Market and Competition Law Review / VOLUME X / No. 1 / APRIL 2026

The Application of EU Competition Law to Reverse Payment Patent Settlements in the Pharmaceutical Sector: Current Status under Article 101 TFEU*

*Alessandra Campiglia***

ABSTRACT: Over the past few decades, the pharmaceutical sector has witnessed the occurrence of a particular type of agreement used to settle patent disputes between originator and generic drug manufacturers: so-called reverse payment patent settlements, also known as pay-for-delay agreements. Due to their peculiarities and the context in which they occur, these settlements raise issues at the intersection of patent protection, competition law, and pharmaceutical regulation. This has made them one of the most contentious issues in the pharmaceutical industry from a competition law perspective. At the EU level, while reverse payment patent settlements have been at the centre of the European Commission's enforcement priorities for years and the target of various infringement decisions adopted since 2013, they have only more recently reached the Court of Justice. Since 2020, the Court of Justice has ruled on the compatibility of such settlements with EU competition rules, particularly Article 101 TFEU, on various occasions, most recently in October 2025. Through a series of judgments that have now addressed all relevant EU cases, the Court of Justice has delineated the criteria for the antitrust assessment of reverse payment settlements and the application of fundamental notions of EU competition law, notably that of restriction by object, to these agreements. Against this background, this article aims to analyse the current status of pay-for-delay agreements under EU competition law, in particular, Article 101 TFEU. To this end, it first frames the pay-for-delay issue within the context in which it emerged and in light of the existing literature. It then examines the approach to these agreements adopted at the EU level, with particular reference to the recent case law of the Court of Justice. In doing so, it focuses on two key points,

* Date of reception: 01.12.2025; Date of acceptance: 12.01.2026.
DOI: https://doi.org/10.34632/mclawreview.2026.18247.
** Ph.D. student in Law and Innovation (University of Macerata, Law Department, Italy); a.campiglia@unimc.it.

namely the assessment of potential competition and of the agreements as restrictions by object under Article 101(1) TFEU.

KEYWORDS: reverse payment patent settlements; pharmaceutical sector; Article 101 TFEU; restriction by object.

1. Introduction

Over the past few decades, the pharmaceutical sector has witnessed the occurrence of a particular type of agreement used to settle patent disputes between originator and generic drug manufacturers: so-called reverse payment patent settlements, also known as pay-for-delay agreements.

The interest in reverse payment patent settlements was initially observed in the United States (US), where they emerged as a practice rooted in the unique dynamics of product market entry under US pharmaceutical regulation.[1] This has led to the development of an extensive body of scholarly literature on the topic and has given rise to significant antitrust litigation

[1] The reference is, in particular, to specific rules governing approval procedures for generic drugs introduced by the Drug Price Competition and Patent Term Restoration Act (Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §§ 355, 360; 35 U.S.C. §§ 156, 271) (which amended the Federal Food, Drug, and Cosmetic Act (Pub. L. No. 75-717, 52 Stat. 1040 (1938)). Specifically, generic companies are permitted and incentivised to challenge originators' patents and attempt to enter the market before patent expiry. Indeed, by filing an Abbreviated New Drug Application with a so-called Paragraph IV certification, a generic applicant asserts that the originator's listed patents are either invalid or will not be infringed by the generic product. The incentive to be the first to file such an application consists of a 180-day period of marketing exclusivity, commencing with the first commercial marketing of the relevant product, during which the product in question is the sole generic version competing with the corresponding brand-name drug. See 21 U.S.C. § 355(j). The provision on the 180-day exclusivity and its interpretation are regarded as having created the stronger incentives for both originator and generic companies to prefer settlement over litigation in the context of their patent disputes and to include reverse payments in settlement agreements. On the nature of pay-for-delay settlements in the US as a by-product of the existing regulatory framework, see generally: C. Scott Hemphill, "Paying for delay: Pharmaceutical patent settlement as a regulatory design problem", *New York University Law Review* 81, no. 5 (2006): 1553-1623; Matthew Avery, "Continuing abuse of the Hatch-Waxman Act by pharmaceutical patent holders and the failure of the 2003 amendments", *Hastings Law Journal* 60, no. 1 (2008): 171-200; C. Scott Hemphill and Mark A. Lemley, "Earning exclusivity: Generic drug incentives and the Hatch-Waxman Act", *Antitrust Law Journal* 77, no. 3 (2011): 947-989; Robin Feldman and Prianka Misra, "The fatal attraction of pay-for-delay", *Chicago-Kent Journal of Intellectual Property* 18, no. 1 (2019): 249-283.

involving pay-for-delay cases, with the Federal Trade Commission also devoting considerable attention to the issue.[2]

Reverse payment settlements have likewise become a subject of heightened scrutiny within the European Union (EU). In the Final Report of the inquiry into the pharmaceutical sector, adopted in 2009, the European Commission proposed a categorisation of pharmaceutical patent settlements and identified those involving pay-for-delay as a category with the potential to raise antitrust concerns.[3] Pay-for-delay agreements have since been at the centre of the Commission's enforcement priorities, as evidenced by the continuous monitoring of patent settlements and the active enforcement of competition rules in respect of them in recent years.[4]

Due to their peculiarities and the context in which they occur, reverse payment patent settlements raise issues at the intersection of patent protection, competition law, and pharmaceutical regulation. On the one hand, this has made them one of the most contentious issues in the pharmaceutical industry from a competition law perspective, as their central position in antitrust debates and their status as an enforcement priority for competition authorities in both the EU and the US in past years demonstrate. On the other hand, the complex nature of these settlements has complicated their antitrust assessment, leaving courts with the task of shaping the framework for evaluating their legality under competition laws.

The highest courts in both the US and the EU have provided guidance on the matter. While the US Supreme Court delivered the landmark decision on the topic more than a decade ago,[5] pay-for-delay settlements have

---

[2] See, e.g., Federal Trade Commission, *Pay-for-delay: How drug company pay-offs cost consumers billions. An FTC staff study*, January 2010, https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf. For a more general overview, see "Pay for delay", Federal Trade Commission, accessed November 28, 2025, https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay. See also *infra* note 5.

[3] European Commission, *Pharmaceutical sector inquiry: Final report*, July 8, 2009, https://competition-policy.ec.europa.eu/document/download/5b2773da-34dd-4b18-9555-5433dc69c8a8_en?filename=pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf, 268ff.

[4] For an overview of the practices, besides pay-for-delay agreements, toward which the Commission directed its enforcement in more recent years, see European Commission: Directorate-General for Competition, *Update on competition enforcement in the pharmaceutical sector (2018-2022). European Competition Authorities working together for affordable and innovative medicines: Report from the Commission to the Council and the European Parliament* (Publications Office of the European Union, 2024), https://data.europa.eu/doi/10.2763/427709.

[5] The US Supreme Court ruled on reverse payment patent settlements in the *Actavis* case in 2013 (*FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (hereafter *Actavis*)). The antitrust analysis of reverse pay-

only more recently reached the Court of Justice. Since 2020, the latter has ruled on the compatibility of such agreements with EU competition rules, particularly Article 101 of the Treaty on the Functioning of the European Union (TFEU), on various occasions. Importantly, the Court did so, most recently, in October 2025, when it delivered its latest ruling on the topic. Through a series of judgments that have now addressed all relevant EU cases, the Court of Justice has delineated the criteria for the antitrust assessment of reverse payment settlements and the application of fundamental notions of EU competition law, notably that of restriction by object, to these agreements.

Against this background, this article aims to analyse the current status of pay-for-delay agreements in EU competition law, in particular under Article 101 TFEU. To this end, it first frames the pay-for-delay issue within the context in which it emerged and in light of the existing literature. It then examines the approach to these agreements adopted at the EU level, with particular reference to the recent case law of the Court of Justice. In

---

ment settlements delineated by the majority opinion of the Supreme Court is based on the rule of reason standard; this requires a case-by-case evaluation of the impact of such agreements on competition, balancing their pro- and anti-competitive effects to determine whether they should be characterised as a restriction of competition. Within this framework, the relevant anti-competitive harm, namely the prevention of the risks of competition, is inferred from a "large and unjustified" reverse payment, the size of the payment being regarded as providing a "workable surrogate" for the weakness of the originator's patent. See *Actavis*, 157-159. The implementation of *Actavis* and the structuring of the rule of reason set out therein were entrusted to lower courts. The latter's decisions highlighted the absence of clear guidance from the Supreme Court and a number of open issues that have given rise to uncertainties in the application of *Actavis*. Among the most contentious issues were the proper definition of the term "payment" and when it can be considered "large and unjustified", these determinations being crucial to the rule-of-reason inquiry established by the Supreme Court. See, e.g.: Aaron Edlin et al., "Activating *Actavis*", *Antitrust Magazine* 28, no. 1 (2013): 16-23; Aaron Edlin et al., "The *Actavis* inference: Theory and practice", *Rutgers University Law Review* 67, no. 3 (2015): 585-635. In the post-*Actavis* landscape, a particularly noteworthy development in the case law is provided by the recent case *Impax* (*Impax Labs., Inc. v. FTC* 994 F.3d 484 (5th Cir. 2021)). In a nutshell, the significance of the case arises from the fact that the court has had the opportunity to rule on all the elements of the analysis under *Actavis*'s rule of reason – aspects that had previously represented matters of contention; in doing so, the court has further developed the rule-of-reason inquiry, tracing its burden-shifting framework. The case, however, is rather complex. For a detailed discussion of the case, see Margherita Colangelo, *Regulation, innovation and competition in pharmaceutical markets: A comparative study* (Hart Publishing, 2023): 113-116. For comprehensive accounts of the US context, which cannot exhaustively be traced here, see: Kristen O'Shaughnessy et al., "A decade of *FTC v. Actavis*: The reverse payment framework is older, but are Courts wiser in applying it?", *Antitrust Law Journal* 86, no. 2 (2024): 473-502; Michael A. Carrier and Edward Bank, "The missing caselaw of reverse-payment settlements", *St. John's Law Review* 98, no. 5 (2025): 959-1074.

doing so, it focuses on two key points, namely the assessment of potential competition and of the agreements as restrictions by object under Article 101(1) TFEU, while also situating this line of case law within the broader context of the Court's jurisprudence. Finally, it concludes with some final remarks on the issues addressed.

2. Competition between originator and generic drug manufacturers and the pay-for-delay issue

Reverse payment patent settlements have emerged in the pharmaceutical sector in the competitive dynamics between originator and generic drug manufacturers. The reason for this can be attributed to the highly complex framework in which they compete – a framework characterised by a prominent intersection of sectoral regulation and patent protection and designed to balance the numerous interests at stake, including the need to sustain innovation and ensure widespread access to affordable medicines.[6]

Under the regulatory framework governing the pharmaceutical sector, regulators control access to the market for medicinal products, notably through procedures aimed at granting them marketing authorisations.[7] In addition to regulatory barriers, market entry for pharmaceutical products is also hindered by the presence of patents.[8] Indeed, patent protection

---

[6] The pharmaceutical sector stands out for the unique and complex intersection of regulation, intellectual property, as well as competition law. See generally Colangelo, *Regulation, innovation and competition in pharmaceutical markets*.

