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AN EVENT STUDY OF PERINDOPRIL (SERVIER) REVERSE PAYMENT PATENT SETTLEMENTS' CASE: IS KRKA TRULY AN EXCEPTION WITHIN THE PAY-FOR-DELAY COMMISSION DECISION?

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Abstract The article aims to fill the gap in the literature on reverse payment patent settlements between patent-holders and generic pharmaceutical firms in EU competition law. Based on the event study of the Perindopril (Servier) case of the European Commission, the research provides a novel assessment of the welfare effects of Commission enforcement and the following judiciary decision on the legality of Commission sanctions. Within the case, the analysis paid particular attention to the generic corporation Krka because Commission fined Krka for the settlement with Servier that did not include the reverse payment, and the Commission decision did not survive the scrutiny of the General Court. The relative economic power of Krka in the perindopril market is also a factor that, together with the enforcement effect assessment, provides a different perspective of the event study's normative implications to the existing research.

Keywords
event study,
welfare effects,
reverse payment patent settlement,
pay-for-delay,
patent litigation,
EU competition law,
antitrust enforcement evaluation

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1 Introduction

The reverse payment patent settlement in the pharmaceutical industry attracts the attention of antitrust enforcers due to its peculiarity, where the holders of patent rights are paying the alleged infringers of those rights to refrain from infringing – making the transaction similar to successful extortion. In light of competition law concerns, this means that the patent-holder firm makes the "reverse" payment to the generic drug company to delay the entrance to the market with its generic drug within the patent settlement where the originator invokes the alleged infringement of the patent drug by the generic entrants. Thus, the market uncertainty is removed, the parties divide the monopoly profits from the originator patent product, and the generics delay entering the market and consequently deprive the consumer of the lower prices of the increased competition. The inconsequential role of patent sectoral regulation in assessing competitiveness and antitrust legality of those settlements is established on both sides of the Atlantic; however, the concerns and objections remain present in competition law and economics literature.

The article examines the EU Servier case[1] of the European Commission (Commission or EC), in which reverse payment patent settlements between the originator Servier and five generic undertakings were condemned and heavily fined, and provides welfare effects of antitrust enforcement with applied event study methodology. All generic undertakings addressed in the Commission decision were listed in stock exchanges; thus, the effects of the competition law enforcement can be assessed regarding its effectiveness. The event study enables the observation of instantaneous stock market valuation of the effects of antitrust enforcement on the (future) profitability of inspected public corporations, where the observed stock prices are compared with the predicted prices by the model if there is no event (Davies and Ormosi, 2012; Delgado, Otero, Pérez-Asenjo, 2016).

The unique role of Krka within the Servier case is that Servier and Krka did not settle with classical reverse payment from Servier to Krka, as it was done in other settlements, and the reverse payment was not arranged. Nevertheless, Krka and Servier were fined for licensing the Servier drug to Krka, which had the exclusive right to market it in its main geographical markets for the payment of royalty fees

[1] Perindopril (Servier) (Case AT. 39612) Commission Decision of 9 July 2014 C(2014)4955 [2014] OJ C 393/7.

that were made in a "normal" direction from generic to the originator, not in a reverse way as in other cases. Krka's decision has been annulled at the appeal before General Court (GC), mostly due to lack of reverse payment (for co-infringers, the Commission decision has been held lawful at the appeal). Thus, the deterrence effect is observed for all the generics to make Krka's welfare change assessment more reliable.

The event studies on reverse payment patent settlements have been conducted for US antitrust environment (Drake and McGuire, 2016; Drake, Starr, McGuire, 2015; Hartman, Drake, McGuire, 2019; McGuire, Drake, Elhauge, Hartman, Starr, 2016), but not for the EU competition law enforcement. Also, the US research has focused on its domestic regulatory patent framework (Hartman *et al.*, 2019; Panattoni, 2011) and the time of patent settlement, not the acts of antitrust enforcers. The article tries to approach the issue from a different angle, namely to assess the effectiveness of competition law enforcement on the patent settlement parties (Hüschelrath and Leheyda, 2010). It also, for the first time, delivers the evaluation of the condemnation of patent settlement that does not include reverse payment but that it was analogous to its allegedly anticompetitive effects sanctioned as it would be reverse payment settlement. The analysis demonstrates certain limitations for applying the event study as a tool for assessing the legality of reverse payment settlements.

The article begins with a review of the literature on reverse payment patent settlements (Section 2), and the Servier case is briefly described (Section 3). The event study method is conducted to evaluate the wealth effects for three antitrust enforcement events (Section 4). The findings of empirical investigations and the discussion of results are provided for Krka and four other generic undertakings (Section 5). Finally, the article ends with concluding remarks (Section 6).

2 Literature on reverse payment patent settlements

EU competition law and US antitrust law almost simultaneously accepted authoritative stance on the legality of reverse payment patent settlements in 2013 when US Supreme Court decided on the merits of the Actavis case[2] on 17 June, and

[2] FTC v. Actavis, Inc., 133 S. Ct. 2223, 2237 (2013).

the Commission fined parties of pay-of-delay settlements in the Lundbeck case[3] on 19 June. The fundamental arguments of those two decisions are pretty analogous, although there are some dissimilarities in argumentation due to the different legal regimes. According to both approaches, the settlement between the pharmaceutical originator (brand owner, patentee) and the generic company that is trying to enter the market with its generic product (bioequivalent of patented drug) is illegal if the parties settled conditions in a way that the (large, unjustified – Actavis) payment from the originator to the generic is made so that the generic is induced due to the accepted payment (Lundbeck) to delay the entrance to the market with its generic drug. The Lundbeck case emphasized the inducement role of payment; thus, the incentive to settle comes from the payment, not the dissolution of the patent dispute, and the infringement is, under this context, restricting the competition by object. While the US Supreme Court nominally established the rule of reason to assess the legality of reverse payment patent settlements, the reasoning of the Actavis decision due to the elimination of the scope of the patent argument (same approach as in the EU) makes those settlements presumably illegal. Pay-for-delay settlements in the pharmaceutical sector have their economic and institutional background, and the competition enforcement law reactions have their intensive attention in academic circles, which will be overviewed in this section.

