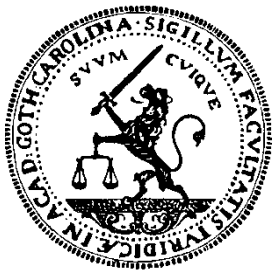

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Reverse Payment Patent Settlements as Restrictions by Object under Article 101(1) TFEU

LAGM01 Master Thesis

European Business Law
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Supervisor: Julian Nowag

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Contents

Summary

This thesis examines the CJEU's case law on value transfers between originator and generic undertakings, in the context of patent settlements, to ascertain the criteria for determining when such a practice amounts to a restriction of competition by object.

The thesis finds that the CJ's rulings in *Generics* and *Lundbeck* clarifies the treatment of more straightforward RPPSs and follows established case law on restrictions by object. According to these judgements, a RPPS will amount to a restriction by object where (i) the generic company's market entry is restricted, (ii) the value transfer from the originator to the generic manufacturer can only be explained by a commercial interest to exclude competition from the market and (iii) no pro-competitive effects cast a 'reasonable doubt' as to the agreements harmful nature. It is shown that the crucial question is whether the generic manufacturer accepts the restrictions to its market entry in recognition of the patents validity, or whether it is induced to do so in the form of value transfers.

The thesis analysis of the GC's ruling in *Servier* however shows that 'side deals' as parts of patent settlements remains a challenging area of law. While the GC's finding, that coupling a licence agreement, concluded under market terms, with a settlement does not raise antitrust concern, is logically consistent with the reasoning underpinning *Generics* and *Lundbeck,* other aspects of the judgement are less self-evident. In particular, the Courts' assessment of value transfers under licence agreements and the relevance of pro-competitive effects associated with such agreements, when juxtaposed to the CJ's line of reasoning in *Generics* and *Lundbeck*, indicates that there are some disparities giving rise to legal uncertainty.

Sammanfattning

Förevarande uppsats undersöker EU-domstolens praxis avseende värdeöverföringar mellan originaltillverkare av läkemedel och generikaföretag i samband med patentförlikningar (så kallade 'RPPSs') för att urskilja under vilka förutsättningar ett sådant förfarande utgör en syftesöverträdelse.

Analysen visar att EU-domstolens avgöranden *Generics* och *Lundbeck* förtydligar bedömningen av mer okomplicerade RPPSs och är förenlig med EU-domstolens praxis om syftesöverträdelser. Enligt dessa rättsfallen utgör en RPPS en syftesöverträdelse när (i) det generikaföretagets marknadsinträde begränsas, (ii) värdeöverföringen från originaltillverkaren till generikaföretaget endast kan förklaras av ett kommersiellt intresse att det inte ska finnas konkurrens på marknaden och (iii) inga konkurrensfrämjande effekter ger upphov till rimligt tvivel om avtalets skadliga verkningar. Uppsatsen visar att den avgörande frågan i bedömningen är huruvida det generikaföretaget begränsar marknadstillträdet till följd av deras erkännande av patenträttens giltighet, eller om det är värdeöverföringen som ger incitament till att inte inträda och konkurrera på marknaden.

Uppsatsens analys av tribunalens dom i *Servier* visar däremot att den konkurrensrättsliga bedömningen av 'sidoavtal' till patentuppgörelseavtal är desto mer osäker. Domstolens konstaterande att förbinda ett licensavtal med ett patentuppgörelseavtal inte är problematiskt, då det vanligtvis grundar sig på parternas erkännande av patentets giltighet, är förenligt med EU domstolens övergripande resonemang i *Generics* och *Lundbeck*. Uppsatsen visar dock att tribunalens analys av värdeöverföringar inom ramen för ett licensavtal och de konkurrensfrämjande effekter associerade med licensen inte är helt förenlig med EU-domstolens tillvägagångssätt i *Generics* och *Lundbeck,* vilket ger upphov till rättsosäkerhet.

Acknowledgements

I wish to express my gratitude to my nearest and dearest for their support and patience throughout my academic journey. Especially my parents for always being my pillars of support and encouraging me to do my best.

Further, I want to thank my supervisor Julian Nowag without whose guidance, insightful remarks and reassurance this thesis would not have been possible. I could not have asked for a better co-pilot during this process.

Lund, May 2022

Melina Idolor

Abbreviations

API	Active Pharmaceutical Ingredient
CJEU	Court of Justice of the European Union (which consist of the Court of Justice and the General Court)
CJ	Court of Justice
CMA	UK Competition and Markets Authority
Commission	European Commission
Dir. 2001/83	Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use.
EFPIA	European Federation of Pharmaceutical Industries Associations
EMA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
IPRs	Intellectual Property Rights
MA	Marketing authorisation
NCA	National Competition Authority
RPPS	Reverse Payment Patent Settlement

Reg. 726/2004	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Technology Transfer Guidelines	Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements [2014] OJ C 89/3
TFEU	Treaty on the Functioning of the European Union
TTBER	Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom

1. Introduction

1. 1 Background

Following its 2008-2009 inquiry into the pharmaceutical sector, the Commission first identified RPPSs as a phenomenon raising potential antitrust concern.[1] In principle, patent settlements are not prohibited. Legitimate settlement agreements are concluded to avoid or resolve patent-related disputes, saving the parties litigation costs and courts and administrative agencies time and effort. From an antitrust perspective, problems generally only arise when a value transfer occurs from the originator to the generic company, in consideration for the latter delaying or abandoning its proposed entry.[2]

In 2013 and 2014 the Commission adopted its first two infringement decisions, classifying the investigated agreements as by object restrictions under Article 101 TFEU and imposed substantial fines.[3] Following the appeal against the Commission's *Lundbeck* decision and a preliminary reference in the *Generics* case, the CJ in 2020 and 2021 confirmed the Commission's and NCA's view that the investigated agreements were anticompetitive by object.[4] Conduct which is classified as a 'by object' restriction is presumed to be anti-competitive by its very nature. As a result, the alleging party, most often the Commission or NCA, does not have to carry out a detailed analysis of the real effects of the agreement.[5] Whether RPPSs should qualify as by object restriction, or rather should be treated according to their actual effects on competition, has however sparked considerable debate in academia.[6]

Further, in light of the Commissions intense antitrust scrutiny and enforcement against RPPSs, it can be expected that undertakings will shy away from cash transfers, favoring more 'sophisticated' settlement agreements, comprising multiple commercial arrangements. How such 'side

[1] Final Report in the Pharmaceutical Sector Inquiry [2009] para. 16.

[2] Third Report on the Monitoring of Patent Settlements [2012] para. 3-4.

[3] Case COMP/AT.39226 – *Lundbeck* [2013] OJ C/80/13 and COMP/AT.39612 – *Servier* [2014] OJ C/393/7.

[4] Case C-307/18 *Generics* [2020] EU:C:2020:52 and Case C-591/16 *Lundbeck* [2021] EU:C:2021:243.

[5] Alison Jones, Niamh Dunnes & Brenda Sufrin, *EU competition law* (7th ed, Oxford University Press 2019) 218.

[6] For discussion see e.g. Stanislas De Margerie, 'Pay-for-Delay Settlements: In Search of the Right Standard' [2013] 36(1) World Competition 85; Patrick Actis Perinetto, 'Generics (Paroxetine), or the New Unbearable Lightness of Patents in Competition Law' [2021] 17(2) European Competition Journal 437; Pablo Ibáñez Colomo, 'Pay-for-Delay and the Structure of Article 101(1) TFEU: Points of Law Raised in Lundbeck and Paroxetine' [2020] 10(10) Journal of European Competition Law & Practice 59; Nathalie Ska, Philipp Werner & Christian Pau 'Pay-for-delay Agreements: Why the EU Should Judge them by their Effects' [2017] 8(7) Journal of European Competition Law & Practice 437. Further, the US Supreme Court decided in 2013 that RRPSs are to be treated under a 'rule of reason' approach, i.e. be the subject of a fully-fledged analysis (akin to the 'effects analysis' in the EU). See *FTC v Actavis, Inc*., 570 U.S. 136 (2013).

deals' ought to be treated has however received modest attention in the literature and jurisprudence. As a result, the antitrust status of such deals is uncertain.[7]

1. 2 Purpose and Research Question

The purpose of this thesis is to critically analyse how the concept of restrictions of competition by object under Article 101(1) TFEU has been applied by the CJEU to value transfer between an originator and generic undertaking, in the context of a patent settlement (i.e., RPPSs). To answer the main research question, the following sub-questions will be examined:

1. Are originator and generic undertakings in competition, despite the existence of a patent covering the originator's product?
2. What is a restriction by object?
3. Under which conditions does a RRPS amount to a restriction by object?
4. Does the CJ adopt the same approach, when establishing object restrictions, in RPPS cases as it has in non-RPPS cases?
5. Is the GC's assessment of licencing agreements as 'side deals' to RRPSs in *Servier* in conformity with the legal framework for RPPSs set out by the CJ in the later cases *Generics* and *Lundbeck*?

1. 3 Methodology and Material

This thesis pursues a descriptive function. The purpose is to systemise, describe and interpret the existing law with the aim to divulge *de lege lata*. To fulfil this purpose, a traditional legal dogmatic (doctrinal) method has been used in preparing and writing this thesis. The legal dogmatic method is primarily concerned with analysing traditional, authoritative sources of law, e.g. legislative texts, case law, legislative history and doctrine, to establish the applicable law.[8]

Further, as the thesis is concerned with EU law, the European legal method has been adopted. According to Reichel, the European legal method refers

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[7] See for discussion Amalia Athanasiadou, 'Side-Deals as Part of Pharma Patent Settlements: a New Landscape after Servier and Paroxetine?' [2020] 41(12) European Competition Law Review, 620.

[8] Jan Kleinerman, 'Rättsdogmatisk metod' in Maria Nääv & Mauro Zamboni (eds.), *Juridisk Metodlära [Legal Methodology]* (2nd ed, Studentlitteratur, 2018) 22-23; Bert Lehrberg, *Praktisk juridisk metod [Practical Legal Methodology]* (9th ed, Iusté Aktiebolags, 2016) 203; Jan M. Smits, 'What is Legal Doctrine? On the Aims and Methods of Legal-Dogmatic Research' in Rob van Gestel, Hans-W. Micklitz and Edward L Rubin (eds), *Rethinking Legal Scholarship: A Transatlantic Dialogue* (Cambridge University Press, 2017) 212.

to a way of treating the different legal sources of the EU by taking the characteristics of the EU legal order into consideration.[9]

The binding sources of EU law are primary and secondary law. For the purpose of this thesis the most relevant sources of primary and secondary legislation are Article 101 TFEU, Reg. 726/2004, Dir. 2001/83 and the TTBER. Further, case law from the CJEU is of great importance since the Court has the exclusive competence over interpreting the EU Treaties.[10] In addition to primary law and case law, the thesis uses soft law, such as guidelines and communications. While soft law sources are not legally binding in themselves, such documents are often normative in practice and provide guidance as to the interpretation of the law.[11] As the Commission is the principal enforcer of the EU's competition rules, soft law instruments issued by the Commission in this field are considered indicative of what is considered legal and exert great persuasive influence.[12] Lastly, opinions of Advocate Generals and legal doctrine are used to facilitate a better understanding of the law and for discussion purposes.

1. 4 Delimitations

First, the conclusion of a RPPS can constitute an abuse of a dominant position under Article 102 TFEU. This thesis is however limited to considering RPPSs under Article 101(1) TFEU and does not examine such practices under Article 102 TFEU.

Second, since the thesis is confined to analyse the concept of restrictions by object in relation to RPPSs, restrictions by effect will only be examined to the extent it is necessary to explain the prior concept.

Third, the thesis only seeks to analyse RPPSs from an EU competitive law perspective. Hence, the US antitrust approach to such agreements will not be discussed. Nor will the practice be examined from a patent or intellectual property law perspective.

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[9] Jane Reichel, 'EU-rättslig metod' in Maria Nääv & Mauro Zamboni (eds.), *Juridisk Metodlära [Legal Methodology]* (2nd ed, Studentlitteratur, 2018) 120-121 and 129.

[10] Article 276 TFEU.

[11] Article 288(4) TFEU; Paul Craig & Gráinne De Burca, *EU law: Text, Cases and Materials* (7th ed, Oxford University Press, 2020) 530 and 537.

[12] Reichel (n 8) 128-129; Jones, Dunnes & Sufrin (n 5) 93-94.

1. 5 Outline

The thesis is divided into six main sections. Chapter two provides a general foundation for the remainder of the thesis by describing the main features of the pharmaceutical sector (section 2.1). For the purpose of this thesis, the regulatory areas which will be analysed are legislation governing patents (section 2.2) and the marketing authorization system (section 2.3).[13] Next, the available routes for generics wishing to enter the market are presented (section 2.4). Lastly, the Commissions' theoretical framework for understanding RPPSs is described (section 2.5).

Chapter three explores the notion of restriction by object (section 3.1) to discern the requirements for adopting a restriction by object. To address the fourth sub-question, only CJ jurisprudence on restrictions by object 'outside' RPPS cases is explored, with the purpose of establishing the 'traditional approach' for adopting restrictions by object. Further, the notions of restriction by effect (section 3.2) and potential competitor (section 3.3) are examined.

The fourth chapter examines the cases concerning RPPSs which the EU Courts have adjudicated on. The analysis begins with the CJ's rulings in the cases *Generics* (section 4.1) and *Lundbeck* (section 4.2). Lastly, the General Court's ruling in the case *Servier* is analysed (section 4.3).

Chapter five is discussional and critically analyses the thesis finds, addressing mainly the first (section 5.1), fourth and fifth subquestions (section 5.2).

Lastly, the sixth chapter summarises the thesis findings and answers the main research question.

[13] These systems prescribe rules which any company wanting to sell a pharmaceutical product has to abide by, thereby determining the conditions for competition. See further Commission, *Final Report,* para. 248-249.

2. Concepts and Contextualization

2. 1 The Pharmaceutical Sector

2. 1. 1 Research and Development

Innovation lies at the core of the pharmaceutical industry.[14] The lack of adequate treatment for many diseases is a source for continuous R&D efforts aimed at developing medicines containing new APIs.[15] Such innovation is time-consuming, expensive and risky. The first stage of research is focused on understanding the processes behind a disease ('pre-discovery'). In the initial stage, as many as 10 000 compounds may be considered and whittled down to just 10 to 20 which in next stage are assessed for efficacy and safety using computerised models, cells and animals ('drug discovery' followed by 'preclinical testing'). The remaining compounds, on average only five, are tested in human trials which usually take six to seven years to complete ('clinical trials').[16] The aim of clinical trials is to confirm product safety and efficacy as well as determining dosage regimen and method of delivery (e.g. oral or intravenous).[17]

According to a OECD report from 2018, the probability of obtaining marketing approval for a medicine entering the first phase of clinical trials ranges from 7% to 45%, depending on the type of medication, disease, indication and approval process. Further, the successful development of a new medicine on average takes 10 to 15 years.[18]

2. 1. 2 The Supply Side

In the pharmaceutical sector, there are primarily two types of companies on the supply side. First, companies which carry out research into new medicines, develop them from the laboratory, conduct clinical trials required to obtain marketing authorization and subsequently sell them on the market (hereinafter called 'originator' undertaking). The originators' products are largely patent-protected and enjoy additional regulatory exclusivities.[19]

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[14] Stuart O. Schweitzer & John Lu Zhong (2018). *Pharmaceutical economics and policy. perspectives, promises, and problems* (3rd ed, Oxford University Press, 2018) 30.

[15] Final Report in the Pharmaceutical Sector Inquiry [2009], para. 2.

[16] Sandra Kraljevic, Peter J Stambrook & Kresimir Pavelic, 'Accelerating drug discovery' [2004] 5(9) EMBO Reports 838.