[7] With regard to the US context, see the normative reference at *supra* note 1. At the EU level, the primary regulatory points of reference for the access of medicinal products to the market are: 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 [2001] OJ L 311/67 (as subsequently amended) (hereafter Directive 2001/83/EC); Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L 136/1 (as subsequently amended) (hereafter Regulation (EC) No. 726/2004).

[8] At the EU level, patents are granted either by national patent offices or by a central body, the European Patent Office (EPO) (established by the European Patent Convention (Convention on the Grant of European Patents of 5 October 1973)). In both cases, patents are national rights, which means, in particular, that they are enforced at the national level. Indeed, even where a patent is granted by the EPO, the resulting European patent is not a unitary right but takes effect as a bundle of national titles. It should, however, be noted that, in 2023, the so-called "unitary patent system" entered into force. Since then, applicants may request unitary effect for an EPO-granted patent, which, accordingly, will have the same effects and provide uniform protection in all participating

is widespread within the sector, typically covering originator products and creating additional obstacles, particularly for generic competitors.[9] More specifically, originator companies engaged in the research and development of new medicines typically obtain multiple patents (namely, primary patents protecting the active ingredient and secondary patents covering ancillary aspects of a drug), and benefit from periods of regulatory exclusivity that derive directly from the grant of marketing authorisation for their products. These forms of protection primarily serve to reward the vast investments in research undertaken by originator companies, enabling them to shield their products from competition and to earn returns on those investments. Indeed, research and development activities, and the related generation of data demonstrating the safety and efficacy of new medicinal products, entail considerable costs and risks that originator companies are required to incur, being the grant of marketing approval for their products contingent upon the submission of such data.[10] Conversely, generic manufacturers seeking approval to market a generic version of an already authorised brand-name drug are not required to provide safety and efficacy data; instead, they need only demonstrate the bioequivalence of the generic product with the brand-name drug, being allowed to rely on the research results contained in the reference originator drug's application.[11] In this context, competition between originator and generic companies occurs after the periods of exclusivity enjoyed by the former under both regulatory and intellectual property (IP) systems

---

Member States, with a Unified Patent Court having exclusive jurisdiction over its enforcement (see, in particular, Regulation (EU) No. 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L 361/1, and the Agreement on a Unified Patent Court [2013] OJ C 175/1).

[9] In addition to patents, supplementary protection certificates are available to extend the period of protection of pharmaceutical products, operating as a means of offsetting the loss of effective patent protection that results from the time spent on the marketing authorisation procedure (see Council Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the creation of a supplementary protection certificate for medicinal products [2009] OJ L 152/1 (as subsequently amended)).

[10] The main provisions on the marketing authorisation for reference medicinal products are laid down in Directive 2001/83/EC, Articles 6 and 8.

[11] A so-called abridged application is available to applicants seeking marketing authorisation for a generic medicinal product. See Directive 2001/83/EC, Article 10, which also lays down the periods of regulatory exclusivity for reference originator products.

have expired.[12] At this point, generic manufacturers can enter the market with products equivalent to those of the originators and that thus represent substitutes for them. As generic drugs are offered at lower prices than brand-name ones, originator and generic firms primarily compete on price.

The introduction of generic alternatives into the market has been shown to lead to a significant decline in the prices of pharmaceuticals.[13] On the one hand, this makes timely generic entry at the end of the originators' exclusivity periods of crucial importance. Such an entry favours the availability of lower-cost drugs, benefiting consumers and healthcare budgets, and is therefore supported and promoted by sectoral regulation.[14] On the other hand, generic market entry poses a considerable threat to originators' market position and revenues due to the resulting reduction in drug prices.

In these circumstances, originator companies have strong incentives to seek ways to avoid or at least minimise the impact of their generic competitors' market entry. Opportunities for potentially anti-competitive practices particularly arise at the intersection of patent protection and the regulation of market access for medicinal products.[15] Among patent-related strategies, reverse payment patent settlements occupy a prominent

---

[12] The EU pharmaceutical regulation, however, explicitly excludes patent linkage (i.e., the practice of linking the marketing approval of generic drugs to the patent status of the reference originator drug). This means that generic companies are not required to prove non-infringement of the originator's patent to receive approval and market their products (see Directive 2001/83/EC, Article 126, and Regulation (EC) No. 726/2004, Article 81).

[13] See, e.g., European Commission, *Update on competition enforcement in the pharmaceutical sector*, 22, reporting findings that prices of innovative medicines drop on average by 40% in the period after generic entry, and that generic drugs enter the market at a price that is on average 50% lower than the initial price of the corresponding originator product.

[14] In addition to the simplified procedure referred to above (see *supra* note 11), to facilitate the prompt entry of generic drugs to the market following the expiry of the originator's exclusivity, provisions are in place that allow applicants seeking marketing authorisation for a generic drug to conduct the tests necessary for submitting their application before the expiry of any patents (and supplementary protection certificates) protecting the originator's reference product – the so-called Bolar provision –, provided for by Directive 2001/83/EC, Article 10. Once on the market, the earning of market share by generic products is also promoted through substitution laws. Such laws – widespread across several countries – provide for the mandatory or optional substitution of generic drugs for their brand-name counterparts by pharmacies.

[15] On the opportunities for what has been termed "regulatory gaming", see generally Stacey L. Dogan and Mark A. Lemley, "Antitrust law and regulatory gaming", *Texas Law Review* 87, no. 4 (2009): 685-730.

position, notably because of their peculiar nature: both the originator and the generic company stand to benefit from the conclusion of these agreements.

Pay-for-delay agreements are typically concluded as part of settlements of patent disputes between originator and generic companies.[16] The distinguishing feature of these settlements is that the patent holder (originator) pays the alleged infringer (generic company), rather than the opposite – hence the term reverse payment patent settlements. Moreover, the terms of such settlements typically include an agreement on the timing of the generic company's market entry. A pay-for-delay agreement can thus be defined as an agreement between a brand-name pharmaceutical company holding one or more patents on a medicinal product and a potential generic entrant, whereby the former agrees to provide the latter with some form of compensation, which may consist of direct monetary payments or other forms of value transfers (e.g., distribution agreements, or commercial benefits granted through favourable terms in licensing agreements or other side deals). In exchange, the generic company accepts various restrictions on its market entry (e.g., non-challenge or non-compete clauses), thereby delaying such entry until an agreed date – typically the originator company's patent expiration or, more generally, beyond the time the generic firm could otherwise have expected to enter the market in the absence of the agreement.[17]

The context in which these settlements are concluded makes them particularly controversial from an antitrust perspective. This is due to the pharmaceutical sector's particular sensitivity to delays in the introduction of generic drugs into the market and the frequent presence of patents of uncertain validity and scope. In this latter regard, it should be noted that patent litigation is inherently uncertain. As highlighted in the literature, none of the actors involved – namely originator and generic companies, courts, as well as patent offices – has perfect information about the true validity and scope of patents, which means that they all operate under a

[16] For a general overview of pharmaceutical patent settlements, in particular those involving pay-for-delay, see Amalia Athanasiadou, *Patent settlements in the pharmaceutical industry under US antitrust and EU competition law* (Kluwer Law International, 2018).

[17] For detailed accounts of the structure and variants of pay-for-delay agreements, see: C. Scott Hemphill, "An aggregate approach to antitrust: Using new data and rulemaking to preserve drug competition", *Columbia Law Review* 109, no. 4 (2009): 647ff.; Robin Feldman and Evan Frondorf, *Drug wars: How big pharma raises prices and keeps generics off the market* (Cambridge University Press, 2017), 34ff.; Robin Feldman, "The price tag of 'pay-for-delay'", *Science and Technology Law Review* 23, no. 1 (2022): 33ff.

degree of uncertainty.[18] In such a context, settling a patent dispute, including through reverse payments, can, in principle, be a rational and legitimate choice for both parties. The settlement secures revenue streams for both the originator and the generic company. It removes the uncertainty surrounding both firms' future profits, which are dependent on the outcome of the patent dispute (and, for the generic company, also on the number of other generics that would enter the market should the originator's patent be invalidated).[19] In addition, the comparatively higher risks faced by originator companies, whose prospective losses upon generic entry may be substantial and significantly exceed the generic firm's potential gains, may account for the inclusion of reverse payments in settlement agreements.[20] At the same time, a settlement that avoids a final determination on patent validity and/or infringement may unduly delay the market entry of generic products;[21] by delaying the potential for competition between the originator and the generic company, it also postpones the benefits that would derive therefrom, primarily in terms of lower prices.

---

[18] On this point, see Frank Maier-Rigaud, Nathan Blalock, and Oliver Gannon, "Reverse payments: An EU and US perspective", in *EU law of competition and trade in the pharmaceutical sector*, ed. Pablo Figueroa and Alejandro Guerrero (Edward Elgar Publishing, 2019), 42-43. The Authors attribute recourse to settlements in patent disputes to imperfect information. In a scenario of perfect information, patent litigation and settlements would instead be unnecessary, as "[p]atent bodies (…) would not grant invalid patents to originators that generic companies would be able to challenge successfully in court".

[19] Maier-Rigaud, Blalock, and Gannon, "Reverse payments", 46ff.

[20] See Michael Clancy, Damien Geradin, and Andrew Lazerow, "Reverse-payment patent settlements in the pharmaceutical industry: An analysis of U.S. antitrust law and EU competition law", *The Antitrust Bulletin* 59, no. 1 (2014): 164, arguing that "[d]ue to the cumbersome system for enforcing patents in the EU and the automatic price reductions triggered by the entry of a generic supplier, originator companies have very strong incentives to settle, even in cases where they hold strong patent rights" and that, during settlement negotiations, "it is only logical that generic suppliers would seek to exploit the higher risk faced by originators to extract a payment".

[21] Arguments in the literature have highlighted the nature of patents as probabilistic rights that confer upon patent holders the right not to exclude competitors automatically but to attempt such an exclusion by asserting their patents in court (see: Carl Shapiro, "Antitrust limits to patent settlements", *The RAND Journal of Economics* 34, no. 2 (2003): 391-411; Mark A. Lemley and Carl Shapiro, "Probabilistic patents", *Journal of Economic Perspectives* 19, no. 2 (2005): 75-98). Moreover, it has been noted that most patent litigation in the pharmaceutical sector and associated settlements pertain to secondary patents. These patents are generally considered *de facto* weaker than primary patents, as they are less likely to meet patentability requirements and are easier for generic manufacturers to circumvent. As such, they provide originator companies with less effective barriers to the entry of generics and are more likely to be invalidated or deemed not infringed during litigation. See C. Scott Hemphill and Bhaven Sampat, "Drug patents at the Supreme Court", *Science* 339, no. 6126 (2013): 1386-1387.