The legal monopoly of a patent, an intellectual property (IP) right, also provides the originators with an economic monopoly position accompanied by high prices and high-profit margins. Due to the dynamic efficiency considering the protection of innovation risks, this monopoly pricing is not by itself undesirable from the economic welfare perspective (Schmidt, 2019). On the other hand, the allocative efficiency is clearly enhanced by the new entrance of generic competitors who reshape the existing monopoly situation due to patent drug protection and introduce a more competitive oligopoly setting. The empirical research confirms the idea that the generic entry of homogenous products (bioequivalent drugs) significantly and substantially alters the market conditions by lowering drug prices far more than in the case of competition between brand owners among differentiated therapeutic substitutes (Frank and Hartman, 2015). Nevertheless, at the moment when the generics are entering the market, the oligopoly is asymmetrical in terms of sales and absolute profits due to the originator monopoly, and the corresponding generic (at

[3] Lundbeck (Case AT.39226) Commission Decision of 19 June 2013 C(2013)3803 [2013] OJ C 80/13.

least initial) share of the market pie for generics is multiple times lower than for originators (Ruben Jacobo-Rubio, Turner, Williams, 2016). Hence, there is a considerable economic incentive for the patentees to preserve their market advantage due to IP protection so that monopoly profits would not decrease in an emerging oligopoly due to new market players and lower prices of generic drugs.

When originators try to protect their position on the market, they are inclined to prolong the patent protection by filing secondary patents on drug ingredients' formulation and/or process (Kyle, 2016). These secondary patents are usually weaker than product patents in a technical and legal sense, and most disputes are regarding those follow-on patents. The common originator aim is not only in solely obstructing new entrance but also in reducing the perceived market forgone opportunities in patent monopoly protection due to the marketing delay between the time of patent registration and the time of first marketing of the patented drug, which is on average delayed for a couple of years between those stages. However, in the desire to prolong patent protection, originators can create thicket patents for which the patentability is questionable at first sight and are not necessarily filed in good faith but to block the generic entry (Zakka, 2017).

Alongside pharmaceutical companies' economic motives, an institutional context further determines the likelihood of the controversial reverse payment patent settlements. In the US, the Hatchman-Waxman Act provides the generic with the economically founded motive to file the approval for a new drug where the non-infringement of existing patents or their invalidity is being claimed under IV Paragraph certifications (Clancy, Geradin, Lazerow, 2014; Colangelo, 2017; Drake *et al.*, 2015; Geradin, Ginsburg, Safty, 2015). Successful first submission gives the generic company 180 days of marketing exclusivity, and the patent holder is de facto obliged to file an infringement claim where the generic company counterclaim is usually concerning the invalidity of the invoked patent. In the EU, there is no comparable mechanism; the patent protection is still not unified on the EU level with no unitary patent that can be unilaterally invoked regardless of national patent protection, and the marketing authorization regarding drug safety can be obtained on the EU level, but this is, in essence, ineffectual if the national court finds the patent infringement (Colangelo, 2017; Kyle, 2016). The risks of unharmonized, diverging national patent judicial outcomes are present in the EU (Esposito and

Montanaro, 2014) but not in the US, where, on the other hand, the race to get the first generic drug approval guides the potential patent litigation.

The resolution of the patent dispute by reverse payment settlement is the outcome of the above briefly outlined economic and institutional factors, and academics critically examine the competition law adjudication from the antitrust perspective with different normative conclusions. The critics of the EU and US antitrust scrutiny of pay-for-delay settlements emphasized and complemented the reasons that were extensively explained in Justice Roberts's dissenting opinion in the Actavis case (Colangelo, 2017; Gowen, 2016; Krickl and Avery, 2014; Meunier and Padilla, 2016; Schmidt, 2019; Straus, 2016). The first argument is that the scope of the patent should determine the borderlines of the legality of the settlement, so if the parties are settling within the limits of patent protection, where the patent is presumed valid, then the settlement is presumably legal. The (in)validity of the patent is primarily the regulatory concern of IP law and should not be resolved through competition law enforcement (Colangelo, 2017; Krickl and Avery, 2014; Meunier and Padilla, 2016; Schmidt, 2019; Straus, 2016). The Actavis decision breaks up with the preexisting US exclusionary relationship between antitrust and sectorial regulation, while in the EU, the tradition of competition law scrutiny additional to regulation is preserved. Without assessing the possible validity of the patent or holding it legal till the revocation or invalidity, the examination of settlement is bound by the existence of reverse payment. Moreover, the second argument criticizes the presumed influence of large payment as an inducement that cannot be explained as per se anticompetitive only due to its size because the economic consequences for both brand and generic are substantial with accompanied litigation risk where the binary outcome is unknown till the final decision, but the parties have to make a rational probabilistic assessment of patent validity and aligning infringement in time of settlement (Meunier and Padilla, 2016; Straus, 2016). Hence the settlement is instigated by reasonable litigation risks (also its costs and risk aversion), and the antitrust enforcement interferes with another legal institution of settlement (Gowen, 2016). Higher payment does not inevitably signal weak patents but is a consequence of mitigating risks (Krickl and Avery, 2014). The third argument is a nexus of previous ones because without the examination of patent validity and justifiability of litigations risks resolution, the exact height of the lawful level of reverse payment cannot be determined, and the nominal rule of reason in US antitrust and by object restriction in EU competition law with nominally allowed procompetitive

counterclaim remains presumably illegal. On the other hand, traditional legal scholarship views reverse payments as prima facie illegal due to their peculiarity in transaction direction (Zakka, 2017).