[17] Ingrid Torjsesen, 'Drug development: the journey of a medicine from lab to shelf' (2015).

[18] OECD, 'Competition and Regulation Issues in the Pharmaceutical Industry' (2018) 16.

[19] Once the patent has expired, a supplementary protection certificate can extend a patent right for a maximum of five years. In addition to these IPRs, pharmaceutical products are usually afforded regulatory exclusivity consisting of eight years of data exclusivity and ten years of market exclusivity in accordance with Dir. 2001/83 and Reg. 726/2004. See further Sven Bostyn, Thyra de Jongh, Alfred Radauer & Joost Poort 'Effects of Supplementary Protection Mechanisms for Pharmaceutical Products' (2018) Technopolis Group.

Secondly, companies which produce and sell generic versions of the originators' products, once IPRs and other exclusivities have elapsed (hereinafter called 'generic' undertaking). Generic products have the same API as the originators' reference product and can therefore be used for the same treatments.[20] Due to the different cost structure of originator and generic undertakings,[21] generic products are usually offered at substantially lower prices.[22] As a result, generic market entry will trigger price competition and alter the market structure significantly.[23]

2. 2 European Patent Law

2. 2. 1 Compound and Process Patents

As discussed in section 2.1, the pharmaceutical sector is R&D intensive. The clear disparity between the high risk and cost of innovation, and the low risk and cost of imitation, illustrates the need for protection from imitation, for there to be innovation. Patent protection allows originators to recoup their significant investment in R&D.[24]

In the pharmaceutical industry, patentable inventions can be grouped into two categories. The first kind of inventions are new APIs and new formulations of existing APIs ('compound patents'). The application for the compound patent must indicate how the API can be reproduced. As a result the compound patent will usually protect the API in itself in addition to the process for its production as described in the patent application.[25] Secondly, new ways of producing APIs may be patented ('process patents').

Compound patents enjoy absolute protection, prohibiting third parties from manufacturing, disposing, using, importing and keeping the API. The scope of protection conferred by a process patent is however more limited. Instead, the proprietor right is limited to preventing (i) the *de facto* use of the patented process; (ii) the sale, use or import of the products that are directly generated through the protected process; or (iii) the possessing of such products for any reason other than personal use.[26]

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[20] Final Report in the Pharmaceutical Sector Inquiry [2009], para. 22.

[21] For instance, generics do not need to maintain costly R&D and marketing departments.

[22] Generic prices average about 25% of the originator price. See European Parliament 'Differences in costs of and access to pharmaceutical products in the EU' (2011) 26.

[23] Final Report in the Pharmaceutical Sector Inquiry [2009], para. 209-238.

[24] See Hirotaka Nonaka, 'FTO (Freedom to Operate) in the Pharmaceutical Industry.' (2018) MIPLC Studies 34 <https://directory.doabooks.org/handle/20.500.12854/48170> accessed 25 May 2022 15-16.

[25] Article 83 EPC and Article 29 TRIPS Agreement.

[26] Article 64 EPC and Article 28 TRIPS Agreement.

2. 2. 2 Absence of an EU Patent

The EU lacks a common EU-wide patent. While the EPC provides for a common application procedure, EPC patents are issued in accordance with and protected by domestic legislation.[27] Moreover, there is no common litigation framework for enforcing EPC patents. Hence, an originator seeking enforcement for patent infringement must sue the alleged infringer in each state individually, making multiple litigation inevitable.[28] It has been argued that the fragmented European patent system, making the enforcement of patent rights complicated[29] and expensive, compels originators to settle even when they have strong patent rights.[30]

2. 3 The Marketing Authorisation System

2. 3. 1 Rationale

In the EU, only medicinal products which have obtained marketing authorisation ('MA') can be placed on the market. The objective is to protect public health by ensuring that only products of good quality and with a positive benefit-risk ratio as regards safety and efficacy are marketed within the EU. As a result, MA decisions are taken on the basis of only scientific criteria concerning the quality, safety and efficacy of the medicinal product concerned. Factors such as the patent status are therefore not to be taken into account.[31]

2. 3. 2 Patent Linkage

Under EU law, it is not allowed to take patent law in consideration for the issuance of MA.[32] Accordingly, the regulatory national authorities do not link the granting of MAs for generic or biosimilar products to the status of

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[27] Justine Pila & Paul Torremans, *European Intellectual Property Law* (2nd ed, Oxford University Press, 2020) 103-104.

[28] EPO, Assessment of the impact of the EPLA on litigation of European patents.

[29] Due to differences in e.g., substantive and procedural national law, diverging decisions on the substance of the cases are not uncommon. See e.g., Final Report in the Pharmaceutical Sector Inquiry [2009], para. 664. The risk of contradicting decisions not only undermines legal certainty but makes litigation incalculable. See EPO, Assessment of the impact of the EPLA on litigation of European patents (n 28) 2-3.

[30] See Micheal Clancy, Damien Geradin & Andew Lazerow, 'Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of U.S. Antitrust Law and EU Competition Law' (2015) 59(1) Antitrust Bulletin 164.

[31] Article 81 of Reg. 726/2004 and Article 126 of Dir. 2001/83.

[32] See Article 81 of Reg. 726/2004 and Article 126 of Dir. 2001/83 that stipulate that only grounds set out in the Regulation and Directive can be inferred to refuse, suspend or revoke MA.

the patent(s) for the originator reference product ('patent linkage').[33] Under patent linkage, the national authority, depending on the jurisdiction in question, may refuse the MA application until the patent expires or inform the patent holder to enable it to take any relevant action. Such a practice upholds IPRs and avoids costly litigation, proponents argue.[34] On the other hand, regulatory authorities are often unequipped to make informed decisions on issues of patent validity and infringement. Further, generics fear that poor quality patents would create unjustified barriers to entry.[35] As Union legislation prohibits patent linkage for the issuance of MA, generic manufacturers have to perform their own patent clearance studies to decide if their drug infringes on brand-name patents.

2. 4 Generic Market Entry

A generic undertaking can enter the market after either (i) the originator's patent and/or regulatory exclusivities has expired; (ii) the originator's patent is found to be invalid; or once (iii) the generic version of the pharmaceutical product is declared not to infringe the originator's patent. Further, some generic firms decide to (iv) enter the market before the expiry of the relevant patents, prepared to challenge the patent if sued for infringement (referred to as launching 'at risk'). Lastly, (v) generics may enter the market with a licence from the originator patentee.[36]

2. 5 Defining RPPSs

2. 5. 1 Introduction

RPPSs are usually structured in the following manner. The originator company **A** holds one or more patents covering its brand-name product **X**. The generic company **B** takes steps towards entering the market with its generic version of product **X**, claiming that the patents held by **A** are *invalid* and/or not *infringed* by its generic product. Subsequently, either the originator **A** sues the generic **B** for patent infringement, or the generic **B** initiates action for invalidity of the originators **A** patents. Before a final decision is handed down on the matter of patent validity or patent infringement **A** and **B** settle.[37]

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[33] See Article 10 Dir. 2001/83; Baker McKenzie, 'Global Guide to Patent Linkage' (Kluwer Competition Law Blog, 2016) <https://www.bakermckenzie.com/en/insight/publications/guides/global-guide-to-patent-linkage> accessed 25 May 2022, 4.

[34] Baker McKenzie (n 32) 2.

[35] Final Report in the Pharmaceutical Sector Inquiry [2009], para. 336; Baker McKenzie (n 32) 2.

[36] Roox K, Pike J, Brown A and Becker S 'Patent-Related Barriers to Market Entry for Generic Medicines in the European Union: A Review of Weaknesses in the Current European Patent System and their Impact on Market Access of Generic Medicine' [2008] 5(4) Journal of Generic Medicines Bulletin 267.

[37] Amalia Athanasiadou, 'Patent Settlements in the Pharmaceutical Industry under US Antitrust and EU Competition Law' [2018] 75 International Competition Law Series 1.

As part of the settlement agreement, **A** undertakes to make a *value transfer* to **B**. Value is transferred in the opposite direction compared to the usual scenario in patent infringement settlements, where the alleged infringer agrees to pay the patent holder (hence the term '*reverse* payment patent settlements'). In return for a value transfer, the generic **B** agrees to not enter the market with its product for the duration of the agreement (hence the term 'pay-for-delay').[38]

2. 5. 2 The Categorisation of RPPSs

Following the pharmaceutical sector inquiry, the Commission began monitoring RPPSs and requested undertakings to provide copies of their settlements. Based on this information, eight Monitoring Reports have been released.[39] The reports divided RPPSs into two main categories, as shown by figure 1 below. First the Commission made a distinction between agreements which do not restrict generic market entry ('*A-type'*) and agreements that do ('*B-type')*. Second, within category B a subsequent distinction is made between agreements which do not stipulate a value transfer from the originator to the generic undertaking ('*B.I-type'*), and which do ('*B.II-type'*).[40]

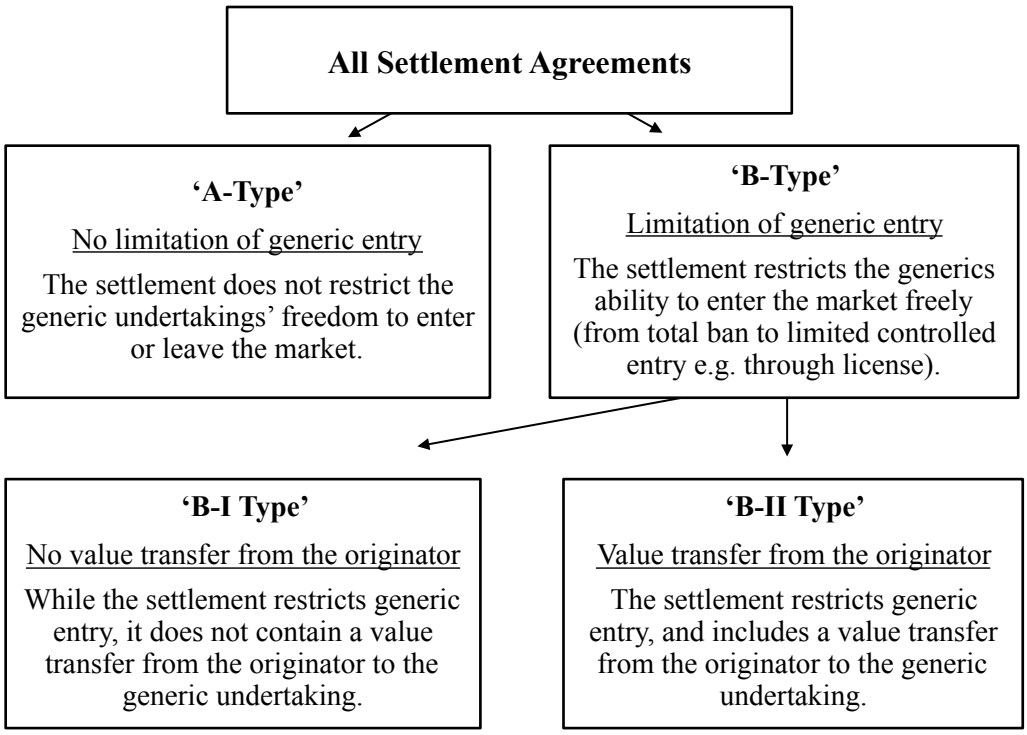

Figure 1: The Commission's categorisation of RPPSs

[38] Athanasiadou (n 38) 1.

[39] See Commission, 'Archive on Monitoring of patent settlements' < https://ec.europa.eu/competition/sectors/pharmaceuticals/archive/index.html > accessed 25 May 2022.

[40] Final Report in the Pharmaceutical Sector Inquiry [2009], para. 741-742.

As settlements within category *A* allow immediate market entry by the generic undertaking such agreements are deemed prima facie 'unproblematic' from an EU competition law perspective.[41] The same usually applies to *B-I* settlements, unless the restrictions exceed the scope of the patent[42] or, in the case of the so-called 'sham patents'[43].[44]

B-II agreements will on the other hand generally face intense antitrust scrutiny as they contain two problematic elements (i.e., a restriction of market access and a transfer of value). However, the Commission has stated that such agreements must nonetheless be assessed on a case-by-case basis.[45] Indeed, the Commission has stated that *B-II* agreements are not problematic where the value transfer is (i) linked to the strength of the patent as perceived by the settling parties;[46] is (ii) is necessary in order to reach a legitimate solution which is acceptable for the parties.[47]

As shown by Figure 2 to the right, 11% of patent settlements in 2016, examined in the last Monitoring Report were *B-II* agreements, whereas the rest either involved no reverse payment or did not limit generic entry.[48] The value transfer in the identified *B-II* agreements, took different forms but usually included a direct payment only or a licence, or the combination of both.[49]

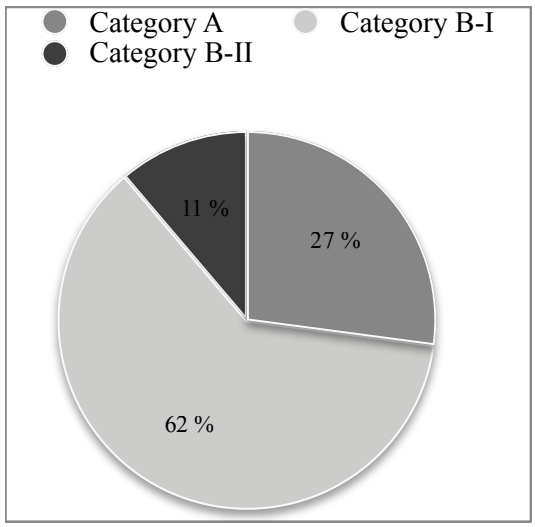

Figure 2: Settlements analysed in the Commission's 8th Monitoring Report

[41] Third Report on the Monitoring of Patent Settlements [2012], para. 11.

[42] Meaning that the restrictions imposed upon the generic undertaking goes beyond that patents (i) geographic scope, (ii) period of protection or (iii) exclusionary scope. See Fourth Report on the Monitoring of Patent Settlements [2013], para. 4.

[43] Meaning that the patent holder knows that the patent concerned does not meet the patentability criteria. This could be the case where a patent has been granted on the basis of incorrect, misleading or incomplete information. See Fourth Report on the Monitoring of Patent Settlements [2013], para. 4.

[44] Third Report on the Monitoring of Patent Settlements [2012], para. 12.

[45] Final Report in the Pharmaceutical Sector Inquiry [2009], para. 763.

[46] The restrictions imposed upon the generic must however not beyond the rights granted by patent law, i.e., stay within the patents (i) geographic scope, (ii) period of protection or (iii) exclusionary scope. See COMP/AT. 39226 – *Lundbeck* (n 3) recital 638.

[47] See COMP/AT.39226 – *Lundbeck* (n 3) recital 639.

[48] Eight Report on the Monitoring of Patent Settlements [2016], para. 30.

[49] Ibid, para. 12.

3. Article 101(1) TFEU

3. 1 The Notion of Restrictions by Object

3. 1. 1 Introduction

The object category only encompasses collusion which reveals 'in itself a sufficient degree of harm to competition'[50] or, in other words, types of collusion which 'by their very nature' have the potential to restrict competition.[51] It refers to practices which are regarded as so obviously being designed to negatively impact competition, that a bright-line rule against them is applied.[52] The category therefore encompasses 'the most serious violations' of EU competition law.[53]

In the following, the relationship between restrictions by object and effect is explained (section 3.1.2) and the rationale underpinning the categorization of certain practices as by object types of collusions explored (section 3.1.3). Next, to define the concept of restrictions by object and discern the legal test for their establishment, case-law pertaining to the object-analysis is examined (section 3.1.4).