As the extensive legal and economic literature on the topic demonstrates[22], the primary antitrust concern surrounding pay-for-delay settlements relates to the presence of reverse payments. These payments can align the interests of originator and generic firms in ways that undermine competition: there is a risk that the originator is effectively buying off potential competition, thereby turning what might otherwise be a lawful settlement into an anti-competitive agreement. Specifically, the value transferred from the originator to the generic company may represent compensation for delaying market entry. In doing so, the originator avoids the risks of earlier competition and preserves supra-competitive profits derived from maintaining high drug prices – profits that may be shared with the generic company. All this is to the detriment of consumers, who are denied access to lower-cost generic drugs.[23]

3. Reverse payment patent settlements under EU competition law

At the EU level, reverse payment patent settlements have been subject to investigations by the Commission. These investigations have led to a series of infringement decisions adopted since 2013, in which the Commission concluded that the agreements violated the prohibition of Article 101 TFEU.[24]

In particular, the Commission found the agreements examined in *Lundbeck*,[25] *Servier*,[26] and *Teva/Cephalon*[27] to be restrictive of competition by object. This conclusion rested on the following elements, alongside

---

[22] On the role of the reverse payment in relation to the parties' incentives and the resulting settlement, as well as the date of generic entry, specifically with regard to the US context, see, *inter alia*: Hemphill, "An aggregate approach to antitrust", 635ff.; Michael A. Carrier, "Unsettling drug patent settlements: A framework for presumptive illegality", *Michigan Law Review* 108, no. 1 (2009): 73-74; Feldman and Frondorf, *Drug wars*, 35-36; Erik Hovenkamp, "Antitrust law and patent settlement design", *Harvard Journal of Law & Technology* 32, no. 2 (2019): 451ff.

[23] See Feldman, "The price tag", 10, arguing that "[w]ith pay-for delay settlements, brand-name companies can extend their monopoly by taking advantage of shared interests with generic companies", and "consumers bear the costs".

[24] The Commission's investigations into pay-for-delay agreements encompassed both agreements concluded in the context of (at least potential) patent disputes and those unrelated to such disputes. See Commission decision of 10 December 2013, *Fentanyl*, Case AT.39685, the only case not associated with a patent dispute or settlement.

[25] Commission decision of 19 June 2013, *Lundbeck*, Case AT.39226 (hereafter *Lundbeck*, Commission decision).

[26] Commission decision of 9 July 2014, *Perindopril (Servier)*, Case AT.39612 (hereafter *Servier*, Commission decision).

[27] Commission decision of 26 November 2020, *Cephalon*, Case AT.39686 (hereafter *Cephalon*, Commission decision).

important case-specific considerations: the originator and generic companies were at least potential competitors; the generic firms had committed, through the agreements, to limit their independent efforts to enter the market with their generic products; and the settlements involved a transfer of value from the originator that substantially reduced the generic companies' incentives to pursue independent market entry.[28] Although these findings rendered an examination of the effects of the agreements unnecessary, the Commission nevertheless conducted an effects analysis in *Servier* and *Teva/Cephalon*, demonstrating the agreements' anti-competitive effects.[29]

At the judicial level, the General Court's judgments largely upheld the Commission's approach and the findings deriving therefrom.[30] Importantly, after the Commission adopted its first decisions on reverse payment settlements (i.e., *Lundbeck* and *Servier*) and the General Court issued its judgments on the related appeals, the Court of Justice delivered a preliminary ruling on the topic in *Generics*[31] in 2020.

The considerations and assessments made by the Commission and the General Court, as well as the questions referred to the Court of Justice that gave rise to the preliminary ruling,[32] revealed several controversial issues surrounding the determination of whether a reverse payment settlement

---

[28] Summaries of the Commission's findings and references to the relevant sections of the decision can be found in the following paragraphs: *Lundbeck*, Commission decision, paras. 661-662; *Servier*, Commission decision, paras. 1154-1155; *Cephalon*, Commission decision, paras. 581-585.

[29] See *Servier*, Commission decision, paras. 1273ff., 1482ff., 1628ff., 1813ff., 2001ff., and *Cephalon*, Commission decision, paras. 1039ff. Although it will not be discussed as outside the scope of the present paper, it is worth noting that, in *Servier*, the Commission also found an infringement of Article 102 TFEU; specifically, it found that Servier had abused its dominant position through a combination of two practices, namely the acquisition of competing technologies and the conclusion of reverse payment settlements (see *Servier*, Commission decision, paras. 2793ff.).

[30] The only exception is the finding of a restriction of competition in relation to the agreements between Servier and Krka. See: judgment of 8 September 2016, *H. Lundbeck A/S and Lundbeck Ltd v. European Commission*, T-472/13, EU:T:2016:449 (hereafter Case T-472/13 *Lundbeck*); judgment of 12 December 2018, *Servier SAS and Others v. European Commission*, T-691/14, EU:T:2018:922 (hereafter Case T-691/14 *Servier*); judgment of 18 October 2023, *Teva Pharmaceutical Industries Ltd and Cephalon Inc. v. European Commission*, T-74/21, EU:T:2023:651 (hereafter Case T-74/21 *Teva/Cephalon*).

[31] Judgment of 30 January 2020, *Generics (UK) Ltd and Others v. Competition and Market Authority*, C-307/18, EU:C:2020:52 (hereafter *Generics*).

[32] *Generics*, para. 21. Although the questions referred to the Court of Justice by the United Kingdom Competition Appeal Tribunal also concerned the interpretation of Article 102 TFEU, the approach to the issues relating to Article 101 TFEU is most relevant to the present analysis.

restricts competition and, crucially, whether it does so "by object". Critical points notably concerned the following aspects: the weight to be accorded to matters relating to the patents involved, such as their scope and strength, the uncertainty surrounding the outcome of the patent dispute, and the presumption of validity they enjoy, as well as how these factors influence the evaluation of the agreements' harmfulness to competition.[33]

Generics provided the awaited guidance from the Court of Justice on these and related issues.[34] In doing so, it laid down principles that have informed subsequent assessments by the Commission and the EU courts. *Generics* thus became the primary point of reference for the evaluation of these agreements under EU competition law. It has since been progressively complemented by the key contributions of subsequent judgments delivered by the Court in the context of the appeals in the cases investigated at the EU level.

Against this background, the following sections analyse the current status of reverse payment patent settlements under Article 101 TFEU in light of the key points around which the EU approach to these agreements

[33] On the Commission and the General Court's approaches to these issues before the Court of Justice intervened on the matter and critical remarks on their assessments of reverse payment settlements, see, *inter alia*: Margherita Colangelo, "Reverse payment patent settlements in the pharmaceutical sector under EU and US competition laws: A comparative analysis", *World Competition* 40, no. 3 (2017): 489-493; Sandra Marco Colino et al., "The *Lundbeck* case and the concept of potential competition", *Concurrences*, no. 2 (2017): 41ff.; Eugène Buttigieg and Henri Piffaut, "The EU General Court's *Servier* judgment", *Journal of Antitrust Enforcement* 7, no. 2 (2019): 279-302; Pablo Ibáñez Colomo, "Pay-for-delay and the structure of article 101(1) TFEU: Points of law raised in *Lundbeck* and *Paroxetine*", *Journal of European Competition Law & Practice* 10, no. 10 (2019): 591-608; Camilla Signoretta, "Reverse-payment settlements under EU and US patent Law: Convergence in remedies", *GRUR International* 72, no. 1 (2023): 4-9.

[34] The Court of Justice largely followed the stance taken by the Advocate General in her Opinion on the case (Opinion of Advocate General Kokott of 22 January 2020, *Generics (UK) Ltd and Others v. Competition and Market Authority*, C-307/18, EU:C:2020:28 (hereafter Opinion of AG Kokott, *Generics*)). For comprehensive overviews on the various issues addressed in *Generics*, see, e.g.: Jotte Mulder and Clara Ceulemans, "The European Court of Justice in Generics UK: New frontiers regarding the legitimacy of patent settlements in competition law?", *European Pharmaceutical Law Review* 4, no. 2 (2020): 123-131; Pat Treacy, Sophie Lawrance, and Olivia Henry, "'Pay-for-delay' agreements: Guidance from the Court of Justice of the European Union in Case C-307/18 *Generics (UK) Limited & Others v. Competition and Markets Authority*", *Journal of Intellectual Property Law & Practice* 15, no. 6 (2020): 460-469; Krystyna Kowalik-Bańczyk, "Commentary on C-307/18 *Generics (UK) Ltd v. Competition and Markets Authority*: Competition delayed, competition denied?", *Journal of Antitrust Enforcement* 9, no. 3 (2021): 592-603.

revolves, as derived from the Court of Justice's judgments in *Generics*, *Lundbeck*,[35] *Servier*,[36] and *Teva/Cephalon*.[37]

3.1. Originator and generic companies as potential competitors

As a threshold requirement, for reverse payment patent settlements to fall within the prohibition laid down in Article 101(1) TFEU, the parties involved must be at least potential competitors at the time the agreements are concluded.[38] In this regard, it is noteworthy that, in *Servier*, the Court of Justice expressly presented the assessment of the existence of (potential) competition to be restricted as the initial stage of the analysis of the agreements.[39]

In principle, the idea that generic companies that have not yet entered the market and are in dispute with the originator over the latter's patents and their potential to impede such entry are in a relationship of potential competition with the originator is not straightforward. In particular, the understanding of the notion of competition as comprising only lawful competition, with the consequence that market entry in breach of an IP right would not count as potential competition, could hinder the finding of a competitive relationship.[40] A crucial issue, discussed extensively in the relevant rulings, has therefore been whether, and if so under what circumstances, an originator company and a generic manufacturer concluding an agreement in the above context may be considered potential competitors.[41]

---

[35] Judgment of 25 March 2021, *H. Lundbeck A/S and Lundbeck Ltd v. European Commission*, C591/16 P, EU:C:2021:243 (hereafter *Lundbeck*).

[36] Judgment of 27 June 2024, *European Commission v. Servier SAS and Others*, C-176/19 P, EU:C:2024:549 (hereafter *Commission v. Servier*); judgment of 27 June 2024, *Servier SAS and Others v. European Commission*, C-201/19 P, EU:C:2024:552 (hereafter *Servier v. Commission*).

[37] Judgment of 23 October 2025, *Teva Pharmaceutical Industries Ltd and Cephalon Inc. v. European Commission*, C-2/24 P, EU:C:2025:825 (hereafter *Teva/Cephalon*).