Several authors have already analyzed the effects of patent litigation on welfare with the event study methodology for the US antitrust environment. Panattoni (2011) analyzes the impact of Paragraph IV patent infringement decisions on originator stock prices and finds that they disproportionately involve drugs with the highest revenues, significant periods of patent protection, and a substantial portion of all brand drugs facing generic entry. The patent decisions have a considerable influence on brand firm values. Another event study also examines Paragraph IV patent litigations and finds that brand firms in those disputes value deterring entry by far more than generic firms value the right to enter – the deterrence value of brands at $4.6 billion on average compared to generic entrants' value for the right to enter at $236.8 million (R. Jacobo-Rubio, Turner, Williams, 2020). The authors estimate the average bargaining surplus to be just under $2 billion per case, and they offer some evidence of pay-for-delay settlement decreasing the allocative efficiency.

Drake *et al.* (2015) divided their sample of patent settlements into those with and without reverse payment. For settlements with the indication of a reverse payment, brand stock prices increased on average 6% at the announcement, and settlements without reverse payment had no significant effect on the market value of originators. McGuire *et al.* (2016) propose applying an event study to assess the anticompetitiveness of reverse payment patent settlements. The advantages of event study are objective traders' assessment reliability, a rebuttal of risk aversion claims due to rational investors' decisions, and assessing patent holder profits rather than only transferred payment value.

For the post-Actavis reverse payment settlement between AstraZeneca (originator) and Ranbaxy (generic), Drake and McGuire (2016) find the stock market capitalization increase of AstraZeneca and Ranbaxy of $2.8 billion and $0.3 billion, respectively. They conclude that the market increase is evidence of anticompetitive effects. Similarly, Hartman *et al.* (2019) investigated the Cephalon settlements with generic challengers and saw its stock price value increase of $1 billion as a sign of delayed generic entry due to the settlement beyond the market expectation.

3 Perindopril (Servier) case overview

Besides the Servier case (2014), Commission has fined brand and generic companies for pay-for-delay arrangements in three additional cases: Lundbeck (2013), Fentanyl[4] (2013), and Cephalon[5] (2020). While Lundbeck and Cephalon represent classical reverse payment patent settlements, the Fentanyl case sanctioned the co-promotion agreement for the fentanyl between the Dutch subsidiaries of Johnson & Johnson (originator) and Novartis (generic) on the national market, where there were agreed monthly payments from the brand to the generic firm because the generic firm accepted to delay the launch of its own product, but the patent itself was not disputed.

The Servier case has several characteristics that significantly distinguish the decision from other Commission pay-for-delay decisions, and within the case, the role of Krka, a Slovenian generic company, is specific. First, the case entails the largest footprint regarding economic and institutional inputs and consequences. Hence, the total case imposed fine is the largest (EUR 428 million to the second largest Lundbeck fine of EUR 146 million), the number of decision recitals is the highest[6] (3,187 to Lundbeck's 1,397), the number of firms – single legal entities addressed by the decision (13 to Lundbeck's 12) and the number of undertakings – a group of firms jointly and severally liable for the same amount of fine (6 to Lundbeck's 5). It is the case for which all sanctioned firms filed the action against Commission decision before General Court. Second, in the Servier case, the Commission imposed fines not only for infringement under Article 101 for concluding the reverse payment settlements, but it found for the first time that the originator (Servier), with its too-aggressive patenting strategy by invoking blocking patents, reverse payments settlements and acquisitions of rivals' IP rights, also abuse its dominant position on brand drug market under Article 102. Also, for the first time, the Commission reasoned that the pay-for-delay settlements could be assessed as the by-effect restriction of competition under Article 101, not only by object. However, both legal novelties failed the scrutiny before the General Court (regarding Article 102, the decision was annulled, and the by-effect analysis was seen as irrelevant – ineffective

[4] Fentanyl (Case AT.39685) Commission Decision of 10 December 2013, C(2013) 8870 [2015] OJ C 142/15.
[5] Cephalon (Case AT.39686) Commission Decision of 26 November 2020, C(2020) 8153) [2021] OJ C 32/07.
[6] Servier case is also the lengthiest case by number of recitals in the period 1990-2015 among all Commission infringement and also merger prohibition decision.

due to existing by object founded infringement). Third, the case includes the facts about the time-changing patent decisions on the validity of an essential secondary patent by national courts and the European Patent Office (EPO), but this was not considered as the mitigating circumstance due to patent litigation risk by the Commission in light of the fact of reverse payment.

Finally, the Servier case embraces the unique role of Krka, which did not receive the reverse payment but got the license for the brand drug in exchange for a royalty fee. Although the Commission considered Krka's settlement with Servier as a reverse "payment" settlement due to supposedly illegal economic inducement to share the markets, the GC annulled the Commission's decision in this part. However, the other "normal" reverse payment settlements were judicially reviewed as illegal. Hence, the pay-for-delay should, as a rule, include reverse payment, not only speculative economic transfer due to an allegedly too-low price level that is hard to establish if the royalties are paid from the generic company to the originator, so the value of "fair" royalties (higher for Krka) should be determined for normative counterfactual standard (Commission did not adduce evidence and establish facts in the matter).

Perindopril is used primarily for treating hypertension and heart failure, and it was originally developed by Servier and marketed under the brand names Coversyl and Prestarium. The primary patent was filed in 1981 and expired in 2001, but due to the supplementary protection certificates, the patent protection was prolonged till 2003/2005, depending on the Member States. Perindopril was Servier's blockbuster, the most successful product to date, with global sales exceeding USD 1 billion (EUR 800 million) in 2006 and 2007, with EBIT of EUR 250 million in 2007. Between 2003 and 2008, Servier tried to defend its monopoly position by challenging the generic companies, sending them warning letters, invoking as many as 35 patents, including barrage patents (17 of them according to the Servier internal documents), (three) patents with no inventive value, and engaging in 25 court cases regarding the perindopril patent protection. The crucial secondary patent was the '947 patent that was not assessed internally by Servier as invalid, and it was a part of the national litigations and opposition procedure before the EPO. Eventually, it was also the pivotal part of reverse payment settlements that were found to be infringing Article 101 by the Servier and generic contestants. The Servier also aimed to foreclose the

perindopril market by buying out the patents and stocks from competing producers of active pharmaceutical ingredients (API).

