[13] C-307/18 *Generics (UK) and Others*. Information relating to the case is available at: Court of Justice of the European Union, 'Case Information: Case C-307/18 *Generics (UK) and Others* (*CURIA*) <www.curia.europa.eu/juris/liste.jsf?pro=&lgrec=bg&nat=or&oqp=&dates=&lg=&language=en&jur=C%2CT%2CF&cit=none%252CC%252CCJ%252CR%252C2008E%252C%252C%252C%252C%252C%252C%252C%252C%252C%252Ctrue%252Cfalse%252Cfalse

1.5 Outline

This thesis is divided into three discussion chapters. Chapter 2 of the thesis will examine the complex legal framework in which the reverse payment settlement agreements operate. At first, patent law and the incentives for pharmaceutical companies to enter into reverse payment settlements that arise out of that legal regime will be discussed. After that, a brief consideration will be given to the problems for consumers that result from the settlements and finally, Article 102 TFEU and its application will be discussed on a general level.

Chapter 3 will consider the current case law in the EU, namely, the Commission decision in *Servier* and the CMA decision in *Paroxetine*. An attempt will be made to shed some light into the current approach adopted by competition authorities towards pharmaceutical reverse payment settlement agreements under Article 102 TFEU by looking into some of the common features in these decisions.

Lastly, chapter 4 will consider whether reverse payment settlements should fall within the scope of Article 102 TFEU and what would be the most suitable legal test for the competition law assessment of these agreements, object-based analysis or effects-based analysis. This will be done by analysing whether and when reverse payment settlements have a restrictive effect on competition, which would justify competition law scrutiny under Article 102 TFEU. After that, the thesis will examine whether the current approach gives enough consideration to the legal and economic context of the agreements and to the importance of patents. The author will argue and aim to demonstrate the unsuitability of the current approach adopted by the competition authorities in the EU, as it undermines the patent law aspect inherent in the reverse payment settlements. Finally, an argument will be put forward that where an originator acts within the scope of its patent(s), the EU competition law authorities should adopt an effects-based approach to their

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&num=307%252F18&td=%3BALL&pcs=Oor&avg=&page=1&mat=or&jge=&for=&cid=128754> accessed 21 May 2018; Competition Appeal Tribunal, 'Cases: 1252/1/12/16 GlaxoSmithKline PLC v Competition and Markets Authority' (*CAT*) <www.catribunal.org.uk/237-9158/1252-1-12-16-GlaxoSmithKline-PLC.html> accessed 19 May 2018.

assessment, as it would more effectively take into account the legal and economic context in which these agreements operate.

2 LEGAL FRAMEWORK IN THE PHARMACEUTICAL SECTOR

2.1 Legal framework in general

The pharmaceutical industry is IP-intensive and it is regulated heavily on national, EU, and international levels.[14] The legal framework impacting the pharmaceutical sector consists primarily of patent law, competition law, market authorisation rules and the Convention on the European Pharmacopoeia.[15] The aim of this complex legal regime is to reward and promote innovation in the pharmaceutical sector, while simultaneously ensuring the safety, quality and effectiveness of drugs in the European market.[16] It also aims to promote single market integration by guaranteeing the free movement of drugs in the internal market and by keeping the price level of medicinal products affordable in order to protect the interests of EU citizens and national health budgets.[17]

The relevant legal regimes for the purposes of this thesis are patent law and competition law, and therefore, the market authorisation rules and the European Pharmacopoeia will not be examined in detail. However, before discussing the importance of patent law in the pharmaceutical sector and the incentives for pharmaceutical companies to enter into reverse payment settlements that arise out of it, it should be noted that while all pharmaceutical products are subject to the market authorisation rules, the process for generic companies is quicker, simpler and cheaper in order to encourage generic entry.[18] Furthermore, the relevant authorities are not allowed to take economic considerations, such as IPRs, into account in the process of granting a market authorisation.[19] The European Pharmacopoeia, on the other hand, is

[14] *Servier* (n7) para 62.
[15] *Servier* (n7) para 62; Moufang (n4) 54-55.
[16] *Servier* (n7) para 62; Christian R. Fackelmann, 'Clinical data, data exclusivity and private investment protection in Europe' in Josef Drexl and Nari Lee (eds), *Pharmaceutical Innovation, Competition and Patent Law* (Edward Elgar Publishing Ltd 2013) 149.
[17] *Servier* (n7) para 62; Fackelmann (n16) 150; Commission, 'Antitrust: Pharmaceuticals' (*European Commission*, 20 March 2017) <www.ec.europa.eu/competition/sectors/pharmaceuticals/antitrust_en.html> accessed 4 April 2018.
[18] *Servier* (n7) para 74; Fackelmann (n16) 150-154.
[19] Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1, Recital 13.

the 'single reference work for the quality control of medicines in Europe'.[20] It provides common standards for the quality of medicines to be used by health care professionals, as well as by generic companies during the development, production, and marketing of generic versions of brand-name drugs.[21]

2.2 Patent law

A patent is a legal title, which protects novel and non-obvious inventions and grants a patent owner a variety of exclusive rights.[22] A valid patent confers on the patent holder a limited monopoly[23] over the patented product or process for a maximum period of 20 years from the filing date.[24] The exclusive rights granted by a patent are, however, negative in a sense that a patent gives the patent holder the right to prevent others from using or exploiting the patented product without the permission of the patent holder.[25] It does not give the patent owner a positive right to exploit and abuse the patent.[26] Indeed, the right to stop third parties from exploiting the innovation is one of the most fundamental features of a patent, thus allowing the patent holder to constrain certain forms of competition within the scope of the patent.[27] In other words, patents may, in certain circumstances, provide an exception to the EU competition law rules.

To balance the exclusive right granted by a patent against competition law considerations, the protection provided by a patent is limited both in time and in scope.[28] The possible exceptions to competition law rules are generally considered to be justified by the advantages to the public that follow from

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[20] *Servier* (n7) para 77.
[21] *Servier* (n7) paras 77 & 79.
[22] *Servier* (n7) paras 63 & 67.
[23] The monopoly is limited as there may be other, competing and non-infringing products on the market.
[24] *Servier* (n7) para 63; Charlotte Waelde, Abbe Brown, Smita Kheria and Jane Cornwell, *Contemporary Intellectual Property: Law and Policy* (4th edn, OUP 2016) para 11.4; Whish & Bailey (n1) 812.
[25] Valerio Torti, *Intellectual Property Rights and Competition in Standard Setting* (Routledge 2016) 28; Steven Anderman & Hedvig Schmidt, *EU Competition Law and Intellectual Property Rights: The Regulation of Innovation* (2nd edn, OUP 2011) 58.
[26] Anderman & Schmidt (n25) 58; Whish & Bailey (n1) 811.
[27] This was recognised by the Commission in *Servier*. See *Servier* (n7) para 63. Whish & Bailey (n1) 812; Jonathan D. C. Turner, *Intellectual Property and EU Competition* (2nd edn, OUP 2015) para 1.02.
[28] Turner (n27) para 1.50; Torti (n25) 27.

promoting and rewarding innovation, as well as from the publication of the invention.[29] It should also be noted that in the EU, a patent can be challenged by anyone and at any time.[30] This, again, balances IP and competition law considerations against each other by identifying 'weak' patents which do not justify exceptions to competition law rules, thus forming an essential part of a system of competition.[31]

Patents in Europe are governed and protected mainly by the national laws of the EU Member States, despite some efforts to harmonisation at the EU level.[32] The conditions for and the substantive law of patentability in Europe are governed by the European Patent Convention ('EPC') and in the EPC Member States, the substance of the national provisions on patentability is identical to the provisions of the EPC.[33] However, matters relating to the scope, infringement and enforcement of a patent are primarily still governed by national laws.[34] Consequently, a patent granted by a patent authority of an EU Member State is enforceable only in that particular jurisdiction. The differences between the national patent law regimes make the enforcement of patents often very difficult and expensive for patent holders.[35]

The R&D of new drugs in the pharmaceutical sector is an exceptionally high-risk, expensive and time-consuming endeavour for originator companies.[36] It is potentially also a very high-reward undertaking,

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[29] Turner (n27) para 1.50.

[30] In the US, a party wishing to challenge a patent must have a 'standing', i.e. the challenger must wait until the patent holder has somehow signalled an intention to enforce its patent. Robin Jacob, *IP and Other Things: A Collection of Essays and Speeches* (Hart Publishing/Bloomsbury 2015) 222-223.

[31] Josef Drexl, '"Pay-for-delay" and blocking patents - targeting pharmaceutical companies under European competition law' (2009) IIC 40(7) 751, 753.

[32] *Servier* (n7) para 64; Case 24/67 *Parke Davis v Centrafarm* EU:C:1968:11, p.72; Case 35/87 *Thetford Corporation v Fiamma* EU:C:1988:353, paras 12-15. See also Trevor Cook, *EU Intellectual Property Law* (OUP 2010) Chapter 7.

[33] All EU Member States are also EPC Member States. Moufang (n4) 55.

[34] Moufang (n4) 55.

[35] Michael Clancy, Damien Geradin and Andrew Lazerow, 'Reverse-payment patent settlements in the pharmaceutical industry: An analysis of U.S. antitrust law and EU competition law' (2014) The Antitrust Bulletin 59(1) 153, 163.

[36] According to Deloitte, it costs originator companies nowadays almost USD2 billion to bring a new drug to market. This number also incorporates the cost of failures, the impact of acquired and in-licensed assets, as well as the internal R&D expenditure. A study by the Tufts Center for the Study of Drug Development, on the other hand estimated that only roughly 12 percent of drugs that enter clinical testing eventually successfully enter the market. The study estimated that the cost of R&D of a successful new drug is as high as USD2.8 billion, including the cost of failures and that on average it takes 13.5 years to develop and bring one new drug successfully to market. See, Deloitte Centre for Health Solutions, 'A new future

as the originator companies usually charge high monopoly prices on their innovative brand-name drugs during the patent exclusivity period. It is this possibility of future profits that provides originators the incentives to invest in the R&D of new drugs in the first place, which, in turn, encourages innovation.[37] Further, the profits also promote innovation by financing the R&D of new products, insofar as they are financed out of current cash flows.[38]

These monopoly prices take into account the high costs and risks of pharmaceutical R&D and allow originator companies to recoup their investments.[39] Originators also need to recover investments made in other, unsuccessful projects, since only a small fraction of researched products eventually make it to the market.[40] These considerations make the exclusivity period extremely valuable to originators.