[38] See, e.g.: *Generics*, paras. 31-32; *Lundbeck*, paras. 52-53.

[39] *Commission v. Servier*, para. 99; *Servier v. Commission*, para. 78. Within the framework delineated by the Court, the second stage of the analysis involves determining whether such agreements, in light of their economic characteristics, fall within the characterisation of a restriction by object.

[40] On this point and the difficulty of determining the competitive relationship between originator and generic companies, see: Ibáñez Colomo, "Pay-for-delay and the structure of article 101(1) TFEU", 593ff.; Pablo Ibáñez Colomo, *The new EU competition law* (Bloomsbury Publishing, 2023), 211-212, 214.

[41] The only case in which potential competition was not disputed in the appeals was *Teva/Cephalon* (on the existence of a competitive relationship between Teva and Cephalon, see *Cephalon*, Commission decision, paras. 640-659).

The Court of Justice addressed this issue consistently throughout the relevant cases, confirming that potential competition between originator and generic companies can be found.

As a starting point, the Court identifies the test for determining the existence of potential competition in the "real and concrete possibilities" criterion.[42] When an agreement has the effect of temporarily keeping an undertaking outside a market, the relevant question is thus whether, absent the agreement, there would have been real and concrete possibilities for that company to enter the market. On the one hand, this criterion precludes the finding of a potential competitive relationship from being based on a purely hypothetical possibility of market entry or a mere wish of the undertaking to do so. On the other hand, it is unnecessary to demonstrate with certainty that entry would actually have occurred.[43] Rather, it is necessary to prove the existence of real and concrete possibilities of entering the market, which must be established on the basis of a body of consistent facts and assessed in light of the specific market context.[44]

Moreover, the Court considers that additional factors may confirm the existence of potential competition, including subjective ones, provided they are not decisive for that purpose. Objective factors notably include the conclusion of an agreement between undertakings when one of them was not present on the market, which is regarded as providing a "strong indication"[45] of a competitive relationship. The incumbent's subjective perception of an undertaking outside the market as a potential entrant, where that perception affects its conduct on the market, is also relevant to the assessment.[46]

Taking into account the regulatory constraints typical of the pharmaceutical sector (especially the requirement to obtain marketing authorisation

---

[42] *Generics*, para. 36 (citing judgment of 28 February 1991, *Delimitis*, C-234/89, EU:C:1991:91, para. 21); *Lundbeck*, para. 54; judgment of 26 October 2023, *EDP – Energias de Portugal and Others*, C-331/21, EU:C:2023:812 (hereafter *EDP*), para. 60.

[43] *Generics*, paras. 37-38; *Lundbeck*, para. 55. See Niamh Dunne, "Potential competition in EU law", *European Competition Law Review* 42, no. 12 (2021): 639, arguing that the Court placed the criterion of real and concrete possibilities "somewhere above the standard of a mere hypothetical chance, but considerably below that of a guaranteed certainty of entry".

[44] *EDP*, para. 63 (citing *Generics*, para. 39). See also *Servier v. Commission*, paras. 123-124.

[45] *Generics*, para. 55 (citing judgment of 20 January 2016, *Toshiba Corporation v. Commission*, C-373/14 P, EU:C:2016:26, paras. 33-34).

[46] On this whole point, see, in particular: *Generics*, paras. 42, 54-55; *Lundbeck*, paras. 74-78; *EDP*, paras. 69-71.

for medicinal products) and the presence of IP rights, notably patents, held by originator companies, the Court of Justice applied the notion of potential competition to the specific context in which reverse payment settlements were concluded as follows. From the Court's perspective, in the context of the opening of the market for a medicinal product to generic manufacturers, the latter's real and concrete possibilities of entering the market hinge on: first, their firm intention and inherent ability to enter; and second, the absence of insurmountable barriers to market entry.[47]

Accordingly, it is necessary to determine whether, at the time the agreement was concluded, the generic company had taken sufficient preparatory steps to enable it to enter the market within a timeframe that would impose competitive pressure on the originator.[48] These steps include: measures taken to obtain the requisite marketing authorisations for its product and to secure an adequate stock of that product (e.g., through the conclusion of supply contracts); legal steps undertaken to challenge the originator's patents; and marketing initiatives. Whether those steps will be finalised in due time or prove successful is immaterial.[49]

According to the Court, preparatory steps of the kind referred to above are relevant for the purpose of proving that the generic manufacturer has both a firm intention and an inherent ability to enter the market in circumstances where, as in all the cases under consideration, the primary patents have already expired (i.e., the active ingredient has entered the public

---

[47] See *Lundbeck*, para. 56 (citing *Generics*, paras. 40-41, 58).

[48] It is worth mentioning here that, in *Servier*, the Court of Justice held, concerning the assessment of the agreements between Servier and Krka as restrictions by effect, that to determine whether the agreements had a proven effect on potential competition, the analysis of the counterfactual scenario amounted to analysing whether that potential competition existed (i.e., to ascertaining whether Krka had a real and concrete possibility of entering the markets concerned and that the threat of such an entry could be regarded as realistic and credible). See *Commission v. Servier*, para. 355. This position can be framed within the broader context of the approach to restrictions by effect adopted by the Court of Justice (which it is not within the scope of this paper to examine): the issue was tackled in *Generics* and *Servier* (only with regard to the agreements with Krka) (see *Generics*, paras. 112-122, and *Commission v. Servier*, paras. 337-358).

[49] *Generics*, paras. 43-44; *Lundbeck*, paras. 57, 83-84 (where the Court held that the absence of a marketing authorisation at the time the agreement is concluded will not preclude a generic company from being regarded as a potential competitor); *Servier v. Commission*, paras. 119-120 (where the Court held that any delay in the process of market entry has no bearing on the generic company's status as a potential competitor, as long as it continues to exert competitive pressure on the originator as a result of its firm intention and inherent ability to achieve such entry).

domain), while secondary patents still cover certain aspects of the relevant originator products at the time the settlement agreements are concluded.[50]

Closely linked to this is the fact that, in the Court's reasoning, the existence of a patent protecting a manufacturing process of an active ingredient in the public domain cannot, as such, be regarded as an insurmountable barrier to the generic firm's market entry.[51] Importantly, this is regardless of: first, the presumption of validity attached to that patent (which applies automatically upon grant); second, the uncertain outcome of the dispute as to the validity of the patent; third, the existence of injunctions granted by a court, whereby the generic company is prohibited, on an interim basis, from selling the generic version of the originator medicine. In the Court's view, these factors are irrelevant for the purposes of applying Article 101 TFEU, as they shed no light on the outcome of any dispute on the validity of the patent.[52]

Key considerations as to the relevance to be given to the originator's patent underlying this stance, thoroughly discussed in *Generics*, include the following: uncertainty as to the validity of patents is a fundamental characteristic of the pharmaceutical sector; the presumption of validity attached to an originator medicine's patent does not amount to a presumption that a generic version of that medicine properly placed on the market is illegal; a patent does not guarantee protection against challenges to its validity; such actions, and in particular the "at risk" launch of a generic medicine (i.e., with the possibility of infringing the originator's patents) and the consequent court proceedings, commonly occur in the period before or immediately after the market entry of such a product; obtaining marketing authorisation for a generic medicine does not require demonstrating that such a marketing does not infringe the originator's patent.[53]

---

[50] See, in particular, *Servier v. Commission*, paras. 80, 118. Commentators highlighted that demonstrable intention is put on an equal footing with the ability to enter (Dunne, "Potential competition", 641).

[51] See: *Generics*, para. 46; *Lundbeck*, paras. 58-59. One of the arguments raised by Servier to dispute the findings of potential competition allowed the Court to specify that even the subjective perception that, absent a definitive finding of validity, the generic company may have of the originator's patent as sufficiently strong to deter entry is not, in itself, decisive with regard to the existence or otherwise of potential competition; moreover, is has no bearing on the assessment of either the generic company's inherent ability to enter or the objective existence of insurmountable barriers to such an entry (see *Servier v. Commission*, paras. 107-111).

[52] See: *Generics*, paras. 47-53, 102; *Lundbeck*, para. 58; *Servier v. Commission*, para. 112.

[53] See *Generics*, para. 51.

With regard in particular to patent disputes between originator and generic companies, the Court of Justice considers that, far from precluding any competition between them, such disputes rather constitute evidence of the existence of a potential competitive relationship.[54] Where such disputes are still pending, it is therefore necessary to examine all the relevant aspects of the economic and legal context before concluding that the originator and the generic manufacturer are not potential competitors. In turn, it is only where the validity of the patent has been definitively established by all the courts before which that question was pending that the Court considers it difficult to conceive that a potential competitive relationship between the patent holder and the generic manufacturer could still exist.[55]

The Court of Justice also denies that evidence relating to the subsequent outcome of the patent dispute (e.g., the confirmation of patent validity), which had justified the conclusion of the agreement, could retrospectively rebut the claim that the parties to that agreement were potential competitors at the time of its conclusion.[56]

Once a competitive relationship between the originator and the generic company is established on the basis of objective factors and is not called into question by insurmountable barriers to entry, other elements may substantiate its existence. The conclusion of settlement agreements with generic manufacturers that were not yet operating in the market, and the existence of transfers of value to those companies in exchange for the postponement of their market entry, are particularly relevant in this regard.[57] They arguably assume relevance insofar as they reveal the originator's perception of the risk posed by the generic manufacturers to its commercial interests, suggesting that the latter companies are viewed by the originator as at least potential competitive threats.[58]

---

[54] Ibid., paras. 52, 100.

[55] See *Commission v. Servier*, paras. 132, 431.

[56] Such evidence, unknown to the companies at the time the agreement is concluded, is incapable of having influenced their conduct and therefore of shedding light on the existence or absence of a competitive relationship between them (*Lundbeck*, paras. 68-71).

[57] See, e.g.: *Generics*, paras. 54-56 ("the greater the transfer of value, the stronger the indication" of the existence of a competitive relationship); *Lundbeck*, para. 78; *Servier v. Commission*, para. 82.

[58] *Generics*, para. 57. See Dunne, "Potential competition", 642 (the Author also highlights potential criticisms, such as the circular nature of this approach, in the sense that the conclusion of the agreement "serves to confirm the presence of potential competition, which in turn justifies the classification of the arrangement itself as anti-competitive in character").

