9-1988

Wealth Effects of the Drug Price Competition and Patent Term Restoration Act of 1984

Raymond T. Brastow

Longwood University, brastowrt@longwood.edu

David Rystrom

Western Washington University

Follow this and additional works at: http://digitalcommons.longwood.edu/business_facpubs

Part of the [Business Commons](#)

Recommended Citation

Brastow, Raymond T. and Rystrom, David, "Wealth Effects of the Drug Price Competition and Patent Term Restoration Act of 1984" (1988). *Business & Economics Faculty Publications*. Paper 1.
http://digitalcommons.longwood.edu/business_facpubs/1

This Article is brought to you for free and open access by the College of Business & Economics at Digital Commons @ Longwood University. It has been accepted for inclusion in Business & Economics Faculty Publications by an authorized administrator of Digital Commons @ Longwood University. For more information, please contact hinestm@longwood.edu.

WEALTH EFFECTS OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984

by Raymond Brastow and David Rystrom*

1. Introduction

In September of 1984, President Reagan signed into law a compromise bill that sped up and simplified the government certification process for generic drugs that are substitutes for patented brand-name drugs and in return granted brand-name manufacturers longer patent protection. This law, the Drug Price Competition and Patent Term Restoration Act of 1984, was the end result of a series of debates and proposed changes in patent protection laws that began in 1959. The final version of the law contained provisions that were both favorable and unfavorable to drug producers; therefore, the expected net impact upon drug producing firms was not immediately clear. This paper examines the impact of this change in government regulation by examining stock prices of drug firms around the time of the legislative discussion of the bill in the summer of 1984. Using daily stock returns, we find a significant increase in stock prices of firms primarily engaged in the manufacture of generic drugs. We find no significant impact on prices of firms engaged in the manufacture of already existing, brand name drugs. Thus, the Act appears to have produced net benefits to the drug industry.

The paper is organized as follows: Section 2 provides the historical background to the legislation and the sequence of events leading to the passage of the law. Section 3 discusses the economic significance of the law and describes the hypothesis to be tested. Section 4 describes the data and the methodology of the study. Section 5 presents the results and their interpretation, and Section 6 summarizes the findings.

2. Congressional Action on Drug Prices, Patents, and Competition

Debate over the effect of patents on the pharmaceutical industry has continued in Con-

gress for more than 25 years. In December of 1959, the Subcommittee on Antitrust and Monopoly of the Senate Judiciary Committee began hearings on the relationship between patents, high drug prices, and large profits in the drug industry. The hearings continued through 1960 and by 1961 a series of amendments to the 1938 Food, Drug and Cosmetic Act were proposed which were designed to foster competition among drug companies. Although the bill was widely supported, debate over its provisions kept it from making rapid progress until significant changes were made in committee. Ironically, the version which eventually reached the floor and was passed in 1962 had been stripped of the provisions which dealt with the original concerns: drug prices and profits.¹ The law was chiefly concerned with the safety and effectiveness of new drugs and resulted in the FDA approval process becoming more lengthy; drugs had to be proved effective as well as safe. The law did, however, require that the generic name of a drug be on its label, thus providing the impetus for eventual generic competition.

Throughout the succeeding two decades, continuing debate took place concerning the effects of patents on the drug industry. In addition to the allegation that patents create "excessive" profits, the 1962 legislation had created a different concern: the new drug approval (NDA) process had become so lengthy that it took much of the 17-year patent period to bring a drug to market. To correct this, the Patent Extension Act of 1981 was passed by the Senate on July 9; this bill would have granted extensions of patents for up to seven years to drugs that had been the subject of a lengthy approval process. However, the bill failed to pass in the House of Representatives in a very close roll-call vote. It was sent back to committee and died at the end of 1982, at least

* Assistant Professor Economics, Longwood College, and Assistant Professor of Finance, Western Washington University.

partly because of intense lobbying by the generic drug industry.