Generic companies, instead of investing in the R&D of new drugs, merely 'copy' brand-name drugs developed by originator companies. The cost of replicating a pharmaceutical product or a process is considerably lower, and consequently, the generic companies do not incur the same high costs and risks of pharmaceutical R&D as the originator companies.[41] Because of this asymmetry regarding the costs and risks borne by originators on the one hand, and by generics on the other, protecting and rewarding innovation is crucial. Patents are typically considered to be the best way to achieve such sufficient protection and compensation to the originator and indeed, the pharmaceutical sector is strongly reliant on the patent system.[42]

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for R&D? Measuring the return from pharmaceutical innovation 2017' (*Deloitte*) <www2.deloitte.com/content/dam/Deloitte/ch/Documents/life-sciences-health-care/ch-lshc-measuring-roi-pharma.pdf> accessed 3 April 2018, p.16; Steven M. Paul and others, 'How to improve R&D productivity: the pharmaceutical industry's grand challenge' (2016) Journal of Health Economics 203, 205.

[37] Jonathan B. Baker, 'Beyond Schumpeter vs. Arrow: How Antitrust Fosters Innovation' (2007) Antitrust L. J. 74 575, 579-580.

[38] C. Scott Hemphill, 'Unjustified Delays in Generic Drug Competition' (An expert paper by Scott Hemphill submitted at the 121st meeting of OECD Competition Committee on 18-19 June 2014, DAF/COMP/WD(2014)76, *OECD*, 6 June 2014) available at: <www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DAF/COMP/WD(2014)76&docLanguage=En> accessed 30 April 2018, p.2.

[39] Jacob (n30) 235-236.

[40] Jacob (n30) 237.

[41] Lionel Bently and Brad Sherman, *Intellectual Property Law* (4th edn, OUP 2014) 417.

[42] Moufang (n4) 54-55; Georgios Tsouloufas, 'Limiting pharmaceutical parallel trade in the European Union: regulatory and economic justifications' (2011) E.L. Rev. 36(3) 385, 390; Bently & Sherman (n41) 417.

2.3 Underlying reasons for reverse payment settlements

Generally, when an originator's primary patent protecting the active ingredient of a medicine expires or is about to expire, generic companies commence preparations to introduce cheaper generic versions of the brand-name drug.[43] Wide-spread generic entry leads to a significant and permanent drop in drug prices for the benefit of the consumers, i.e. national health insurance systems or national health budgets and individual patients, which is why the Commission is particularly keen to promote it.[44] However, the originator often still holds secondary patents at this point, which provide more limited protection than the primary patent. Disputes regarding the originator's patents often arise in this context, either because the originator brings an action against a generic company claiming that the generic version of the brand-name product infringes the originator's secondary patents and/or the generic claims that the originator's secondary patent is invalid and should be revoked.[45] Also, a generic may defend an infringement claim by stating that their product does not infringe any of the originator's patents because it was produced using a patent-free manufacturing process.[46]

Patent litigation is often complex, expensive and time-consuming and in most cases, the outcome of the litigation is far from certain.[47] Due to the fact that patents are often enforced before national courts in accordance with national patent and procedural laws, a further element of uncertainty for both

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[43] Ute Zinsmeister and Maria Held, 'Pay-for-delay or reverse payment settlements - a war of roses between competition and patent law in Europe and in the US? European Commission fines Lundbeck and other pharma companies for delaying market entry of generic medicines' (2013) E.C.L.R. 34(12) 621, 622; Commission, 'Pharmaceutical Sector Inquiry – Preliminary Report: Fact Sheet "Originator-Generic competition"' (*European Commission*, 28 November 2008) <www.ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/2_Originator_Generic_competition.pdf> accessed 8 April 2018, p.1.

[44] For example, following wide-spread generic market entry, the prices of perindopril fell on average by 90 per cent in the UK compared to the originator companies' former price levels. Commission, 'Antitrust: Commission fines Servier and five generic companies for curbing entry of cheaper versions of cardiovascular medicine' [2014] IP/14/799 (<www.europa.eu/rapid/press-release_IP-14-799_en.htm> accessed 2 April 2018). See also, *Paroxetine* (n8) paras 3.62 & 3.63.

[45] Zinsmeister & Held (n43) 622.

[46] Zinsmeister & Held (n43) 622.

[47] In the US case *FTC v. Watson Pharmaceuticals, Inc*., the US Court of Appeals for the Eleventh Circuit stated that '[e]ven the confident patent owner knows that the chances of prevailing in patent litigation rarely exceed seventy percent. Thus, there are risks involved even in that rare case with great prospects.' *FTC v. Watson Pharmaceuticals, Inc.* 677 F. 3d 1298 (2012); 102 USPQ 2d 1561, 1571-1572; Schröder (n6) 510.

parties is created by the fact that the outcome of the legal battle might differ from one Member State to another.[48] Furthermore, prolonged litigation often causes severe damage to the public image and reputation of the companies involved.[49]

Patent law allows the parties to settle the dispute privately. It is generally accepted that settlements are in the public interest as they save the resources of courts and other administrative bodies and avoid unnecessary litigation in courts.[50] It is, therefore, hardly surprising that the abovementioned considerations provide strong incentives for both parties to settle the dispute by capping the costs and avoiding the possibility of losing the court case.

2.4 Reverse payment settlements: Harm to consumers

Often, an originator's loss in profits is greater than the profits gained by generics following their market entry and there is, therefore, a possibility for both parties to benefit from a settlement.[51] By concluding a reverse payment settlement, the originator, in exchange for a value transfer to the generics, preserves its exclusive right created by the patent, and the high profit margins for the duration of the agreement.[52] The generics, on the other hand, generally have much more limited resources at their disposal than the originator companies, and they, too, are usually better off by delaying market entry and by sharing the originator's market monopoly rents than by continuing litigation in courts.[53] However, as a consequence, consumers have to keep paying high monopoly prices for the originator's product.[54] In some

[48] Zulli and others (n6) 3.
[49] Zinsmeister & Held (n43) 622.
[50] This was also explicitly acknowledged by the Commission in para 5 of its *Lundbeck* decision. *Lundbeck* (Case AT.39226) Commission decision of 19 June 2013 C(2013) 3803 final. Summary of Commission Decision of 19 June 2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union and Article 53 of the EEA Agreement (Case AT.39226 — Lundbeck) (2015/C 80/07) [2015] OJ C 80/13.
[51] *Servier* (n7) para 1147.
[52] *Servier* (n7) paras 1146-1147.
[53] Drexl (n31) 753.
[54] Herbert Hovenkamp, 'Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision' (2014) Minn. J.L. Sci. & Tech. 15(3) 3, 8.

cases, originators might even raise their prices following the conclusion of a reverse payment settlement.[55]

As mentioned above, generic entry is about price competition which benefits consumers, for instance, in the form of lower prices.[56] Indeed, in the Final Report on the Pharmaceutical Sector Inquiry, the Commission estimated that two years after generic market entry, generic versions of a brand-name drug cost on average 40 percent less than the brand-name drug prior to the generic market entry.[57] It should be noted here that the pharmaceutical market is atypical in several respects, and generally, the consumers of pharmaceutical products are indifferent to matters such as branding, thus making price a crucial consideration.[58] The competition authorities' view is that, in the absence of reverse payment settlements, the generics would continue their efforts to challenge the originator's patents before courts. Should the generics prevail in litigation, the avenue to the market would be open not just for the challenger, but also for other generic manufacturers, and as a result, wide-spread generic entry and significant price drops would occur.

The Commission has taken the view regarding reverse payment settlements that potential competitors are foreclosed from the market not by virtue of the exclusionary nature of a patent, but by a value transfer from an originator. The Commission sees reverse payment settlements as equivalent to an undertaking paying off its potential competitors, thus creating obstacles to generic market entry.[59] In other words, the Commission argues that these agreements are used by originator companies unjustifiably to extend their

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[55] Hovenkamp (n54) 8.

[56] Commission, 'Communication from the Commission – Guidance on the Commission's enforcement priorities in applying [Article 102 TFEU] to abusive exclusionary conduct by dominant undertakings' [2009] OJ C 45/7 ('Article 102 Guidance Paper'), para 5; Drexl (n31) 753.

[57] Commission, 'Communication from the Commission – Executive Summary of the Pharmaceutical Sector Inquiry Report' of 8 July 2008, available at: <www.ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf> accessed 21 April 2018, p.9.

[58] Hovenkamp (n54) 9-10.

[59] *Servier* (n7) paras 1147 & 1151. The General Court affirmed the Commission's view that the value transfers made by originators amount to buy-offs of potential competitors in Case T-472/13 *H. Lundbeck A/S and Lundbeck Ltd v European Commission* EU:T:2016:449, para 352.

market monopolies and, as a consequence, to hinder effective competition on the market to the disadvantage of consumers.

2.5 Article 102 TFEU: Abuse of a dominant position

Article 102 TFEU prohibits '[a]ny abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it […] in so far as it may affect trade between Member States'. Article 102 TFEU, therefore, has three main constituent elements: dominance[60], abuse and effect of trade between EU Member States. Since the purpose of this thesis is to discuss whether and under which circumstances pharmaceutical reverse payment settlements constitute an abuse of a dominant position, only the concept of abuse will be examined here. However, before turning to the notion of abuse, a brief consideration needs to be given to the policy objective Article 102 TFEU aims to achieve.

2.5.1 Policy objective of Article 102 TFEU

In general, there appear to be two main schools of thought: one sees the protection of the process of competition as the main objective of Article 102, while the other argues that the ultimate goal of EU competition law rules is the protection of competition for the benefit of the European consumers.[61] While there are convincing arguments on both sides, the EU Commission has in the recent years placed a heavy emphasis on the essential role of consumer welfare in the interpretation and application of EU competition law.[62]

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[60] The concept of dominance relates to the degree of economic strength and independence enjoyed by the undertaking due to a lack of effective competitive constraints. This, in turn, means that the degree of competition within the relevant market is weakened as a result of the ability of the dominant undertaking to prevent effective competition and to alter the structure of the market. See, Case 27/76 *United Brands Company and United Brands Continentaal BV v Commission of the European Communities*, EU:C:1978:22, para 65; Article 102 Guidance Paper (n56) para 10; Miguel de la Mano, Renato Nazzini & Hanz Zenger, 'Article 102' in Jonathan Faull, Ali Nikpay & Deirde Taylor (eds) *Faull and Nikpay: The EU Law of Competition* (3rd edn OUP 2014) paras 4.124-4.125.