To sum up, the Court of Justice's approach excludes the possibility that the mere existence of a patent precludes a finding of potential competition.[59] At the same time, it rules out the possibility that taking into account any relevant patent as part of the context entails engaging with patent considerations when assessing potential competition. Specifically, competition authorities need not assess the strength of the patent or the likelihood that the dispute would be resolved with a finding that the patent is valid and infringed.[60] What matters is solely whether the generic manufacturer exerts an effective constraint on the originator within the specific economic and legal context in which the agreement is concluded.[61]

Commentators have interpreted this approach – which does not take IP considerations into account – as reconciling the traditional stance according to which competition law does not engage with, or question, the existence of IP rights with the possibility of finding potential competition even when there is an uncertain probability that market entry would require infringing a valid patent.[62]

As is apparent from the foregoing, the pay-for-delay cases have provided the Court of Justice with ample opportunity to address the issue of potential competition. The reach of the principles that can be derived therefrom, at least in their core, extends beyond the specific context in which they

---

[59] See Mariateresa Maggiolino, "Antitrust law and the right to settle: The Case of Pay-for-Delay Settlements", *Concorrenza e Mercato* 28, no. 1 (2021): 120, arguing that "to verify whether there is a restriction of competition, EU institutions are not satisfied with the existence of a patent".

[60] The assessment of the rights conferred by a patent must rather concern the question whether, notwithstanding the existence of that patent, the generic company has real and concrete possibilities of entering the market at the relevant time (see *Servier v. Commission*, para. 81 (citing *Generics*, para. 50)). See Kowalik-Bańczyk, "Commentary on C-307/18 *Generics (UK) Ltd v. Competition and Markets Authority*", 602, arguing that "it is the relationship between undertakings that is a condition *sine qua non* to adjudicate on the existence of potential competition, rather than an objective assessment of whether the patent protection would be upheld". See Polen Bayrak, "Reexamining pay-for-delay agreements: anticompetitive practices or strategic settlements under article 101(1) TFEU?", *European Competition Journal* 21, no. 2 (2025): 348, arguing that "the threshold for qualifying a generic company as a potential competitor seems to be quite low. Any possibility of invalidating a patent or escape a finding of infringement would suffice, irrespective of the likelihood of success". For critical remarks on the Court of Justice's approach to the role of patents in the competition law assessment, see Patrick Actis Perinetto, "*Generics (Paroxetine)*, or the new unbearable lightness of patents in competition law", *European Competition Journal* 17, no. 2 (2021): 437-472.

[61] Pablo Ibáñez Colomo, "The legal status of pay-for-delay agreements in EU competition law: *Generics (Paroxetine)*", *Common Market Law Review* 57, no. 6 (2020): 1943.

[62] Ibid.

were developed. Yet the relevance of the individual, more specific items of evidence identified in those cases remains less straightforward.[63] In this regard, it can be noted that the Commission's 2023 Guidelines on horizontal cooperation agreements[64] specifically draw upon *Generics* and *Lundbeck*, and the criteria relating to potential competition set out therein, when setting out the factors that may be relevant to assessing the existence of such a competitive relationship.[65]

The Court of Justice has recently had the occasion to provide guidance on the relevance of the criteria elaborated in *Generics* beyond pay-for-delay cases in *EDP*, where the topic of potential competition arose precisely in connection with that issue.[66] The Court clarified that the interpretation of the notion of potential competition and the standard of proof set out in *Generics* cannot be considered of general application.[67] Relatedly, the Court also made clear that its case law on reverse payment settlements has not added autonomous additional requirements for the purpose of establishing the existence of potential competition. In this context, it stressed the context-dependent relevance of criteria such as the taking of preparatory steps toward market entry (their significance was linked, in those cases, to the numerous barriers to entry characterising pharmaceutical markets). Accordingly, such steps are relevant to the assessment of potential competition only insofar as they may be appropriate for demonstrating the real and concrete possibilities of entering the market.[68]

3.2. Pay-for-delay agreements as restrictions by object under Article 101(1) TFEU

The Court of Justice's approach to reverse payment patent settlements concluded between originator and generic companies that were at least potential competitors was then based on the existence of a restriction of

---

[63] For considerations on this point, see Dunne, "Potential competition", 643-644.

[64] Communication from the Commission, *Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements* (2023/C 259/01), July 21, 2023 (hereafter Horizontal Guidelines).

[65] Ibid., para. 16.

[66] *EDP*, paras. 59ff.

[67] Ibid., paras. 65-66.

[68] Ibid., paras. 75-76. On the same points, and more generally for a discussion on potential competition, see Opinion of Advocate General Rantos of 2 March 2023, *EDP – Energias de Portugal and Others*, C-331/21, EU:C:2023:153, paras. 35-85.

competition by object.[69] As will be discussed below, the relevant judgments have consistently held that reverse payment settlements can be treated as restrictions by object for the purposes of the application of Article 101(1) TFEU. At the same time, they have stressed that these agreements do not amount, in principle, to by-object infringements, and have indicated the circumstances in which they qualify as such, against which the specific settlements at issue were then assessed. To this end, the Court of Justice has repeatedly been called upon to interpret the notion of restriction by object. The interpretation provided in that context has both influenced and reflected the evolving understanding of the notion over time. Two points are worth stressing at the outset. First, the core analytical framework for reverse payment settlements, as developed in *Generics*, has been subsequently reiterated without change. Second, as regards other aspects of the analysis, the application of the notion of restriction by object has varied in line with the broader evolution in the case law.

In line with established case law, the key consideration in characterising an agreement as a restriction by object is whether it reveals a degree of economic harm to the proper functioning of competition that renders an examination of its effects unnecessary.[70] This presupposes an assess-

[69] The appropriateness of treating reverse payment settlements as restrictions by object has been questioned in the literature in the light of the need for a case-by-case assessment of these agreements under an effects-based analysis. This position can particularly (though not exclusively) be found in the debate preceding the Court of Justice's rulings on the matter. See, e.g.: Ginevra Bruzzone and Sara Capozzi, "The procompetitive and anticompetitive impact of patent settlements", in *Competition and patent law in the pharmaceutical sector: An international perspective*, ed. Giovanni Pitruzzella and Gabriella Muscolo (Kluwer Law International, 2016), 27-29; Maier-Rigaud, Blalock, and Gannon, "Reverse payments", 40; Bernadette Zelger, "By object or effect restrictions – Reverse payment settlement agreements in light of *Lundbeck*, *Servier*, and *Generics*", *Journal of European Competition Law & Practice* 12, no. 4 (2021): 273-283. See also Valérie Meunier and Jorge Padilla, "Should reverse payment patent settlements be prohibited per se?", *Concurrences* 3 (2016): 8-9.

[70] The standard set by the Court of Justice in judgment of 11 September 2014, *Groupement des Cartes Bancaires (CB) v. European Commission*, C-67/13 P, EU:C:2014:2204, para. 58, and consistently reiterated thereafter, is that of a restrictive interpretation of the notion of restriction by object, which can only be applied to agreements that reveal, in themselves, and having regard to their content, their objectives, and the economic and legal context of which they form part, a sufficient degree of harm to competition (see, e.g.: judgment of 23 January 2018, *F. Hoffmann-La Roche and Others v. Autorità Garante della Concorrenza e del Mercato*, C-179/16, EU:C:2018:25, paras. 78-79; *Generics*, para. 67; judgment of 2 April 2020, *Gazdasági Versenyhivatal v. Budapest Bank Nyrt. and Others*, C-228/18, EU:C:2020:265 (hereafter *Budapest Bank*), paras. 51, 54; judgment of 21 December 2023, *European Superleague Company S.L. v. Unión de Federaciones Europeas de Fútbol (UEFA), Fédération Internationale de Football Association (FIFA)*, C-333/21, EU:C:2023:1011

ment, based on objective considerations, that may involve a detailed analysis of the agreement, its objectives and the economic and legal context in which it operates.[71] In the case of pay-for-delay settlements, the transfers of value resulting from the agreements are of particular importance in that assessment.[72]

The context in which reverse payment patent settlements are concluded, as traced by the Court of Justice, is one in which such agreements are capable of restricting competition. The Court, in fact, takes the view that challenges to the validity and scope of patents are part of normal competition in sectors where exclusive rights in relation to technology exist.[73] However, it considers that a delay in the market entry of generic medicines resulting from a patent settlement that involves value transfers to the manufacturer of those medicines cannot be regarded, in all cases, as a collusive practice constituting a restriction by object.[74]

The Court's reasoning starts from the consideration that the transfers of value may prove to be justified. This would be the case where the generic manufacturer receives sums from the originator that correspond to compensation for the costs of, or the disruption caused by, the dispute between them (e.g., the expenses and fees of that manufacturer's advisers), or remuneration for the actual and proven supply of goods or services to the originator.[75] The Court elaborated on this point in *Servier* and *Teva/Cephalon*, explaining that reverse payments by way of those sums are justified in terms of competition in that they are consistent with the generic company's recognition of the originator's patent validity underlying the settlement of the dispute.[76]

The reverse payment, however, plays a decisive role in establishing the anti-competitiveness of these settlements whenever it has no explanation

---

(hereafter *European Superleague Company*), paras. 161-162, 165; *Servier v. Commission*, para. 75; judgment of 29 July 2024, *Banco BPN/BIC Português SA and Others v. Autoridade da Concorrência*, C-298/22, EU:C:2024:638, paras. 43-44).

[71] See, e.g., *Servier v. Commission*, para. 87. The fact that the undertakings acted without having an intention to restrict competition or that they pursued certain legitimate objectives is not decisive for the purposes of the application of Article 101(1) TFEU (*Servier v. Commission*, para. 77, citing *European Superleague Company*, para. 167).

[72] Case T-74/21 *Teva/Cephalon*, para. 41.

[73] See, e.g.: *Generics*, para. 81; *Commission v. Servier*, para. 105; *Teva/Cephalon*, paras. 61-62.

[74] *Generics*, para. 84; *Servier v. Commission*, paras. 83, 163; *Teva/Cephalon*, para. 63.

[75] See, in particular: *Generics*, paras. 85-86; *Servier v. Commission*, para. 163; *Teva/Cephalon*, para. 63.

[76] See *Teva/Cephalon*, para. 64 (citing *Servier v. Commission*, para. 164).

other than the commercial interest of both the patent holder and the party allegedly infringing the patent not to engage in competition on the merits: in this case, the agreements must be characterised as restrictions of competition by object.[77]

Thus, when assessing a reverse payment patent settlement, it is first necessary to ascertain whether the net gain from all transfers of value made by the originator to the generic company – both direct and indirect, pecuniary and non-pecuniary[78] – may be fully justified in the above terms. If this is not the case, it must then be determined whether, in the absence of such justification, the transfers of value can have no explanation other than the originator and generic companies' shared interest in not competing on the merits. With regard to this second step, the legal test used by the Court of Justice requires ascertaining whether the net gain (including any justified costs) is sufficiently large actually to act as an incentive for the generic manufacturer to refrain from entering the market.[79] This implies that a by-object infringement can be found only where the restriction of competition resulting from the settlement agreement (e.g., through non-compete and non-challenge clauses) is based not

---

[77] See, in particular: *Generics*, para. 87; *Lundbeck*, para. 114.

