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INDEPENDENT RESEARCH REPORT

Pricing the Patent Cliff

Investor Anticipation and Stock Reactions to Pharmaceutical Loss of Exclusivity

PREPARED BY

Joe Reeves
Groundwork Advisory LLC
joe@groundworkadvisoryllc.com | 269-270-9676

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RESEARCH REPORT

Abstract

This research aims to quantify the impact of FDA Loss of Exclusivity (LoE) events on the stock prices of publicly traded U.S. pharmaceutical firms from 1980 through 2024. I employ event study methodology to measure the market's reaction by calculating Cumulative Abnormal Returns (CARs) over a narrow event window, [-5,+5] days, centered on the LoE date. Daily abnormal returns are estimated using a market model derived from a pre-event estimation window of [-250,-30] trading days.

The study utilizes Loss of Exclusivity dates drawn primarily from the FDA Orange Book and supplemented by Purple Book biologic files. The initial breadth consisted of 2,003 LoE events, covering 495 unique applicants. Through a multi-stage matching pipeline with variables like PERMNOs, tickers, CUSIPs, and name-normalized fuzzy matches, 1,524 events were successfully matched to CRSP security identifiers, representing 155 distinct PERMNOs. Of these matched events, 1,309 achieved alignment to CRSP trading days, accounting for weekends and holidays. The final baseline sample, requiring sufficient estimation data (at least 150 trading days in the [-250, -30] estimation window), included 760 LoE events. This final sample used for the Cumulative Abnormal Return analysis represented 124 unique firms.

Normal returns were established using the Market Model over an estimation window of [-250, -30] trading days, continuously compounding returns to ensure the mathematical accuracy of cumulative return calculations. The primary finding reveals a strong, statistically significant negative market reaction to LoE events. Specifically, the mean Cumulative Abnormal Return over the [-5, +5] trading day event window was calculated as -2.02% (discrete return equivalent). This result rejects the null hypothesis (mu CAR=0) with a high t-statistic of -4.35 and an exceptionally low p-value of < 0.0001. Further analysis indicates the market reaction is immediate, with the largest daily Average Abnormal Return (AR) of -0.81% occurring on the event day (T0). This signifies that the market adjustment to the value-eroding event was not completed in the anticipation period. Instead of showing perfect efficiency (where AR = 0 on T0), the significant abnormal return demonstrates the speed and magnitude of the market's reaction to the event, which led to a large price correction on that day to reflect the negative financial implications.

760	124	-2.02%
LOE EVENTS	UNIQUE FIRMS	MEAN CAR

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Introduction

The economic structure of the pharmaceutical industry relies on temporary monopoly power granted by intellectual property protection. This exclusivity is essential, allowing companies to recoup their high research and development for new therapies. However, this period of high profitability is finite, culminating in the Loss of Exclusivity, commonly known as the "patent cliff." The patent cliff represents an abrupt decline in revenues when patent protection for leading products expires. The consequences are severe: for the U.S. market, a blockbuster drug (one with annual sales exceeding $1 billion) can lose up to 80% or more of its revenue within the first year of facing generic or biosimilar competition (Moran, 2025). This financial shock is particularly material for pharmaceutical firms whose enterprise value depends heavily on a limited number of protected products. The current wave of patent expirations, particularly from 2025 to 2030, threatens up to $400 billion in revenue across the industry (ABcontributor, 2025). The timing of patent expiration is the single most sensitive assumption in any pharmaceutical valuation model (DrugPatentWatch, 2025). Therefore, understanding how the market reacts to the end of this exclusivity period is meaningful for corporate strategy and financial analysis. The narrow research question guiding this descriptive analysis is:

> **How do public pharmaceutical firms' stock prices react to FDA Loss of Exclusivity (LoE) events?**

I used the event study methodology, a quantitative technique widely utilized in finance research to measure the impact of discrete corporate events on shareholder wealth (MacKinlay, 1997). The methodology rests on the premise that efficient capital markets incorporate new, market-relevant information (such as the LoE event) into stock prices. By calculating Abnormal Returns and aggregating them into Cumulative Abnormal Returns around the LoE date, I isolate the short-term return effect attributable specifically to the loss of exclusivity. This analysis uses a final sample of 760 events across 124 unique firms, leveraging daily stock returns to provide a quantification of this industry-specific risk.

