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Articles

Event Study Analysis in Cases with Multiple Brand-Generic Reverse-Payment Settlements

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Event st competitive impa stry. Evide ard a brand manufac upon generic ons. In practice and settleme such cases, with a st e drug Provigil. tial generic competitors over a two-month period beginning in December 2005. Event study

methods can readily be applied to such a case. Cephalon's total increase in stock value across four narrow windows around each settlement totaled over $1.0 billion, indicating the agreements delayed generic entry beyond the market's expectation.

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Notes

1 Saving e-patent expiry b e as savings for all ge

2 Strategies include secondary patenting, reverse payment settlements, restrictions on drug distribution, and citizen petitions. For a summary, see Vokinger et al. (2017).

3 Edlin et al. (2015) argue that the main form of evidence used in reverse-payment antitrust cases, the presence of an otherwise 'unjustified' payment from the brand to the generic, also applies in the case of multiple generics.

4 Bioequivalence means that the active ingredient in the generic is the same as in the branded version and that it is released and absorbed into the body at the same rate and to the same extent as in the branded versions.

5 There were at least 140 brand-generic settlements during each of the fiscal years 2011–2015. See FTC, 'Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2015,' November 2017. https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-9.

6 See also Lemley and Shapiro (2005: 91): 'There is no reason to assume that bargaining between the monopolist and the potential entrant to maximize their joint profits will lead to a socially optimal settlement. … the monopolist and the entrant will have an incentive to negotiate in a way that leads to the monopoly level of output and the mon monopoly profits: t t.'"

7 For ex y exclusivi Paragraph IV filing rn a first-filer the

8 The M acted in 200 applicant to forfeit it rfeiture provisio

9 Elhaug es. Writing in this cont litigation exclusio elfare is called ex occurred.'

10 McGuire's testimony in the Solodyn litigation trial included presentation of event study results. In re: Solodyn (Minocycline Hydrochloride) Antitrust Litigation, Transcript of Jury Trial Day 9 before the Honorable Denise J. Casper, United States District Court District of Massachusetts. Hartman's testimony in Vista HealthPlan Inc., et. al., Plaintiffs v. Cephalon, Inc., et al., Defendants, in the United States District Court for the Eastern District of Pennsylvania, CA No. 06-CV-01833 (in. re. the settlements analyzed here) included the presentation of event study results. Other courts have allowed other experts, including Scott Hemphill and Einer Elhauge, to testify about event study methods in reverse payment cases. See Cipro Cases I and II, in the Superior Court of the State of California in and for the County of San Diego, Reporter's Transcript of Proceedings 27 October 2016 and United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund, et al., Plaintiffs., v. Teikoku Pharma USA, et al., Defendants, Order on Pending Motions, 3 November 2017.

11 The FTC vs. Cephalon Complaint (2008) indicates that before the reverse payment settlements, 'current Street expectations are for generic competition in the mid-2006 time frame.'

12 Financial analysts interpreted the Provigil settlements described in this paper in this way. For example, see Davis, Shaw, and Kim (2005): 'Although it only takes one generic to erode Provigil, we take today's news as a very optimistic sign that the probability that gen… han 100%. What we… ned generic entry at … to the stock.'

13 Othe… e for the generic … ess of a threat … legal decis… ursue litigation… generics in our anal…

14 See E… nely valuable … avoid antitrust … rd to complex … ayments by

subsidiary consideration.' See also Hemphill (2009), particularly pp. 666–668, where Hemphill points out side deals between brand and generic firms are infrequent outside of patent settlements.

15 On 25 January 2006, Cephalon's use of its drug Sparlon for ADHD was delayed by the FDA, which likely explains the sharp movements in trading volume and share price.

16 We calculate the expected return, $E[R^t]$, as $\alpha\hat{} + \beta\hat{}MR^t$ where $\alpha\hat{}$ and $\beta\hat{}$ are coefficients estimated from a linear regression of the Cephalon stock return on day t on the market returns on that day, MR^t. The percentage changes in the S&P 500 Stock Price index market returns are used for the market index. $\alpha\hat{}$ is the constant term estimated in that model and $\beta\hat{}$ is the estimated coefficient on MR^t.

17 The abnormal return is the difference between the actual return and the expected return: $A^t = R^t - E[R^t]$. For the market model used here, the expected return is based on the corresponding event window market return and the OLS estimates of $\alpha\hat{}$ and $\beta\hat{}$ from the equation in Note 16.

18 See McWilliams, Siegel, and Teoh (1999: 353) describing the method of summing abnormal returns across multiple related events: 'This approach would isolate the effect of [the event] because it allows for the inclusion of all abnormal returns actually related to the ev

19 The r normal return o prior 120-day peri window.

20 Robe d the increase e settlement agreem 's stock] is a resu get six more ye cted.' The $4 billio tion after removin he settleme l as a signal of antic

21 For e an et al. 2005) described the value of the side deal to Cephalon as negligible: 'We can't imagine

that Cephalon needs Teva's raw material or considers Teva's IP that material, so we have to assume that this structure, with three separate deals, allows Cephalon to make payments to Teva today and still pass FTC standards.'