[78] See Amalia Athanasiadou, "Side-deals as part of pharma patent settlements: A new landscape after Servier and Paroxetine?", *European Competition Law Review* 41, no. 12 (2020): 620-630. In *Servier*, the settlement and licensing agreements between Servier and Krka were found to restrict competition by object on the ground that Krka's access to its core markets without the risk of patent infringement under the licence acted as a significant incentive for it to accept marketing restrictions in Servier's own core markets under the settlement. The Court of Justice considered this *quid pro quo* equivalent, from an economic point of view, to a transfer of value within the meaning of *Generics*. See *Commission v. Servier*, paras. 451-460. For a comment on the classification of settlements that include a licensing agreement as restrictions by object, see Damien Neven and Georges Siotis, "The judgment of the Court of Justice in *Perindopril* (*Servier*), Case AT.39612: A comment on the KRKA licensing agreement", *Journal of European Competition Law & Practice* 15, no. 8 (2024): 557-561. It is interesting to note that, in the context of the revision of the Technology Transfer Block Exemption Regulation and accompanying Guidelines, the Commission included the Court of Justice's case law on pay-for-delay settlements and the essential criteria for characterising these agreements as restrictions by object in the draft guidelines (Communication from the Commission, *Approval of the content of a draft for a Commission Regulation on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements and a draft for Commission Guidelines on the application of Article 101 of the Treaty to technology transfer agreements* (C/2025/5024), September 16, 2025).

[79] See: *Generics*, paras. 90-93; *Servier v. Commission*, paras. 164-165; *Teva/Cephalon*, paras. 64-65. For critical remarks on the wording of the test developed by the Court, see Stefan Enchelmaier, "Restrictions 'by object' after *Generics*, *Lundbeck*, and *Budapest Bank*: Are we any wiser now?", *Journal of Antitrust Enforcement* 11, no. 1 suppl. (2023): i96-i97.

on the generic company's recognition of patent validity but on a transfer of value that constitutes an inducement for that manufacturer to refrain from competition.[80]

To reach such a conclusion, the net gain need not necessarily be greater than the profits that the generic company would have made had it succeeded in the patent litigation. Rather, it must be shown to be sufficiently beneficial to encourage that manufacturer to refrain from competing with the originator.[81] *Teva/Cephalon* brought an important contribution to this. The Court of Justice addressed the issue of the characterisation as a restriction by object of a settlement agreement that included a package of commercial transactions (among which were supply, distribution, and licensing agreements). It took the view that, in such a case, the relevant question to establish a restriction by object is whether those transactions can be explained in a plausible manner (i.e., whether their aim is not to restrict competition by inducing a potential competitor not to enter the market in exchange for an unjustified value transfer). According to the Court, if it is found that, absent the restrictive clauses contained in the settlement agreement, the parties would not have concluded the commercial transactions, then it could be inferred that those transactions have no explanation other than the restriction of competition agreed in that agreement.[82]

In doing so, the Court of Justice has therefore emphasised that, for the purposes of characterising an agreement as a restriction by object, what matters is whether that agreement, taken as a whole, reveals a degree of harm to competition. This, in turn, means that, in the context of the analysis, it is necessary to assess the settlement agreement as a whole rather than each of its clauses in isolation, particularly where such clauses are closely linked. Similarly, where multiple commercial transactions and the

---

[80] *Teva/Cephalon*, para. 66.

[81] See, in particular, *Generics*, para. 94.

[82] See *Teva/Cephalon*, paras. 71-86. On this basis, the Court of Justice upheld the Commission and General Court's finding of a restriction by object and the method used to reach it, namely establishing, based on a hypothetical scenario (i.e., examining the transactions absent the restrictive clauses), whether the transactions departed from normal market conditions and thus their incentive effect. The Court stressed that this differed from the counterfactual method used to analyse the effects of the agreements. In this context, it confirmed that counterfactual elements may be taken into account to identify a restriction by object (*Teva/Cephalon*, para. 75, citing *Budapest Bank*, paras. 82-83).

settlement agreement form part of a single contractual framework, they should be assessed together.[83]

The emphasis placed by the Court on the specific characteristics of the settlement agreements – from which their harmfulness to competition can be inferred according to the above assessment – as decisive for their characterisation as restrictions by object has implications on various levels. First, it affects how experience is understood and the role it plays when establishing the restriction by object. Specifically, a lack of experience, in the sense of prior decisional practice, with a certain conduct (i.e., reverse payment settlements) cannot preclude characterisation of an agreement exhibiting those characteristics as restrictive of competition by object, even if it occurs in a specific context such as that of IP rights.[84] Second, it precludes the possibility that the characterisation as a restriction by object of a reverse payment settlement that reveals a degree of harm to competition in light of the above characteristics could be undermined by the fact that the agreement does not exceed the scope and remaining period of validity of the originator's patent.[85]

---

[83] See *Teva/Cephalon*, paras. 68, 83-84. See also *Servier v. Commission*, para. 294. This also shows that complexity as such is not an obstacle to the finding of a restriction by object (in this sense, specifically with regard to *Servier*, see Robert Hardy, "The ECJ's guidance on patent settlements and the 'buying off of competition': The *Servier (Perindopril)* rulings", *Common Market Law Review* 62, no. 6 (2025): 1893ff.

[84] See: *Lundbeck*, paras. 130-131; *Servier v. Commission*, para. 144; Case T-74/21 *Teva/Cephalon*, para. 55. Cf. *Budapest Bank*, para. 76. See also Horizontal Guidelines, para. 24. For discussions on this point, see: Jotte Mulder and Wolf Sauter, "Anticompetitive pharmaceutical patent settlements: The EU cases on pay-for-delay", in *EU Competition law and pharmaceuticals*, ed. Wolf Sauter, Marcel Canoy, and Jotte Mulder (Edward Elgar Publishing, 2022), 93, arguing that "the approach taken implies that a transfer of value that cannot be justified would qualify the agreement as market sharing. (…) The Court therefore suggests that even though some types of behaviour can be considered novel, their qualification in competition law terms is not necessarily so new"); Pablo Ibáñez Colomo, "Restrictions by object under article 101(1) TFEU: From dark art to administrable framework", *Yearbook of European law* 43 (2024): 251, arguing that the "*Budapest Bank* doctrine applies only to genuinely novel practices"; according to the Author, a reverse payment settlement that "serves no plausible purpose other than a restrictive one (…) will be nothing other than a 'naked restraint' aimed at sharing markets. Since there is abundant experience about the rationale and impact of 'naked restraints' on competition, the *Budapest Bank* doctrine would have no role to play".

[85] See *Generics*, paras. 96-99 ("[i]f it were accepted that such factors made it possible to exclude from characterisation as a 'restriction by object' a practice capable of displaying, in itself, a sufficient degree of harm to competition, that would be liable excessively to circumscribe the scope of that concept, even if it is to be interpreted strictly"). See also *Lundbeck*, para. 121 (citing *Generics*, para. 97, where the Court emphasised that a patent "does not grant its holder the right to enter into

It follows from the foregoing that the determination of whether a reverse payment patent settlement restricts competition by object requires a case-by-case assessment to verify whether the transfers of value ultimately have as their sole explanation the parties' interest in refraining from competing. In fact, although the reverse payment is taken as the benchmark for such an assessment,[86] its presence alone cannot be a sufficient ground for presuming the anti-competitive object of the settlement agreement.[87] The Court of Justice leaves open, in principle, the possibility that the gain resulting for the generic company has a plausible explanation other than a restrictive one (i.e., buying off competition), which would preclude the finding of an infringement by object.[88]

In this sense, as some scholars have highlighted, this line of case law confirms that the evaluation of an agreement's object is a "case-by-case, context-specific inquiry",[89] and emphasises the importance of context in identifying the precise purpose of an agreement and, therefore, the existence of a restriction by object.[90]

---

agreements contrary to Article 101 TFEU"). See Maggiolino, "Antitrust law and the right to settle", 124, arguing that "[a] way to conceptualize the patent scope is to look at the rights that patentees can exercise. Under this approach, in no jurisdiction are patentees allowed to pay their rivals to not challenge the validity of their patents or not to enter the market with non-infringing goods".

[86] See Emanuela Arezzo, "Patent portfolios and competition law: Some reflections after the recent RPSA cases", *Market and Competition Law Review* 7, no. 1 (2023): 126, noting that "the circumstance that a settlement agreement (…) contains an obligation on the side of the supposed damaged party to give some sort of monetary payment or other economic benefit to the supposed counterfeiter surely represents the first warning sign". It is worth noting the absence in the Court of Justice's reasoning of any reference to the size of the reverse payment as a possible indicator of the strength or weakness of the originator's patent – a point that was present in the reasoning of both the Commission and the General Court in *Lundbeck* (see: *Lundbeck*, Commission decision, paras. 639-641; Case T-472/13 *Lundbeck*, paras. 352-353). Commentators highlighted that the Court of Justice's approach, which removes the possibility that the assessment may involve an analysis of the actual scope or strength of the patent, is more in line with recent approaches to restrictions by object (Mulder and Sauter, "Anticompetitive pharmaceutical patent settlements", 91-92).

[87] See Ibáñez Colomo, "The legal status of pay-for-delay agreements in EU competition law", 1942-1943, arguing that "concluding that reverse payment settlements amount in principle to a 'by object' infringement would not only have failed to capture the complexities and the economic and legal peculiarities of the pharmaceutical industry, but would have disincentivized the conclusion of some agreements with a convincing pro-competitive rationale".

[88] It is for the Commission to show that the transfers of value have no explanation other than a restrictive one (see *Teva/Cephalon*, paras. 91-94).

[89] Ibáñez Colomo, "The legal status of pay-for-delay agreements in EU competition law", 1945.

[90] Alison Jones, Brenda Sufrin, and Niamh Dunne, *Jones & Sufrin's EU competition law: Text, cases & materials* (Oxford University Press, 2023), 883.

The Court of Justice's judgments on pay-for-delay settlements have thus confirmed that the context of conduct forms "an essential part of the characterisation exercise".[91] At the same time, however, they have revived some of the recurring issues arising from the analysis of an agreement's object within its legal and economic context, linked in particular to the extent of such an inquiry. Among these are the contextual factors relevant to such an analysis, how it should be carried out, and where to draw the boundary with the analysis of the effects on competition.[92] Notably, in this regard, the judgments in this area have put under the spotlight the role of pro-competitive effects when ascertaining whether conduct reveals the degree of harm required to be characterised as a restriction by object. Indeed, the treatment of pro-competitive effects across the various cases arguably represents the aspect of the analysis of the agreements that has proven to be most controversial and a source of interpretative uncertainty.

