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

Raymond S. Hartman , Keith M. Drake & Thomas G. McGuire


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Keywords: Pharmaceuticals Antitrust Reverse payment Event studies Patent settlements

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## Disclosure statement

No potential conflict of interest was reported by the authors.

## Notes

- 1 Saving on generic drug sales from the expiration of a brand-name drug's patent is a common source of savings for all generic drug sales.
- 2 Strong evidence of generic drug sales restrictions on brand-name drugs (see [Lambert and Shapiro 2017](#)).
- 3 Edlin et al. (2017) find that reverse payment antitrust cases reduce generic drug sales by the generic drug sales.
- 4 Bioequivalence is required for generic drugs to be marketed at the same rate as in the brand-name drug sales.

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 monopoly price... an easy way for the parties to settle and achieve full monopoly profits: the incumbent can pay the potential entrant not to enter the market.’”

7 For extensive discussion of the unintended incentive effects of the 180-day exclusivity period, see Hemphill and Lemley (2011). The authors argue that Paragraph IV filing (as opposed to a win in litigation or an at-risk launch) should not earn a first-filer the 180 days of exclusivity.

8 The Medicare Prescription Drug, Improvement, and Modernization Act, enacted in 2003, created a 180-day exclusivity period for the first generic applicant to enter the market. If a generic applicant fails to enter the market within this period, it forfeits its right to the 180-day exclusivity period. 15 U.S.C. § 1124a(c)(1).

9 Elhaug et al. (2015) found that the 180-day exclusivity period is often violated. Writing in *Journal of Law and Economics*, they argue that the 180-day exclusivity period is often violated because of the high cost of litigation. They argue that the 180-day exclusivity period is often violated because of the high cost of litigation. They argue that the 180-day exclusivity period is often violated because of the high cost of litigation.

10 M. Elhaug, J. L. L. (2015) *Journal of Law and Economics*, 58(1), 1–28. Transcript of the oral argument in *Abbott v. Cephalon*, 135 S. Ct. 1820 (2015), transcript available at [https://www.supremecourt.gov/opinions/135pdf/14-1304\\_20151208.pdf](https://www.supremecourt.gov/opinions/135pdf/14-1304_20151208.pdf). The Eastern District of Virginia (the court in which the case was heard here) included other experts, including a pharmacologist and a physician, who testified that the 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 generics enter the market at the end of June 2006 is somewhere less than 100%. What we like best about this, is that seemingly the entire market has assumed generic entry at that time; any delay is all upside to our forecasts and we think also to the stock.'

13 Other generic manufacturers submitted ANDAs later but were not eligible for the generic exclusivity period as non-first filers. These other generics pose far less of a threat to the brand because they would need to win a final, non-appealable legal decision.

litigation. Pursue generics in our analysis.

14 See B. nely valuable avoid antitrust rd to complex payments by subs 8, where Hemphent outside of patent

15 On 21 delayed by the FDA, share price.

16 We c ^ are coefficient 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.  $\alpha^{\wedge}$  is the constant term estimated in that model and  $\beta^{\wedge}$  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  $\alpha^{\wedge}$  and  $\beta^{\wedge}$  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 event while minimizing contamination from other events.'

19 The reported t-statistics are calculated as the ratio of the cumulative abnormal return over the standard deviation of the daily abnormal returns during the prior 120-day period multiplied by the square root of the number of days in the event window.

20 Robert Baldino, Cephalon's CEO at the time of the settlements, attributed the increase in market capitalization to unexpected profits obtained through the settlement agreements (George [2006](#)): 'A lot of [Wall Street's enthusiasm for Cephalon's stock] is a result of the fact that we've been able to get six more years of life extension on our \$4 billion of sales by removing the uncertainty of the settlement. It's a signal of anticipated future growth.'

21 For example, see [Baldino et al. 2005](#) that we have to make payments to Cephalon to make



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