Method and Data

The dataset construction involved three primary stages: event identification, gathering market data, and matching/filtering to ensure data availability.

Event Data and Identification (T0)

The primary data source for the LoE date (T0) was the FDA Orange Book application-level dates. This regulatory information, supplemented by the Purple Book biologics data and historical FDA files, defines the breadth of LoE events for U.S. publicly traded pharmaceutical firms between 1980 and 2025, but CRSP returns data limited the study to 2024. After sorting and filtering, the event dataset comprised 2,003 LoE events. Issues arose obtaining PERMNOs for all of the Orange and Purple FDA companies that were listed after separating the company names form the source txt files because of CRSP data limitations.

Market Data

Daily stock return data was retrieved from the Center for Research in Security Prices (CRSP) database. CRSP daily stock files were aggregated from 1980-2024, resulting in nearly 4.9 million return observations. This raw data was deduplicated, yielding 3,013,285 unique firm-date daily return observations. I used regular daily returns (ret) rather than delisting returns (dlyret) for observed returns in the study. The CRSP value-weighted market return (vwretd) was used to proxy for the market portfolio in calculating expected returns.

Multi-Stage Matching Pipeline

To link the 2,003 regulatory event dates to their correct tradable security identifiers, I mainly used PERMNOs. These are the most reliable, but I tried to get other matches with a multistage matching pipeline.

CRSP Identification: I started by downloading all CRSP daily stock file data available with PERMNOs, then I searched up many companies (~500) individually with the CRSP company lookup function to find PERMNOs. Only some yielded results due to niche or private pharma companies that did not have data in CRSP. This was followed by matches based on normalized firm names, tickers, CUSIPs, and token-based fuzzy matches. This process successfully matched 1,524 events to 155 distinct PERMNOs.

Trading-Day Alignment

Because some of the LoE events fall on weekends or non-trading days, I matched them to the CRSP calendar with a three-step alignment strategy (Exact Match, Next-Day Match, Closest-Day Match) to account for weekends and holidays. This resulted in 1,309 events successfully aligned. To ensure reliable parameter estimation for the model, a filter was applied, requiring a minimum of >=150 trading days in the estimation window. This process yielded the final baseline dataset of 760 LoE events, encompassing 124 distinct firms. This final sample represents approximately 37.9% of the total initial events. To increase validity, checks confirmed the consistency of results using relaxed minimum estimation requirements of >=120 days (N=765) and >=90 days (N=772).

Final Sample Filtering

The analysis relied on a pre-event period of [-250,-30] trading days to serve as the estimation window. This window, spanning 221 trading days, provided an average of 220.5 trading days per event where I used market-model OLS regression to obtain beta and alpha parameters for each firm to derive expected returns. A 25-day gap (days -30,-6) was enforced to prevent patent-related information leakage from contaminating the estimation. The Event Window used to capture the market reaction was the symmetric period of [-5,+5] trading days, totaling 11 days.

Event Study Method

The event study methodology, frequently utilized in finance research to isolate the stock price impact of corporate announcements, was applied to the final dataset.

Model: The Market Model, which relates a stock's daily return to the market return, controlling for systematic risk with continuous compounding, was what I used.

Market Model (continuous compounding): $r_{i,t(cc)} = \alpha_i + \beta_i * r_{m,t(cc)} + \varepsilon_{i,t}$

All stock returns were converted into continuously compounded returns using: r(cc) = ln(1 + r). This allows daily abnormal returns to be summed directly when computing cumulative abnormal returns.