[61] Luc Peeperkorn, 'Coherence in the Application of Articles 101 and 102: A Realistic Prospect or an Elusive Goal?' (2016) World Competition 39(3) 389, 390-391; Wouter P.J. Wils, 'The Judgment of the EU General Court in *Intel* and the So-Called More Economic Approach to Abuse of Dominance' (2014) World Competition 37(4) 405, 417-418.

[62] See, e.g. Article 102 Guidance Paper (n56) paras 1, 5, 6 & 23; Johannes Laitenberger, 'Enforcing EU competition law: Principles, strategy and objectives' (44th Annual Conference on International Antitrust Law and Policy, Fordham University, New York City,

Furthermore, as pointed out by Luc Peeperkorn in his article, in addition to the fact that both Articles 101 and 102 TFEU refer to the welfare of consumers, there has been a tendency in recent Article 102 case law towards acknowledging 'the protection of competition for the benefit of consumers' as the main objective of EU competition law rules.[63] The emphasis on protecting the interests and welfare of consumers, both directly and indirectly through protecting the structure of effective competition is also clearly present in the Commission's decision in *Servier*.[64]

2.5.2 Abuse

Dominance in itself is not illegal.[65] However, by virtue of being dominant, 'a special responsibility not to allow its conduct to impair genuine undistorted competition on the common market' is imposed on dominant undertakings.[66] While the exact scope and meaning of this special responsibility often depends on the nature of and the circumstances on the relevant market, in practice, holding a dominant position means that a practice which is regarded lawful when implemented by a non-dominant undertaking, might be considered to infringe Article 102 TFEU if adopted by a dominant undertaking.[67] The underlying ratio is that a dominant undertaking should not be allowed to use its substantial economic strength to abuse such a position.

Article 102 TFEU does not define 'abuse' and while it does provide a list of examples of abusive behaviour in Article 102(2)(a)-(d), the list is non-

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15th September 2017) <www.ec.europa.eu/competition/speeches/text/sp2017_11_en.pdf> accessed 12 March 2018, p.6; Whish & Bailey (n1) 19 & 204.

[63] Peeperkorn refers to cases such as Case C-209/10 *Post Danmark A/S v Konkurrencerådet ('Post Danmark I')* EU:C:2012:172, paras 20 & 24; and Case C-23/14 *Post Danmark A/S v Konkurrencerådet ('Post Danmark II')* EU:C:2015:651, para 69. Peeperkorn (n61) 392. Furthermore, in *TeliaSonera*, the CJEU held that the Article 102 TFEU applies 'not only to practices which may cause damage to consumers directly […], but also to those which are detrimental to them through their impact on competition'. Case C-52/09 *Konkurrensverket v TeliaSonera Sverige AB* EU:C:2011:83, para 24.

[64] See, e.g. *Servier* (n7) paras 1151-1152, 2921, 2957, & 2997.

[65] Whish & Bailey (n1) 202.

[66] Case 322/81 *NV Nederlandsche Banden Industrie Michelin v Commission of the European Communitie ('Michelin I')* EU:C:1983:313, para 57.

[67] Cases C-395/96 P and C-396/96 P *Compagnie Maritime Belge Transports SA v Commission of the European Communities* EU:C:2000:132, para 114; Vivien Rose & David Bailey, 'Article 102' in Vivien Rose and David Bailey (eds), *Bellamy and Child: European Union Law of Competition* (7th edn, OUP 2013) para 10.057.

exhaustive.[68] The task of defining the concept of 'abuse' has been left to the EU Courts. There is no one case which would comprehensively define 'abuse', but in *Hoffman-La Roche*, the CJEU gave a definition which is commonly cited.[69] Abuse was defined by the CJEU as 'an objective concept relating to the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where, as a result of the very presence of the undertaking in question, the degree of competition is weakened and which, through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators, has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition'.[70]

This definition has been criticised, among other things, for the failure to capture exploitative abuses, i.e. practices which harm competition by exploiting consumers or other undertakings who are dependent on the dominant undertaking.[71] It does, however, capture exclusionary abuses, i.e. practices which restricts competition, for instance, by eliminating competitors and/or raising barriers to market entry for potential competitors. What is more, the case introduced the notion of competition on merits.[72] This language has been embraced by the EU Courts and the Commission to distinguish between practices which are considered to constitute lawful competition on merits and those 'abnormal' competitive practices that are abusive and unlawful under Article 102.[73]

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[68] See, e.g. Case 6/72 *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities* EU:C:1973:22, para 26; Case T-201/04 *Microsoft Corp. v Commission of the European Communities* EU:T:2007:289, para 860; Case C-280/08 *P Deutsche Telekom AG v European Commission* EU:C:2010:603, para 173.
[69] Case 85/76 *Hoffmann-La Roche & Co. AG v Commission of the European Communities* EU:C:1979:36; Whish & Bailey (n1) 208.
[70] *Hoffmann-La Roche* (n69) para 91.
[71] Whish & Bailey (n1) 208.
[72] Rose & Bailey (n67) para 10.064; Whish & Bailey (n1) 208.
[73] See, e.g. Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* EU:C:2012:770, para 75; *Servier* (n7) paras 2917 & 2942; Whish & Bailey (n1) 209.

2.5.2.1 Object and effect restrictions under Article 102 TFEU

Defining whether a certain practice by a dominant undertaking is abusive is not an easy task. Clearly distinguishing exclusionary conduct from competition on merits has proven to be especially challenging and the discussion over the true nature of Article 102 remains lively.[74] In the recent years, there has been an apparent trend towards adopting an effects-based analysis in Article 102 cases.[75] However, the case law is rather ambivalent in its approach to exclusionary abuses. In some cases[76], the EU Courts have stated the need to establish anticompetitive effects in order for the practice to be considered abusive, while in other cases[77], certain practices, which might be functionally equivalent to the first category, have been held to be *prima facie* abusive without the need to prove actual or likely foreclosure effects.[78]

Dr. Ibáñez Colomo argues in his article, that there is a logic behind the case law, if one considers the principles of and the object/effect distinction under Article 101 TFEU.[79] Dr. Ibáñez Colomo sets out a convincing argument that much like in the context of Article 101, some practices are considered abusive by their very nature, i.e. they are restrictive of competition 'by object' under Article 102 as well.[80] Practices falling within this category do not constitute competition on merits and they are considered to be highly likely to have adverse effects on competition and unlikely to have redeeming virtues. The Courts in these cases have held that there is no requirement to show anticompetitive effects, but instead, such effects can be presumed.

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[74] See, e.g. Pablo Ibáñez Colomo, 'Beyond the "More Economics-Based Approach": A Legal Perspective on Article 102 TFEU Case Law' (2016) C.M.L. Rev. 53 709; Peeperkorn (n61) 389; Wils, (n61); Patrick Rey & James S. Venit, 'An Effects-Based Approach to Article 102: A Response to Wouter Wils' (2015) World Competition 38(1) 3.

[75] Whish & Bailey (n1) 211.

[76] For refusal to deal, see e.g. Joined cases C-241/91 P and C-242/91 P *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities (Magill)* EU:C:1995:98. For margin squeezes, *Deutsche Telekom* (n68) paras 231 & 234; *TeliaSonera* (n63) paras 55-59.

[77] For exclusivity rebates, see *Hoffmann-La Roche* (n69) paras 89-90; Case C-78/70 *Intel Corp. v European Commission* EU:T:2014:547, paras 80-81. For predatory pricing, Case C-62/86 *AKZO Chemie BV v Commission of the European Communities* EU:C:1991:286, para 71.

[78] Ibáñez Colomo (n74) 714-720.

[79] Ibáñez Colomo (n74).

[80] Ibáñez Colomo (n74) 721-724. A similar argument is set out in Pablo Ibáñez Colomo and Alfonso Lamadrid de Pablo, 'On the notion of restriction of competition: what we know and what we don't know we know' (*SSRN*, 18 October 2016) <www.papers.ssrn.com/sol3/papers.cfm?abstract_id=2849831> accessed 22 April 2018.

Furthermore, like in Article 101 cases, the CJEU in *Intel* referred to the 'capability' of a practice to create anticompetitive foreclosure effects as a threshold for abusive conduct, meaning that a competition enforcer satisfies its burden of proof by showing that anticompetitive effects are plausible.[81]

The effects-based analysis, on the other hand, has been applied to practices which are plausible means of creating both pro- and anticompetitive effects in the legal and economic context in which they operate, which is why a more detailed analysis of the net effects of the practice is required.[82] Such analysis requires assessment of the counterfactual, i.e. had the practice in question not been implemented by the dominant undertaking, and assessment of whether the practice in question has affected or is likely to affect the ability and/or incentives of the competitors to compete.[83] Under the effects-based analysis, the threshold for finding an abuse is, thus, 'likelihood'.[84] Dr. Ibáñez Colomo argues that like in Article 101 cases, 'likelihood' is a much higher threshold than 'capability' which is applied in the context of by object infringements.[85]

In sum, just like in the context of Article 101 TFEU, the crucial difference between the two types of exclusionary abuses lies in the fact that in the case of by object abuses, anticompetitive and exclusionary effects can be presumed. Consequently, the competition enforcer's burden of proof is lightened and the burden shifted onto the defendant to demonstrate the incapability of the practice to have an adverse effect on competition. On the other hand, in the case of by effect abuses, competition law enforcer's burden of proof is much higher, as they are required to engage in a more detailed analysis of the relevant market and of the practice in question to show adverse effects on competition and consequently, to find an infringement of EU competition law.