In the Servier case, Commission sanctioned six undertakings for reverse payment settlements: the originator Servier contains four firms (a parent company and three subsidiaries) and five generic undertakings – Unichem (then Niche), Mylan (then Matrix), Teva, Lupin, and Krka (Table 1). Except for Krka and Lupin, where only the mother corporation was liable, parents and subsidiaries were jointly and separately liable for the same amount of fines. Servier was fined EUR 41 million for the infringement under Article 102; thus, the total fines of EUR 289 million for Servier were threefold the fines imposed on generics for the infringements under Article 101. The fines were reduced at the appeal before GC[7] for Krka, for which the whole fines were annulled and partially for Servier due to the annulment of the decision on Article 102 infringement, Krka settlement, and partially the height of the fine for Mylan settlement.

Table 1: Servier case descriptive statistics for Commission and General Court decisions

	Country of origin	Fine per undertaking (EUR)	N° of firms within the undertaking	Fine reduced by the GC
Servier	France	330,997,200	4	102,668,310
Krka	Slovenia	10,000,000	1	10,000,000
Teva	Israel	15,569,395	3	0
Mylan	USA	17,161,140	2	0
Lupin	India	40,000,000	1	0
Unichem	India	13,968,773	2	0

For generics, imposed fines roughly equal to the received payments from the Servier, which the Commission assessed as net value transfers because the Servier mostly did not get anything economically valuable in return. Mylan's, Lupin's, and Teva's fines are precisely equal to the received payment, while Unichem's is reduced to certain costs that could partially justify the received payment from Unichem's standpoint,

[7] General Court, judgments of 12 December 2018, Case T-705/14, Unichem Laboratories Ltd v European Commission, ECLI:EU:T:2018:915; Case T-701/14, Niche Generics Ltd v European Commission ECLI:EU:T:2018:921; , Case T-691/14, Servier SAS and Others v European Commission, ECLI:EU:T:2018:922; Case T-684/14, Krka Tovarna Zdravil d.d. v European Commission, ECLI:EU:T:2018:918; Case T-682/14, Mylan Laboratories Ltd and Mylan, Inc. v European Commission, ECLI:EU:T:2018:907; Case T-680/14, Lupin Ltd v European Commission, ECLI:EU:T:2018:908; Case T-679/14, Teva UK Ltd and Others v European Commission, ECLI:EU:T:2018:919; Case T-677/14, Biogaran v European Commission, ECLI:EU:T:2018:910.

although Commission claims at the same time that the payment is considered as the net value. Krka's fines equal the profits that Krka earned in the infringement period on Central and East European (CEE) markets due to the settlement agreement. For the Servier, the fines under Article 101 roughly correspond to one year EBIT in the infringement period.

The settlements consisted of the obligation not to challenge the Servier patents (most importantly patent '947) and not to enter the perindopril market for a specified number of years. Except for Teva, the settlements covered the entire EU. The settlements with Unichem and Mylan were reached on the same date (8 February 2005), and they included identical arrangements because Unichem and Mylan had a cooperation contract for perindopril. They both agreed to non-compete and non-challenge clauses in exchange for GBP 11.8 million for each one. Teva concluded a settlement with Servier on 13 June 2006 for GBP 5 million to merely enter the agreement and agreed to purchase perindopril exclusively from Servier for distribution in the UK, not to launch its own product (one actual possibility was also to cooperate with Krka). Due to a contractual clause, it got GBP 5.5 million in compensation as liquidating damages for the non-supply of perindopril from Servier in 2006 and 2007. Lupin agreed to a settlement with Servier on 30 January 2007 for the payment of EUR 40 million and the possibility of a distributional contract in the future. Lupin sold process patents to Servier and got back the non-transferable license in the license agreement.

Krka's settlement from 27 October 2006 was exceptional to the above briefly described settlements. Mainly, there was no reverse payment from Servier within the settlement, although, in a later Assignment and License Agreement (ALA) of 5 January 2007, Servier acquired two process patents from Krka for a total payment of EUR 30 million. Krka settled to usual non-compete and non-challenge clauses, however with the license agreement, Krka gets the exclusive irrevocable license on the '947 patent for six CEE Member States where Krka has a most economic interest in exchange for a 3% royalty fee on the Krka net sales of perindopril. However, Krka was excluded from the Western market, mainly the UK, and a de facto duopoly situation emerged regarding the EU market with the geographical division, where Servier refrained from entering the CEE markets where Krka was present. According to the Commission assessment, ALA payment for Krka's process patents of EUR 30 million that were licensed and transferred back to Krka could entail at

most EUR 6 million benefits for Servier. However, the Commission was flawed and inconsistent in the reasoning, and it did not definitely relate the ALA to the settlement agreement, so the patent payments were not considered to be classical reverse payments by themselves.

