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

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Abstract

Event studies of stock price movements have been used to assess the anticompetitive impact of ‘reverse-payment’ settlement of patent disputes in the drug industry. Evidence for an anticompetitive effect is found when financial markets reward a brand manufacturer with larger stock market capitalization – signaling the agreed upon generic entry date was more profitable (i.e. later) than investors’ expectations. In practice, reverse-payment cases can involve multiple generic competitors and settlements. This paper considers how event-study methodology applies in such cases, with a study of the stock price movements of Cephalon, manufacturer of the drug Provigil. Cephalon entered into four patent litigation settlements with potential 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.

Keywords:

Pharmaceuticals | Antitrust | Reverse payment | Event studies | Patent settlements

JEL CLASSIFICATIONS:

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Disclosure statement

No potential conflict of interest was reported by the authors.

Notes

1 Savings were calculated by computing the difference between average pre-patent expiry brand price and average generic prices and attributing this difference as savings for all generic units sold (Generic Pharmaceutical Association 2016: 18).

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 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 'failure-to-market' provisions that could cause a first generic applicant to forfeit its 180-day exclusivity eligibility. See Karst (2014). However, these forfeiture provisions have rarely been applied.

9 Elhauge and Krueger (2012) apply a similar standard to Paragraph IV cases. Writing in this context: '… any settlement exclusion period that exceeds the expected litigation exclusion period necessarily harms ex post consumer welfare.' Consumer welfare is called ex post 'because it is calculated assuming the innovation has already 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 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 in order to launch and have much less of a financial incentive to pursue litigation to its conclusion. Thus, we do not include settlements with these generics in our analysis.

14 See Edlin et al. (2013), particularly p. 18, noting that 'Ordinarily, a genuinely valuable fee-for-service deal could be kept separate from the settlement to avoid antitrust problems. A degree of skepticism is therefore warranted with regard to complex reverse-payment settlements where the parties justify the large payments 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 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 patent litigation getting resolved for Provigil… We were able to get six more years of patent protection. That's $4 billion in sales that no one expected.' The $4 billion sales figure roughly lines up with the increase in market capitalization after removing taxes and costs and discounting to the time of the settlements. The settlements and the unvarnished statements by Baldino were characterized as a signal of anticompetitive conduct by the FTC (Leibowitz 2006).

21 For example, after the Teva settlement, a Morgan Stanley report (Goodman 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.'

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