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[81] *Intel* (n77) paras 138 & 141-143; Pablo Ibáñez Colomo, 'Comments on Case C-413/14 P, Intel: presumptions, effects-based analysis and open questions' (*Chillin'Competition*, 6 September 2017) <www.chillingcompetition.com/2017/09/06/comments-on-intel-presumptions-effects-based-analysis-and-open-questions/> accessed 22 March 2018.
[82] Ibáñez Colomo (n74) 724-726; Ibáñez Colomo & Lamadrid de Pablo (n80) p.45.
[83] Ibáñez Colomo & Lamadrid de Pablo (n80) p.45.
[84] Ibáñez Colomo & Lamadrid de Pablo (n80) pp. 34-36.
[85] Ibáñez Colomo (n81).

For these reasons, the CJEU stated in *Cartes Bancaires*, that in the context of Article 101, restrictions by object are to be reserved only for the most severe and obvious restrictions of competition.[86] The Court clarified that an object restriction is one which 'by [its] very nature [restricts] competition' and 'reveals in itself a sufficient degree of harm to competition'.[87] The Court also held that the object category is to be interpreted narrowly, and that experience and economic analysis are required for the establishment of an infringement.[88] Where the contextual analysis of an agreement does not reveal an anticompetitive object, the effects-based analysis is to be applied.[89] Since Articles 101 and 102 TFEU serve the same ends and the application of similar principles throughout Articles 101 and 102 brings coherence in the application of EU competition law rules, it is desirable to apply the *Cartes Bancaires* principles also in the context of Article 102 TFEU.[90]

[86] Case C-67/13 P *Groupement des cartes bancaires (CB) v European Commission* EU:C:2014:2204.
[87] C*artes Bancaires* (n86) para 125.
[88] C*artes Bancaires* (n86) paras 51 & 58.
[89] C*artes Bancaires* (n86) para 52.
[90] *Continental Can* (n68) para 26; Ibáñez Colomo (n74) 727 & 739; Peeperkorn (n61).

3 REVERSE PAYMENT SETTLEMENTS IN THE EU

3.1 Reverse payment settlement cases in the EU

After the Final Report on the Pharmaceutical Sector Inquiry was published in 2009, the Commission has continued monitoring patent settlements in the pharmaceutical industry.[91] So far, the Commission has adopted three decisions involving reverse payment settlements between pharmaceutical companies: *Lundbeck (Citalopram)*[92], *Fentanyl*[93] and *Perindopril (Servier)*. The Commission decisions in *Lundbeck* and in *Servier* were appealed to the GC, respectively. The GC delivered its first judgement concerning pharmaceutical reverse payment settlements in *Lundbeck v Commission* on 8 September 2016, fully confirming the Commission's findings in *Lundbeck.*[94] *Servier* is still pending before the GC. In addition, the Commission is currently in the process of investigating a patent settlement between a US-based originator, Cephalon, Inc., and an Israel-based generic, Teva Pharmaceutical Industries Ltd., concerning Modafinil, a drug used to treat certain sleeping disorders, such as narcolepsy.[95]

As said in the introduction, the focus of these cases has been generally on the collusive nature of the settlement agreements. At the moment, *Servier* is the first and only Commission decision concerning pharmaceutical reverse payment settlements where, in addition to finding an Article 101 TFEU

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[91] Reports on the monitoring of patent settlements and other material related to the Pharmaceutical Sector Inquiry are available at: Commission, 'Pharmaceuticals: Sector inquiry and follow-up' (*European Commission*, 9 March 2018) <www.ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/> accessed 8 April 2018.

[92] *Lundbeck* (n50).

[93] *Fentanyl* (CASE AT.39685) Commission decision of 10.12.2013 C(2013) 8870 final. Summary of Commission Decision of 10 December 2013 relating to a proceeding under Article 101 of the Treaty on the Functioning of the European Union (Case AT.39685 — Fentanyl) (2015/C 142/10) [2015] OJ C 142/21.

[94] *Lundbeck v Commission* (n59); Commission, 'Antitrust: Commission welcomes General Court judgments upholding its Lundbeck decision in first pharma pay-for-delay case' [2016] MEMO/16/2994, available at <www.europa.eu/rapid/press-release_MEMO-16-2994_en.htm > accessed 22 April 2018.

[95] Commission, 'Antitrust: Commission opens investigation against pharmaceutical companies Cephalon and Teva' [2011] IP/11/511, available at <www.europa.eu/rapid/press-release_IP-11-511_en.htm> accessed 17 April 2018. Materials related to the Cephalon and Teva investigation are available at: Commission, 'Antitrust/Cartel cases: 39686 Cephalon' (*European Commission*) <www.ec.europa.eu/competition/elojade/isef/case_details.cfm?proc_code=1_39686> accessed 27 April 2018.

infringement, the Commission also targeted Servier's unilateral conduct as a dominant undertaking under Article 102 TFEU. As the topic of this thesis relates to the treatment of reverse payment settlements under Article 102 TFEU, the *Lundbeck* and *Fentanyl* decisions will not be discussed in detail.

Reverse payment settlements have also attracted the attention of competition authorities on a national level. In 2016, the UK CMA delivered a decision against an originator, GlaxoSmithKline plc. ('GSK') for breaches of the Chapter I prohibition[96] and the Chapter II prohibition[97] of the Competition Act 1998.[98] The CMA decision was appealed to the CAT which subsequently referred the case to the CJEU for a preliminary reference.[99]

This chapter will first briefly describe the facts in *Servier* and in the UK case *Paroxetine*, after which the argumentation in these cases will be examined. The focus will be on the Commission's argumentation in *Servier* and reference to the CMA's findings in *Paroxetine* will be made mainly for comparative purposes.

3.2 Facts in *Servier* & in *Paroxetine*

The *Servier* decision concerned perindopril, which is the active ingredient of a French originator company, Les Laboratories Servier's ('Servier') blockbuster cardiovascular medicine used to treat conditions such as high blood pressure and heart failure.[100] Revenue from the sale of perindopril accounted for a large portion of Servier's total turnover and the company described the drug as its 'dairy-cow-product' in its internal strategy

[96] The Chapter I of the Competition Act 1998 targets anticompetitive agreements and is the UK equivalent of the EU Article 101 TFEU.
[97] The Chapter II of the Competition Act 1998 concerns abuse of a dominant position and is the UK equivalent of the EU Article 102 TFEU. Hereafter, whenever this thesis refers to Article 102 TFEU in the context of the *Paroxetine* decision, it also includes the Chapter II prohibition. Whish & Bailey (n1) 384.
[98] *Paroxetine* (n8); Competition and Markets Authority, 'Press release: CMA fines pharma companies £45 million' (*GOV.UK*, 12 February 2016) <www.gov.uk/government/news/cma-fines-pharma-companies-45-million> accessed 12 April 2018.
[99] *GlaxoSmithKline PLC v Competition and Markets Authority* [2018] CAT 4. Materials related to the case are available at: CAT, 'Cases: 1252/1/12/16 GlaxoSmithKline PLC v Competition and Markets Authority' (*Competition Appeal Tribunal*) <www.catribunal.org.uk/237-9158/1252-1-12-16-GlaxoSmithKline-PLC.html> accessed 20 March 2018.
[100] *Servier* (n7) para 2144.

documents.[101] The primary patent covering the perindopril molecule had expired for the most part across Europe in 2003.[102] Servier still held several secondary process patents but these provided weaker protection to perindopril and the company no longer had exclusivity over the production and sales of perindopril.[103]

Around the time of the expiry of Servier's primary patent, several generic companies were preparing for market entry by attempting to get access to non-infringing manufacturing technologies and by challenging Servier's secondary patents. As a response, Servier started preparing a strategy to defend itself against the drastic price decreases and sales volume drops which would result from widespread generic entry. This strategy had several elements, including the creation of patent clusters[104], tightening technical standards in the European Pharmacopoeia, and product hopping[105].[106]

Despite the patent clusters and the stricter technical standards, a number of generic companies continued their efforts to develop non-infringing manufacturing technologies and to enter the market with their generic perindopril.[107] Because of this, Servier implemented, within the broader strategy, a narrower, 'targeted exclusionary strategy […] to remove, before market entry, all close sources of competitive threats on the up- and down-stream markets for perindopril with the potential to overcome notably the patent and regulatory barriers'.[108]

Subsequently, Servier began acquiring alternative manufacturing processes and the accompanying IPRs from its potential generic

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[101] *Servier* (n7) paras 103 & 105.
[102] *Servier* (n7) paras 93 & 95 (Table 2).
[103] *Servier* (n7) para 94 (Table 1).
[104] One of the patents filed by Servier in relation to the patent clusters was the '947 patent, which was described by generic companies as the biggest obstacle for the development of generic perindopril. The '947 patent was eventually revoked in the UK by the Court of Appeal in 2008 and the EPO annulled the patent in 2009. See, *Servier* (n7) paras 124-126.
[105] Product hopping is used to refer to a practice whereby an originator introduces a second-generation version of a brand-name drug to the market with the intention to withdraw the first-generation drug from the market as part of the late lifecycle strategy of the drug. As a consequence, depending on the national regulatory system, substitution of the brand-name product to a generic drug by pharmacists is made impossible or at least significantly more difficult.
[106] *Servier* (n7) paras 4, 8, 106, 107, 115, 118, 132 & 218.
[107] *Servier* (n7) paras 139 & 140.
[108] *Servier* (n7) para 2793.

competitors.[109] In particular, Servier purchased an alternative technology and the related know-how from a Swiss company, Azad (the 'Azad Technology Acquisition'), which, according to Servier's assessment, did not infringe any of Servier's patents. [110]

Regardless of the above, some generics still carried on with their attempts to enter the market by challenging Servier's patents before various courts. However, whenever a generic came close to succeeding, Servier and the generic in question reached a settlement.[111] Servier concluded a total of five settlement agreements with the generic companies it considered to be its closest competitors.[112] Under the settlements, Servier paid significant sums, or other inducements, to the generic companies, in exchange for a contractual promise by the generics not to challenge Servier's secondary patents and to stay out of the market for the duration of the agreements.[113] Under one of the agreements, instead of a cash payment, Servier offered the generic in question a licence for seven national markets, provided that the generic company agreed to cease its efforts to enter all other EU markets.[114]

The CMA decision, *Paroxetine,* concerned GSK's bestselling antidepressant medicine.[115] Much like in *Servier*, the primary patent for the paroxetine molecule had expired, but GSK still held several process patents and at that time, generic companies were attempting to enter the paroxetine market.[116] GSK brought infringement actions against two of these companies.[117] However, instead of litigating the case all the way through, GSK and the generics settled the disputes. Under the settlement agreements, GSK agreed to make payments and other value transfers to the generics, and in return, the generics agreed to stop their efforts to enter the market for the duration of the agreements.[118] Additionally, GSK entered into an agreement with a third generic company prior to initiating legal proceedings against the