Patent hearings began in 1983 in both houses. In 1984, the Drug Price Competition and Patent Term Restoration was introduced into both the Senate and the House. The compromise bill was intended to counterbalance the patent extension aspects of the 1982 bill by adding benefits to generic interests. It had three major provisions:

1. Extension of an abbreviated approval process to generic versions of drugs approved after 1962. Existing law provided for this abbreviated approval only for generic versions of drugs for which the original patented version was approved before 1962. A firm wishing to produce a generic version of a drug approved after 1962 had to go through the same lengthy NDA process as the original patent-holder. This provision was the most important one of the bill; it would clearly reduce time and costs to bring generic substitutes to market.

2. Direction to the FDA to postpone approval of a generic drug that was the subject of litigation over patent infringement brought by the patent holder. The postponement would be in force until the case was decided, but could last no longer than eighteen months.

3. Single extension of a first patent for drugs subject to FDA approval. The extension would last two years for drugs awaiting approval at the time of the bill's enactment and up to five years for drugs submitted for approval after enactment. However, the total length of patent protection could not exceed fourteen years from the date of FDA approval. This had the effect of moderately lengthening the patent protection period for some brand-name drugs.

This version of the bill was perceived as being favorable to generic drug producers, even though it had been constructed as a carefully built compromise which had the support of all trade groups and the leadership of both parties. However, eleven major brand-name manufacturers split with their trade group and lobbied against the bill. When the bill was sent to the Senate Labor and Human Resources Committee, it was strongly opposed by those brand-name manufacturers and consequently was altered again in committee to grant additional protection to brand-name firms. The amended bill was reported favorably by the committee on August 8, containing three new provisions.

1. The maximum postponement of generic drug approval during patent infringement litigation was extended from 18–30 months.

2. For new drugs without active patents, no generic version could be approved for two, three, or five years after the approval of the original, depending on the nature of the drug.

3. The patent-holder could decide the patent for which to request an extension. The original version of the bill had specified that the first patent would be the only one eligible for an extension.²

The Senate passed the bill on August 10. The house passed an almost identical version on September 6, the Senate agreed to the House version on September 12, and the President signed it into law on September 24. Passage of the bill was the culmination of a 25 year debate on drug prices and patents.

3. Economic Implications and Hypotheses

The Drug Price Competition and Patent Term Restoration Act of 1984 was a compromise bill which conferred benefits to manufacturers of both brand-name and generic drugs. The major provision of an abbreviated approval process for generic drugs was clearly of benefit to generic drug producers; generic drugs could be brought to market considerably sooner and at lower cost than under the previous law. However, this benefit may have been partially or completely offset by provisions protecting brand-name firms that extended patent lengths and granted increased protection to new unpatented drugs, thus delaying the potential introduction of generic competitors in the future.

Since in an efficient stock market stock prices reflect the market's expectation of the future profitability of a firm, the market's assessment of the expected impact of a new law can be examined by observing changes in stock prices associated with times of legislative action on the bill. By analyzing daily stock prices we examine the hypothesis that investors viewed the legislation to be on balance a net benefit to the generic industry. Formally, we perform a test for the null hypothesis that there was no impact on share prices from the legislation. Similarly, we also examine the expected effect of the bill on

brand-name producers by examining the behavior of the stock prices of those firms.

Although the bill was involved in congressional deliberations for several months (see Table 1), we chose August 8 as the pivotal date for our analysis of stock prices. At that time the Judiciary Committee reported to the Senate the final compromise version that satisfied the objections of the eleven major brand-name manufacturers who had refused to endorse earlier versions of the bill. This event had two effects: it overcame the final opposition to the bill, making passage appear more probable, and it granted additional protection to brand-name interests. Therefore, the net impact of the event on generic firms' stock prices could have been positive or negative. If the bill's passage was widely anticipated prior to August 8, then generic stock prices would have fallen due to downward revision of the previously anticipated impact of the bill. Generic stock prices would have risen if the compromise provisions resulted in newly formed anticipations of passage of a bill which was on balance favorable to the generic industry. Similarly, a decrease in prices of brand-name firms' stocks would indicate an increased probability of passage of a bill unfavorable to these firms, while an increase in their stock prices would reflect the anticipated benefits of the additional provisions.