Krka's settlement most descriptively demonstrates the risks of patent litigations, the diverse national litigations outcomes, and the economic motives behind the eventual patent settlement. Firstly, EPO Opposition Division upheld the '947 patent on 27 July 2006, which was a negative (shocking) surprise for Krka, according to internal documents. Secondly, Krka intended to enter the UK market, and it was faced with the Servier patent infringement action regarding the '947 patent. The UK court granted Servier a preliminary injunction and rejected Krka's motion for summary judgment on the patent's invalidity on 4 October 2006 (though in the same month, the Hungarian court rejected Servier's application for interim relief). Thus, at the time of Krka's settlement, the prospects of the patent litigation were not seemingly meritorious to Krka. The UK '947 patent was eventually found invalid on 6 July 2007, and the EPO revoked the '947 patent on 6 May 2009. The revocations of Servier secondary patent caused the competition law infringement to end in respective markets because the settlements included the provisions which bound the settlement validity to the validity of the disputed patent. The economics of Krka's settlements are evident in the already strong Krka's presence in the CEE market, while the risks and the potential gains in the UK market were substantially higher and lower, respectively. Furthermore, the corresponding sales of Servier in the UK (Western markets) were substantial on the other hand.

GC judgments confirm the condemnation of settlements agreements as by-object restriction of competition under Article 101, except for Krka's settlement, where no reverse payment was made. The lack of direct reverse payment, licensing of IP rights, the royalty fee that was not proven to be unreasonably low, and the possibility of Servier entering the licensed CEE market did not allow the conclusion of the infringement per se. All GC's decisions are now under appeal before the second instance Court of Justice (ECJ).

4 Event study method and data sampling

The event study method assesses the impact of new information on the stock value of observed public corporations (Fama, Fisher, Jensen, Roll, 1969), and it is based on the semi-strong market efficiency hypothesis according to which all public information is reflected in stock market prices (Fama, 1970). In the following empirical investigation, the event study demonstrates the welfare effects of the Commission enforcement, at least from the outlook of sanctioned undertakings. Event studies are an example of the practical application of econometrics in policy analysis for assessing the impact of events on investor wealth; they enable measuring the wealth effect of litigation, statutory change, or regulatory change (Bhagat and Romano, 2002a, 2002b).

In order to reliably conduct an event study, several methodological steps should be fulfilled within the traditional method (Klick and Sitkoff, 2008; MacKinlay, 1997): the event dates should be defined and dates on which the information on the events become public; the actual returns on event dates have to be measured; the expected returns based on the historical stock prices and their relationship with market prices should be calculated for the estimation of event affected returns; the abnormal returns should be computed by subtracting expected returns from actual returns; finally the statistical significance of abnormal returns should be assessed.

There are three important events regarding the antitrust enforcement in the Servier case:

- Surprise inspections on the undertaking premises on 24 November 2008 (dawn raid),
- Commission fining decision on 9 July 2013 (EC decision),
- and GC judgments concerning the undertakings' action against EC decisions on 12 December 2018 (GC decision).

The Factiva database was checked for the moment when the press first covered those events and whether any confounding events could disturb the effects of antitrust events. For dawn raids, the first news articles were published on 26 November, two days after the official date of investigations; therefore, this first news

date was used as the dawn raid cut-off event date for stock price analysis. For EC and GC decisions, the adoption of these decisions immediately becomes public news, so the official and first news days perfectly overlap.

Only Servier is not a public corporation, but all generic corporations are listed on stock exchanges, and for them, the stock prices and accompanying local market indices data were gathered from the Thompson Reuters Datastream. Then the traditional market model with stock prices for undertakings and their historical relationship with the local market index has been applied to calculate the abnormal returns and expected returns according to the traditional market model (MacKinlay, 1997). For estimation, 250 trading days have been included in the estimation period. Thus, the trading days from the 270th day before the event to the 21st day before the event were included in the estimation model, and 20 trading days before the event were excluded as a buffer for possible leakage pre-event influences. By subtracting the estimated expected returns from actual returns, the abnormal returns were obtained in Stata (Kaspereit, 2015).

The statistical significance of abnormal returns on event dates was assessed by the one-sided Patell's test, widely used in finance research, which standardizes abnormal returns by their standard deviation (Patell, 1976). The anticipated hypothesis was that the undertaking stock prices would react accordingly to the positiveness of the enforcement activity. Thus, the market reaction should be negative for dawn raids because the dawn raid signals that the undertaking was highly likely caught in an illegal (profitable) activity that should be completed due to the initiated investigation. The market should react negatively to EC decisions because they imply direct negative monetary consequences via imposed fines and indicate lower chances of continuing or even repeating (profitable) illegal conduct. Regarding GC decisions, the market should respond negatively to the rejection of undertakings appeals and positively to the success of the action claims.

The abnormal returns are obtained not only for the event dates but also on a cumulative basis before and after the event within different event windows of multiple days to account for possible pre-event leakages of information and slower adoption of new information into the post-event stock prices. However, the event windows are kept relatively narrow not to lose statistical power (Bhagat and Romano, 2002a; MacKinlay, 1997).

5 Results of empirical investigation and discussion

All generic undertakings are publicly listed corporations; hence the comparison of antitrust enforcement with its effects on stock prices can be shown for them, and Krka's exceptional part within the sanctioned reverse payment settlements is tested. Although the small sample of undertakings does not allow for the multivariate analysis, the descriptive paralleling of infringers can provide qualitative insights that can at least partially explain Krka's stock price reaction to antitrust events, and it can also offer rough counterfactual for Krka's performance with the evaluation of market reaction to co-infringers from the same case. The institutional and economic circumstances can jointly determine the extent of market reaction (Table 2). The financial figures are obtained from the Datastream database, and the imposed fines by the Commission are normalized by two measures: the ratio of fines to market capitalization and the ratio of fines to sales. Sales and total assets are also shown to account for the undertaking size; operating profit margin and return on equity are profitability measures, and the total assets turnover ratio and current ratio demonstrate the undertaking's overall efficiency and liquidity. Comparing the measures in couples ensures the robustness of the following conclusions regarding the impact of fines and the financial strength of generic infringers that can have a certain impact on stock price reactions.