3. 1. 2 Relation between Restrictions by Effect and Object

The conditions for restrictions by object and effect are alternative, not cumulative.[54] According to settled case law the assessment is sequential: first one considers whether there is a restriction by object, and only if the answer is negative, it is necessary to consider the effects.[55] Once a restriction by object has been identified the agreement's effects are presumed and the onus falls on the contracting parties to justify the agreement under Article 101(3) TFEU. In contrast, in cases of less obvious offences the claimant has the burden of proving anti-competitive effects under Article 101(1) TFEU. The classification of an agreement therefore has important implications for the burden of proof.

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[50] Jones, Dunnes & Sufrin (n 5) 219; Richard Whish & David Bailey, *Competition law* (9th ed, Oxford University Press 2018) 127; Case C-67/13 *CB* [2014] EU:C:2014:2204 para 49.

[51] Guidelines on the application of Article 81(3) of the Treaty [2004] OJ C101/97, para. 21.

[52] Jones, Dunnes & Sufrin (n 5) 218.

[53] Filippo Amato, 'Defining Agreements and Concerted Practices Restricting Competition' in Bernardo Cortese(eds.), *EU competition law: Between Public and Private Enforcement* (Wolters Kluwer, 2013) 39; Maria Ioannidou & Julian Nowag 'Can two wrongs make it right? Reconsidering minimum resale price maintenance in the light of Allianz Hungária' [2015] 11(2-3) European Competition Journal, 348.

[54] Case 56/65 *STM* [1966] EU:C:1966:38 p. 249.

[55] Case C-172/14, *ING Pensii* EU:C:2015:484, para. 30.

Yet, the distinction between restrictions by object and effect has not been clear. Indeed, many aspects of the object methodology remain contested. While it is undisputed that the legal and economic context of an agreement must be considered in establishing an object restriction, confusion lies around the extent of such an inquiry. Put differently, at what point does necessary analysis of *context* stop and inappropriate analysis of *effects* start? The quest for a clear test for object restrictions has been described as a Sisyphean struggle where national courts, looking for clarification, submit their questions to the CJ. The CJ on the other hand, seemingly satisfied with the status quo, resorts to standardised expressions on the concept of object restrictions. While each judgement adds another piece of the puzzle the object methodology remains elusive.[56]

3. 1. 3 Rationale

Procedural economy and legal certainty mainly underpin the notion of restrictions by object. First, by easing the burden on competition authorities in cases of obvious restrictions, resources of the justice system are conserved.[57] Secondly, the allocation of certain practices to the by object box creates legal certainty and has a deterrent effect by providing predictability, allowing market participants to adapt their conduct accordingly.[58]

Ultimately, the justification for prohibiting by object types of practices is comparable to the concept of risk offences (‘*Gefährdungsdelikte*’) in criminal law. The punishment for driving under influence of alcohol or drugs is deemed warranted wholly irrespective of whether actual danger or accident is endured. Similarly, undertakings infringing EU competition law may be subject to a fine if they engage in by object types of practices, irrespective of whether the general public suffers harm.[59]

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[56] See Sam MacMahon Baldwin,‘The Sisyphean quest for a clear test – on ‘by object’ methodology, gin & tonics, and Budapest Bank’ (Kluwer Competition Law Blog 2020) <http://competitionlawblog.kluwercompetitionlaw.com/2020/05/04/the-sisyphean-quest-for-a-clear-test-on-by-object-methodology-gin-tonics-and-budapest-bank/> accessed 25 May 2022.

[57] As noted by Advocate General Wahl in § 35 in his Opinion in Case C-67/13 *CB* [2014] EU:C:2014:2204 and Advocate General Wathelet in § 58 of his Opinion in Case C-373/14 *Toshiba* [2015] EU:C:2015:427 market-analysis are usually both complex and time-consuming.

[58] See Opinion of Advocate General Kokott in Case C-8/08 *T-Mobile Netherlands* [2009] EU:C:2009:343 para. 43; Opinion of Advocate General Wathelet in Case C-373/14 *Toshiba* (n 57) para. 58.

[59] Ibid, para. 47.

3. 1. 4 The Legal Test for Establishing Restrictions by Object

According to settled case law, in establishing a restriction by object one must have regard to three factors: the agreement's (i) content, its (ii) objectives, and (iii) economic and legal context.[60] An agreement amounts to a by object restriction where an analysis of the agreement's content, objectives, and context reveals a sufficiently deleterious impact on competition.[61]

The notion has been defined objectively, hence the subjective intentions of the parties is not decisive for finding a restriction by object.[62] The concept of the agreements 'content' refers to what the parties have agreed upon. To discern the true content of an agreement not only written clauses are considered but also the behaviour of the parties.[63]

3. 1. 4. 1 The Quest for a Clear Methodology

Certain types of restrictions have in jurisprudence been identified as by object restrictions. In particular, agreements which constrain competition between actual or potential competitors without producing any objective countervailing benefits are likely to be considered to be pursuing a restrictive objective. Examples of problematic horizontal agreements are such which aim to fix prices, reduce output, or share markets.[64]

At the same time, jurisprudence has from the outset prescribed that the agreement's *context* must also be taken into account.[65] Early case law has however not suggested that the *effects* of an agreement should be taken into account when it has as its object the restriction of competition.[66] How detailed the contextual analysis ought to be has been the source of much debate, as the Court in later judgments has suggested that the

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[60] These criteria were first set out in the *STM* case and have been reiterated in later case law. See Case 56/65 *STM* (n 54) p. 248-249; C-67/13 *CB* (n 50) para 53; C-228/18 *Budapest Bank* [2020] EU:C:2020:265 para 51.

[61] Jones, Dunnes & Sufrin (n 5) 219.

[62] See Case C-209/07 *BIDS,* para. 21; Case C-67/13 *CB* (n 50) para. 54; Jones, Dunnes & Sufrin (n 5) 220; Whish & Bailey (n 50) 127.

[63] Jones, Dunnes & Sufrin (n 5) p. 220.

[64] Further, the object category entails horizontal (i) rig bidding; (ii) agreements which aim to reduce capacity; (iii) agreements which aim to fix purchase or selling prices; and (iv) boycotting of a competitor. See Jones, Dunnes & Sufrin (n 5) 220-221.

[65] See e.g. Cases 56 and 58/64, *Consten and Grundig*, p. 343; Case *STM* (n 54) p. 249.

[66] Albeit the CJ in some cases has allowed for a limited effects analysis when examining whether (i) the agreement has an appreciable effect on competition and trade; and (ii) as an aspect of the contextual analysis. See Ioannidou & Nowag (n 53) 350-356; Csongor István Nagy, 'EU Competition Law Devours Its Children: The Proliferation of Anti-Competitive Object and the Problem of False Positives' [2021] 23 Cambridge Yearbook of European Legal Studies, 294.

contextual analysis might include a limited effects analysis.[67] Indeed, over the years the CJ's case law gave the impression that the object box was incrementally broadened to encompass other 'new' more elusive practices.[68]

Pre-*Allianz*: The Traditional Formalistic Approach

The traditional conception of restriction by object functioned by creating a relatively clear list of clauses that were automatically condemned, while other restrictions had to be scrutinised under the effect analysis.[69] The approach to object restrictions was formalistic and textual, subsuming the agreement under a by object type of collusion (e.g. price fixing, market sharing, output restriction), rather than subjecting the investigated agreements to a comprehensive assessment.[70]

The *Allianz* Doctrine: Expanding the Notion of Restrictions by Object

In *T-Mobile* [2009] the CJ made expansive statements about the notion of an object restraint, stating that it is sufficient that the conduct 'has the *potential* to have a negative impact on competition' in the sense that the conduct must 'simply be *capable* in an individual case, having regard to the specific legal and economic context' to restrict competition.[71] Hence, the Court opted for a 'capability' criterion. According to this standard of harm, it suffices that the practice has the potential to negatively impact competition — the extent of such effects (i.e. whether these are serious or trivial) not being relevant.[72]

Further, in *Allianz* [2013] the CJ expanded the contextual analysis for object restrictions by allowing for a more detailed effect analysis.[73] The Court held that the investigated agreements concluded between insurance companies and car repairers would amount to by object restrictions if the referring court found that it likely that, having regard to the economic context, 'competition on that market would be eliminated or seriously weakened following the conclusion of those agreements'.[74] When assessing the likelihood of such a result the referring court should, according to the CJ, take the following into consideration; (i) the structure of that market; (ii) the

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[67] See e.g. Case C-8/08 *T-Mobile Netherlands* [2009] EU:C:2009:343; Case C-32/11, *Allianz Hungária* [2013] EU:C:2013:160; Ioannidou & Nowag (n 53) 350-352 and 356-363; Nagy (n 66) 294.

[68] Whish & Bailey (n 50) 128; Jones, Dunnes & Sufrin (n 5) 225-226; Bernard Amory, Geoffroy Van De Walle & Natalie Smuha,'The Object-Effect Dichotomy and The Requirement of Harm to Competition: On the Road to Clarity after Cartes Bancaires?' in Damien Gerard, Massimo Merola and Bernd Meyring (eds) '*The Notion of Restriction of Competition: Revisiting the Foundations of Antitrust Enforcement in Europe'* (Bruylant, 2017) 41.

[69] See Nagy, 2021, p. 292; Amory, Van De Walle & Smuha (n 68) 41.

[70] Nagy (n 66) 292-293.

[71] Case C-8/08 *T-Mobile Netherlands* (n 67) para. 31 (emphasis added).

[72] Amory, Van De Walle & Smuha (n 68) 42-43.

[73] Ioannidou & Nowag (n 53) 356.

[74] Case C-32/11, *Allianz Hungária* (n 67) para. 48.

existence of alternative distribution channels and their respective importance; and (iii) the market power of the companies concerned[75] — factors which previously had been examined as part of the market-analysis to establish a restriction by effect.[76] Further, when determining the agreement's context the Court held that (i) the nature of the goods or services, (ii) the real conditions of the functioning of the market and (iii) the structure of the market should be considered.[77]

These rulings were criticised as leading to 'false positives' and eroding the distinction between by object and by effect infringements.[78] First, since agreements are automatically condemned under Article 101 once an anti-competitive object is established, the concept 'anti-competitive object' should be understood narrowly and applied exceptionally. Automatic condemnation ought to be reserved for types of agreements that in jurisprudence have been proven to always or almost always harm competition and consumer welfare. Secondly, requiring an analysis of market conditions and the effects of a particular agreement to establish an object restriction seems to inappropriately blur the analysis required in object and effects cases respectively. As noted above, the purpose of the by object category is to sidestep detailed market analysis in the case of obvious restraints.[79]

Post-*CB*: The Return to a More Restrictive Approach?

It was against this backdrop the CJ handed down its judgement in the case *CB* [2014].[80] The ruling was welcomed as it offered some clarity on the notion of restriction by object.[81] Firstly, the Court for the first time expressly stated that the concept of restriction of competition by object is to be construed *restrictively* and therefore reserved exclusively for practices

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[75] Ibid.

[76] Nagy (n 66) 296.

[77] Ibid, para. 36.

[78] Jones, Dunnes & Sufrin (n 5) 227; Nagy (n 66) 307.

[79] Jones, Dunnes & Sufrin (n 5) 227; Nagy (n 66) 563.

[80] Case C-67/13 *CB* (n 50).

[81] While the Court did not openly overrule *Allianz* most commentators have understood the *CB* ruling as putting a halt to the expansionist approach and as the Court embracing a more traditional, restrictive approach to restrictions by object. See James Killick & Jermie Jourdan, 'Cartes Bancaires: A Revolution Or A Reminder of Old Principles We Should Never Have Forgotten?' [2014] Competition Policy International <https://www.competitionpolicyinternational.com/assets/Uploads/EUDec14-3.pdf> accessed 25 May 2022 10; Whish & Bailey (n 50) 130; Eugène Buttigieg 'The Servier judgments—the GC's evolving case law on 'pay-for- delay' patent settlement agreements'' [2019] 7 Journal of Antitrust Enforcement 281; Amory, Van De Walle & Smuha (n 68) 41-42; Bernadette Zelger, 'By Object or Effect Restrictions—Reverse Payment Settlement Agreements in light of Lundbeck, Servier, and Generics' [2020] 12(4) Journal of European Competition Law & Practice 281; Nagy however suggests that *CB* does not overturn *Allianz,* see Nagy (n 66) 296-302.

which must be 'regarded, by their very nature, as being harmful to the proper functioning of normal competition'.[82]

Secondly, the CJ clarified that the standard of harm for establishing object restrictions is not mere 'capability' of harm as previously indicated in *T-Mobile.* Instead*,* the conduct must in itself reveal 'a *sufficient degree of harm*'.*[83]* The lower standard of harm for restrictions by the object of *T-Mobile* must therefore be considered to be rejected by the CJ.[84]

Thirdly, the CJ seemingly endorsed the relevance of *experience* (i.e. past practice) in determining whether a conduct should be qualified as object restriction.[85] It follows that the object category is inappropriate for agreements requiring a detailed market analysis, such as cases involving complex measures or where experience with the restraint is limited.[86]

On the other hand, the question as to the correct level of scrutiny into contextual elements in a 'by object' analysis remained rather unclear after *CB*.[87] The crucial question is to draw the fine line between the contextual analysis in the object-inquiry, and the more extensive analysis required to establish a restriction by effect.[88] According to the CJ in *CB* all relevant aspects of the economic and legal context in which that practice takes place must be taken into account, in particular 'the nature of the services at issue, as well as the real conditions of the function and structure of the markets'.[89] While this implies a certain advanced level of review, such an analysis must nonetheless, given the rationale and distinction between restrictions by object/effect,[90] be understood as less extensive than an analysis of the agreements' effect.[91]

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[82] Case C-67/13 *CB* (n 50) 50 and 58.

[83] In fact, the Court held that the 'essential legal criterion' for ascertaining whether a practice amounts to a restriction by object is that the investigated practice reveals 'in itself a sufficient degree of harm'.
See Case C-67/13 *CB* [2014], para. 57 which have been repeated in later cases e.g. Case C-172/14, *ING Pensii* (n 55) para. 30-31; Case C-345/14 *Maxima Latvija* [2015] EU:C:2015:784 para. 18-20; Compared to the lower standard in Case C-8/08 *T-Mobile* (n 67) para. 31.

[84] Killick & Jourdan (n 81) 4; Amory, Van De Walle & Smuha (n 68) 43-44.

[85] Case C-67/13 *CB* (n 50) para. 51.

[86] Jones, Sufrin & Dunne (n 5) 228; Killick & Jourdan (n 81) 8.

[87] Alfonso Lamadrid de Pablo, '10 Comments on the ECJ's Judgment in Case C-67/13 P, Groupement des Cartes Bancairer' (Chillin' Competition 2020) <https://chillingcompetition.com/2020/12/17/10-comments-on-the-commissions-dma-proposal/> accessed 25 May 2022.

[88] Amory, Van De Walle & Smuha (n 68) 45.

[89] See Case C-67/13 *CB* (n 50) para. 53 which later was readapted in Case *ING Pensii* (n 55) para. 33; Case C-286/13 *Dole* [2015] EU:C:2015:184 para. 117-118; Compared to Case C-32/11 *Allianz* (n 67) para. 48.

[90] See sections 3.1.2 and 3.1.3 above.

[91] Amory, Van De Walle & Smuha (n 68) 45-56; Nagy (n 66) 305.