[109] *Servier* (n7) para 141.
[110] *Servier* (n7) paras 145, 369 & 2820.
[111] *Servier* (n7) para 7.
[112] Servier concluded agreements with Niche/Unichem, Matrix (now part of Mylan), Teva, Krka and Lupin. See, *Servier* (n7) paras 7 & 2123-2127.
[113] *Servier* (n7) e.g. paras 7, 174 & Section 4.3.
[114] *Servier* (n7) para 7.
[115] *Paroxetine* (n8) paras 1.4 & 3.22.
[116] *Paroxetine* (n8) para 1.5.
[117] Generics (UK) Limited ('GUK') and Alpharma Limited.
[118] *Paroxetine* (n8) para 1.8.

generic.[119] Under this agreement, the generic agreed to abandon its efforts to enter the market independently of GSK and to distribute limited amounts of GSK's paroxetine product. Again, in exchange, GSK made significant value transfers, including cash payments, to the generic.[120]

3.3 Article 102 TFEU infringements

While Servier's anti-generic strategy had several different elements, the Commission concluded that Servier's narrow strategy deviated from competition on merits in breach of Article 102 TFEU. The strategy, which comprised of acquiring competing technologies and concluding patent settlements with its generic competitors, constituted 'a single and continuous infringement' of Article 102 TFEU and breached the special responsibility imposed on the company as a dominant undertaking.[121] The Commission imposed a fine of almost €331 million on Servier for breaches of Articles 101 and 102 TFEU.[122]

In *Paroxetine*, the agreements concluded by GSK were held to amount, in themselves, to an abuse of a dominant position in breach of EU and UK competition law rules and the GSK received a fine of over £37.6 million.[123]

3.3.1 Abuse

The Commission commenced its assessment of Servier's practices by stating that generally, a strategy protecting an originator's market position against generic entry is legitimate 'to the extent it resorts to measures representing competition on the merits (competition on product quality, strength of the patented technologies and similar)'.[124] The Commission, thus, acknowledged that a dominant undertaking is, as a general rule, allowed to have a 'broad' strategy to protect its commercial interests against the effects

[119] Norton Healthcare Limited which traded in the UK as IVAX Pharmaceuticals UK.
[120] *Paroxetine* (n8) para 1.7.
[121] *Servier* (n7) para 2996. The Commission set out the general principles for finding an abuse of a dominant position under Article 102 TFEU as laid down in the CJEU's settled case law in *Servier* (n7) paras 2759-2762.
[122] Commission (n44).
[123] Competition and Markets Authority (n98).
[124] *Servier* (n7) para 2766.

of early generic entry. The Commission then went on to emphasise that 'a narrower strategy […], which, in the context of Servier's special responsibility as a dominant undertaking, [deviates] from competition on the merits and [is] capable of producing foreclosure effects will not be immune to antitrust scrutiny'.[125]

In the Commission's view, Servier had both broad and narrow anti-generic strategies.[126] The Commission makes the distinction between the two types of anti-generic strategies explicitly, and hence, distinguishes lawful competition on merits from unlawful exclusionary behaviour, but at times the line between the two appears fairly blurred in the decision.[127] The Commission refers to the creation of patent clusters and the raising of technical standards as part of Servier's broader strategy.[128] When these actions did not have a desirable effect on the activities of the generic companies, Servier implemented a narrower strategy comprising of the patent settlements and of the Azad Technology Acquisition.

3.3.1.1 Azad Technology Acquisition in Servier

The Commission began its assessment of the Azad Technology Acquisition by stating that '[t]echnology transfers whereby one firm acquires technology from another firm are usually pro-competitive in that they can help to diffuse the use of that technology'.[129] In fact, the Commission emphasised on several occasions that the Azad Technology Acquisition did not constitute a separate abuse but that it '[contributed] to the foreclosure effect of the overall single infringement of Article 102 of the Treaty'.[130] The Commission concluded that the effects of the Azad Technology Acquisition could not be isolated from those of the reverse payment settlements which pursued the objective of delaying generic entry.[131]

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[125] *Servier* (n7) para 2766.
[126] *Servier* (n7) paras 2766, 2773 & 2793.
[127] The Commission emphasises throughout the decision the complementary nature of the practices and the two types of strategies. See, e.g. *Servier* (n7) para 2777; Sophie Lawrance, Elisabetta Rotondo, and Pat Treacy, 'IP and Competition: A Survey of Developments' (2016) J.C.E.L. & Pract. 7(3) 227, 236.
[128] *Servier* (n7) paras 2770-2771.
[129] *Servier* (n7) para 2799.
[130] *Servier* (n7) para 2802.
[131] *Servier* (n7) para 2802.

The Commission argued that Servier's acquisition of Azad's technology obstructed the development and growth of competition in the perindopril active pharmaceutical ingredient ('API') technology market and of the potential supply of non-infringing perindopril API.[132] By acquiring the technology, which was considerably more advanced than the other non-infringing technologies being developed at the time, Servier successfully excluded a number of generic projects from entering the market, thus, forcing them to start again from scratch.[133] The Commission concluded that the Azad technology was acquired for the sole purpose of '[strengthening] the defense mechanism' for perindopril and removing it from the market as a non-infringing alternative to Servier's own technologies.[134] As there were only few patent-free manufacturing processes at the time, generic entry was delayed and some generic companies were prevented from entering the market as a result of the acquisition.[135]

3.3.1.2 Reverse payment settlements in *Servier*

The five patent settlement agreements which were the basis of the Commission's finding of the object and effect infringement of Article 101 TFEU, were also subjected to competition law scrutiny under Article 102 TFEU. The Commission's argument was that by persistently and systematically concluding the five reverse payment settlements, Servier used its substantial economic strength to induce almost all of its immediate generic competitors to refrain from entering the perindopril market.[136]

The Commission argued that there was a 'distinct unilateral aspect' to the agreements, 'based on the fact that Servier used its market power in order to induce a number of close generic threats to withdraw from competition with Servier', which justified the parallel application of Articles 101 and 102 TFEU.[137] Several considerations were relevant in the Commission's opinion in establishing the additional unilateral element. The Commission referred to

[132] *Servier* (n7) para 2917.
[133] *Servier* (n7) para 2917.
[134] *Servier* (n7) paras 144 & 150.
[135] *Servier* (n7) paras 6 & 140.
[136] *Servier* (n7) para 2960.
[137] *Servier* (n7) paras 2923-2925 & 2931.

the fact that the patent settlements were the result and an expression of Servier's strategy to use all means at its disposal to prevent or at least delay the market entry of generic perindopril.[138] Additionally, as the owner of the key patents, Servier was in a unique position to devise an exclusionary strategy consisting of conclusion of the agreements.[139] The Commission also used this as a feature to distinguish Servier's role in the conclusion of the agreements from that of the generic companies.[140] Furthermore, the conclusion of this chain of settlement agreements, which 'systematically targeted' Servier's closest potential competitors, was made possible in the Commission's opinion by Servier's almost monopolistic market position in the perindopril market and the Commission stated that Servier had used the substantial profits from its sales of perindopril to pay off its generic competitors.[141] Finally, the Commission found that the cumulative and self-reinforcing effect of the agreements, which was greater than the effect of each individual agreement, and which was made possible by Servier's strong market position, fell outside competing on merits.[142]

In light of Servier's strong market position and the limited competition on the market for perindopril formulations, the Commission concluded that these reverse payment settlements were *capable* of delaying generic entry and prolonging Servier's strong market position on the relevant markets to the detriment of the consumers.[143] Servier, by systematically targeting its generic competitors was able to stop all close potential competitors from challenging its patents before courts and avoided the risk of having its patents revoked.[144] In the absence of objective justifications for the settlement agreements, the Commission concluded that the conclusion of the agreements was abusive behaviour forming a constitutive element of Servier's narrow strategy.[145]

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[138] *Servier* (n7) paras 2933 & 2936.
[139] *Servier* (n7) paras 2933, 2993 & 2934.
[140] *Servier* (n7) para 2935.
[141] *Servier* (n7) paras 2933, 2937 & 2945.
[142] *Servier* (n7) paras 2933 & 2942.
[143] *Servier* (n7) paras 2943-2944, 2953-2957 & 2960.
[144] *Servier* (n7) paras 2945 & 2953.
[145] *Servier* (n7) paras 2958-2960.

3.3.1.3 The combined effect of Servier's abusive practices & the single and continuous infringement of Article 102 TFEU

The Commission's emphasis on the 'complementary' and 'intertwined' nature of the Azad Technology Acquisition and the patent settlements is clear throughout its analysis of the Article 102 TFEU infringement in that they 'worked together in a consistent way to remove […] sources of competition'.[146] While the elements of Servier's broader strategy were held not to contribute to the foreclosure effects, the Commission still considered them to be relevant for its assessment under Article 102, as it helped explain why competition from potential generic entrants was particularly limited and why Servier was able to close the remaining avenues of entry available to the generics by implementing its narrow exclusionary strategy.[147]

In the Commission's opinion, this strategy had the objective of excluding competitive threats on the relevant markets and had a significant effect on the structure of competition on the perindopril market and each transaction was held to make sense only in light of the overall strategy.[148] The Commission concluded that the combination of the reverse payment settlements and the Azad Technology Acquisition constituted a 'single and continuous exclusionary strategy […] *capable* of producing foreclosure effects' (emphasis added) on the relevant markets, deviating from normal competition on merits, and thus, amounting to an abuse of a dominant position under Article 102 TFEU.[149]

3.3.2 Abuse in *Paroxetine*

In *Paroxetine*, the CMA found that the reverse payment settlements were, in themselves, abusive and in violation of Article 102 TFEU. The CMA argued that the GSK had engaged in methods different to those which are characteristic to 'normal competition' by making payments and other value transfers, and thereby had induced the generics to refrain from challenging

[146] *Servier* (n7) para 2965. For references to the 'complementary' and 'intertwined' nature of the agreements, see, e.g. *Servier* (n7) paras 2777, 2783, 2794, 2802 & 2919.
[147] *Servier* (n7) paras 2772 & 2971.
[148] *Servier* (n7) paras 2987 & 2997.
[149] *Servier* (n7) paras 2987 & 2997.