The approach initially adopted by the Court of Justice in *Generics* indicates that the settlement agreements would not constitute restrictions by object if accompanied by pro-competitive effects capable of giving rise to a reasonable doubt as to whether they cause a sufficient degree of harm to competition.[93] Indeed, the Court in *Generics* required that pro-competitive effects relied upon by the parties – provided they are demonstrated, relevant, and agreement-specific – be taken into account, as elements of the context of the agreement, for the purpose of characterising it as a

---

[91] Ibid. 252. The Court of Justice's judgments have, from the outset, stressed that the precise purpose of an agreement must be considered within its context (see, e.g., judgment of 30 June 1966, *Société Technique Minière (L.T.M.) v. Maschinenbau Ulm GmbH (M.B.U.)*, 56/65, EU:C:1966:38, 249).

[92] How restrictions by object should be identified (and, notably, the role of context), as well as the interpretation and application of the notion as emerging in particular from the Court's case law, represent widely debated issues. Among the most recent comments on the matter, see: Alison Jones, "The Court of Justice's judgment in *Generics (UK) v. Competition and Markets Authority* and the object/effect dichotomy", *Journal of Antitrust Enforcement* 9, no. 3 (2021): 604-614; Enchelmaier, "Restrictions 'by object' after *Generics*, *Lundbeck*, and *Budapest Bank*"; Ibáñez Colomo, "Restrictions by object under article 101(1) TFEU"; Mária T. Patakyová, "What does 'by object', in effect, mean? In search for the ultimate determination criterion", *Market and Competition Law Review* 9, no. 2 (2025): 37-68. The topic has also been discussed by the Advocate Generals in their Opinions: see, e.g., Opinion of Advocate General Bobek of 5 September 2019, *Gazdasági Versenyhivatal v. Budapest Bank Nyrt. and Others*, C-228/18, EU:C:2019:678 (hereafter Opinion of AG Bobek, *Budapest Bank*), paras. 40-51, and Opinion of Advocate General Rantos of 5 October 2023, *Banco BPN/BIC Português SA and Others v. Autoridade da Concorrência*, C-298/22, EU:C:2023:738, paras. 41-50.

[93] *Generics*, para. 111.

restriction by object. In the Court's view, those effects should be taken into account in order to assess the objective seriousness of the practice and, consequently, determine the means of proving it. Pro-competitive effects would preclude the finding of a restriction by object when they are sufficiently significant to justify a reasonable doubt as to the agreement's anti-competitive object.[94]

This passage, in which the Court explicitly recognised the relevance of pro-competitive effects as contextual elements, has given rise to diverging interpretations. Some authors have regarded this as an innovative point.[95] Others have instead seen it as confirmation that pro-competitive effects are also relevant, as elements of the economic and legal context, under Article 101(1) TFEU at the stage of the analysis of an agreement's object.[96]

The idea that considering the pro-competitive effects in the above sense was part of the framework for establishing a restriction by object set out in *Generics* is also reflected in the approaches taken by both the Commission and the General Court in *Teva/Cephalon*. Indeed, they examined the pharmaceutical companies' claims of pro-competitive effects, ultimately reaching the conclusion that the settlement agreement could not produce pro-competitive effects that would be demonstrated, relevant, sufficiently significant, and not uncertain, and thus capable of casting reasonable doubt on its anti-competitive object.[97]

Taken together, *Generics* and its practical application in *Teva/Cephalon*, as well as the words of the Court of Justice in *Lunbeck*,[98] suggest that the

---

[94] Ibid., paras. 103-107. See also Opinion of AG Kokott, *Generics*, paras. 158-166.

[95] Enchelmaier, "Restrictions 'by object' after *Generics*, *Lundbeck*, and *Budapest Bank*", i94-i95. The Author highlighted that the pro-competitive effects "are described in a way (…) that does not allow any abstract speculation or general labels. Instead, a meticulous examination of the actual situation and developments on the relevant market is necessary". He also pointed out possible issues associated with integrating such considerations into the assessment, including confusion with the analysis under Article 101(3) TFEU.

[96] In this sense, see: Ibáñez Colomo, "The legal status of pay-for-delay agreements in EU competition law", 1945-1946, arguing that "the judgment confirms – in a much more explicit way (…) – that the pro-competitive effects of an agreement must, as elements of the economic and legal context, be considered when evaluating whether it amounts to a restriction by object"; Stavros Makris, "Procompetitive effects in EU competition law", in *Antitrust and the bounds of power – 25 years on*, ed. Oles Andriychuk (Hart Publishing, 2023), 144ff., referring to the role of pro-competitive effects at that stage of the analysis as that of "counter-indicators" of what would otherwise be a restriction of competition.

[97] See: *Cephalon*, Commission decision, paras. 974-1012; Case T-74/21 *Teva/Cephalon*, paras. 167-191.

[98] See *Lundbeck*, paras. 136-137.

parties to an agreement would be able to show that it is a source of pro-competitive effects for the purposes of rebutting its characterisation as a restriction by object; to that end, mere unsubstantiated assertions are not, however, sufficient.[99]

It can also be noted that the Court reiterated the stance towards pro-competitive effects, in the same terms as in *Generics*, in a series of subsequent judgments.[100] Notably, however, no such reference is found in more recent judgments.

Conversely, in *Servier* (building upon *European Superleague Company*)[101], the Court of Justice explicitly stated that, in the economic and legal context of which an agreement forms part, it is not necessary to examine the effects of that agreement on competition, be they actual or potential, or negative or positive.[102] Consequently, any positive or pro-competitive effects of an agreement cannot be taken into account to determine whether it should be characterised as a restriction by object under Article 101(1) TFEU, including for the purpose of assessing whether it reveals the degree of harm required for such a characterisation.[103] Based on the wording employed in these judgments, the Court seems to have moved away from

---

[99] See also: *Budapest Bank*, paras. 82-83; Opinion of AG Bobek, *Budapest Bank*, paras. 78-81. It had been observed that the Court's judgments in *Generics* and *Budapest Bank*, taken together, show that the parties to an agreement may be able to "show that the practice is a 'plausible' source of pro-competitive gains", and that "[e]vidence in this sense must not be conclusive, (…) it is enough that it provides 'strong indications' about the pro-competitive (or at least ambivalent) effects of the practice" (Ibáñez Colomo, "The legal status of pay-for-delay agreements in EU competition law", 1948). See also Ibáñez Colomo, "Restrictions by object under article 101(1) TFEU", 238, where the Author argues that firms may disprove the alleged restrictive object of a practice by presenting arguments and evidence relating to the practice's pro-competitive aims; according to the Author, at the "'by object' stage", "arguments pertaining to the pro-competitive aims of a practice (…) have always had a fundamental role to play, and this insofar as they can shed light on whether the behaviour under consideration can be rationalized on non-restrictive grounds".

[100] See: judgment of 12 January 2023, *HSBC Holdings plc and Others v. European Commission*, C-883/19 P, EU:C:2023:11, paras. 139-143, 196-197; judgment of 29 June 2023, *Super Bock Bebidas SA and Others v. Autoridade da Concorrência*, C-211/22, EU:C:2023:529, paras. 35-37; judgment of 26 October 2023, *Autoridade da Concorrência and Others v. Ministério Público*, C-331/21, EU:C:2023:812, paras. 102-106. This position is also reflected in the Commission's Horizontal Guidelines, para. 28.

[101] *European Superleague Company*, para. 166.

[102] See, in particular, *Commission v. Servier*, para. 288, and *Servier v. Commission*, para. 76.

[103] *Commission v. Servier*, para. 288 (these statements were made in response to Servier's claim that the General Court was entitled to take into account the pro-competitive effects of the agreement, as contextual factors, to rebut the finding of a restriction by object). The General Court had previously taken the view that "the Commission (…) cannot, when examining whether the object of

Generics and the recognition of the relevance of pro-competitive effects at this stage of assessment.[104]

The most recent case, *Teva/Cephalon*, has not shed further light on this point, as the Court of Justice has not expressly ruled on it. However, in his Opinion on the case, Advocate General Rantos had highlighted that the judgments in *European Superleague Company* and *Servier* had clarified the Court's position in *Generics* precisely in the sense that it is not necessary to take into account any positive or pro-competitive effects of conduct to determine whether it should be characterised as a restriction by object.[105]

4. Concluding remarks

The primary recurring concern raised about pay-for-delay settlements is the presence of reverse payments: in particular, the benefits they provide not only to originators but also to generic companies by delaying generic competition, and the related incentives for both parties to enter into such agreements, ultimately at the expense of healthcare systems and consumers.

In light of the Court of Justice's rejection of the relevance of patent considerations, including the outcome of the underlying patent dispute, for assessing the anti-competitiveness of reverse payment settlements, its restriction-by-object approach takes the payment from the originator to the generic company as the benchmark for evaluating the legality of these agreements under antitrust law. Thus, the Court acknowledged the risks inherent in pay-for-delay agreements. It was, however, careful to clarify that the mere presence of a reverse payment does not render a patent settlement unlawful under EU competition law. Accordingly, the Court identified the circumstances under which a transfer of value from the originator to the generic company amounts to a payment to avoid competing for a certain period (i.e., an unlawful payment for delay), from which the particular harmfulness to competition of these agreements can be derived.

---

an agreement is restrictive and, in particular, in assessing the economic and legal context of that agreement, completely ignore its potential effects" (Case T-691/14 *Servier*, para. 304).

[104] On this point, see Pablo Ibáñez Colomo, "Key takeaways from the Servier saga: Object, (pro and anticompetitive) effects and counterfactual (I)", *Chillin'Competition*, 2024, https://chillingcompetition.com/2024/07/01/key-takeaways-from-the-servier-saga-object-pro-and-anticompetitive-effects-and-counterfactual-i/.

[105] Opinion of Advocate General Rantos of 27 March 2025, *Teva Pharmaceutical Industries Ltd and Cephalon Inc. v. European Commission*, C-2/24 P, EU:C:2025:222, para. 79.

Settling pharmaceutical patent disputes with reverse payments is therefore not, in principle, prohibited. Still, findings of infringements of Article 101 TFEU and, in particular, of restrictions by object have been reached in all relevant cases. What can be noted is that the assessment of reverse payment settlements has led to the development of a set of established principles on several key aspects that have guided the outcomes in each case and ensured a broadly consistent approach to these agreements.

From a broader perspective, the significance of the case law on pay-for-delay lies in its contributions to the wider issue of assessing agreements as restrictions by object under Article 101(1) TFEU. As the previous discussion shows, this line of case law forms part of the evolving interpretation and application of the notion of restriction by object within the Court of Justice's jurisprudence, while also informing ongoing debates on the subject.

Against a backdrop in which the Court of Justice has now ruled on all pay-for-delay cases, a final observation seems worth making. With respect to issues strictly connected to reverse payment patent settlements, one can fairly say that the pay-for-delay saga has left little doubt about their current status in EU competition law. Still, and despite the consistency highlighted above, a closer analysis reveals that the case law has not been equally clear on some aspects relevant to the broader analysis of an agreement's object, thereby leaving them surrounded by a degree of uncertainty.