Abnormal and Cumulative Abnormal Return Calculation

Abnormal Return (AR): The daily abnormal return is the difference between the actual daily return and the predicted return. Daily abnormal returns in continuous-compounded terms were calculated as:

$AR_{i,t(cc)} = r_{i,t(cc)} - [\hat{\alpha}_i + \hat{\beta}_i * r_{m,t(cc)}]$

Cumulative Abnormal Return (CAR): The CAR for event i is calculated by summing the abnormal returns across the event window.

$CAR_{i(cc, -5 \text{ to } +5)} = \sum AR_{i,t(cc)} \text{ from } t = -5 \text{ to } t = +5$

To provide an economically interpretable measure, the continuous-compounding CAR was converted to a discrete return: $CAR_{i(discrete)} = \exp(CAR_{i(cc)}) - 1$

Statistical Testing

Across the final baseline sample of 760 LoE events, the mean CAR, expressed as a discrete return, was -2.02%. Statistical significance was evaluated using a two-tailed t-test against the null hypothesis that the mean CAR equals zero. The results indicated a highly significant negative market impact, with a t-statistic of -4.35 and a p-value below 0.0001.

Descriptive Statistics

To give a more rounded context of the variables, the descriptive statistics are represented below. The min and max for returns variables seem like implausible outliers, but smaller volatile "penny stocks" will have higher jumps, and stocks reopening at a drastically different price after a halt will cause this.

Table 1. Descriptive Statistics

Variable	N	Mean	Median	Std Dev	Min	25th Pctl	75th Pctl	Max
Daily Stock Return	169,349	0.13%	0	4.4%	-78.5%	-1%	1.1%	489%
Daily Market Return	169,349	0.054%	0.09%	1.18%	-17.1%	-0.42%	0.59%	11.5%
Alpha	760	0.00013	0.0003	0.0024	-0.02%	-0.00055	0.0013	0.0086
Beta	760	0.79	0.757	0.48	-2	0.47	1.03	3.4

Results

The analysis strongly supports the research hypothesis and demonstrates that LoE events are associated with a measurable destruction of shareholder wealth, reflected through negative abnormal stock returns.

The primary goal of the event study was to measure the Cumulative Abnormal Return CAR over the [-5, +5] trading day window, representing the 11-day period surrounding the LoE event date. CAR values were calculated by summing the continuously compounded Abnormal Returns generated from the Market Model for each of the 760 events included in the final baseline sample, which spans 124 unique pharmaceutical firms. The statistical test evaluated whether the average CAR differs significantly from zero under the null hypothesis that the true mean CAR equals zero.

The mean CAR for the baseline sample, expressed as a discrete return equivalent, is -2.02 percent. The statistical test indicates that this negative return is highly significant. The calculated t-statistic is -4.35, and the associated p-value is less than 0.0001. The 95 percent confidence interval for the mean CAR ranges from -2.93 percent to -1.11 percent, confirming that the interval does not include zero, providing strong evidence of a systematic negative market reaction to LoE announcements. These results reject the null hypothesis at the 5 percent level and validate the economic effect.

Table 2 presents the baseline result and the outcomes of relaxing the required amount of trading days. The baseline sample, which requires at least 150 estimation-window trading days, produces a standard error of 0.004638. The 120 trading day window check increases the sample to 765 events and yielding a mean CAR of -2.06 percent. The 90 trading day window, includes 772 events, and produces a mean CAR of -2.08 percent. In both robustness specifications the t-statistics remain between -4.46 and -4.53, and p-values remain below 0.0001, indicating consistent and statistically significant results across all sample definitions.