4. Data and Methodology

We first examine the stock prices of the five publicly traded firms primarily engaged in the manufacture of generic drugs: Bolar Pharmaceutical, Lypghomed, Mylan Labs, Par Pharmaceutical, and

Zenith Labs. Bolar Pharmaceutical was traded on the American Stock Exchange (ASE) while the four others were traded in the Over-the-Counter (OTC) market. Daily stock prices were obtained from Standard and Poor's Daily Stock Price Record. The closing price was used for Bolar Pharmaceutical while the asked price was used as the daily price for the OTC stocks.³

We also examine the stock prices of six major firms engaged in the manufacture of brand-name drugs that were often mentioned in the news as being vulnerable to imminent competition from generic substitutes. These firms were American Home Products, Merck, Pfizer, Searle, Smithkline Beckman, and Upjohn. This list is not exhaustive of all producers of vulnerable brand name drugs; we constrained our sample to publicly traded firms for which production of brand name drugs was an important source of revenue and profits.⁴ All of these firms' stocks were traded on the New York Stock Exchange; we used daily closing prices in the analysis.

For each group of firms, a time series of daily common stock returns was constructed for two periods during 1984. The first period consists of the 100 trading days from January 5, 1984 through May 25, 1984. This period is used as a comparison period for analysis because it precedes the time of congressional deliberation and action. The second period consists of the 101 trading days from May 29, 1984 through October 18, 1984. This period includes the dates of all congressional discussion and action on the bill and is centered on August 8, 1984, the date of final Senate Committee action on the bill (see Table 1). Average returns for each day are calculated as the arithmetic mean of the individual returns of the companies in each group. This return can be interpreted as the return to an equally-weighted portfolio of the stocks in each group. The use of portfolio returns averaged across securities mitigates the possible influence of firm-specific effects.

We then calculate market adjusted returns for each portfolio by subtracting the daily return on the Standard and Poor's 500 Composite Index from each daily portfolio return to get a measure of return corrected for market movements. This produces a series of returns for each group of firms; we then observe the market adjusted return on and surrounding the dates of legislative events.

Brown and Warner (1980, 1985), Dann

TABLE 1
Selected Events Associated with the Drug Price
Competition and Patent Term Restoration
Act of 1984

June 12	House Energy and Commerce Committee reports bill
July 28	House Judiciary Committee reports bill
August 8	Senate Judiciary Committee reports revised bill
August 10	Senate passes bill on voice vote
September 6	House passes bill 362-0
September 24	President signs bill

(1980), and others have demonstrated that the tests using “raw” returns, mean adjusted returns, market adjusted returns, or risk adjusted returns produce results that are quite similar, especially when daily returns are analyzed. Adjusting returns for risk has little or no impact on results or power of tests when daily returns are used. We report our results in terms of market adjusted returns in order to demonstrate the magnitude of the “abnormal” portion of the impact, but the significance of our results was unchanged when we examined raw returns and mean adjusted returns.⁵

5. Empirical Results

Table 2 presents cumulative market adjusted portfolio returns around the date of final congressional committee action on the bill for generic firms and brand-name firms. Column 1 identifies the trading date relative to day 0, which is August 8, the day that the Senate committee reported the final version of the bill. Columns 2 and 3 present the cumulative market

TABLE 2
Cumulative Market Adjusted Portfolio Rates of
Return for 101 Trading Days Surrounding
August 8, 1984

Trading Day	Generic Firms	Brand Name Firms
- 50	-0.03	-0.21
- 40	3.75	1.81
- 30	4.73	4.96
- 20	8.46	-2.32
- 10	6.10	-3.39
- 5	12.80	-3.68
- 4	11.53	-3.79
- 3	11.26	-4.83
- 2	11.66	-6.22
- 1	15.29	-5.17
0	15.57	-5.75
+ 1	19.27	-6.64
+ 2	22.35	-5.25
+ 3	20.92	-5.20
+ 4	21.40	-5.65
+ 5	22.72	-5.52
+ 10	27.79	-6.49
+ 20	26.15	-5.73
+ 30	17.18	-6.67
+ 40	18.47	-3.16
+ 50	15.41	-2.38

adjusted daily returns for the equal weighted portfolio for each group of firms. It is apparent from the table that generic firms' stock prices rose markedly over this period, with much of the increase occurring near August 8. Brand name firms' stock experienced slight negative market adjusted returns over the same time period.