GSK's market position in the market for paroxetine.[150] Like in *Servier*, GSK's conduct was held to deviate from its special responsibility as a dominant undertaking and the CMA concluded that GSK's conduct, lacking an objective justification, 'tended to restrict competition or was *capable* of having that effect' (emphasis added).[151]

In addition to stating that the agreements were capable of having anticompetitive effects on the market, the CMA also analysed, 'for completeness', the likely effects of the agreements on competition in light of the counterfactual.[152] The CMA concluded that had it not been for the agreements, the generics would have continued with their efforts to challenge GSK's patents in courts and to enter the market for paroxetine independently of GSK, or alternatively, GSK and the generics would have settled on less restrictive terms which would have represented the uncertainty regarding the strength of GSK's patents and the outcome of the patent litigation.[153] It should be noted, however, that in its assessment of the counterfactual, the CMA did not consider the possibility of the GSK prevailing in litigation.

3.4 What do we know based on current case law?

The *Servier* decision has faced quite a lot of criticism from a number of authors. Hull and Clancy have suggested that the Commission 'went out of its way to construct an abuse' and the single and continuous infringement consisting of a combination of two distinct practices.[154] They also considered that the approach taken by the Commission in applying Article 102 TFEU to reverse payment settlements was rather 'robust'.[155] Others have questioned the Commission's decision to apply Articles 101 and 102 TFEU concurrently to the agreements, and argued that the Commission failed to clearly identify the additional, unilateral aspect justifying the parallel application of Articles

[150] *Paroxetine* (n8) para 8.36.
[151] *Paroxetine* (n8) para 8.36.
[152] *Paroxetine* (n8) paras 8.37-8.56.
[153] *Paroxetine* (n8) para 8.52.
[154] David W. Hull and Michael J. Clancy, 'The Application of EU Competition Law in the Pharmaceutical Sector' (2017) J.E.C.L. & Pract. 8(3) 205, 207.
[155] Hull & Clancy (n154) 218.

101 and 102 TFEU.[156] It has also been pointed out that 'the circumstances under which a pharmaceutical company will abuse its dominant position are not clear', which is of course highly unfortunate from a legal certainty perspective, and makes it very difficult for originator companies in a dominant position to settle patent disputes without the risk of facing competition law liability.[157]

The decisions in *Servier* and in *Paroxetine* are currently the only cases in which Article 102 TFEU has been applied to reverse payment settlements in the pharmaceutical sector. Ska, Werner & Paul suggest that this approach may be explained by the specific facts and features of these cases, and indeed, the Commission was explicit in stating in *Servier* that the finding of the abuse was limited to the specific circumstances of this case.[158] The case, therefore, does not create a precedent or a set of general principles applicable to pharmaceutical patent settlement agreements in the context of Article 102 TFEU.[159]

Nonetheless, the decisions do shed light on the way settlement agreements involving significant reverse payments from an originator to a generic are likely to be treated in the future, as the case law shows the competition authorities' determination to weed out such settlements from the pharmaceutical sector. In *Servier*, the Commission concluded that the abuse of a dominant position comprised the combination of the reverse payment settlements and the Azad Technology Acquisition. The Commission did not identify either practice as a separate abuse but found that they constituted a single and continuous infringement of Article 102, emphasising the complementary nature of the practices throughout the decision. In *Paroxetine*, on the other hand, the CMA found the agreements themselves to amount to an abuse in breach of Article 102 TFEU. It is, therefore, unclear whether reverse payment settlements should, in themselves, fall within the scope of Article 102 TFEU.

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[156] Lawrance and others (n127) 236; Nathalie Ska, Philipp Werner & Christian Paul, 'Pay-for-delay Agreements: Why the EU Should Judge them by their Effects' (2017) J.E.C.L. & Pract. 8(7) 437, 449.
[157] Ska and others (n156) 450.
[158] *Servier* (n7) para 2996.
[159] *Servier* (n7) para 2996.

In both cases the significant reverse payments and other value transfers from the originators were held to induce the potential generic competitors to withdraw from competition, and thus, to fall outside lawful competition on merits in breach of the special responsibility imposed on Servier and GSK as dominant undertakings.[160] Both the Commission and the CMA referred to the 'capability' of the dominant undertakings' conduct to create foreclosure effects on the relevant market, which is suggestive of the adoption of the 'by object' approach to the assessment of the settlement agreements under Article 102 TFEU.[161] Furthermore, the Commission did not analyse the effects of the agreements in light of the counterfactual but held that from an *ex ante* perspective the reverse payment settlements were capable of having adverse effects on competition, which further supports the author's submission that the Commission and the CMA adopted an object-based approach to their assessments of the abuses.[162]

Several authors have criticised the Commission and the GC's decisions to apply the object-based analysis to reverse payment settlements under Article 101 due to the fact that the settlement agreements are closely linked to the originator's patents.[163] In light of the discussion in the previous chapter, the author of this thesis will now turn to consider whether reverse payment settlements should, in themselves, be subjected to competition law scrutiny under Article 102 TFEU, and what would be the most suitable test for assessing such agreements.

[160] *Servier* (n7) paras 2926 & 2942; *Paroxetine* (n8) para 8.36.
[161] See, e.g. *Servier* (n7) paras 2943-2944, 2953-2957, 2960 & 2979; *Paroxetine* (n8) para 8.36.
[162] *Servier* (n7) para 2973.
[163] See, e.g. Ska and others (n156); Schröder (n6).

4 REVERSE PAYMENT SETTLEMENTS AS A FORM OF ABUSE

4.1 The significance of balancing competition and patent law considerations

Before discussing whether Article 102 TFEU should be applicable to reverse payment settlements and what would be the most suitable legal test for assessing their legality, it should be noted that both competition and patent law considerations should have a role to play in the assessment. Despite the *prima facie* conflict between the policy objectives of competition and IP laws, it has been acknowledged by both scholars and competition law authorities that competition and patent laws have the same ultimate goals.[164] The importance of finding the right balance between the two areas of law can be demonstrated by contemplating the notions of static and dynamic efficiency. Curzon Price and Walker argue that competition law often puts too much weight on considerations of static efficiency, such as price reductions and increases in output. At the same time, the benefits created by increasing dynamic efficiency, which is predominantly concerned with promoting innovation and is measured in terms of growth in the number of new products and improved quality, are effectively ignored.[165]

There is an argument that if static and dynamic efficiency were alternative policy objectives, dynamic efficiency should be given precedence as the benefits from dynamic efficiency are often more substantial and valuable to the public and consumers in the long term.[166] This, however, does not mean absolute immunity from competition law rules.[167] Putting too much weight on protecting and rewarding innovation might lead to rent-protecting activities, which is both dynamically and statically inefficient, and hence, undesirable from both competition law and patent law perspectives.[168] While the role of competition law cannot be underestimated, both considerations are important and as Curzon Price and Walker state in their article, the

[164] Whish & Bailey (n1) 812.
[165] Tony Curzon Price & Mike Walker, 'Incentives to Innovate v Short-term Price Effects in Antitrust Analysis' (2016) J.E.C.L. & Pract. 7(7) 475, 475-476.
[166] Curzon Price & Walker (n165) 475.
[167] Curzon Price & Walker (n165) 477.
[168] Curzon Price & Walker (n165) 478-479.

fundamental question for competition policy is finding the right level of reward for innovation.[169]

4.2 Effects of reverse payment settlements as a unilateral practice: Are they abusive in themselves?

For a practice implemented by a dominant undertaking to be considered abusive, it needs to have a restrictive effect on competition.[170] As discussed in chapter 2, that effect may either be presumed, as is the case when it comes to by object infringements, or, in case of by effect infringements, the likely effects of the practice must be demonstrated by a competition authority.

It was also pointed out above in chapter 2 that, in Europe, the grant of a marketing authorisation does not depend on economic considerations such as the existence of patents. It thus allows 'at risk' market entry by generic companies, meaning that despite having obtained a marketing authorisation, a generic company might still face patent infringement claims from an originator and be prevented from entering the market.[171] Furthermore, since it is open for anyone to challenge patents at any time, concluding a settlement with one generic does not prevent others from challenging the originator's patents and from entering the market insofar as they fulfil the necessary drug safety and effectiveness requirements.[172]

In Europe, eliminating competition on the relevant market would, therefore, require paying off all potential generic competitors.[173] Achieving full foreclosure on the market is extremely difficult, if not nearly impossible, even though the pharmaceutical sector in Europe is often very concentrated.[174] Dr. Gallasch points out in his article the difficulty of relying

[169] Curzon Price & Walker (n165) 479.
[170] Ibáñez Colomo & Lamadrid de Pablo (n80) p.2.
[171] *Servier* (n7) para 75.
[172] In *Lundbeck v Commission*, 'at risk' entry was held not to be illegal in itself. *Lundbeck v Commission* (n59) para 122; Sven Gallasch, 'A new dimension to EU pharma antitrust product hopping and unilateral pay for delay' (2016) Euro. C.J. 12(1) 137, 143.
[173] This is in stark comparison to the situation in the United States where the regulatory framework enables an originator to effectively foreclose the entire relevant market by settling a patent dispute with the first generic company to attempt market entry. See, Sven Gallasch, 'Activating Actavis in Europe – the proposal of a 'structured effects-based' analysis for pay-for-delay settlements' (2016) Legal Studies 36(4) 683, 702-703; Jacob (n30) 222; Clancy and others (n35) 156.
[174] Final Report (Executive Summary) (n57) p.18

on the conclusion of reverse payment settlements as a stand-alone strategy.[175] Often there are more than one generic company prepared to challenge the originator's patents in courts.[176] In addition, there are other generics which do not have the resources to litigate patent disputes in courts, but instead, are waiting for someone else to clear the way for market entry.[177]

If generic competitors were to enter the market all at once, concluding reverse payment settlements with all of them might be a viable option for an originator to foreclose the market. As Kades points out, paying off several competitors simultaneously might, in fact, be cheaper for the originator than concluding a reverse payment settlement with just one generic company.[178] This conclusion derives from the atypical nature of the pharmaceutical market. The originator and the generics are essentially producing identical products, and therefore, due to the general indifference of consumers to the brand of medicinal products, wide-spread generic entry will drown the price of the product as well as the profit margins of the pharmaceutical companies.[179]