Notably, the CJ omitted any reference to the additional contextual elements set out to consider within the contextual analysis in *Allianz.*[92] While the Court did not explicitly (or implicitly) distance itself from these contextual elements, the omission could indicate that the *Allianz* elements stemmed from the specific, isolated case.[93] In fact, Advocate Wahl in his Opinion in *CB* stated the Courts reference to the additional contextual elements in *Allianz* as 'explain soles by the *specific nature of the facts* giving rise to the request for a preliminary ruling and by the Court's desire to provided the referring court with the fullest possible answer', concluding that said elements therefore were 'specific to that case and cannot be applied generally without giving rise to confusion between restrictions by object and restrictions by effect'.[94]

In *Toshiba* [2016] the CJ adopted a more restrictive view of the contextual analysis. The case concerned a 'gentlemen's agreement' between seven European and Japanese manufacturers of power transformers pursuant to which the Japanese manufacturers agreed to not compete for business in Europe.[95] The Japanese producer Toshiba contested the Commission's characterization of the agreement as a restriction by object, arguing that a more detailed assessment of the legal and economic context around the agreement would reveal that the company was not an actual or potential competitor in the EEA market given the insurmountable barriers to entry.[96] The Court however, rejecting Toshiba's plea for a more detailed contextual analysis, held that once an anticompetitive objective already has been identified, the contextual analysis may be 'limited to what is *strictly necessary* in order to establish the existence of a restriction of competition by object'.[97] The CJ's approach in *Toshiba* resembles the 'sliding scale' under US antitrust law according to which the more obvious the restriction, the less contextual analysis is required.[98] It seems to follow, where an agreement exhibits obvious common denominators of a by object type of collusion (such as the market-sharing cartel[99] at issue in the case at hand) a

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[92] See Case C-32/11, *Allianz Hungária* (n 67) para. 48.

[93] Amory, Van De Walle & Smuha (n 68) 46-47.

[94] Opinion of Advocate General Wahl in Case C-67/13 *CB* (n 57) para. 80 and 84.

[95] Case C-373/14, *Toshiba* [2016] EU:C:2015:427 para. 10-11.

[96] Ibid, para. 19-20.

[97] Ibid, para. 29.

[98] Amory, Van De Walle & Smuha (n 68) 53.

[99] Market sharing constitute a 'hardcore' cartel offense and are explicitly mentioned as prohibited in Article 101(1)(c) TFEU.

limited contextual analysis suffices.[100] Hence, the *nature* of the contested conduct seems to determine the level of scrutiny as limited analysis according to the CJ suffices in cases of 'classic' restrictions by object, such as price-fixing and market-sharing.[101]

A couple of years later, further guidance was given in the case *Budapest Bank* [2020]. Advocate General Bobek proposed a two-step analysis for the identification of an object restriction. The first step is a formal assessment, in which one would consider the *content* of the agreement and its *objectives*, to ascertain whether the agreement may be subordinated under a by object type of collusion, i.e. whether the disputed agreement exhibits common denominators whose harmful nature is 'in the light of experience, commonly accepted and easily identifiable'.[102] Here, 'experience' refers to 'what can traditionally be seen to follow from economic analysis, as confirmed by the competition authorities and supported, if necessary by case-law.[103] The second step serves as a sanity check, in which one assesses whether the agreement's legal and economic *context* prevents the subsumption of the agreement under the object category.[104] Applying this logic, Advocate General Bobek expressed doubts as to whether the investigated agreement could be categorised as an object restriction. In particular, lack of a 'reliable and robust wealth of experience' showing that such practices commonly are regarded as anti-competitive called in to question the by object categorization.[105]

In its judgement, which relied heavily on the opinion of the Advocate General, the CJ re-emphasized that restrictions by object are to be interpreted restrictively and assessed within the content-objective-context

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[100] This approach was also followed in the subsequent Case C-469/15 *FSL Holdings* [2017] EU:C:2017:308. According to the undertakings, which had been fined by the Commission for participation in a price-fixing banana cartel, a more detailed contextual analysis would exculpate them (Case C-469/15 *FSL Holdings*, para. 90-98). As proposed by Advocate General Kokott in her Opinion, the CJ held that the identification of a practice with a readily apparent anticompetitive object negates any need to consider whether the wider context might disprove its harmful nature (see Opinion of Advocate General Kokott in Case C-469/15 *FSL Holdings*, para. 100-101; compared to Case C-469/15 *FSL Holdings,* para. 106-107). See further Amory, Van De Walle & Smuha (n 68) 52-33; Patrick Harrison, 'Toshiba v Commission: Do two Wrongs Make a Right? The CJ Takes Another Step Away From Allianz Hungaria' (Kluwer Competition Law Blog, 2016) <http://competitionlawblog.kluwercompetitionlaw.com/2016/03/14/toshiba-v-commission-two-wrongs-make-right-cjeu-takes-another-step-away-allianz-hungaria/ > accessed 25 May 2022 ; Niamh Dunne,'Characterizing Hard Core Cartels Under Article 101 TFEU' [2020] 65(3) Antitrust Bulletin 381-382.

[101] See Opinion of Advocate General Kokott in Case C-469/15 *FSL Holdings* EU:C:2017:308, para. 100; Case C-373/14 *Toshiba* (n 95) para. 28-29; Amory, Van De Walle & Smuha (n 68) 54.

[102] Opinion of Advocate General Bobek in Case C-228/18 *Budapest Bank* [2020] EU:C:2020:265, para. 42.

[103] Ibid (emphasis added).

[104] Ibid, para. 43 and 49-50.

[105] Only in one previous case had such type of collusions been found to amount to a restriction by object by the Commission and there was seemingly no consensus among economists as to the collusions alleged harmful nature. See ibid, para. 63, 66-68.

framework.[106] Significantly, the Court, endorsing Bobek's reasoning in this aspect, held that to justify the finding of a restriction by object there must be 'sufficiently reliable and robust experience for the view to be taken that the agreement is, by its very nature, harmful to the proper functioning of competition'[107]. Given the factual elements put forward by the parties in the particular case, the Court found that the investigated agreement (a so-called 'MIF agreement') could not be subordinated under a by object type of collusion. Instead, a detailed effects analysis, including consideration of the counterfactual had to be carried out to assess whether the agreement amounted to a restriction by effect.[108]

The question which naturally arises is which more precisely this 'experience' criteria entails — i.e. when is experience sufficient for allowing the allocation of certain agreements into the 'by object box'? While the Court held that such experience must be 'sufficiently reliable and robust'[109] and 'sufficiently general and consistent'[110], it did not further elaborate on its meaning. Since paragraph 76 of the ruling explicitly cites Bobek's Opinion it seems reasonable to turn to the Opinion for further clarification.[111] 'Sufficiently reliable and robust' should reasonably be understood as requiring the experience to be *substantial* enough for doubtlessly holding that the collusion generally is harmful to competition.[112] In other words, the belief that such practices are generally harmful to competition must be sufficiently *widespread* (i.e. there must be a consensus about the status of the type of collusion in the practice of courts and authorities or within mainstream economics).[113] That such experience further must be 'sufficiently general and consistent' ought to be understood as requiring the *overall result* of the investigated type of collusion to reveal a sufficient harm. Experience that a type of collusion merely sporadically entails sufficient harm could reasonably not warrant a presumption of illegality.[114]

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[106] Case C-228/18 *Budapest Bank* (n 60) para. 51 and 54.

[107] Ibid, para. 76 (emphasis added).

[108] Ibid, para. 76-79.

[109] Ibid, para. 76.

[110] Ibid, para. 79.

[111] Ibid, para. 76 which refers to para. 54 and 63-73 of the Advocate General's Opinion.

[112] See Opinion of Advocate General Bobek in case C-228/18 *Budapest Bank* (n 102) para. 63; Joar Lindén,'Restriction by Object: A Restriction Based Purely on Experience or also on Effects?' [2021] 4(1) Nordic Journal of European Law <https://journals.lub.lu.se/njel/article/view/23446> accessed 25 May 2022 87-88.

[113] See Opinion of Advocate General Bobek in case C-228/18 *Budapest Bank* (n 102) para. 63; See Opinion of Advocate General Wahl in case C-67/13 *CB* (n 57) para. 79; Lindén (n 112) 87-88.; Pablo Ibáñez Colomo, 'The 'robust and reliable experience' requirement in Budapest Bank: why it is a consequence of the case law (and why it is not relevant in pay-for-delay cases*'* (Chillin' Competition 2020) <https://chillingcompetition.com/2019/05/30/persistent-myths-in-competition-law-ii-the-analysis-of-the-counterfactual-is-not-relevant-when-a-practice-is-restrictive-by-object/> accessed 25 May 2022.

[114] See Lindén (n 112) 89.

Another interesting aspect of the *Budapest Bank* ruling is the Court's approach to the role of pro-competitive effects for the purpose of finding an object restriction. As the object category only encompasses conduct which reveals sufficient harm 'by its very nature' it follows, as a matter of logic, that an object classification is ill-suited for agreements which gives rise to sufficient pro-competitive effects.[115] In *Budapest Bank*, the fined undertakings put forward evidence indicating that absent the investigated agreement prices would have been higher.[116] The CJ held that where there are 'a priori, strong indications capable of demonstrating' that an agreement is pro-competitive or 'contradictory or ambivalent evidence in this regard', such evidence must be taken into account in the examination of whether there is a restriction by object.[117] While not explicitly stated by the Court, the burden of proof ought to be on the defendant.[118]

Conclusion: Still Scope for Clarification

While the cases above have offered some clarity to the by object methodology and signal a shift towards a stricter standard, the CJ's approach post-*CB* has nonetheless shown some inconsistencies. In particular, the different levels of scrutiny applied by the CJ in regards to the contextual analysis continues to cause confusion.[119] It is however clear that (i) the notion of restrictions by object relates to practices that by their very nature are harmful to the proper functioning of normal competition and (ii) the concept is to be interpreted restrictively to only encompass behaviour where sufficient harm can be expected in light of experience.

The question which remains, and is less straightforward, is how a restriction by object is to be identified in a particular case. In an attempt to patch up a workable methodology for the rest of the thesis, two different approaches to establishing restrictions by object are presented below (3.1.4.2).

3. 1. 4. 2 Approaches to Establishing Restrictions by Object

As the CJ has yet to spell out a consistent workable methodology for establishing restrictions by object, scholars and Advocate Generals have been spurred to provide operative frameworks for finding restrictions by object. As the most eminent approach in case law, the contextual approach

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[115] See Massarano N, 'The unclear effects of the Budapest Bank experience?' [2021] 42(2) Competition Law Review 66.

[116] Case C-228/18 *Budapest Bank* (n 60) para. 81-82.

[117] Ibid, para. 82.

[118] See Massarano (n 115) 67.

[119] See e.g. Amory, Van De Walle & Smuha (n 68) 47-56; Opinion of Advocate General Wathelet in Case C-373/14 *Toshiba* (n 57) para. 42-62.

has been accepted by most commentators as the current standard.[120] In particular, two readings have emerged.[121]

The first approach, a two-prong test proposed by Advocate General Wathelet in *Toshiba,* separates *obvious* and *less obvious* categories of by object types of collusion.[122] First, the agreement's content, objectives and context is assessed to ascertain whether an ’obvious’ object infringement can be identified.[123] Once an ’obvious’ object infringement has been established, the contextual analysis should be ’limited to what is *strictly necessary* in order to establish the existence of a restriction of competition by object’[124]. Secondly, only where the anti-competitive nature of the investigated practice is not as obvious, a more thorough assessment of the legal and economic context is called for. In the contextual analysis (i) the nature of the goods or services, (ii) the real conditions of the functioning of the market and (iii) the structure of the market are usually to be considered. Only in exceptional cases are the additional *Allianz* contextual elements (e.g. market power) to be considered.[125]

Yet another approach, also a two-step analysis, was proposed by Advocate General Bobek in *Budapest Bank.* First*,* regard must first be had to the *content* and *objective* of the practice in question to ascertain whether the investigated agreement can be presumed anticompetitive by its very nature in the light of sufficiently robust and reliable experience.[126] Secondly, a *contextual* analysis must be carried out to assess whether the investigated agreement, despite a match in the first step, features elements precluding the agreement from restricting competition.[127] In other words, the contextual analysis is used to verify whether the alleged object restriction in fact has the potential to restrict competition.[128]

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[120] However, Nagy advocates for a textual approach. As agreements should fall within the category of object collusion if it is anticompetitive by its *nature* only the agreements ‘characteristics’ should determine if the agreement restricts competition by object Nagy argues. The inquiry should therefore be limited to suffices to circumstances within ’the four angles of the contract’. See further Nagy (n 66).

[121] See Christian Bergqvist, ’When does agreements restrict competition in EU Competition law?’ [2020] pp. 1-29 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3650755> Accessed 25 May 2022 14.

[122] Opinion of AG Wathelet in Case C-373/14 *Toshiba* (n 57) para. 87-91; Bergqvist (n 121) 14-15.

[123] Ibid, para. 88-89.

[124] See Case C-373/14 *Toshiba* (n 95) para. 29.

[125] Opinion of Advocate General Wathelet in Case C-373/14 *Toshiba* (n 57) para. 90-91; Amory, Van De Walle & Smuha (n 68) 55-56.

[126] Opinion of Advocate General Bobek in Case C-228/18 *Budapest Bank* (n 102), para. 42.

[127] To that end, (i) the nature of the goods or services, (ii) the real conditions of the functioning of the market and (iii) the structure of the market should be considered. See Opinion of AG Bobek in Case C-228/18 *Budapest Bank* (n 102) para. 43 and 48-50; Opinion of Advocate General Wahl in Case C-67/13 *CB* (n 57) para. 44-45.

[128] See Ioannidou & Nowag (n 53) 349; Jussi Koivusalo, ‘The pursuit of an anti-competitive outcome - restrictions of competition by object after GUK and Budapest Bank’ [2021] 42(6) European Competition Law Review, 319.

3. 2 The Notion of Restrictions by Effect

3. 2. 1 Introduction

Where an agreement does not reveal a sufficient degree of harm to competition, it is necessary to analyse its effect on actual and potential competition before it can be found to infringe Article 101(1) TFEU.

To facilitate a proper understanding of the notion of restrictions by effect, first the key features of the process that led the Commission to endorse a more effects-based approach to EU competition law is explored (section 3.2.2). Next, the legal test for establishing restrictions by effect as described in the Commission's guidelines and defined in the CJ's case law is explained (section 3.2.3).

3. 2. 2 The Modernization Journey

The terms 'modernization' and 'effects-based approach' have been buzzwords and the focus of attention in EU competition law and policy since the late 1990s. While US courts, influenced by Chicago School arguments since the 1980s had been carrying out more in-depth economic analysis, the Commission's approach to enforcement was criticised for over-relying on form-based presumptions of illegality.[129] Under the Commission's 'form-based' approach agreements were treated according to formal legal categories, e.g. one set of rules applied to selective distribution agreements and yet another to franchising agreements.[130] Factors such as market power or market structure and effects on price or output were generally neglected. While such antitrust enforcement presents some merits for both firms and competition authorities, such as legal certainty and reduction of enforcement costs, it's also associated with significant shortcomings.[131] In particular, the approach was criticised for being out of touch with contemporary economic theory and leading to an overly broad application of Article 101 and 102 TFEU.[132]

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[129] See Anne Witt, 'The Enforcement of Article 101 TFEU – What has happened to the Effects Analysis?' [2018] 55(2) Common Market Law Review, 417 and 419-423; David J. Gerber, 'Two Forms of Modernization in European Competition Law' [2007] 31(5) Fordham International Law Journal <http://ejlt.org/article/view/17> accessed 25 May 2022, 1245 and 1248-1249.

[130] See Barry E. Hawk,'System Failure: Vertical Restraints and EC competition law' [2007] 32(4) Common Market Law Review. 984.

[131] See Nicolas Petit, 'From Formalism to Effects? – The Commission's Communication on Enforcement Priorities in Applying Article 82 EC' [2009] 32(4) World Competition, 486.

[132] See Hawk (n 130) 984-986.