Table 3 examines the dates of August 8, 9, 10 (Friday), and 13 more closely by presenting the daily market adjusted returns for each portfolio of firms. August 8 is the date that the altered version of the bill was reported by the Senate committee while August 10 is the date that the Senate passed the bill. Since the exact time during the day that the information became available to the market is unclear, the information may have been impounded into stock prices on the event day and/or the subsequent day. We find that the August 9 market adjusted return is 3.70% and the August 10 market adjusted return is 3.07% for generic firms, both of which are statistically significant at the 5% confidence level.⁶ This is strong evidence supporting the hypothesis that the bill, even after alterations favoring brand-name interests, provided net benefits to generic firms; the joint events of the committee's reporting of the bill and the Senate's passage of the bill caused an unanticipated increase in the aggregate wealth of shareholders of generic drug companies of over 6%. Based on the prices and number of shares outstanding for these firms as of August 8, this abnormal return translates into an increase in wealth by shareholders of approximately forty million dollars.

The evidence about brand-name firms is less conclusive. There is positive market adjusted return, statistically significant at the 5% level, for August 10, the date of Senate passage; no other significant returns are evident. We interpret this evidence to indicate that the market viewed passage of the bill as providing net benefits to brand-name firms, relative to prior expectations. That is, while the bill may indeed have had a net negative impact on brand-name firms (which is suggested by the cumulative returns shown in Table 2), the final passage of the altered version of the bill was a pleasant surprise producing a positive impact on brand-name stock prices. However, it is surprising that there is no observable impact for brand-name firms on August 8 or August 9. In addition, we note that the cumulative four-day return for

TABLE 3
Daily Market Adjusted Returns for Generic and Brand-Name Drug Companies
August 8–August 13, 1984

	Generics		Brand Names	
	Rp(%)	t-statistics	Rp(%)	t-statistic
Aug 8	0.28	0.03	−0.58	−0.90
Aug 9	3.70	2.73*	−0.89	−1.40
Aug 10	3.07	2.23*	1.40	2.28*
Aug 13	−1.42	−1.32	0.05	0.11

$$t \text{ statistic} = \frac{R_p - \bar{R}_c}{s(1 + 1/n)^{1/2}}$$

where: R_p = the daily portfolio return on day 0

$\bar{R}_c$ = the mean portfolio return during the control period, 0.26% for generics and 0.08% for brand-names
 s = the sample standard deviation of the time series of the portfolio returns during the control period, 1.26% for generics and 0.62% for brand-names

n = the number of observations in the control period, $n = 100$

* Significant at the 5% level.

brand-name firms for the dates examined in Table 3 is approximately zero. Therefore, an appropriate conclusion may be that the passage of the Act had no net impact on brand-name firms.

Our hypothesis is that there was a significant impact upon drug manufacturers' stock prices at the time that the market judged passage of the bill to be likely. We have focused our study on the dates of August 8 and August 10, but there is obviously some difficulty in determining the appropriate dates to be examined for any event of this kind; the market is constantly reassessing the probability of a bill's passage throughout the legislative process, so the total impact of the law on stock prices may be spread over several days of legislative events. (Schwert (1981) reviews the application and difficulties of using stock market data to assess the impact of legislative actions.)