However, such a scenario is unlikely, and in most cases, the generics enter the market one by one.[180] Generics, just like the originators, have their own commercial interests to protect and their actions, too, are driven by the possibility of profits. Thus, the first generic entrant is likely to set its price level as close to the originator's prices as possible to reap bigger profits.[181] In order to induce the generic to withdraw from competition, the value transfer

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[175] Gallasch (n172) 143.
[176] Gallasch (n172) 143.
[177] Jorge Padilla & Valérie Meunier, 'Should Reverse Payment Patent Settlements Be Prohibited per se? (*SSRN*, 8 May 2015) <www.papers.ssrn.com/sol3/papers.cfm?abstract_id=2604071> accessed 3 May 2018, pp.9-10.
[178] Michael Kades, 'Whistling Past the Graveyard: The Problem with the Per Se Legality Treatment of Pay-for-Delay Settlements' (2009) Competition Policy International 5 143, 158; Sven Gallasch, 'The Anticompetitive Misuse of Intellectual Property Rights in the European Pharmaceutical Sector' (DPhil thesis, University of East Anglia 2014) available at: <www.ueaeprints.uea.ac.uk/50554/1/Sven_Gallasch_-_4170733_-_PhD_Thesis_-_The_anticompetitive_misuse_of_intellectual_property_rights_in_the_European_pharma~1.pdf> accessed 21 April 2018, p.99.
[179] Kades (n178) 158.
[180] Gallasch (n178) p.99.
[181] Robin Jacob, 'Patents and Pharmaceuticals – a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry' (Public presentation of preliminary findings, Brussels, 28 November 2008) <www.ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf> accessed 26 April 2018, p.5.

would have to correspond to the generic's expected profits, which in case of the first generic entrant would be almost as high as those of the originator. For the originator, the problem here is that after settling with the first generic company, it will face the same situation with the second generic challenger and so on.[182] Therefore, depending on the structure of the market, the cost of relying on reverse payment settlements as a stand-alone strategy to achieve market foreclosure in this scenario would be a rather expensive one.

In sum, achieving full market foreclosure by relying exclusively on a strategy consisting of reverse payment settlements is a highly unlikely. Instead of market foreclosure, a delay in generic entry is the more likely consequence of reverse payment settlements. Depending on the structure of the market, it is arguable that concluding reverse payment settlements with just one or two generic companies would have a rather small effect on the market.

While Article 101 TFEU is primarily concerned with restrictions that have an appreciable effect on competition, the CJEU has been explicit in stating that there is no *de minimis* doctrine under Article 102.[183] This makes sense when one considers the underlying ratio of the *de minimis* doctrine. The doctrine allows competition authorities to presume that where the parties involved have little power on the relevant market and their economic strength is weak, an agreement between the parties is unlikely to have anticompetitive effects.[184] It, therefore, follows logically that since Article 102 TFEU is triggered when an undertaking is dominant on the relevant market, i.e. it enjoys 'a position of economic strength'[185], and the degree of competition on the market is already weakened as a result of the presence of that undertaking, it can be safely presumed that the undertaking's practices are likely to have appreciable effects on the market.[186]

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[182] Gallasch (n 178) p.100.
[183] Case 5-69 *Franz Völk v S.P.R.L. Ets J. Vervaecke* EU:C:1969:35; Case C-226/11 *Expedia Inc. v Autorité de la concurrence and Others* EU:C:2012:795, para 37; *Post Danmark II* (n63) paras 70-73; Commission, 'Communication from the Commission — Notice on agreements of minor importance which do not appreciably restrict competition under Article 101(1) of the Treaty on the Functioning of the European Union (De Minimis Notice)' [2014] OJ C 291/1; Whish & Bailey (n1) 148; Ibáñez Colomo & Lamadrid de Pablo (n80) p.37.
[184] Ibáñez Colomo & Lamadrid de Pablo (n80) p.37.
[185] *United Brands* (n60) para 65.
[186] Ibáñez Colomo & Lamadrid de Pablo (n80) p.38.

Whereas the CJEU in *Post Danmark II* stated that, in principle, any practice by a dominant undertaking may constitute an abuse, the Court further clarified recently in *Meo* that not every disadvantage to competitors, which results from a practice implemented by a dominant undertaking, amounts to an infringement of Article 102.[187] Dr. Ibáñez Colomo and Lamadrid de Pablo argue in their article that a practice implemented by a dominant undertaking tends to fall within Article 102 when it has adversely affected, or is likely to affect, competitors' incentives and ability to compete on the market, which then has an adverse effect on the welfare of consumers.[188]

Based on the considerations above, the author of this thesis agrees with the Commission's argumentation in *Servier* in that reverse payment settlements may delay generic entry, rather than cause exclusionary effects in themselves. However, in light of the special responsibility of a dominant company, the author submits that Article 102 TFEU could be triggered in situations where a dominant undertaking, with considerable economic strength and financial resources, pursues a unilateral strategy consisting of a systematic and persistent conclusion of reverse payment settlements with its generic competitors. Such a strategy can cause significant delays, and thus, have a negative impact on consumers even if the market foreclosure is not full and permanent. Especially where the market is particularly concentrated, the impact of concluding several settlements on the relevant market might be considerable.

4.3 Unilateral element justifying the application of Article 102 TFEU

In accordance with the CJEU's case law, Articles 101 and 102 TFEU can be applied in parallel to agreements between two undertakings.[189] However, in *Tetra Pak*, the GC held that the Commission must demonstrate

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[187] Case C-525/16 *MEO – Serviços de Comunicações e Multimédia SA v Autoridade da Concorrência* EU:C:2018:270, paras 26 & 30; Pablo Ibáñez Colomo, 'Case C-525/16, Meo – Serviços de Comunicações e Multimédia: a major contribution to Article 102 TFEU case law' (*Chillin'Competition*, 20 April 2018) <www.chillingcompetition.com/2018/04/20/case-c-525-16-meo-servicos-de-comunicacoes-e-multimedia-a-major-contribution-to-article-102-tfeu-case-law/> accessed 25 April 2017.

[188] Ibáñez Colomo & Lamadrid de Pablo (n80) p.41.

[189] The Commission relied on cases like *Compagnie Maritime Belge* (n67) para 33, *Hoffmann-La Roche* (n69) para 116 & T-83/91 *Tetra Pak International SA v Commission of the European Communities* EU:T:1994:246, paras 21, 25 and 30. Servier (n7) para 2917.

the existence of an additional element which distinguishes the two breaches from each other.[190] The purpose of this additional element, which needs to be external to the agreements under scrutiny, is to prevent the Commission from merely recycling the elements of an Article 101 TFEU infringement in its assessment of the agreement under Article 102 TFEU.[191]

The author submits, based on the Commission's argumentation in *Servier*, that establishing that reverse payment settlements are part of a unilateral strategy on part of the dominant undertaking would be sufficient to satisfy the requirement of an 'additional element'.[192] As found by the Commission in *Servier*, the generics operating on the relevant market are generally aware of the activities of the originator.[193] In accordance with the Commission's findings, the existence of such a unilateral strategy might put pressure on the generic companies to agree to stay out of the market in exchange for a value transfer. Furthermore, as was established above, concluding several subsequent reverse payment settlements is likely to be extremely costly for an originator, and therefore, only an originator in a dominant position and with vast financial resources would be able to rely on such a strategy, making it easy to establish a causal link between the practice and the undertaking's strong economic position on the market.[194]

4.4 Reverse payment settlements: Abusive by object?

As established in the previous chapter, both in *Servier* and in *Paroxetine*, 'capability' of the agreements to have restrictive effects on competition was used as the relevant threshold for satisfying the competition authorities' burden of proof. It was argued above that this is suggestive of the Commission and the CMA adopting an object-based approach towards assessing the agreements under Article 102 TFEU, even though the CMA also assessed the likely effects of the agreements.

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[190] *Servier* (n7) para 2931.
[191] *Servier* (n7) para 2931.
[192] Case T-51/89, *Tetra Pak Rausing SA v Commission of the European Communities*, EU:T:1990:41, para 24. See also, *Servier*, para 2936.
[193] See, e.g. *Servier* (n7) para 1265.
[194] See, *Servier* (n7) para 2937.

When assessing the restrictions on competition, both the Commission and the CMA emphasised the role of the value transfers in inducing the generics to withdraw from competition and the subjective intentions of the originators to prolong their monopolistic market positions.[195] In *Servier*, the Commission also highlighted the cumulative effect of the five agreements in delaying generic market entry and restricting competition on the relevant markets. Further, neither decision gave consideration to the possibility that the generics might have been excluded from the market by the exclusionary character of the originators' patents. By adopting an *ex ante* approach to assessing the legality of the settlements, the Commission avoided taking a position regarding the strength of the originators' patents.[196] It should be noted, however, that at the time of the conclusion of the agreements, there was a degree of genuine uncertainty as to the validity of the agreements, even though in *Servier*, the patent '947 was subsequently revoked.[197]

Dr. Ibáñez Colomo has noted that the EU Courts tend to modify their approach to assessing by object restrictions of Article 101 TFEU whenever market integration considerations appear to be at stake.[198] This *sui generis* approach centres around the means used to achieve the objective, the subjective intentions of the parties and the apparent anticompetitive effect of the agreement, but it fails to put sufficient weight on the possibly legitimate aims and the potential procompetitive effects of the agreement.[199] Thus, it often almost completely ignores the legal and economic context in which the agreement operates.[200] The author argues here that the approach adopted by the Commission and the CMA resembles the *sui generis* approach identified by Dr. Ibàñez Colomo and that it fails to put enough weight on the existence and importance of the originators' patents.

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[195] See, e.g. *Servier* (n7) para 2984.
[196] *Servier* (n7) para 2973.
[197] Gabriella Muscolo, 'Abuse of Litigation, Abuse of Patent and Abuse of Dominance: Where Do We Stand?', in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective* (Kluwer Law International 2016) 121.
[198] Pablo Ibáñez Colomo, 'Article 101 TFEU and market integration' (2016) J.C.L.& E. 12 (4) 749, 754.
[199] Ibáñez Colomo (n198) 760.
[200] Ibáñez Colomo (n198) 760.