Table 2: Fine normalization to market capitalization and sales and financial figures of infringers at the Commission decision year

	KRKA	TEVA	MYLAN	LUPIN	UNICHEM
Ratio of fine to market cap value	0.00441	0.00042	0.00125	0.00700	0.05761
Ratio of fine to net sales	0.00839	0.00103	0.00306	0.03028	0.10529
Net sales (million €)	1,191	15,126	5,604	1,321	132
Total assets (million €)	1,768	37,620	11,473	1,186	133
Operating profit margin (%)	20.59	22.06	20.95	25.21	11.66
ROE (%)	12.40	12.96	29.99	30.26	20.78
Total assets turnover	0.67	0.40	0.49	1.11	0.99
Current ratio	2.47	1.17	1.28	2.32	2.52

According to normalized fines' measures, Krka is in the middle, on the third spot, concerning fines height and their rough financial impact on the penalized generic undertakings. Most heavily fined are Unichem and Lupin, while Teva and Mylan are the least. Teva and Mylan are also the biggest corporations; on the other hand, Unichem is the smallest one, and in the middle, Krka and Lupin are relatively close

regarding size. Lupin is the most profitable, followed by Mylan, and Unichem is the least profitable; however, Krka and Teva have similar profitability ratios as Unichem. Lupin and Unichem seem to be the most efficient ones according to total assets turnover ratios and current ratios. Based on the above findings, the overall impression is that Krka is in the average position regarding expected sanctions' impact and financial strength; Unichem is the most exposed to fines and with the least economic power, while Teva is the most robust sanctioned generic competitor.

Krka market investors reacted as anticipated to the three antitrust events if we examine the abnormal and cumulative abnormal returns with the event window of 40 days before and after the events (Figure 1). The most dramatic one-day price fall was on the first news date on the dawn raid when the price dropped by –4.76% (Table 3). However, the price trend within the broadest event window (–20 20) is without visible direction for a dawn raid but more visibly negative for EC decision and positive for GC judgment.

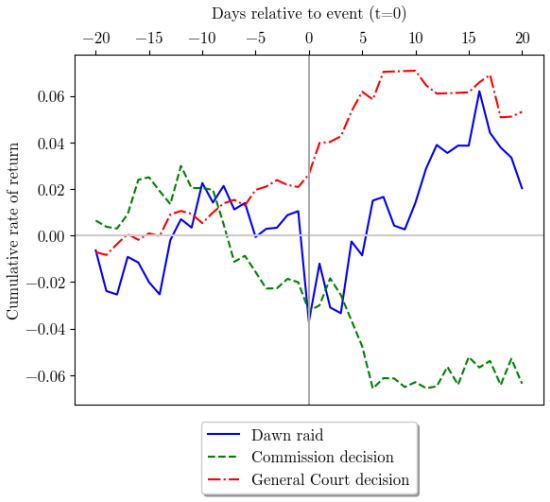

Figure 1: Krka's cumulative abnormal return trend around antitrust events from the 20th trading day before the events until the 20th trading day after the events
Source: own.

The dawn raid caused a statistically significant price reduction of Krka's stock not only on the event day but also during the immediate event windows (0 1; –1 1, 0 3; 0 5; –5 5), which demonstrates the devastating impact perceived by investors due to

beginning of Commission investigations regarding patent settlements (Table 3). The dawn raid does not cause significant price reactions for broader event windows. The market response to the EC decision is similarly negative as for dawn raid; however, it is less significant and substantial in immediate event windows and more significant and economically larger in broader event windows – up to –5.04% value decrease for event windows (–10 1). In the largest post-event window (–1 20), the returns decrease by –4.50%, which shows the substantial informationally echoing effect of the Commission decision. The GC decision that annulled the EC decision in part that addressed Krka's settlement caused the price to rise accordingly to expectations. Only the abnormal return of 0.54% on the event date itself is insignificant, but all other returns are significantly positive – up to a 4.91% price increase in the post-event window (–1 10).

Table 3: Returns for Krka at dawn raid, Commission decision, and General Court judgment

t	Dawn raid	EC decision	GC Decision
0 – event	–4.76%***	–1.24%*	0.54%
(0 1)	–2.25%***	–0.99%*	1.89%**
(–1 1)	–2.09%**	–1.14%	1.81%*
(0 3)	–4.39%***	–0.55%	2.18%***
(0 5)	–1.90%***	–2.75%**	4.09%***
(–5 5)	–2.25%**	–3.89%***	4.88%***
(–10 1)	–1.55%	–5.04%***	3.05%*
(–1 10)	0.53%	–4.44%***	4.91%***
(–20 1)	–1.21%	–3.00%	3.98%
(–1 20)	1.15%	–4.50%***	3.15%***

*Cumulative abnormal returns for event windows and abnormal returns for the event day (0) are reported; one-sided test for significance levels: * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.*

Although Krka's market reactions to three enforcement events match the initial research expectations, further examination is needed to validly connect the returns' changes to the possible causal impacts of events. The longitudinal time dimension is observed from dawn raid till the GC decisions for all generics in regard to market capitalization and stock price yearly momentum (Table 4). The undertaking sizes by market capitalizations have the same order as for total assets and sales figures, but more interestingly, they all move in the same direction – rising from dawn raid to EC decision and then decreasing till GC decisions. This shows a clear correlation pattern due to the joint economic conditions for generic pharmaceuticals. Also, the yearly stock price momentum includes some resemblance among undertakings; thus, the dawn raid is associated with the lowest momentum and the EC decision with the

highest. Teva and Mylan experienced more volatile changes yearly, while Unichem was the most volatile, and Krka and Lupin had similar ups and downs.