As a response, the Commission in the late 1990s embarked upon a mission to modernise EU competition law and policy. The substantive modernization process included two main components — the narrowing of the goals of competition law and the utilisation of neoclassical economics to define the standards and methods of EU competition law.[133] For the Commission, the modernised 'more economic approach' meant the adoption a consumer welfare standard[134] and a commitment to carry out more in-depth assessments of the conduct's economic effects.[135]

3. 2. 3 The Legal Test for Establishing Restrictions by Effect

3. 2. 3. 1 The Need to Conduct a Market Analysis and Establishing a 'Counterfactual'

According to the Commission, consumer welfare should be the benchmark against which agreements are tested.[136] In the case *Mastercard* the CJ held that for an agreement to restrict competition by effect it must be 'liable to have an *appreciable adverse impact* on the *parameters of competition*, such as the price, the quantity and quality of the goods or services'.[137]An agreement can have such an adverse impact by inter alia 'appreciably reducing competition between the parties to the agreement or between any one of them and third parties'.[138]

To explain to the business community and NCAs how the Commission intends to assess effects of agreements on competition under the consumer welfare and effects-based approach four sets of guidelines were issued. The guidelines set out a theoretical framework for assessing the effects of agreements which do not have an anticompetitive object.[139]

The Commission proposes a two-step test for assessing the effects of agreements. First, the plaintiff must demonstrate that the investigated agreement *leads to a restriction of competition* either through coordination

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[133] Gerber (n 129) 1247.

[134] In place of the set of goals developed over time in case law (e.g. fostering economic integration in Europe and the protecting the process of competition), the modernised approach envisions one central goal - consumer welfare. See Anne Witt,'The European Court of Justice and the More Economic Approach to EU Competition Law—Is the Tide Turning?' [2019] 64(2) The Antitrust Bulletin, 176-178; Gerber (n 129) 1247.

[135] See Witt (n 134) 171-186.

[136] See *White Paper on the Modernisation of the Rules Implementing Articles 85 and 86 of the EC Treaty* [1999] OJ C132/1, paras. 56–57.

[137] Case C-382/12 *MasterCard* [2014] EU:C:2014:2201 para 93 (emphasis added).

[138] Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements [2011] OJ C 11/1, para 27.

[139] See Guidelines on Vertical Restraints [2010] OJ C 130/1; Horizontal Co-operation Guidelines (n 138); Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements [2014] OJ C 89/3.

or foreclosure.[140] Secondly, it must be proved that the restriction of competition has the effect of *reducing consumer welfare*, e.g. in the form of higher prices, reduced output, lower quality or diminished levels of innovation.[141]

It follows from case law that both a market analysis and a counterfactual method should be adopted. Absent such analysis infringement decisions have been suspended and remanded.[142] The use of counterfactual analysis stems from the 1966 *STM* case, in which the CJ proclaimed the following:

> 'The competition in question must be understood within the actual context in which it would occur *in the absence of the agreement in dispute*. In particular it may be doubted whether there is an interference with competition if the said agreement seems really necessary for the penetration of a new area by an undertaking.'[143]

Under a counterfactual analysis the conditions of competition that would have prevailed in the absence of the practice are evaluated to ascertain whether the alleged restriction of competition is attributable to the investigated practice. In essence, the purpose is to assess whether there is a *causal link* between the practice and the alleged restriction.[144]

In *Maxima Latvija* the CJ emphasised that an assessment of effects must be based on a detailed analysis of the economic and legal context in which the investigated agreement occurs. Further, the Court specified five factors which must be considered when deciding whether an agreement falls within the effects box; (i) the clause that is said to constitute a restriction on competition: (ii) the relevant market/markets in which the effects should be assessed; (iii) a theory of harm[145]; (iv) the counterfactual; and (v) the available evidence on the existence of the alleged effects.

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[140] Guidelines on Vertical Restraints (n 139) para. 96–127; Horizontal Co-operation Guidelines (n 138) para. 26–47; Technology Transfer Guidelines (n 139) para. 156–180.

[141] Guidelines on Vertical Restraints (n 139) para. 128–229; Horizontal Co-operation Guidelines (n 138) para. 55–334; Technology Transfer Guidelines (n 139) para. 181–273.

[142] See e.g. joined cases T-374, 375, 384 and 388/94 *European Night Services* [1998] EU:T:1998:98, para. 139-147 and Case T-328/03 O2 [2006] EU:T:2006:116 para. 65-117. See also Case C-382/12 *MasterCard* (n 137) para. 118–121 wherein the CJ stressed the importance of establishing a 'counterfactual'.

[143] Case 56/65 *STM* (n 54) p. 250 (emphasis added).

[144] See Pablo Ibáñez Colomo & Alfonso Lamadrid de Pablo, 'On the notion of Restriction of Competition: What we Know and What we Don't Know we Know' in Damien Gerard, Massimo Merola and Bernd Meyring (eds) '*The Notion of Restriction of Competition: Revisiting the Foundations of Antitrust Enforcement in Europe'* (Bruylant, 2017) 282-283.

[145] Meaning a theory as to how and why an agreement and/or clause is likely to have negative effects on competition. For examples of possible theories, see Horizontal Co-operation Guidelines (n 138) para. 33-38 and Guidelines on Vertical Restraints (n 139) para. 100 and 224.

3. 3 The Notion of Potential Competitor

While both horizontal and vertical agreements may be caught by the Article 101 prohibition,[146] the application of said provision usually varies depending on whether the agreement is horizontal or vertical.[147] As a general rule, agreements between rival undertakings (i.e horizontal agreements) are more damaging to competition than agreements concluded between undertakings at different levels of the production chain (i.e. vertical agreements).[148] The qualification of an agreement as horizontal or vertical depends on the market definition and the parties' position herein.[149]

A horizontal relationship exists where undertakings already are operating on the same market.[150] It is less clear-cut whether an undertaking not currently active on the market, but which might at some point in the future enter it, could be regarded as a potential competitor. For the purpose of this thesis, the crucial question is whether originator and generic firms are in potential competition despite the presence of a patent. As will be explored further in chapter 4, parties to RPSSs have contested that this is the case.[151] The question is of critical importance since if – at least – potential competition does not exist between the parties, the agreement cannot be categorised as a restriction by object nor by effect.

While the Commission has a well-established practice of analysing potential competition in the context of the EU Merger Control Regulation,[152] the potential competition doctrine has received less attention in the Article 101 jurisprudence.[153] Indeed, the most directly focused case law from the CJ on potential competition under Article 101 TFEU are the recent *Generics* and *Lundbeck* cases.

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[146] Case 56 and 58/64 *Consten and Grundig* [1966] EU:C:1966:41.

[147] For instance, there are different guidelines for horizontal cooperation agreements and for vertical agreements. See further Whish and Bailey (n 50) 122.

[148] Case C-32/11 *Allianz* (n 67) para 43.

[149] Bergqvist (n 121) 4.

[150] Horizontal Co-operation Guidelines (n 138) para. 10; Whish and Bailey (n 50) 122.

[151] See sections 4.1.3 and 4.2.3.

[152] See COMP/M.1846 – *GlaxoSmithKline* [2000]; COMP/M.2922 – *Pfizer/Pharmacia* [2003]; COMP/M.3687 - *Johnson & Johnson* [2005] OJ C 111/9; Mario Todino, Geoffroy van de Walle & Lucia Stoican, 'EU Merger Control and Harm to Innovation — A Long Walk to Freedom (from the Chains of Causation)' [2018] 64(2) The Antitrust Bulletin, 15-17.

[153] Niamh Dunne, 'Potential Competition in EU Law' [2021] 08/2021 LSE Legal Studies Working Paper No. 08/2021, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3871310> accessed 25 May 2022, 2.

4. Jurisprudence on RPPSs

4. 1 *Generics* (Paroxetine)

4. 1. 1 Introduction

On 30 January 2020, the CJ handed down its judgement in *Generics* in response to a request for a preliminary ruling in the context of an appeal against a decision of the CMA. In the following, the proceedings underlying *Generics* are described (section 4.1.2), followed by an analysis of the CJ's judgment on the notions of 'potential competitor' (section 4.1.3) and 'restriction by object' (section 4.1.4).

4. 1. 2 Factual background

In 1991, GlaxoSmithKline ('GSK') began marketing Paroxetine, a prescription-only used to treat depressive and anxiety-related disorders, in the UK under the brand name 'Seroxat'. GSK's compound patent protection for Paroxetine hydrochloride, the API of Seroxat, expired in January 1999 and in December 2000 GSK's right to data exclusivity relating to that API expired, leaving generic manufacturers free to seek a MA under the abridged procedure.[154] GSK had however obtained a series of secondary patents, covering for new forms of the API and the process to produce them ('the Anhydrate Patent'), which expired in 2016.[155]

By mid-2000, several generic manufacturers planned to enter the UK market with generic Paroxetine and submitted applications for MA for this purpose.[156] In that context, disputes concerning the validity of GSK's secondary patents arose between GSK and those generic manufacturers. Subsequently, GSK and the generic manufacturers entered into agreements in settlement of those disputes. During the agreement's validity, the generic manufacturers agreed (i) not to seek revocation for the Anhydrate Patent (a so called 'non-challenge clause'), and (ii) not enter the UK market for Paroxetine on their own (a so called 'non-compete clause'). In return, GSK undertook to (i) make payments to the generic manufacturers[157], and (ii) sell the generic manufacturers a limited amount of Paroxetine that they would then distribute in the UK at a set price.[158]

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[154] Case C-307/18 *Generics* (n 4) para. 7-8.

[155] Ibid, para. 9.

[156] Ibid, para. 10.

[157] These payments e.g. included (i) $12.5 million for the purchase all GUK's, one of the generic manufacturers, stock of generic Paroxetine intended for sale in the UK and (ii) £0.5 million for paying 50% of GUK's costs in the litigation.

[158] Ibid, para. 12-14 and 22-26.

In February 2016, the CMA, which took the view that the agreements infringed Article 101 (and Article 102) by delaying the market entry of generic Paroxetine, imposed fines totaling £44.99 million on GSK and the generic manufacturers.[159]

4. 1. 3 The Notion of Potential Competitor

The CJ first considered questions 1 and 2, by which the referring court, in essence, asked whether the generic manufacturers, for the purpose of Article 101(1) TFEU, could be regarded as potential competitors of GSK, despite the process patent held by GSK.[160]

The CJ began by recalling that the prohibition of Article 101(1) TFEU only covers coordination which has a negative and appreciable effect on competition within the internal market.[161] In the context of horizontal agreements, the requirement of 'applicability' means that the coordination must involve undertakings who are – at least – in potential competition with each other.[162]

For the generic to be characterised as a 'potential competitor' there must be '*real and concrete possibilities*' for market entry.[163] Under this standard, the mere wish or desire of the generic manufacturer to enter the market or purely hypothetical possibility of such entry does not suffice. Conversely, it is not required to demonstrate with certainty that the manufacturer will in fact enter the market concerned.[164] The 'real and concrete possibilities' criterion is therefore pitched by the CJ above the standard of a mere hypothetical chance, but considerably below that of a guaranteed certainty of entry.[165]

The assessment of whether potential competition exists must be carried out 'having regard to the structure of the market and the economic and legal context within which it operates'.[166] Applying the context-specific approach to the case at hand, the CJ held that account must be taken of (i) the

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[159] Ibid, para. 28.

[160] Ibid, para. 34.

[161] Ibid, para. 30-31.

[162] Ibid, para. 32.

[163] Ibid, para. 36 (emphasis added).

[164] Ibid, para. 38.

[165] Dunne (n 153) 5; Francesco Rizzuto & Monika Ewa Lynch, 'The Implications of the Generics UK 'Pay-for-Delay' Ruling of the Court of Justice of the European Union (C-307/18 Generics UK Ltd and Others)' [2020] 4(2) European Competition and Regulatory Law Review, 154.

[166] Case C-307/18 *Generics* (n 4) para. 39.

regulatory constraints present in the pharmaceutical sector[167] and (ii) intellectual property rights, in particular patents, held by originator firms.[168] For this purpose, the Court adopted a two-fold approach. First, the CJ assessed whether the generic had taken '*sufficient preparatory steps* to enable it to enter the market concerned within such a period of time as would impose competitive pressure' on the established originator firm.[169]Preparatory steps (such as obtaining MA, sourcing stock of products and preparing a patent challenge) indicate that the prospective rival has a 'firm intention' and an 'inherent ability' to enter the relevant market.[170]

Second, the referring court must determine whether the generic manufacturer would face 'insurmountable' barriers to entry.[171] In this context the CJ considered the existence of a process patent, for an API in the public domain,

> 'cannot, as such, be regarded as an insurmountable barrier, and does not mean that a manufacturer of generic medicines who has in fact a firm intention and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being subject to infringement proceedings brought by the patent holder, cannot be characterised as a 'potential competitor' of the manufacturer of originator medicines concerned.'[172]

According to the CJ, the argument put forward by GSK and the generic manufacturers that the patent, since litigation was pending, *had to be presumed valid* and therefore amounted to a barrier to entry, did not undermine this finding.[173] The Court noted that the presumption of validity 'sheds no light […] on the outcome of any dispute in relation to the validity of that patent, something which, moreover, cannot ever be known as a result of the very conclusion of the [settlement] agreement.'[174] The presumption of validity could therefore not exclude potential competition, as this would deprive Article 101 TFEU of all meaning and 'frustrate EU competition law.'[175]

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[167] In this context the CJ made reference to Dir. 2001/83 and Reg. 726/2004, i.e. the need for a MA.

[168] Case C-307/18 *Generics* (n 4) para. 40-41.

[169] Ibid, para. 43 (emphasis added).

[170] Ibid, para. 44.

[171] Ibid, para. 45.

[172] Ibid, para. 46. As Advocate General Kokott argues in § 68 of her Opinion in Case C-307/18 *Generics* the presumption of validity of a patent should not ' … be equated with a presumption of illegality of generic products validly placed on the market which the patent holder deems to be infringing the patent'.

[173] Case C-307/18 *Generics* (n 4) para. 47.

[174] Ibid, para. 48.

[175] Ibid, para. 48-49.

Having this said, the CJ stressed that NCAs must not disregard any question relating to patent law since patents protecting originators' products 'are indisputably part of the economic and legal context.'[176] However, the CJEU held it inappropriate for the NCA to review 'the strength of the patent or […] the probability […] that the patent [could be found] valid and [to be] infringed'. Rather, the NCA should assess 'whether, *notwithstanding the existence of that patent*, the manufacturer of generic medicines has real and concrete possibilities of entering the market at the relevant time.'[177]

Lastly, the CJ held that once it had been found that a generic manufacturer has a firm intention and an inherent ability to enter the market, additional elements may serve as validating factors.[178] Elements which indicate that a competitive relationship existed include: (i) 'the *conclusion of an agreement* between a number of undertakings, operating at the same level in the production chain, some of which had no presence in the market concerned',[179] and (ii) *value transfers* from an originator firm to a generic manufacturer 'in exchange for the *postponement* of the latter's market entry, even though the former claims that the latter is infringing one or more of its process patents.'[180] According to the Court, the greater the transfer of value, the stronger the indication.[181]

4. 1. 3 The Notion of Restriction by Object

By the second set of questions, the CJ was invited to clarity in which circumstances RRPSs may amount to a restriction of competition by object.[182]

The CJ recalled that the concept of restriction by object must be interpreted strictly, only encompasses practices which reveal, in themselves, a certain degree of harm to competition, and that this is to be assessed by examining the content of the agreement's provisions, their objectives and the economic and legal context.[183] Having recognized that the pharmaceutical sector is sensitive to a delay in generic market entry,[184] the CJ stated that the

[176] Ibid, para. 50.

[177] Ibid, para. 50 (emphasis added).

[178] Ibid, para. 54.