Bibliography

Arezzo, Emanuela. "Patent portfolios and competition law: Some reflections after the recent RPSA cases". *Market and Competition Law Review* 7, no. 1 (2023): 113-144.

Athanasiadou, Amalia. "Side-deals as part of pharma patent settlements: A new landscape after Servier and Paroxetine?" *European Competition Law Review* 41, no. 12 (2020): 620-630.

Athanasiadou, Amalia. *Patent settlements in the pharmaceutical industry under US antitrust and EU competition law*. Kluwer Law International, 2018.

Avery, Matthew. "Continuing abuse of the Hatch-Waxman Act by pharmaceutical patent holders and the failure of the 2003 amendments". *Hastings Law Journal* 60, no. 1 (2008): 171-200.

Bayrak, Polen. "Re-examining pay-for-delay agreements: Anticompetitive practices or strategic settlements under Article 101(1) TFEU?" *European Competition Journal* 21, no. 2 (2025): 336-357.

Bruzzone, Ginevra, and Sara Capozzi. "The procompetitive and anticompetitive impact of patent settlements". In *Competition and patent law in the pharmaceutical sector:*

An international perspective, edited by Giovanni Pitruzzella and Gabriella Muscolo. Kluwer Law International, 2016.

Buttigieg, Eugène, and Henri Piffaut. "The EU General Court's *Servier* judgment". *Journal of Antitrust Enforcement* 7, no. 2 (2019): 279-302.

Carrier, Michael A. "Unsettling drug patent settlements: A framework for presumptive illegality". *Michigan Law Review* 108, no. 1 (2009): 37-80.

Carrier, Michael A., and Edward Bank. "The missing caselaw of reverse-payment settlements". *St. John's Law Review* 98, no. 5 (2025): 959-1074.

Clancy, Michael, Damien Geradin, and Andrew Lazerow. "Reverse-payment patent settlements in the pharmaceutical industry: An analysis of U.S. antitrust law and EU competition law". *The Antitrust Bulletin* 59, no. 1 (2014): 153-172.

Colangelo, Margherita. *Regulation, innovation and competition in pharmaceutical markets: A comparative study*. Hart Publishing, 2023.

Colangelo, Margherita. "Reverse payment patent settlements in the pharmaceutical sector under EU and US competition laws: A comparative analysis". *World Competition* 40, no. 3 (2017): 471-504.

Dogan, Stacey L., and Mark A. Lemley. "Antitrust law and regulatory gaming". *Texas Law Review* 87, no. 4 (2009): 685-730.

Dunne, Niamh. "Potential competition in EU law". *European Competition Law Review* 42, no. 12 (2021): 638-644.

Edlin Aaron, C. Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro. "The *Actavis* inference: Theory and practice". *Rutgers University Law Review* 67, no. 3 (2015): 585-635.

Edlin Aaron, C. Scott Hemphill, Herbert Hovenkamp, and Carl Shapiro. "Activating *Actavis*". *Antitrust Magazine* 28, no. 1 (2013): 16-23.

Enchelmaier, Stefan. "Restrictions 'by object' after *Generics*, *Lundbeck*, and *Budapest Bank*: are we any wiser now?". *Journal of Antitrust Enforcement* 11, no. 1 suppl. (2023): i72-i101.

European Commission: Directorate-General for Competition. *Update on competition enforcement in the pharmaceutical sector (2018-2022). European Competition Authorities working together for affordable and innovative medicines: Report from the Commission to the Council and the European Parliament*. Publications Office of the European Union, 2024. https://data.europa.eu/doi/10.2763/427709.

European Commission. *Pharmaceutical sector inquiry: Final report*. July 8, 2009. https://competition-policy.ec.europa.eu/document/download/5b2773da-34dd-4b18-9555-5433dc69c8a8_en?filename=pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf.

Federal Trade Commission. "Pay for delay". Accessed November 28, 2025. https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay.

Federal Trade Commission, *Pay-for-delay: How drug company pay-offs cost consumers billions. An FTC Staff Study*. January 2010. https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.

Feldman, Robin. "The price tag of 'pay-for-delay'". *Science and Technology Law Review* 23, no. 1 (2022): 1-49.

Feldman, Robin, and Evan Frondorf. *Drug wars: How big pharma raises prices and keeps generics off the market*. Cambridge University Press, 2017.

Feldman, Robin, and Prianka Misra. "The fatal attraction of pay-for-delay". *Chicago-Kent Journal of Intellectual Property* 18, no. 1 (2019): 249-283.

Hardy, Robert. "The ECJ's guidance on patent settlements and the 'buying off of competition': The *Servier (Perindopril)* rulings". *Common Market Law Review* 62, no. 6 (2025): 1879-1900.

Hemphill, C. Scott. "An aggregate approach to antitrust: Using new data and rulemaking to preserve drug competition". *Columbia Law Review* 109, no. 4 (2009): 629-688.

Hemphill, C. Scott. "Paying for delay: Pharmaceutical patent settlement as a regulatory design problem". *New York University Law Review* 81, no. 5 (2006): 1553-1623.

Hemphill, C. Scott, and Bhaven Sampat. "Drug patents at the Supreme Court". *Science* 339, no. 6126 (2013): 1386-1387.

Hemphill, C. Scott, and Mark A. Lemley. "Earning exclusivity: Generic drug incentives and the Hatch-Waxman Act". *Antitrust Law Journal* 77, no. 3 (2011): 947-989.

Hovenkamp, Erik. "Antitrust law and patent settlement design". *Harvard Journal of Law & Technology* 32, no. 2 (2019): 417-478.

Ibáñez Colomo, Pablo. "Key Takeaways from the Servier saga: Object, (pro and anti-competitive) effects and counterfactual (I)". *Chillin'Competition*. July 1, 2024. https://chillingcompetition.com/2024/07/01/key-takeaways-from-the-servier-saga-object-pro-and-anticompetitive-effects-and-counterfactual-i/.

Ibáñez Colomo, Pablo. "Restrictions by object under Article 101(1) TFEU: From dark art to administrable framework". *Yearbook of European Law* 43 (2024): 224-260.

Ibáñez Colomo, Pablo. *The New EU Competition Law*. Bloomsbury Publishing, 2023.

Ibáñez Colomo, Pablo. "The legal status of pay-for-delay agreements in EU competition law: *Generics (Paroxetine)*". *Common Market Law Review* 57, no. 6 (2020): 1933-1952.

Ibáñez Colomo, Pablo. "Pay-for-Delay and the Structure of Article 101(1) TFEU: Points of law raised in *Lundbeck* and *Paroxetine*". *Journal of European Competition Law & Practice* 10, no. 10 (2019): 591-608.

Jones, Alison. "The Court of Justice's judgment in *Generics (UK) v. Competition and Markets Authority* and the object/effect dichotomy". *Journal of Antitrust Enforcement* 9, no. 3 (2021): 604-614.

Jones, Alison, Brenda Sufrin, and Niamh Dunne. *Jones & Sufrin's EU competition law: Text, cases & materials*. 8th ed. Oxford University Press, 2023.

Kowalik-Bańczyk, Krystyna. "Commentary on C-307/18 *Generics (UK) Ltd v. Competition and Markets Authority*: Competition delayed, competition denied?". *Journal of Antitrust Enforcement* 9, no. 3 (2021): 592-603.

Lemley, Mark A., and Carl Shapiro. "Probabilistic patents". *Journal of Economic Perspectives* 19, no. 2 (2005): 75-98.

Maggiolino, Mariateresa. "Antitrust law and the right to settle: The case of pay-for-delay settlements". *Concorrenza e Mercato* 28, no. 1 (2021): 101-125.

Maier-Rigaud, Frank, Nathan Blalock, and Oliver Gannon. "Reverse payments: An EU and US perspective". In *EU law of competition and trade in the pharmaceutical sector*, edited by Pablo Figueroa and Alejandro Guerrero. Edward Elgar Publishing, 2019.

Makris, Stavros. "Procompetitive effects in EU competition law". In *Antitrust and the bounds of Power – 25 years on*, edited by Oles Andriychuk. Hart Publishing, 2023.

Marco Colino, Sandra, Niamh Dunne, Knut Fournier, Sofia Oliveira Pais, and Derek Ritzmann. "The *Lundbeck* Case and the concept of potential competition". *Concurrences*, no. 2 (2017): 24-50.

Meunier, Valérie, and Jorge Padilla. "Should reverse payment patent settlements be prohibited per se?" *Concurrences* 3 (2016): 1-13.

Mulder, Jotte, and Clara Ceulemans. "The European Court of Justice in Generics UK: New frontiers regarding the legitimacy of patent settlements in competition law?" *European Pharmaceutical Law Review* 4, no. 2 (2020): 123-131.

Mulder, Jotte, and Wolf Sauter. "Anticompetitive pharmaceutical patent settlements: The EU cases on pay-for-delay". In *EU competition law and pharmaceuticals*, edited by Wolf Sauter, Marcel Canoy, and Jotte Mulder. Edward Elgar Publishing, 2022.

Neven, Damien, and Georges Siotis. "The judgment of the Court of Justice in Perindopril (Servier), Case AT.39612: A comment on the KRKA licensing agreement". *Journal of European Competition Law & Practice* 15, no. 8 (2024): 557-561.

O'Shaughnessy, Kristen, Jaclyn Phillips, Daniel Grossbaum, and Lauren Gorab. "A decade of *FTC v. Actavis*: The reverse payment framework is older, but are Courts wiser in applying it?" *Antitrust Law Journal* 86, no. 2 (2024): 473-502.

Patakyová, Mária T. "What does 'by object', in effect, mean? In search for the ultimate determination criterion". *Market and Competition Law Review* 9, no. 2 (2025): 37-68.

Perinetto, Patrick Actis. "*Generics (Paroxetine)*, or the new unbearable lightness of patents in competition law". *European Competition Journal* 17, no. 2 (2021): 437-472.

Shapiro, Carl. "Antitrust limits to patent settlements". *The RAND Journal of Economics* 34, no. 2 (2003): 391-411.

Signoretta, Camilla. "Reverse-payment settlements under EU and US patent law: Convergence in remedies". *GRUR International* 72, no. 1 (2023): 3-21.

Treacy, Pat, Sophie Lawrance, and Olivia Henry. "'Pay-for-delay' agreements: Guidance from the Court of Justice of the European Union in Case C-307/18 *Generics (UK) Limited & Others v. Competition and Markets Authority*". *Journal of Intellectual Property Law & Practice* 15, no. 6 (2020): 460-469.

Zelger, Bernadette. "By object or effect restrictions – Reverse payment settlement agreements in light of *Lundbeck*, *Servier*, and *Generics*". *Journal of European Competition Law & Practice* 12, no. 4 (2021): 273-283.