Table 4: Size (market capitalization) and yearly stock price change (momentum) of infringers at three events

	Krka	Teva	Mylan	Lupin	Unichem
Dawn raid					
Market cap (million €)	1,892	26,268	2,076	705	92
Momentum (yearly)	0.466	1.084	0.747	0.939	0.791
EC decision					
Market cap (million €)	2,268	37,432	13,716	5,711	242
Momentum (yearly)	1.279	1.299	1.508	1.141	1.151
GC decision					
Market cap (million €)	1,784	17,125	13,796	4,543	166
Momentum (yearly)	1.007	1.251	0.796	0.901	0.602

After establishing the institutional and financial context, Krka's market performance can be evaluated to the overall market reactions of all Servier case co-infringers. If we parallel the Krka stock price trend to the average return changes of all generics in the event window (–20 20), we can see idiosyncratic Krka's performance – Figure 2. Although it is not so visible in the entire event window for the dawn raid, the immediate Krka drop is visibly deeper than the average generic reaction at the event date. Furthermore, the distinction is more obvious at the EC decision where Krka has a clear negative trend while the general Servier case trend is even slightly positive, although in the immediate event window (–5 5) is negative. Also, the GC decision is associated with a strong positive trend for Krka; conversely, the trend is negative for the whole Servier case.

The more detailed analysis shows that the statistical significance of estimated returns confirms the potential causal differences between Krka and other fined undertakings (Table 5). At dawn raid, Unichem experiences more negative stock price reactions than Krka, but Unichem's stock price performance is essentially an outlier within the sample because it overreacts for all three events, which is most probably the consequence of its small size and greater risk exposure. Compared with the other three generics, Krka's negative returns are greater on event day and within the narrowest immediate event window (0 1). Also, in a symmetrical immediate event window (–5 5), the reaction is significantly negative, while others, except for Unichem, do not suffer significant market losses.

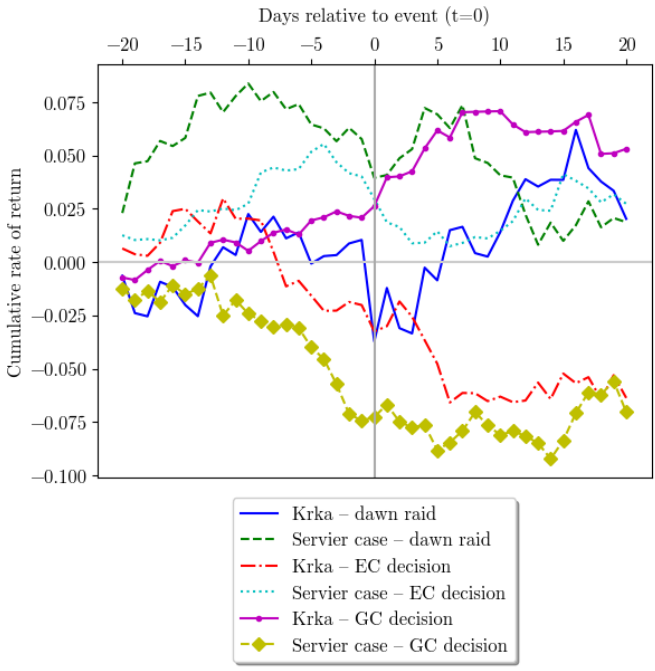

Figure 2: Comparison of Krka's and Servier's case level cumulative abnormal return trends around antitrust events from the 20th trading day before the events until the 20th trading day after the events

Source: own.

At the EC decision event, Krka had the most damaging and also significant market reactions disregarding Unichem's outlier changes that are founded on the extremely high fine in regards to its size. Teva, Mylan, and Lupin do not significantly lose their market value on the event and in immediate windows (0 1; –1 1;–5 5), and in broader event windows, Lupin and Teva suffer significant market drops only in the pre-event window (–10 1). It seems the imposed fines were relatively ineffective for their stock price evaluations, whereas, at the same time, Krka's investors realized significant and substantial losses. Krka market decreases are significant except for the event window (–1 1) and negative for all observed periods.

GC judgments caused the market to react according to expectations, although specific stock price movements were impacted by confounding events that have to be clarified. For Krka, the positive trend was influenced by the interim report with

increasing profits in the period before the event. Mlyan's and Teva's negative performance before the event followed the announcement of other price-fixing investigations. Also, the new chief financial officer's resignation impacted Lupin's market performance before the event. Consequently, the significant negative performance of those three undertakings included the distrusting informational influences from other co-events, and Krka's positive trend had its roots in the positive signals of the interim report.

Table 5: Returns at dawn raid, Commission decision, and General Court judgment for infringers and on case level

	0	(0 1)	(–1 1)	(–5 5)	(–10 1)	(–1 10)
Dawn raid						
Krka	–4.76%***	–2.25%***	–2.09%**	–2.25%**	–1.55%	0.53%
Teva	0.43%	–1.02%	–2.40%*	–0.28%	4.47%***	–5.76%**
Mylan	–0.65%	–0.51%	1.80%	10.38%	–4.00%**	7.82%**
Lupin	2.98%	2.65%	3.39%	6.27%	–8.17%***	–3.16%
Unichem	–7.10%***	–7.30%***	–11.77%***	–16.53%***	–9.26%	–10.56%***
Servier case	–1.82%***	–1.69%**	–2.21%*	–0.48%	–3.70%	–2.23%
EC decision						
Krka	–1.24%*	–0.99%*	–1.14%	–3.89%***	–5.04%***	–4.44%***
Teva	–0.38%	–0.46%	–0.70%	0.25%	4.34%***	–1.35%
Mylan	–1.05%	0.56%	0.77%	–1.86%	–3.64%	1.66%
Lupin	–1.67%	–1.57%	–1.75%	2.26%*	3.15%**	2.13%
Unichem	–0.93%	–8.27%***	–8.70%***	–11.34%**	–1.63%	–11.51%***
Servier case	–1.05%**	–2.15%**	–2.30%**	–2.92%	–0.56%	–2.70%***
GC decision						
Krka	0.54%	1.89%***	1.81%*	4.88%***	3.05%*	4.91%***
Teva	2.31%	3.20%***	2.74%	–10.59%***	–6.26%**	–7.18%
Mylan	2.17%	1.03%	–1.20%	–9.27%***	–9.28%**	–1.45%
Lupin	–3.64%***	–1.19%***	0.42%	–7.25%***	–1.74%	–1.19%
Unichem	–0.50%	–1.15%	–1.58%	–6.42%*	–10.28%***	–0.03%
Servier case	0.17%	0.76%	0.44%	–5.73%***	–4.90%**	–0.99%