Since there are several dates in 1984 on which there was legislative action on the event (Table 1), we also examine the returns associated with those dates. Table 4 presents the market adjusted returns for 3 trading days surrounding each event date described in Table 1. We include the trading day prior to the event, the event date, and the day after the event in our analysis because of the uncertainty about the exact time of the market's first receipt of the information. We also calculate the mean 3-day return and a t statistic to test the hypothesis that the mean

market adjusted return over the 3-day period is significantly different from the mean market adjusted return for the comparison period.⁷

For generic firms, we observe that only the 3-day mean returns for August 8 and August 10 are statistically significant, although the positive returns observed around the June 12 and July 30 events are weakly suggestive of possible impacts. Since the August 8 and August 10 three-day periods are overlapping, we cannot reject the hypothesis that both events jointly produced the abnormal returns associated with the two dates. The evidence is consistent with the hypothesis that passage of the bill increased the wealth of shareholders of generic drug firms.

For brand-name firms, no mean returns are significant for any of the legislative events. This result indicates that the Act had no significant effect on the value of the brand-name firms. This result is not surprising as all of these companies are large and diversified; thus the impact on any single product could be small relative to the rest of a firm's product lines. Any economic effect from the Act could easily be too small to be observed in the firm's stock prices.

6. Conclusion

Our results demonstrate that the compromise drug legislation of 1984 increased the wealth of shareholders in generic drug manufacturing firms; the market evaluated the compromises

TABLE 4
Market Adjusted Returns for 3 Day Periods Around Dates of Legislative Events (%)

A. Generic Firms					
Date	Trading Day Relative To Event			3 Day Mean Return	t-statistics
	- 1	0	+ 1		
June 12	2.55	-0.11	-1.01	0.48	0.29
July 30#	1.31	-0.44	2.92	1.26	1.35
Aug 8	3.63	0.28	3.70	2.54	3.05*
Aug 10	3.70	3.07	-1.42	1.78	1.98*
Sept 6	0.52	-1.77	-0.30	-0.52	-1.03
Sept 24	-0.62	1.56	-0.79	0.05	-0.40
B. Brand-Name Firms					
June 12	0.73	-0.12	0.39	0.33	0.69
July 30#	-0.36	0.00	1.31	0.32	0.65
Aug 8	1.05	-0.58	-0.89	-0.14	-0.61
Aug 10	-0.89	1.40	0.05	0.19	0.30
Sept 6	-0.06	0.55	-0.04	0.15	0.19
Sept 24	-0.62	0.22	0.54	0.05	-0.08

$$t = \frac{R_{p3} - R_c}{\left[\left(\frac{n_a s_a^2 + n_c s_c^2}{n_a + n_c - 2} \right) \left(\frac{1}{n_a} + \frac{1}{n_c} \right) \right]^{1/2}}$$

where: R_{p3} = mean portfolio market adjusted return over 3 days

R_c = the mean portfolio market adjusted return during the control period

s_a = the sample standard deviation of the portfolio market adjusted returns over the 3 day announcement period

s_c = the sample standard deviation of the portfolio market adjusted returns during the control period

n_a = the number of observations in the announcement period, $n_a = 3$

n_c = the number of observations in the control period, $n_c = 100$

* significant at the 5% level

July 28, the date the bill was reported out of the House Judiciary Committee was a Saturday. We use July 30, the first trading day following the event, as day 0.

incorporated in the bill as producing expected net benefits to the generic industry.⁸ In addition, we conclude that the major part of the impact of the bill was capitalized into share prices in the four days surrounding the date of its passage in the Senate Judiciary Committee and the full Senate, more than three months before it became law.

The results of the analysis of brand-name drug manufacturers are not as conclusive but suggest that there was no significant impact on the stock values of brand-name firms. Apparently the compromise features of the final bill and the resolution of uncertainty about the bill were viewed as being favorable to brand names to such an extent as to offset the expected costs

from future competition from generic manufacturing firms.