[179] Ibid, para. 55.

[180] Ibid, para. 56.

[181] Ibid, para. 56.

[182] Ibid, para. 60.

[183] Ibid, para. 67.

[184] As this 'leads to the maintenance […] of a monopoly price […] which has considerable financial consequences, if not for the final consumer, at least for social security authorities.' See Case C-307/18 *Generics*, para. 70.

investigated agreements could not be regarded as having the same nature as market-sharing or market-exclusion agreement, as they did relate to a real patent dispute, subject of proceedings before a national court.[185]

Nonetheless, the Court held it necessary to assess whether RPPSs may be treated as *equivalent* to market-sharing or market-exclusion agreements.[186] In this context, the CJ recalled that the exercise of an IP right might fall within the ambit of the prohibition contained in Article 101(1) TFEU,[187] hence the mere fact that an agreement aims at putting an IP dispute to rest does not shield it from the application of competition law. Accordingly, 'since challenges to the validity and scope of a patent are part of normal competition in the sectors where exclusive rights exist', the Court held that co-operation resulting in an undertaking abandoning such challenges are liable to restrict competition.[188] Citing case-law, the Court continued by stating that 'agreements whereby competitors deliberately substitute practical cooperation between them for the risks of competition' further are liable to amount to restrictions by object.[189] That said, the CJ established that under certain circumstances RRPPs may not be considered a restriction by object - even in the presence of a value transfer from the originator undertaking to the generic.[190] For example, in the situation where a generic, after assessing its chances of success in the court proceedings, decides to not to enter the market a value transfer may be justified, appropriate and strictly necessary.[191]

On the other hand, a restriction by object obtains when there is no other explanation for a value transfer than the 'commercial interests [of the parties] to *avoid competition on the merits*.'[192] In assessing whether this is the case, the net gain from all value transfers (pecuniary and non-pecuniary) must be considered to examine whether (i) the value transfer is justified by the existence of any *quid pro quo* on part of the generic (e.g., compensation for the costs of, or disruption caused by, litigation),[193] and whether (ii) the net gain is sufficiently attractive as to induce the generic to abstain from

[185] Ibid, para. 76.

[186] Ibid, para 77.

[187] Ibid, para. 79.

[188] Ibid, para. 81-83.

[189] Ibid, para. 83.

[190] Ibid, para. 84-85.

[191] Ibid, para. 85-86. In this situation, the value transfer may be justified by, and be necessary for the realization of, of the legitimate objective to compensate for the patent litigation.

[192] Ibid, para. 87 (emphasis added).

[193] Ibid, para. 90-92.

entering the market.[194] Is such the case, the RPPS 'must, in principle, be characterized as a restriction by object'.[195]

Where the parties to the RRPS invoke its pro-competitive effects, the CJEU held that such effects must be considered as elements of the agreements economic context, but only 'in so far as they are capable of calling into question the overall assessment of whether the concerted practice concerned [reveals] a sufficient degree of harm to competition'.[196] To justify a reasonable doubt as to the finding of an object restriction under Article 101(1), thereby moving the agreement into the 'by effect' category, such effects must be 'demonstrated, relevant and specifically related to the agreement concerned' and 'sufficiently significant'.[197] As EU competition law does not recognize a 'rule of reason', the analysis at the categorization stage does not require a full effects analysis nor the balancing of actual pro- and anticompetitive effects, but should be limited to that which is strictly necessary.[198] Having examined the pro-competitive effects of the investigated RSPP:s at issue[199] the CJ held that such were 'not only minimal but probably uncertain' and could therefore not call into doubt that the agreements revealed sufficient harm to competition.[200]

The CJ concluded by ruling that a settlement agreement amounts to an object infringement where the value transfer 'have no other explanation than the commercial interest of the parties to the agreement not to engage in competition on the merits' and where the agreement is not accompanied by proven and sufficient pro-competitive effects.[201]

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[194] Ibid, para. 93.

[195] Ibid, para. 95.

[196] Ibid, para. 103.

[197] Ibid, para. 107.

[198] Ibid, para. 104.

[199] Namely that the agreements did give rise to a *slight price reduction* of Paroxetine.

[200] Ibid, para. 108-110.

[201] Ibid, para. 111.

4. 2 *Lundbeck* (Citalopram)

4. 2. 1 Introduction

On 25 March 2021, the CJ upheld the judgment of the General Court regarding the Commission's decision in 2013, fining Lundbeck and four generic manufacturers a total of €146 million for violating Article 101 TFEU,[202] confirming that (i) Lundbeck and the generic manufacturers, at the time of the settlement agreements, were potential competitors and (ii) that the RPPS:s amounted to restriction by object. As CJ's judgment primarily confirms what had already been decided in *Generics*, the following analysis of the Court's ruling will focus on its key findings on the notions of 'potential competitor' (section 4.2.3) and 'restriction by object' (section 4.2.4).

4. 2. 2 Factual background

In the 1970s, researchers at the pharmaceutical company Lundbeck synthesized a compound now known as Citalopram. Subsequently, clinical trials showed that Citalopram was effective in combatting anxiety-based depression and Lundbeck began marketing Citalopram under the brand name 'Cipramil'. While Lundbeck's original patents, protecting the molecule and two processes to produce it, expired around the year 2000, Lundbeck had in the meanwhile developed a more efficient process for purifying Citalopram, in respect of which it obtained various patents (the 'crystallization process patents').[203] When the crystallization process patents were near the end of its validity period, Lundbeck became aware that four generic manufacturers were preparing to enter the market and as a result, threatened to initiate infringement proceedings against each generic undertaking. Before litigation in court was initiated, the parties however settled.[204]

According to the settlement agreements, Lundbeck would pay the generic undertakings significant amounts, in return for the generics' commitment not to enter the Citalopram market.[205] While the agreements contained non-compete clauses, the generics were not required to refrain from challenging the patent at issue (i.e., they did not include any 'no-challenge' clause).[206]

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[202] COMP/AT.39226 – *Lundbeck* (n 3).

[203] Case C-591/16 *Lundbeck* (n 4) para. 15-22.

[204] COMP/AT.39226 – *Lundbeck* (n 3) para. 4.

[205] Ibid, para. 824, 962, 1013, 1087 and 1174.

[206] Ibid.

4. 2. 3 The Notion of Potential Competitor

First, by its appeal Lundbeck argued that the generics were not potential competitors as its process patents barred them from lawfully entering the market. According to Lundbeck, which was supported by EFPIA in this aspect, where exclusive rights such as patents exist, the Commission ought to be required to demonstrate that there are real and concrete possibilities for lawful market entry. Since Article 101(1) TFEU only protects lawful competition, the launch of generic products that infringe a third parties' IP rights can not constitute the expression of potential competition the argument goes. To support its view, Lundbeck referred to the Technology Transfer Guidelines according to which undertakings that are in a blocking situation due to an exclusive technology right are not considered competitors.[207]

The CJ however dismissed the arguments put forward by Lundbeck.[208] Relying on the two-limb test of the *Generics* judgement, the Court held that potential competition exists where an undertaking (i) has taken 'sufficient preparatory steps' (indicating a firm intention and an inherent ability to enter the market) and (ii) would not face insurmountable barriers to entry.[209] Closely following its reasoning in *Generics*, the CJ held that Lundbeck's patents covering the manufacturing processes of Citalopram, an API in the public domain, did not constitute insurmountable barriers to entry.[210] This since, regardless the presumption of validity, the outcome of any dispute relating to the validity of that patent is not predictable.[211] It was therefore not certain that (i) the generic products would infringe Lundbeck's patents, and (ii) that Lundbeck's process patents would withstand the invalidity claims raised in the generic undertakings' infringement actions.[212] Therefore, to establish the existence of potential competition, the Commission and NCAs do not to have to review the strength of the patent, or the chances that it will be found to be infringed.[213] According to the CJ, these findings were not called into question by the Technology Transfer Guidelines. For one thing, the Court held that the investigated RPPSs could not be equated with the technology transfer agreements. Moreover, the Technology Transfer Guidelines made exceptions for cases in which 'it is not clear whether a particular technology right is valid and infringed'.[214]

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[207] Ibid, para. 43; Technology Transfer Guidelines (n 139) para. 29.

[208] Case C-591/16 *Lundbeck* (n 4) para. 61.

[209] Ibid, para. 52-56.

[210] Ibid, para. 56.

[211] Ibid, para. 58.

[212] Ibid para. 58-61, referring to para. 46-51 in Case C-307/18 *Generics* (n 4).

[213] Case C-591/16 *Lundbeck* (n 4) para. 60.

[214] Ibid, para. 64.

Further, the CJ reiterated that entering the market 'at risk' constitutes a real and concrete possibility of market entry.[215] In fact, one of the generic manufacturers had already entered the market as it had been selling generic Citalopram to its distributor in Sweden for almost five months before the conclusion of the settlement agreement.[216] Moreover, Lundbeck's crystallization process patents did blocked some but not all possibilities of market entry, as generic manufacturers could produced Citalopram either by (i) using the process described in its original compound patent,[217] or (ii) utilizing a entirely new, alternative process developed by the generic manufacture itself.[218]

Second, Lundbeck argued that the General Court had erred in law when it found that some evidence subsequent to the investigated RPPSs (namely documents indicating how the undertakings perceived the strength of Lundbeck's process patents when the agreements were concluded) could be considered, while refusing to take account of other evidence submitted by Lundbeck which also was subsequent to those agreements (e.g., the confirmation, by both the EPO Board of Appeal and the Netherlands Patent Office, of the validity of one of Lundbeck's patents in all relevant aspects in 2009 and the fact that Lundbeck 'had been granted preliminary injunctions or other forms of interim relief' in more than 50% of the proceedings it had initiated in 2002 – 2003'[219]).

The CJ clarified that since potential competiton must have existed at the time when the settlement agreement was concluded, evidence prior to, contemporaneous with, or subsequent to the conclusion of the investigated agreement may only be considered if it sheds light 'on the existence or absence of a competitive relationship between the parties at the time the agreement was concluded'.[220] Considering the nature of the evidence the CJ found that the General Court had not erred in law as the first set of evidence could help to establish the parties' position when the agreements were concluded, while the latter set of evidence (i.e., the subsequent outcome of the dispute) was unknown to the parties at that time and hence incapable of 'shedding light on the existence or absence of a competitive relationship' between them.[221]

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[215] Ibid, para. 59.

[216] Ibid, para. 116.

[217] As the compound patent application according to Article 83 EPC must describe how the API can be reproduced, the original production process will normally expire simultaneously with the patent protecting the API.

[218] Case C-591/16 *Lundbeck* (n 4) para. 62.

[219] Ibid, para. 44.

[220] Ibid, para. 66-67.

[221] Ibid, para. 70-72.

4. 2. 4 The Notion of Restriction by Object

In line with *CB* and later case law, the CJ began its analysis by stating that the concept of restrictions by object must be interpreted strictly and only can be applied to those agreements 'which reveal, in themselves […] a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects'.[222] (para. 112). Reiterating its *Generics* ruling, the CJEU stated that RPPSs constitute restrictions by object only 'when it is plain […] that the transfers of value […] cannot have any explanation other than the commercial interest of both the holder of the patent at issue and the party allegedly infringing the patent not to engage in competition on the merits'.[223] While a case-by-case assessment must be carried out to establish whether the value transfers are to incentivize delayed or abandoned entry, it is not required that such value transfers are greater than the profits which the generic might have expected from market entry.[224] In the case at hand, the CJ held that it was 'principally the size of the reverse payments' (and not the patents) which induced the generics to accept the restrictions to their entry.[225] Moreover, as Lundbeck had not identified any pro-competitive effects attached to the agreements liable to question their harm to competition, the CJ conclude that the General Court had correctly characterised the agreements as restrictions by object.[226]

Lundbeck argued that the General Court had erred in law by not requiring the Commission to examine the 'counterfactual scenario' when establishing a restriction by object.[227] Had the counterfactual case constellation been examined it would have been shown that the generics refrained from entering the market 'not on account of the existence of those agreements, but quite simply on account of the existence of Lundbeck's patents' it was argued. In support of its view, Lundbeck referred to *Generics* in which the CJ by taking into account the pro-competitive effects of the agreements under consideration, according to Lundbeck, acknowledged the importance of the counterfactual analysis when categorising an agreement under Article 101(1) TFEU.[228]

The CJ disagreed, stating that all that is required for a practice to constitute a restriction by object is to establish that it is sufficiently harmful to competition, having regard to 'the content of its provisions […], the

[222] Case C-591/16 *Lundbeck* (n 4) para. 112.

[223] Ibid, para. 114.

[224] Ibid, para. 112-115.

[225] Ibid, para. 117.

[226] Ibid, para. 136-137 and 117-118.

[227] Ibid, para. 139. Compare to § 473 in the General Court's judgment in *Lundbeck* were it was held that the counterfactual only is relevant to an effects analysis. See Case T-472/13 *Lundbeck* [2016] EU:T:2016:449.

[228] Opinion of Advocate General Kokott in Case C-591/16 *Lundbeck* para. 136-137.

objectives which it seeks to achieve and the economic and legal context in which it takes place', not requiring an examination of its effects.[229] Hence, the Court did not find it not necessary to consider the counterfactual scenario for the purpose of characterising a practice as a restriction by object, 'unless the clear distinction between the concept of 'restriction by object' and the concept of 'restriction by effect' […] is to be held not to exist'.[230] The Court's reasoning indicates that taking an agreements pro-competitive effects into consideration is acceptable when establishing a restriction by object as its serves only to determine their objective *gravity*, while establishing a counterfactual aims at quantifying their *effects* (and hence, inappropriate in by object cases). Moreover, as pointed out by Advocate General Kokott in her Opinion it seems incorrect to state that a counterfactual analysis would have shown that the generics refrained from entering the market as a result of the existence of Lundbeck's patents and not the value transfers, since there was uncertainty to the validity of the crystallisation process patents and the infringing nature of the generics products at the time when the RPSSs were concluded.[231] Indeed, 'evidence relating to the period preceding the conclusion of the agreements at issue [showed] that the manufacturers of generic medicines had made considerable efforts to prepare for their market entry and that they did not intend to desist from those efforts on account of Lundbeck's new process patents'[232].

[229] Case C-591/16 *Lundbeck* (n 4) para. 141.

[230] Ibid, para. 140.

[231] See § 140 in the Opinion of Advocate General Kokott in Case C-591/16 *Lundbeck.*

[232] Such evidence included internal documents and e-mail correspondence which revealed that both the generic manufacturers and Lundbeck expressed doubts with respect to whether Lundbeck's crystallisation process patents were valid or would be infringed by the generic Citalopram. See Case C-591/16 *Lundbeck* (n 4) para. 117-118; Case COMP/AT.39226 – *Lundbeck* (n 3) para. 1021-1027. Further, Lundbeck did not dispute that the value transfers were tailored on the profits the generic expected to make had they entered the market for the term of the agreements. See Case C-591/16 *Lundbeck* (n 4) para. 117. Lastly, the generics had had made considerable preparations for their market entry, such as assembling a large stock of generic Citalopram and obtaining required marketing authorization. See Case C-591/16 *Lundbeck* (n 4) para. 38 and 84-86.

4. 3 *Servier* (Perindopril)

4. 3. 1 Introduction

Servier is the second RPPS case which the Commission investigated following its inquiry into the pharmaceutical sector.[233] In 2014, the Commission imposed a fine totaling € 427.7 million upon Servier and the generic undertakings for violating Article 101 and 102 TFEU.[234] In its judgement on 12 December 2018, the General Court upheld the Commission's findings of the restriction of competition by object in regard to the RPPSs between Servier and four generic undertakings.[235] However, the Court disagreed with the finding that the settlement between Servier and Krka constituted a restriction of competition by object nor effect, and as a result annulled the Commission's decision in this regard.[236] The appeals against the ruling of the General Court are pending before the CJ at the moment of writing.[237]

As most of the General Court's findings are in line with the CJ's reasoning in *Generics* and *Lundbeck*, the analysis below will focus on the areas which distinguish it, namely the GC's analysis of the Krka licence agreement (section 4.3.2). First however, the factual background underlying *Servier* is described (section 4.3.2).