Table 2. Validity in Estimation Period

Estimation Window Days	N Events	Mean CARcc	Mean CAR discrete %	Std Dev cc	Std Error	t-Statistic	p-Val
>= 150	760	-2.02%	-1.28%	0.13	0.0046	-4.35	<0.0001
>= 120	765	-2.06%	-1.32%	0.13	0.0046	-4.46	<0.0001
>= 90	772	-2.08%	-1.34%	0.13	0.0046	-4.53	<0.0001

Mean CAR values represent the discrete equivalents of the continuously compounded CARs calculated over the full [-5, +5] event window. The stability of the results across the 760, 765, and 772-event samples confirms that the primary finding is not sensitive to the specific estimation window requirements.

Time Series Analysis of Market Reaction

The strongest single-day reaction occurs on the event day itself, T0, where the mean daily AR reaches -0.8103 percent. This sharp decline indicates an immediate and direct market response to the announcement of the Loss of Exclusivity. The cumulative reaction is not isolated to the event day but instead unfolds across the surrounding days. By the end of the event window on Day +5, the raw CAAR has reached -2.12 percent, while a smoothed CAAR calculated using a five-day moving average (the two days before and after the measured day) ends at -2.07 percent. The pre-event period also shows mildly negative ARs, suggesting either modest anticipation or limited information leakage prior to the event.

Event Window Progression

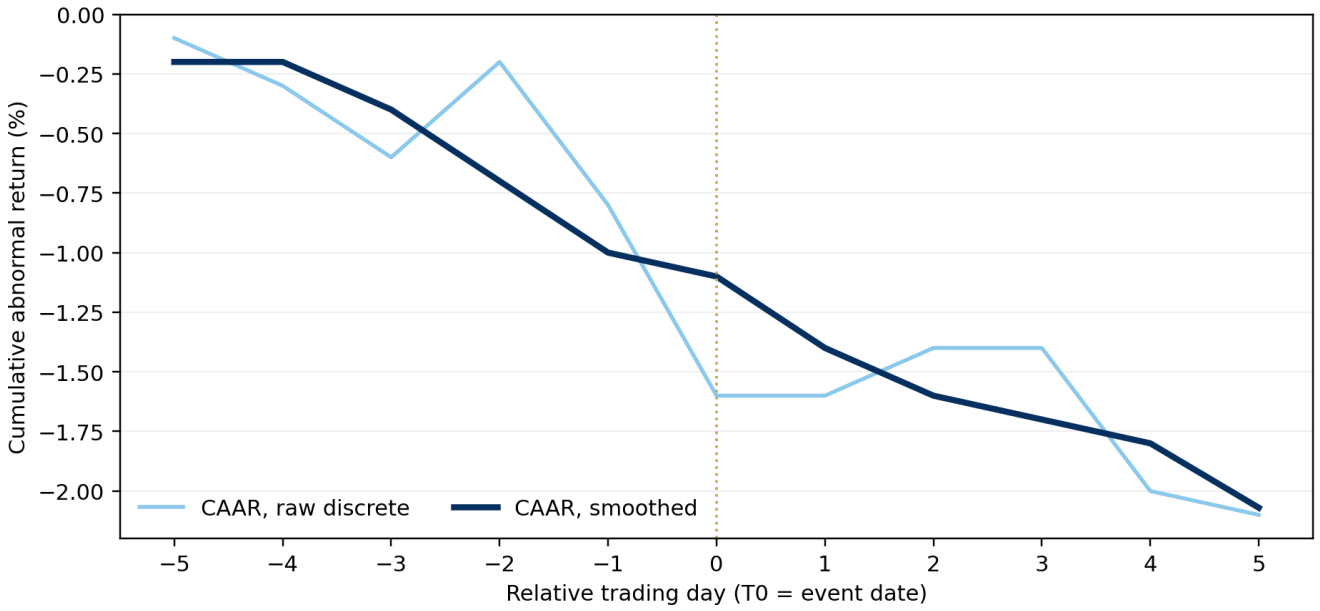
Table 3 provides the detailed daily progression of the CAAR for the baseline sample of 760 events. On Day t-5, the mean daily AR is -0.1225 percent and the cumulative CAAR in continuous-compounded terms is -0.001225, which corresponds to -0.12 percent in discrete form. By Day -1, the cumulative CAAR reaches -0.81 percent. On Day 0, the cumulative CAAR deepens to -1.61 percent. Following the event, the cumulative decline continues, reaching -1.95 percent by Day +4 and culminating at -2.12 percent by Day t+5. These results indicate that the full 11-day window is necessary for the market to fully absorb the negative implications of generic entry.