Notes

1. For a detailed history of the 1962 legislation, see Harris (1964).
2. Patent-holders typically have several patents over a drug and the critical patent which maintains exclusive marketing power is often not the first.
3. We examined the data to determine if use of bid prices or the mean of bid-asked prices altered our results and found no significant differences.
4. Even though we restricted our sample of brand-name drug producers, the firms in our sample are still relatively large ones that produce many

- products other than patent protected drugs. It was not possible to determine what proportion of each firm's sales were of prescription drugs vulnerable to generic competition. The firms did include in their 1984 annual reports the proportion of their sales from their divisions that included pharmaceuticals. The mean percentage of sales of each firm that was accounted for by its division that included prescription drugs was 50%. The range was from Merck's 34% of sales from their "Human and Animal Health Products" division to 66% for Upjohn's "Human Health Care" division. Obviously, prescription pharmaceuticals would constitute only a proportion of sales for each division. However, each company clearly considered prescription drugs to be its "lead products"; the 1984 annual report of each company began with a description and discussion of the firm's major prescription drugs. In some annual reports, the 1984 Act was noted as a potential negative factor for the firm's future sales. We also found some additional evidence that potential loss of sales to a generic competitor is a significant, wealth-reducing event to a large brand-name producer. On July 10, 1984, the Food and Drug Administration approved a generic substitute (produced by a nonpublicly traded firm) for a Merck product, Aldemet, a popular drug for the treatment of high blood pressure. Merck's stock fell 4½ point on the day of the announcement, a negative return of 5.1% for one day. This event, which was not directly related to legislative activity about the 1984 Act, provides some preliminary evidence that an event that increases the probability of generic competition is potentially significant, even to a large diversified firm.
5. We also estimated a Beta coefficient for each portfolio using daily returns from the comparison period. The estimated Beta was .63 for generic firms and .88 for brand-name firms (each statistically significant at the 1% level), indicating that these firms had relatively low levels of systematic risk. We did not risk adjust our returns because of the well-known measurement problems with Betas and the unlikelihood of risk adjusted returns affecting any results when daily data is analyzed.
 6. The t-statistic is distributed Student-t under the assumption that portfolio daily returns are independent, identically distributed, and normal. Where the sample size is large, as here, the test statistic is approximately normal. See Dann (1981), Fama (1976), and Brown and Warner (1985) for a discussion of this test and evidence about distributions of daily returns.
 7. For a discussion of this test, see Dann (1981).
 8. Whether the bill benefited consumers is unresolved by our analysis. The expectation that the generic industry would become more profitable does not necessarily imply that consumers would be expected to gain. Consumer interest groups lobbied for the bill in Congress, presumably because they expected greater availability of generic substitutes to result in savings for consumers. However, welfare implications for consumers hinge on the acceptance by consumers of generic versions of brand-name drugs and on the price response by brand-name producers. If consumers are reluctant to purchase generic drugs, perhaps due to the cost of acquiring information about their quality, and brand-name firms *increase* their prices in response to generic competition then consumers in the aggregate may suffer a welfare loss. See Leffler (1981) for a discussion of the issues involved in new product entry to drug markets.

References

- Brown, S. and J. Warner, 1980, Measuring security price performance, *Journal of Financial Economics*, 205-258.
- Brown, S. and J. Warner, 1985, Using daily stock returns: the case of event studies, *Journal of Financial Economics*, 14, 3-31.
- Congressional Quarterly, Inc., *Congressional Quarterly Weekly Report*, various issues from 1984.
- Dann, L. Y., 1981, Common stock repurchases: an analysis of returns to bondholders and stock holders, *Journal of Financial Economics* 9, 113-118.
- Fama, E. F., 1976, *Foundations of Finance* (Basic Books, New York).
- Harris, Richard, 1964, *The Real Voice*. (MacMillan, New York).
- Leffler, K., The economics of prescription drug advertising, *Journal of Law and Economics* April 1981, 45-74.
- Leftwich, R., 1981, Evidence on the impact of mandatory changes in accounting principles on corporate loan agreements, *Journal of Accounting and Economics* 3, 3-36.
- Schwert, G., 1977, Public regulation of national securities exchanges: a test of the capture hypothesis, *Bell Journal of Economics* 8, 128-150.
- Schwert, G., 1981, Using financial data to measure effects of regulation, *Journal of Law and Economics* 24, 121-158.