4.4.1 Relevance of patents

Stopping third parties exploiting a patented product is a fundamental feature of patent law and the existence of a patent, cannot of itself constitute an abuse.[201] The right of patent owners to protect their patents, to rely on the patents to exclude competitors from exploiting the patented invention, and to settle patent litigation, as part of the subject-matter of the patent has been acknowledged by the Commission.[202] However, the CJEU has held on several occasions that the existence of a patent does not automatically protect an undertaking from liability under competition law rules.[203] The approach taken in *Servier* and in *Paroxetine*, as well as in the other reverse payment settlements cases, arguably reflects the sceptic attitude of competition authorities towards such agreements, and the approach subordinates patent law considerations to those of competition law.[204]

As set out in chapter 2, while patents protect innovation by granting a range of exclusive rights to a patent holder, there are material, geographic and temporal limits to the exercise of those rights. It is perfectly logical for a restrictive practice by a dominant undertaking, which goes beyond the scope of the originator's patent, to be considered abusive under Article 102 TFEU. However, where the apparent restriction on competition remains within the scope of the IPR, as a general rule, the exercise of the IPR does not, in itself, constitute a restriction and amounts to an abuse only in 'exceptional circumstances'.[205] The rationale behind the CJEU case law is that where competition is excluded by the underlying legal framework, such as patent law, the practice in question is incapable of restricting or preventing competition because, in light of the counterfactual, no competition existed.[206]

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[201] Whish & Bailey (n1) 812; Anderman & Schmidt (n25) 73.
[202] *Servier* (n7) paras 1102 & 1196.
[203] See, e.g. Case C-78/70 *Deutsche Grammophon v Metro* EU:C:1971:59 para 11; *Lundbeck v Commission* (n59) paras 119 & 427.
[204] Ioannis Kokkoris, 'United Kingdom – The Pharmaceutical Sector between Patent Law and Competition Law in the UK' in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective* (Kluwer Law International 2016) 308.
[205] *Deutsche Grammophon* (n203) para 11; Anderman & Schmidt (n25) 73.
[206] Ibáñez Colomo (n198) 764; Margherita Colangelo 'Reverse Payment Patent Settlements in the Pharmaceutical Sector Under EU and US Competition Laws: A Comparative Analysis' (2017) World Competition Law and Economics Review 40(3) 471, 491; Ginevra Bruzzone and Sara Capozzi, 'The Procompetitive and Anticompetitive Impact of Patent Settlements',

A problem arises here because the Commission lacks the competence to define the scope and validity of a patent.[207] This, however, does not mean that the Commission is to refrain from taking action and applying competition law rules whenever the scope of a patent is relevant for determining whether there has been a competition law infringement.[208] So far, the Commission appears to have solved this issue by treating reverse payment settlements as object infringements of both Articles 101 and 102 TFEU. Furthermore, in *Servier*, the Commission, by adopting an *ex ante* approach towards the anticompetitive effects of the settlements, avoided taking a position regarding the validity of Servier's patents. In *Paroxetine*, on the other hand, the CMA, while it assessed the likely effects of the agreements, failed to assess all possible counterfactuals.

As was noted above in chapter 2, there is always a degree of uncertainty regarding the validity of even strong patents. However, the validity of a patent is not a spectrum. A patent is either valid or it is not. Due to this uncertainty as to the outcome of the patent litigation, it would seem reasonable that whenever a patent is involved, competition authorities must take into account all possible counterfactuals and cannot simply assume anticompetitive effects.[209] If reverse payment settlements were to be treated as object infringements of Article 102 TFEU and if the existence of patents were to be neglected as the Commission and the CMA have arguably done, pharmaceutical companies might, at least in some cases, end up facing competition law liability where, in reality, they were acting within the scope of the rights conferred upon them by the relevant patent.[210] This would inevitably undermine the commercial value of the originator's patents, which might have a negative impact on the incentives to invest in pharmaceutical R&D.[211] This, in turn, would be detrimental to the consumers in the long term. The current approach adopted by the competition authorities effectively

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in Giovanni Pitruzzella and Gabriella Muscolo (eds), *Competition and Patent Law in the Pharmaceutical Sector: An International Perspective* (Kluwer Law International 2016) 15.

[207] See, e.g. *Lundbeck v Commission* (n59) paras 119 and 140, referring to Case 193/83 *Windsurfing International Inc. v Commission of the European Communities* EU:C:1986:75.

[208] *Windsurfing* (n207) para 119.

[209] Colangelo (n206) 491; Bruzzone & Capozzi (n206) 15.

[210] Bruzzone & Capozzi (n205) 29.

[211] Bruzzone & Capozzi (n205) 29.

implies that only a litigated patent is capable of protecting innovation, which might lead to an increase in patent litigation.

4.4 Effects-based analysis?

The Commission and the CMA appear to have assessed the reverse payment settlements under the object-based analysis. In the author's opinion, such an approach is problematic because the settlement agreements relate to the existence and enforcement of patents and the object-based approach fails to put sufficient weight on the economic and legal context in which these agreements operate and it effectively treats the originator's patents as irrelevant. Due to the complex nature of pharmaceutical reverse payment settlements, where a dominant originator acts within the scope of its patent, a settlement agreement concluded with a generic is not automatically anticompetitive 'by [its] very nature'.[212]

Where a restriction goes beyond the scope of the relevant patent, the justifiability of finding an object infringement of Article 102 is undisputed by the author. However, the author suggests that the effects-based analysis would be better suited for the competition law assessment of reverse payment settlements in all other cases, as it takes the economic and legal context of these agreements more effectively into account. It would also provide a better balance between competition and patent law considerations while not subordinating one to the other.

The author submits that where an originator makes a significant and unexplained value transfer to a generic company in the context of a patent settlement agreement, competition authorities should take a closer look at the patent, its scope and the reasons underlying the agreement. This way, the other possible justifications for the value transfer, such as risk aversion in situations where the originator holds an exceptionally valuable patent, would also be given more consideration.[213] As a general rule, to avoid undermining

[212] *Cartes Bancaires* (n86) para 125; Commission, 'Communication from the Commission — Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements' [2014] OJ C89/3.

[213] Choi, Den Uyl & Hughes argue that an originator concerned with risk aversion might be willing to pay generics significant sums even if it is almost completely sure of the strength of its patent, especially where the patent is particularly valuable. See, William Choi, Bruce

the patent system and overdeterrence, a more suitable approach would be to presume that the originator's patent is valid as patent law already provides a set out boundaries for the exercise of the patent. Furthermore, determining the material, geographic, and temporal scope of a patent would in most cases be an easier exercise for competition authorities than inquiring into the validity of the patent.

Adoption of an effects-based analysis would also make it easier for companies to settle patent disputes and it would be in line with the public policy encouraging settlement of private disputes. Since competition authorities would be required to assess the effects of a reverse payment settlement in light of all possible counterfactuals, an originator could rely on the protection provided by its patents while still not being able to go beyond their scope, thus promoting legal certainty. Furthermore, if an originator were to have serious doubts regarding the validity of its patents, it would have to think twice about concluding these settlements in order to avoid competition liability.

Den Uyl & Mat Hughes, 'Pay- For-Delay Practices in the Pharmaceutical Sector: *Lundbeck*, *Actavis*, and Others' (2014) J.E.C.L. & Pract. 5(1) 44, 51.

5 CONCLUSION

Pharmaceutical reverse payment settlements operate in a complex legal and economic context. Typically, the competition authorities' focus in the cases involving reverse payment settlements has been on the collusive nature of these agreements, but the Commission decision in *Servier* is the first time these agreements have been assessed under Article 102, as well as under Article 101 TFEU. The Commission found that Servier's unilateral strategy, which consisted of the Azad Technology Acquisition and five reverse payment settlements, was abusive and capable of delaying generic entry and producing foreclosure effects. The Commission concluded that while neither of the practices implemented by Servier amounted to a separate abuse, together, they constituted a single and continuous infringement of Article 102 TFEU in breach of the special responsibility imposed on the company as a dominant undertaking. In the UK, the CMA held in *Paroxetine*, that the reverse payment settlements constituted, in themselves, an abuse of a dominant position.

Under the current case law, it is unclear whether and in which circumstances reverse payment settlements by pharmaceutical companies in a dominant position constitute an abuse in breach of Article 102 TFEU. The Commission explicitly stated that the decision in *Servier* was limited to specific facts of the case. However, the general scepticism of the competition authorities towards reverse payment settlements is evident from the decisions. Both the Commission and the CMA applied 'capability' as the threshold for satisfying the competition authority's burden of proof for establishing an abuse, which suggests the adoption of an object-based analysis of the settlement agreements under Article 102 TFEU.

The author submitted above, that due to the already weakened degree of competition on the relevant market reverse payment settlements might, in some cases, fall within the scope of Article 102 TFEU. In light of the special responsibility of a dominant undertaking, especially where a dominant originator systematically and persistently pursues a chain of reverse payment settlements as a unilateral strategy, the application of Article 102 TFEU to the agreements would be justified.

It was argued, however, that the approach taken by the Commission and the CMA in their respective decisions effectively neglects the complex economic and legal context in which these agreements operate. The pharmaceutical sector is characterised by an exceptionally high level of investment and risk in the R&D, which is why ensuring sufficient protection and reward for innovation is crucial. The author submitted that the adoption of an object-based analysis in relation to reverse payment settlements undermines the patent law aspect inherent in the agreements, as it implies that that the originator's patents are irrelevant, void or not infringed, unless litigated in courts. Therefore, in order to avoid overdeterrence and subordinating patent law considerations to competition law, or vice versa, a more suitable approach would be to assess reverse payment settlements under the effect-based analysis since it would better take into account the legal and economic context of reverse payment settlements. As the Commission lacks patent law competence, it would be safer for the Commission to presume that the relevant patent is valid whenever an originator acts within the substantive, temporal and geographic scope of its patent.

The Commission decision in *Servier* has been appealed to the GC and irrespective of the outcome of the appeal, it is likely to be further appealed to the CJEU. In addition, the UK CMA's decision in *Paroxetine* has been sent to the CJEU for a preliminary reference. It will be interesting to see how the CJEU answers the multiple questions surrounding the treatment of reverse payment settlements, under Article 101, as well as under Article 102 TFEU.

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