Table 3. Event Window Results

Relative Day	Avg AR (cc, raw)%	Avg AR (cc, Smoothed)%	N Events	CAAR (cc, raw)%	CAAR (cc, Smoothed)%	CAAR (Discrete raw)%	CAAR (Discrete Smoothed)%
-5	-0.12	-0.2	760	-0.1	-0.2	-0.1	-0.2
-4	-0.2	-0.04	760	-0.3	-0.2	-0.3	-0.2
-3	-0.3	-0.2	760	-0.6	-0.4	-0.6	-0.4
-2	0.4	-0.3	760	-0.2	-0.7	-0.2	-0.7
-1	-0.7	-0.3	760	-0.8	-1	-0.8	-1
0	-0.81	-0.2	760	-1.6	-1.1	-1.6	-1.1
1	0	-0.3	580	-1.6	-1.4	-1.6	-1.4
2	0.2	-0.2	580	-1.4	-1.6	-1.4	-1.6
3	-0.05	-0.1	580	-1.4	-1.7	-1.4	-1.7
4	-0.6	-0.1	580	-2	-1.8	-2	-1.8
5	-0.2	-0.3	580	-2.1	-2.1	-2.1	-2.07

Figure 1 depicts the time series of CAAR in discrete terms from Day -5 through Day +5. The figure shows a gradually declining CAAR leading into T0, followed by a pronounced drop on the event day and a continuation of the negative trajectory through the post-event period. This pattern visually reinforces the statistical evidence of both immediate and persistent negative market adjustments.

Figure 1. Average Cumulative Abnormal Returns Over the Event Window



Conclusion

This study examined 760 Loss of Exclusivity events for U.S. pharmaceutical firms from 1986 to 2024 using an event-study framework. The average CAR of -2.02 percent over the [-5, +5] window shows a clear decline in shareholder value as patent protection ends. The LoE date includes a daily abnormal return of -0.81 percent, showing that even though the exact timing of expiration is publicly available long in advance, the formal regulatory end of exclusivity remains an economically meaningful point for pricing. This reflects investors' adjustment to the certainty that the protected revenue stream has officially ended and that generic entry is now imminent rather than hypothetical. The results are statistically strong, with a t-statistic of -4.35 and a p-value below 0.0001, and the nonzero CAR shows that the findings are not consistent with a fully efficient market that would have incorporated these effects well before the event window.

The results offer practical insight for valuation and risk analysis. The -2.02 percent CAR can serve as a benchmark when modeling the expected short-term impact of upcoming LoE transitions. The consistency of negative returns across nearly four decades of data shows that value pressure at patent expiration is a steady feature of pharmaceutical pricing.

The findings have implications for investors and firms. Investors may use the magnitude and timing of the abnormal returns to assess exposure to future expirations, while firms can rely on this evidence when preparing for valuation pressure during major LoE periods and when planning capital-allocation decisions.

The study has several limitations. It focuses on U.S. publicly traded firms, does not evaluate long-term outcomes beyond the short event window, and relies on archival data rather than strategic or operational information. Future work could compare reactions across regulatory environments, explore variation across therapeutic classes, or connect event-time returns with indicators such as revenue erosion and competitive intensity. Another study route could be analyzing if patent grants are consistent with positive returns, and whether the relation of these events to LoE events affects the study.

Overall, the study provides a clear measurement of the short-term effect of LoE events on shareholder value and offers a basis for understanding how investors adjust expectations when exclusivity ends and generic competition becomes imminent.

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