4. 3. 2 Factual background

In the 1980s, the French manufacturer Servier developed Perindopril, a new medicine for treating high blood pressure.[238] The Perindopril compound patent expired in the early 2000s, but Servier was granted a new patent relating to the API of Perindopril and its manufacturing processes in 2004, the '947 patent'.[239] The validity of the 947 patent was subsequently challenged before the EPO and before various national courts.[240] Between 2005 and 2007, in the course of litigation, Servier entered into various settlement agreements with generic companies.[241]

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[233] COMP/AT.39612 – *Servier* [2014] (n 3).

[234] Ibid, para. 3187.

[235] Case T-691/14 *Servier* [2018] EU:T:2018:922 para. 1959.

[236] Case T-691/14 *Servier* (n 235) para. 1960.

[237] See Cases C-176/19 and C-201/19.

[238] Case T-691/14 *Servier* (n 235) para. 2.

[239] Ibid, para. 4-10.

[240] Ibid, para. 11-15.

[241] Ibid, para. 28-58.

Between October 2006 and January 2007 Servier and Krka entered into a number of agreements.[242] Under the settlement agreement Krka undertook to (i) withdraw from all patent invalidation actions against the 947 patent and to refrain from new patent challenges ('non-challenge'); and (ii) not launch its generic Perindopril ('non-compete').[243]

In contrast to the agreements in *Lundbeck,* the settlement agreement did not provide for a cash payment from Servier to Krka.[244] Instead in separate agreements, Servier (i) granted Krka an exclusive licence to Servier's 947 patent within seven Member States[245] in return for a 3 % royalty on Krka's net sales; and (ii) acquired Krka's competing technology for manufacturing its generic version of Perindopril for €30 million. Under the technology acquisition agreement, Krka undertook to transfer its two process patent applications in return for a grant-back licence.[246] Under the agreements Krka was prohibited from supplying any third party with Perindopril produced by the technology protected by the 947 patent and limited to selling its own generic Perindopril in seven Member States.[247]

According to the Commission, the licence agreements constituted so-called 'side deals' that were linked to the settlement agreement, and had to be understood as *concealed value transfers,* the purpose of which was to reduce the incentives for Krka to independently enter the markets of the remaining Member States..[248] In the Commission view, the settlement agreement and side deals constituted a market-sharing agreement and as such a single and continuous infringement under Article 101 TFEU, restricting competition either by object or by effect.[249] Krka on the other hand argued that the licence was a genuine mutual compromise in the form of a settlement and that there was fierce competition between them and Servier in the seven markets.

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[242] Ibid, para. 43-44.

[243] Ibid, para. 45.

[244] COMP/AT.39612 – *Servier* (n 3) para. 1731.

[245] Prior to the licence agreement, Krka had launched its generic Perindopril 'at risk' in seven central and eastern European (CEE) markets, making it the first generic manufacturer to enter the market for Perindopril. The licence agreement covered the CEE markets where Krka already had entered.

[246] T-691/14 *Servier* (n 235) para. 46-51.

[247] COMP/AT.39612 – *Servier* [2014] (n 3) para. 1765-1773.

[248] Ibid*,* para. 1670.

[249] Ibid, para. 1804-1859.

4. 3. 3 Restriction by Object

4. 3. 3. 1 Side Deals as *Prima Facie* Restrictions by Object

The Court defined side deals as normal commercial agreements that are (i) *linked* to a settlement agreement which contain restrictive clauses (e.g. non-compete or non-challenge clauses); and (ii) involve a *value transfer* from the patent holder to the generic.[250] The link may be temporal,[251] legal[252] or contextual[253].[254] Such a link indicates that the agreements were negotiated together and form part of a single contractual framework, where the commercial contract is meant to disguise a value transfer which induces the generic to accept the settlement agreements restrictive clauses.[255] Therefore, the Court held that the presence of a side deal may constitute a serious indication of an inducement to not compete, and hence a restriction by object.[256]

4. 3. 3. 2 Licence Agreements as *Prima Facie* Legitimate Side Deals

Having stated that a side deal usually is a serious indication of an inducement to not compete, the GC went on to hold that licensing agreements, in principle, do not fall under the category of suspicious side deals — effectively creating an exception for licensing agreement.[257] As a result, the onus lies with the Commission to point to indications other than the mere linking of the licence and settlement agreement establish that the licence was not granted under normal market conditions, but instead was used as a means to conceal an illegitimate value transfer.[258] To justify this finding, the GC put forward five arguments.

First, referring to the Technology Transfer Guidelines the Court held that the grant of a licence is an *appropriate means of putting an end to a patent*

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[250] Ibid, para. 798 and 801.

[251] Meaning that the agreements are concluded on the same day or within a short period of time.

[252] E.g., where the binding nature of one of the agreements is conditional upon the conclusion of the other agreement.

[253] Meaning that it, in the light of the context in which they are concluded, is established that the agreements are indissociable.

[254] T-691/14 *Servier* (n 235) para. 798-799.

[255] Ibid, para. 799 and 802.

[256] Ibid, para. 797.

[257] Ibid, para. 948 and 943; Athanasiadou (n 7) 625; Richard Tepper,'Servier v Commission: Following in the Footsteps of Lundbeck' [2019] 8(2) UCL Journal of Law and Jurisprudence, 124; James Killick, Jérémie Jourdan & Pierre Pêcheux, 'The Servier Judgment: The General Court Annuls the Commission's Market Definition but Confirms the Illegality of Certain Patent Settlement Agreements' [2019] 10(1) Journal of European Competition Law & Practice, 28.

[258] T-691/14 *Servier* (n 235) para. 949.

dispute, as it satisfied the interests of both parties. In particular, that the conclusion of a licence agreement (i) protects the patent, in the interest of the originator; while (ii) authorising the market entry of the generic.[259]

Second, since a licence agreement is based on the parties' *recognition of the patents' validity,* linking a licence agreement to a settlement agreement is justified as it confirms the legitimacy of the patent settlement.[260]

Third, Court held that the non-challenge and non-marketing clauses in the settlement agreement were *'mitigated* by the licence agreement'[261]. By encouraging 'the entry of generic products on the market by eliminating the litigation risk associated with the patent'[262], the licence was said to neutralise the negative effects of the non-compete clause.[263] Moreover, the restrictive effects of the non-challenge clause were also limited as it permitted market entry without the risk of costly litigation[264]. As a result, the agreements did not reveal a 'sufficient degree of harm', the Court held.[265]

Fourth, according to the GC, *inducement is less evident* in the context of a licensing agreement than in other cases 'because such an agreement does not entail a *financial transfer* from the originator company to the generic'[266]. Indeed, the value transfer in the context of a licensing agreement occurs in two ways: (i) a pecuniary transfer of value in the form of the *licence fee* from the generic to the originator; and (ii) a non-pecuniary value transfer from the originator to the generic, as the latter can *enter the market without risk*.[267] The Court further pointed out that 'the royalty paid to the patent holder constitutes a *quid pro quo* for the benefit that the generic company receives from the licence agreement'[268]. To establish an illegitimate, concealed value transfer in cases of licence agreements, the Commission must therefore prove that (i) the royalty is abnormally low.[269] Moreover, to establish a sufficient degree of harm for the purpose of finding

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[259] Ibid, para. 946; Technology Transfer Guidelines (n 139) para. 205.

[260] T-691/14 *Servier* (n 235) para. 947.

[261] Ibid, para. 953 (emphasis added).

[262] Ibid, para. 954.

[263] Ibid.

[264] Ibid, para. 955.

[265] Ibid, para. 956, wherein the GC made a reference to Case C-67/13 *CB* (n 50) para. 49-50.

[266] T-691/14 *Servier* (n 235) para. 950.

[267] Ibid, para. 950-951.

[268] Ibid, para. 951 (emphasis added).

[269] T-691/14 *Servier* (n 235) para. 952.

a restriction by object, (ii) the deviation from normal market conditions needs to be more than evident.[270]

Lastly, the Court argued that its finding was *not in conflict with the TTBER* nor *CJ's case law*.[271] In the former case, Article 2 TTBER stipulates that Article 101(1) TFEU does not apply to technology transfer agreements entered into between undertakings permitting the production of products. Article 5 TTBER however prescribes that the exemption does not apply to licence agreements containing non-challenge clauses. The GC held that this however does not mean that a non-challenge clause of licence agreement falls within the scope of Article 101(1) TFEU.[272] In regard to the latter, the GC recalled that while the CJ in *Windsurfing* [1986] had found that 'a clause in a licence agreement obliging the licensee not to challenge the validity of the patent'[273] infringed Article 101(1) TFEU,[274] it had qualified its position in the later *Bayer* [1988] judgement.[275] In *Bayer,* the CJ held that non-challenge clauses in patent settlement agreements do not automatically run afoul of Article 101(1).[276] Instead, their legality must be determined by taking the legal and economic context into account.[277]

Having justified its exemption for licence agreements, the GC proceeded to assess whether the Commission's finding of a restriction by object in the present case was justified.[278] As the GC found that, at the time the agreements were concluded, a (i) real patent dispute existed between Servier and Krka[279] and (ii) there were consistent indications leading the parties to believe that the 947 patent was valid[280], the mere linking of the licence and settlement agreements could not be understood as an inducement to not compete.[281] The Commission had therefore to show that the licence

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[270] Ibid, para. 953 and 963.

[271] Ibid, para. 957.

[272] Case T-691/14 *Servier* (n 235) para. 958-959.

[273] Case C-193/83 *Windsurfer* [1986] EU:C:1986:75*,* para. 89.

[274] Ibid, para. 92-93. This since it 'is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error' (Ibid, para. 92).

[275] Case T-691/14 *Servier* (n 235) para. 960-961.

[276] Case C-65/86 *Bayern* [1988] EU:C:1988:448, para. 16.

[277] Ibid; Case T-691/14 *Servier* (n 235) para. 961; Thomas Cheng 'Antitrust Treatment of the No Challenge Clause' [2016] 5(2) JIPEL 461.

[278] Case T-691/14 *Servier* (n 235) para. 964.

[279] Ibid, para. 965-969.

[280] Ibid, para. 970. Namely, the (i) EPO's Opposition Division confirming the validity of the 947; and (ii) High Court of Justice (England & Wales), Chancery Divisions granting Servier's application for an interim injunction and denying Krka's motion on annulment of the 947 patent.

[281] Ibid, para. 972.

agreement was not concluded under normal market conditions.[282] In this regard, the GC held that the Commission had not sufficiently shown that the 3% royalty on Krka's net sales was abnormally low, and accordingly a restriction by object was not sufficiently established.[283]

Moreover, the Court rejected the Commission's argument that the agreement could be viewed as market sharing because the licences covered only seven countries in Europe. This since Servier was also commercialising Perindopril in the seven Member States, hence no part of the internal market was reserved for Krka – instead, the licence contributed to the entry of a generic competitor of Servier before the expiry of the 947 patent.[284]

[282] Ibid, para. 973.

[283] Ibid, para. 975-985 and 1030-1032.

[284] Ibid, para. 987-1014.

5. Discussion

5. 1 The Notion of Potential Competitor

According to the CJ's case law on RPPSs, the classification of a generic manufacturer as a potential competitor hinges on the question as to whether the undertaking has 'real and concrete possibilities' of entering the market.[285] The Court rejected both the broad test, where mere hypothetical chance and subjective wish or desire to enter the market suffices, and the narrow test where entry must be proved with certainty. In the author's view, the intermediate test adopted by the Court upholds legal certainty while recognizing that potential competition inevitably is subject to an element of uncertainty.

Under the CJ's approach, the assessment of potential competition in RPPS cases ultimately considers whether the generic manufacturer has 'real and concrete possibilities' to enter the market *notwithstanding* the patent situation. As the presumption of patent validity does not impede generic manufacturers from launching their product at risk the Court holds that potential competition may exist in a market even before the expiration of a patent. Elements of the CJ's reasoning in this regard are in the author's view problematic, in particular its assessment of generic 'entry at risk' (see section 5.1.1).

5. 1. 1 Generic 'Entry at Risk'

The Court's view that 'entry at risk' is an expression of potential competition is not entirely self-evident. Some commentators are of the opinion that 'entry at risk', given the possibility of facing infringement actions, does not constitute a real and concrete possibility of entering the market.[286] This in particular as Article 101 TFEU only protects lawful competition. Indeed, the CJ's interpretation of potential competition has in this regard been criticised for expanding the scope of Article 101 TFEU to also unlawful competition.[287]

While the Court rightfully held that the presumption of validity cannot be equated with a presumption of illegality of *all* generic products, a generic product launched 'at risk' may, following litigation initiated by the originator, be found to infringe the patent proprietor's rights. When a generic product is launched 'at risk' there is yet no proof that the generic company is engaging in lawful competition. Indeed, a generic undertaking

[285] Case C-307/18 *Generics* (n 4) para. 36; Case C-591/16 *Lundbeck* (n 4) para 54.

[286] See Ska, Werner & Paul (n 6) 445; Ibáñez Colomo (n 272) 606-607; Perinetto (n 6) 466-467.

[287] See Ibáñez Colomo (n 272) 606.

deciding to launch 'at risk' knowingly accepts the risk of committing a patent infringement. It is troubling that the Court's reasoning indicates that the willingness of a generic to take the risk of violating patent law to enter the market, is a relevant factor when assessing potential competition.[288]

Having this said, generic 'entry at risk' is not unlawful *ipso facto.* The burden of proof lies with the patent proprietor and until it is proven before the EPO or national court that the generic product infringes the process patents, the generic entry 'at risk' is presumptively lawful. The Court indeed finds itself in a dilemma in RPPS cases as the question of the validity of the originator's patent and/or the existence of an infringement on part of the generic only can be answered with certainty by a final decision of a competent patent court — which cannot materialise due to the investigated settlement agreement. In the present authors view, the CJ found an appropriate solution to the conundrum by holding that absent a ruling declaring that the generic product amounts to a patent infringement, potential competition exists. As a result, 'real and concrete possibilities' to enter the market will encompass entry 'at risk', the legality of which inevitable is uncertain.

5. 2 The Notion of Restriction by Object

5. 2. 1 *Generics* and *Lundbecks*' Consistency with Post *CB* Jurisprudence

The thesis suggests that the CJ's case law on RPPSs is in alignment with post *CB*-case law. First, the Court clearly stated that the fundamental test for finding a object infringement is that the practice reveals 'sufficient degree of harm' in view of its content and objective in the economic and legal context,[289] confirming the higher standard of harm of *CB* and later case law and rejecting the lower standard of *T-Mobile.*[290]

Second, while the CJ did not delve deeper into the question as to the relevance of experience for the characterization of an agreement as a restriction by object, the Court's judgments nonetheless recognizes its

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[288] In particular the CJ's assertion in *Generics*, para. 46 that a 'process patent which protects the manufacturing process of an active ingredient that is in the public domain *cannot, as such, be regarded as an insurmountable barrier,* and does not mean that a manufacturer of generic medicines who has in fact a *firm intention* and an inherent ability to enter the market, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk, upon entering the market, of being *subject to infringement proceedings* brought by the patent holder, cannot be characterised as a 'potential competitor' […].' See also Perinetto (n 6) 449-450.

[289] Case C-307/18 *Generics* (n 4) para. 67; Case C-591/16 *Lundbeck* (n 4) para 112.