*Cumulative abnormal returns for event windows and abnormal returns for the event day (0) are reported; one-sided test for significance levels: * $p < 0.10$, ** $p < 0.05$, *** $p < 0.01$.*

Nevertheless, the post-event window (–1 10) includes insignificant estimates of returns for those three generics, while Krka has a highly significant and also substantial stock price increase of 4.91%. Furthermore, Krka's market performance immediately around the event was significantly positive, while others experienced insignificant both negative and positive stock price reactions. The likelihood of a positive appeal outcome was low, so the unsuccessful litigation did not surprise the

market for the rest of the generics. On the contrary, Krka's meritorious action claim represents a pleasant turnaround for the investors.

Krka lost EUR 90 million market value on the dawn raid event date, EUR 28 million on the Commission decision date, and gained EUR 9 million with the General Court ruling. For the narrowest immediate event window (0 1), the market losses were EUR 42 million for the dawn raid, 22 million for the Commission decision, and a market gain of 33 million for the General Court judgment. These market value changes do not perfectly match the imposed fine of EUR 10 million; they are mostly overreacting if we consider the fines as the standard value to be compared with (two to almost threefold at the EC decision and four times to nine times at dawn raid). In comparison with other generic co-infringers, Teva and Mylan suffered larger (mostly statistically insignificant) market losses in absolute market figures, which is a consequence of their considerably bigger size. Lupin, which is most similar to Krka, did not lose value at the dawn raid, but at EC decision, the loss was on the event date EUR 95 million and EUR 89 million in the immediate event window (0 1). This is approximately slightly more than twofold of imposed fines.

The Krka stock market performance confirms its exceptional role in the Servier case. The market reacted more substantially at the dawn raid because the Krka infringement was still ongoing at the time of inspection, while for most others, the infringements ended before. Also, the Krka stakes were high because Krka was actively present in CEE markets and had ongoing profitable operations, while others mainly refrained from entering the market due to the classical pay-for-delay arrangements. Consequently, Krka's punishment had more severe effects on stock prices than other generics, for which only the Commission recouping illegal profits in the height of accepted reverse payment has direct effects. The effective duopoly between the Servier and Krka had more market-evaluated worth than only settlement payment exchange and subsequent mirrored fines for those payments. The judicial annulment of the Commission decision caused the stock prices of Krka to reverse, roughly resembling the monetary gains for getting back the paid fines.

However, the event study analysis cannot determine whether the Commission's decision on the legality of the reverse payment settlements was right or not. Especially the absolute market value effects that were claimed in the literature to be the standard for the assessment of the pro- or anticompetitiveness have to be viewed

prudently as the mere consequence of size and accompanying larger profits that by themselves, according to Chicagoan tradition, cannot validate the premise of (il)legality. Whether the revenues and the following profits are legal cannot be evaluated on the market reaction itself, which only assesses the present net value of the enforcer's actions. The deterrent effects proxied by the stock price reaction demonstrate that Krka investors were most affected by the Commission's actions, although Krka did not receive the classical reverse payment. If we considered the market value reaction without any reservations, then Krka should be the most severe infringer, but not the recipients of the reverse payments for which the Commission and General Court unanimously establish the illegality of patent settlement. This indicates the weakness of establishing the unlawfulness of reverse payment, seemingly found to be anticompetitive, due to the "substantial" size of the payment effects (and its direction), as it has already been criticized in Roberts's dissenting opinion and competition law and economics literature. Furthermore, the Krka case demonstrates the flaws in condemning the settling parties due to payment and its size impacts on the wealth of investors (Drake and McGuire, 2016), where the legality of the patent is disregarded, so we are left with no solid ground for establishing the legality principle.

6 Conclusion

Krka is an exemption from the reverse payment patent settlement antitrust unlawfulness due to the tautological answer of the nonexistence of reverse payment within the patent settlement. Furthermore, the welfare effects of Commission activities were statistically significant and economically substantial – negative at dawn raid and fining decision and positive due to successful Krka's appeal against the Commission decision. The reverse payment remains the legalistic indicator of the anticompetitiveness of patent settlements. The event study demonstrates that considering the size of stock price movements as an indicator of illegality can be highly risky.

In retrospect, Krka was wrongly raided and sanctioned by the Commission, and the market reacted negatively. However, the reaction is hardly attributed to the presumed anticompetitive effects of the Krka settlement nor – probably even less likely – to the "right" market assessment of the initial wrong condemnation by the Commission that was a case of false positive according to the subsequent General

Court judgment. Krka's stakes were high due to the undisputed market advantage in CEE markets and the development of its generic version of perindopril. Thus, the negation stakes were essentially different from the other generic undertakings that had not yet entered the market and were behind with their own development of generic versions. Hence, the economic impacts of existing market strengths and disadvantages were undoubtedly reflected in Krka and generic competitors' market reactions. However, without the patent risk evaluation, it is hard to conclude how malicious the parties were at the settlements and how they only used the settlement to split the monopoly profits from the patented drug to circumvent the lower competitive profits after the (now delayed) market entry of generic drugs.

The limitation of this research is the fact that the Servier is not a public corporation, so the complete welfare effects could not be assessed. However, the unique example of Krka shows the limitation of event study as a crude normative standard tool in single or small sample size research, and prudence has to be carried out to claim the legality or illegality of reverse payment settlement based on event study analysis. In further research, more efforts could be made to enlarge the sample for multivariate analysis to account for coexisting influences and compare originator and generic market reactions.

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