[290] It is recalled that the CJ in *CB* held that 'sufficient degree of harm' is the 'essential legal criterion' for ascertain whether a practice amounts to a restriction by object, while the Court in the earlier *T-Mobile* case held that a mere 'capability' to harm would suffice. See Case C-67/13 *CB* (n 50); Case C-307/18 *Generics* (n 4) para. 67; Case C-591/16 *Lundbeck* (n 4) para 112; Compared with Case C-8/08 *T-Mobile* (n 67) para. 31.

importance. Whereas the EU Court's jurisprudence confirms that market-sharing or market-exclusion agreements typically restrict competition 'by their very nature', no such reliable previous experience supports the notion that *all* RPPS reveal a 'sufficient degree of harm'. Indeed, as the Commission outlined in its Monitor Reports, not all RPPSs raise antitrust concerns.[291] Given that no prior experience shows that all RPPSs display a sufficient degree of harm to competition, the CJ reserved the by object designation for (i) market-sharing or market-exclusion agreements disguised as RPPSs; and (ii) RPPSs were the value transfer has no other explanation than 'buying off' competition. Therefore, while the CJ upheld finding of a restriction by object in *Lundbeck* and *Generics*, the Court's rulings do not amount to the categorical condemnation of all RPPSs.

Third, the Court's careful dissection of RPPSs, limiting the by-object designation to clear cases where there is no other explanation than a reduction in competition, further complies with the principle that a by-object restriction must be interpreted narrowly.

Fourth, while the CJ found it necessary to consider contextual elements, it omitted reference to the additional contextual elements set out in *Allianz.*[292]

5. 2. 2 Identifying Illegitimate Value Transfers

While the CJ's approach to RSSPs provides undertakings with a margin to argue for the legality of such settlements, key notions remain undefined. The Court asserted that an object restriction will be found 'when it is plain […] that the transfers of value […] cannot have any explanation other than the commercial interest […] not to engage in competition on the merits', but offered no explanation whatsoever as to the definition of 'competition on the merits' in RPPS cases besides stating that it must be assessed whether the net gains of the value transfers are a sufficient incentive for the generics to refrain from entering the market. While some clues as where to draw the line between justified and illegitimate value transfers are given in the CJ's case law,[293] NCAs and undertakings will likely have vastly differing views on what constitutes a sufficient incentive for refraining from participating in the market. Given the lack of purposeful guidance on the allowed limits of value transfers in RPPSs, NCAs are left with significant discretionary powers.

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[291] See section 2.5.

[292] See sections 3.1.4.1 and 3.1.4.3.

[293] Namely that a value transfer may be justified when the sums correspond to compensation for the (i) costs associated with the dispute or (ii) actual supply of goods or services. See Case C-591/16 *Lundbeck* (n 4) para. 115. On the other hand, value transfers which are linked to the generics' projected profit and turnover will raise suspicion. See Case C-591/16 *Lundbeck* (n 4) para. 115 and 135.

Uncertainty is further exacerbated as the concept of 'competition on the merits' never in itself has been given a conclusive definition.[294] Further, the concept has predominantly been used in Article 102 TFEU case-law, not in cases decided under Article 101 TFEU. Indeed, the Commission has been criticised for relying on the notion of 'competition on the merits' as a shortcut to avoid 'the difficult work of defining clear legal principles and standards that embody sound competition policy'.[295] According to critics such a vague concept 'fails to provide clear guidance to pharmaceutical companies concerning what behaviour is and is not allowable under the competition laws'.[296] In the context of RPPSs it was however the CJ that introduced the term 'competition on the merits' as the Commission in its infringement decisions labelled the investigated agreements as market-sharing and market-exclusionary.[297] In the present author's view, the CJ's adoption of the phrase 'competition on the merits' to justify the finding of a restriction by object is unfortunate as it confuses rather than adds clarity to the analysis. As the precise definition of 'competition on the merits' has varied from case to case in the CJ's jurisprudence, its adoption, without further explanation as to the concepts' meaning in RPPS cases, ultimately frustrates legal certainty.

5. 2. 3 The Contextual Analysis as a Tool for Verification

The CJ's approach in both *Generics* and *Lundbeck* resembles the two-step analysis lined out by Advocate General Bobek in *Budapest Bank*.[298] Despite finding that a value transfer cannot be explained by a rationale other than a reduction in competition, the Court deems it necessary to verify the anticompetitive object by conducting a contextual analysis, assessing whether pro-competitive effects cast a 'reasonable doubt' as to the agreement's harmful nature.[299] Accordingly, are pro-competitive effects sufficiently significant, demonstrated, relevant and specifically related to the RPPS concerned, the agreement is moved from the by object category, requiring a detailed effects analysis. A RPPS exhibiting market sharing or

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[294] See for further discussion James Killick, 'The Perindopril Case: Patent Settlements and Acqusition of Technology'' in Damien Gerard, Massimo Merola and Bernd Meyring (eds) '*The Notion of Restriction of Competition: Revisiting the Foundations of Antitrust Enforcement in Europe'* (Bruylant, 2017) 233-236.

[295] See OECD 'What is Competition on the Merits' (2006) <https://www.oecd.org/competition/mergers/37082099.pdf> accessed 25 May 2022, 1. See further Geradin, '*The Uncertainties Created by Relying on the Vague 'Competition on the Merits' Standard in the Pharmaceutical Sector: The Italian Pfizer/Pharmacia Case'*, 344-352; Killick (n 296) 221-230.

[296] Geradin (n 280) 347.

[297] COMP/AT.39226 – *Lundbeck* (n 4) para. 626; COMP/AT.39612 – *Servier* (n 3) para. 3091, 3107 and 3130.

[298] See section 3.1.4.3.

[299] Case C-307/18 *Generics* (n 4) para. 111.

exclusionary elements might therefore not be found restrictive by object.[300] While this methodology can be criticised for importing a (limited) effect-analysis at the object-stage,[301] its merits lay in its preservation of the object category as a designation for practices which 'generally have net negative effects',[302] minimising *Type I* errors and recognizing the objectives underpinning the concept of restriction by object.

5. 2. 4 The Role of Pro-Competitive Effects

While the CJ did not delve deeper into the question as to the extent of such a contextual analysis, it did not conduct a detailed market analysis and explicitly rejected the necessity of a counterfactual scenario in *Lundbeck*. The contextual analysis in the CJ's case law on RPPS therefore seems to be of the same limited nature as the standard adopted in *Toshiba*.[303] This seems appropriate as the contextual analysis in the characterization setting serves a reality check, distinct from the fuller effects analysis aimed at assessing actual or likely effects.

In line with *Budapest Bank* and continuing trend of an economics-based approach toward competition law enforcement, the Court reaffirmed the importance of pro-competitive effects when assessing whether an agreement amounts to a restriction by object. However, the standard of proof required seems stricter in *Generics* compared to *Budapest Bank.* Indeed, in *Generics* the Court spoke of sufficiently significant, demonstrated, relevant and specific pro-competitive effects, while 'strong indications capable of demonstrating' pro-competitive effects were held to suffice in *Budapest Bank.* While the shifting standard of proof at first glance might seem troubling and inconsistent, the Court's approach seems justified once regard is had to the type of restriction identified in the respective cases. While problematic RPPSs, such as the ones examined in *Generics,* seemingly were deemed comparable to market-sharing or market-exclusion agreements (i.e., 'hardcore' restrictions), the harmful nature of the type of agreements investigated in *Budapest Bank* ('MIF agreements') was unclear in light of insufficient experience of such practices. Given the more severe nature of the restrictions at hand in *Generics* it seems reasonable to impose a stricter

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[300] See Alison Jones, 'The Court of Justice's judgment in Generics (UK) v Competition and Markets Authority and the object/effect dichotomy' [2021] 9(3) Journal of Antitrust Enforcement, 610; Francisco Costa-Cabral 'Future-Mapping the Three Dimensions of EU Competition Law: Modernisation Now and After COVID-19?' (2020) 8 TILEC Discussion Paper Series <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3581535> accessed 25 May 2022 249.

[301] See e.g. Costa-Cabral (n 302) 7.

[302] Jones (n 302) 610. As has been discussed in section 3.1.4 above, an object categorization is not appropriate if an agreement is shown to have mixed effects on competition, involves complex measures or where experience with the restraint is limited or insufficiently reliable and robust. This since the concept of restrictions by object is to be interpreted restrictively.

[303] Meaning it is confined 'to what is strictly necessary […] to establish the existence of a restriction of competition by object'.

standard of proof, whereas in *Budapest Bank* even small pro-competitive gains could reasonably be said to raise doubt as to the agreement's harmful nature. According to this line of reasoning it seems reasonable to hold that the greater the transfer of value, the greater pro-competitive effects must be shown to 'justify a reasonable doubt' as to the authority's object characterization. Further, imposing a higher threshold for pro-competitive effects to be taken into account under this stage than under the effects stage, mitigates the risk of blurring the border between object and effect type agreements further. However, an element of uncertainty remains as the CJ did not elaborate provide any guidance on what constitutes relevant pro-competitive effect.

5. 2. 5 Licences as Legitimate Side Deals

5. 2. 5. 1 Consistency with the CJ's RPPS Jurisprudence

The GC's analysis of the Krka licence is consistent with the CJ's approach to RPPSs in at least two aspects: (i) the logic underpinning the exemption; and (ii) it's recognition of pro-competitive effects as important when assessing whether a practice amounts to a restriction by object. First, according to the GC in *Servier*, coupling a licence agreement concluded under market terms with a settlement does not raise antitrust concerns, since the licensing of the litigious patent usually is based on the recognition of the validity of the disputed patent. The underlying reason for exempting licences is consistent with CJ's rulings in *Generics* and *Lundbeck* — the investigated RPPS in the latter cases were condemned for not being based on the validity of the patent, while the licence agreement between Servier and Krka was exempted precisely because it was.[304] Second, in the GC's assertion that the Krka licence 'mitigated' the settlement agreements restrictive clauses, the Court essentially held that a licence on a litigious patent generally gives rise to pro-competitive benefits which must be taken into account.[305] It remains to be seen whether the CJ finds the pro-competitive effects associated with licence agreements to be sufficient to raise reasonable doubt as to the practices harmful nature.

Nevertheless, other aspects of the GC's ruling are not self-evident (see section 5.2.5.2) and seem inconsistent with the CJ's approach to value transfers (section 5.2.5.3).

[304] See Tepper (n 293) 138.

[305] Compare with sections 5.2.3. and 5.2.4 above.

5. 2. 3. 2 'Mitigation' of the Settlement Agreements Restrictive Effects

The GC's finding that a licence agreement neutralises the restrictive effects imposed by the settlement agreements non-challenge and non-compete clauses is not without controversy. First, the Commission has taken the stance that the grant of a licence limits generic market entry since the generics 'presence in the market is controlled by the licensor'[306]. Indeed, licences *may* give the patent proprietor control over the generic undertaking's output and pricing.[307] In the present authors view, such an anti-competitive potential can however not be presumed where the licence is concluded under market terms, but ought instead to be proven by the party alleging infringement.[308]

Second, it has been argued that the Court 'overlooked the issue of patent *infringement* when jumping into its conclusion of "mitigation" of restrictive effects'[309]. The neutralisation of the restrictive clauses indeed assumes that Serviers 947 patent was (i) valid and (ii) infringed by Krkas generic product. If Krkas generic Perindopril did not infringe the 947 patent, Krka could have entered *all* the EU markets – not only the seven Member States under the licence agreement. Hence, the alleged mitigation only occurs if Krkas product was infringing the 947 patent.[310] In the present author's view, the GC's finding of no inducement indicates that the issue of patent infringement was not overlooked by the Court. Since the royalty of 3% was not abnormally low, the licence did not in the Court's view give Krka any compensation vis-à-vis the excluded parts of the market, indicating that Krka believed that the 947 patent was infringed. Had Krka not believed that its product infringed Servier's patent, accepting a licence, which did not compensate for the profit it expected to make in the excluded markets, would not constitute an economically satisfactory solution.

5. 2. 5. 3 Value Transfers under Licences

The GC's assertion that the existence of an inducement is less evident in the case of a licence since such an agreement does not 'does not entail a financial transfer from the originator company to the generic'[311] is in conflict with the CJ's ruling in *Generics,* in which the CJ stressed that *all* value transfers (pecuniary and non-pecuniary, direct and indirect) must be

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306 Commission, *Pharmaceutical Sector Inquiry. Final Report*, p. 1239.

307 Daniel Crane, 'Exit Payments in Settlement of Patent Infringement Lawsuits: Antitrust Rules and Economic Implications' [2002] 54(4) Florida Law Review, 765-766.

308 This since licensing agreements in connection with settlements are considered to generally not cause any antitrust concern. See e.g. Technology Transfer Guidelines (n 139) para. 234-236.

309 Athanasiadou (n 7) 626 (emphasis added).

310 Ibid.

311 Case T-691/14 *Servier* [2018] (n 235) para. 950.

considered.[312] While the key question according to the GC was whether the 3% royalty was abnormally low, the Court should according to the *Generics* approach also have taken into account indirect, non-pecuniary value transfers, such as the market share transferred from *Sevier* to Krka via the licence.[313] Adopting the broader *Generics* standard to value transfers, the conclusion that the Krka licence lacked inducement seems less certain.

[312] Case C-307/18 *Generics* (n 4) para. 90-92; See also Athanasiadou (n 7) 626.

[313] See Athanasiadou (n 7) 625-626.

6. Conclusion

The CJ's line of case law on RPPSs does not bring further clarity to the notion of restrictions by object, but rather clarifies its application to the factual circumstances in RPPS cases. The CJ seems to apply the same approach in RPPS cases as in its later case law on object infringements, primarily *Budapest Bank* and *CB,* albeit slight differences can be identified.

The merit of the CJ's case law on RPPSs lies in the careful assessment of the practice, recognizing that in the absence of sufficient experience RPPSs cannot be subject to automatic condemnation. In the classification step the CJ initially makes a distinction between RPPSs which are concluded in connection with a genuine patent dispute, and those where the dispute is entirely fictitious. In the later situation a restriction by object will rightfully be found, as the settlement agreement aims to disguise a classic market-sharing or market-exclusion agreement between the parties. Where there is genuine patent dispute, it must be assessed whether the agreement nonetheless reveals an aim to not to engage in 'competition on the merits'. Such an aim, and hence a restriction by object, is to be found where the value transfers cannot be explained by a rationale other than a reduction in competition. The crucial question is therefore whether the generics concluded the settlement (thereby refraining from entering the market and challenging the patent) due to (i) their *recognition of the patent's validity,* and hence the fear of losing the patent litigation; or (ii) due to the *value transfers* (i.e., agreeing to share 'a monopolistic market profit'). At this stage, the focus centres on the size of the value transfers and whether any legitimate and proven *quid pro quo* or waivers justify the net gains. Where the parties to the RPPS can justify the value transfers, or demonstrate sufficient pro-competitive effect, the agreement will not amount to a restriction by object, and a fully-fledged effects analysis will be required.

As has been shown above, the 'by object' categorisation of RPPSs spelled out by the CJ in *Generics* and *Lundbeck* requires taking into account a number of factors, and elements of the analysis remain uncertain. While such a detailed legal categorisation can be praised for limiting the automatic condemnation to practices which only reveal a sufficient degree of harm in themselves, it can also be criticised for failing to bring sufficient legal certainty to the antitrust analysis. Indeed, the usefulness of a legal presumption riddled with exceptions is questionable.

While *Lundbeck* and *Generics* have clarified the treatment of more straightforward RPPSs, the legal framework for analysing side deals as parts of settlement agreements is less clear, giving rise to considerable uncertainty. Therefore it will be of particular interest to see how the CJ rules in the *Servier* appeal.

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