Product Liability Litigation:
An Issue of Merck and Lawsuits Over Vioxx
(The Short Version)

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Last working version, final version published in:
Applied Financial Economics December, Vol. 20, Is. 24, 1867-1878

ABSTRACT

Merck & Co., Inc. pulled Vioxx, a $2.5 billon a year nonsteroidal anti-inflammatory drug, off the shelf in September 2004. The removal followed a study that was published reporting Vioxx increased the risk of cardiovascular events after long-term use. In the years since then, many lawsuits have been filed against Merck. This paper examines the incentive to recall a product and the effects of Merck pulling Vioxx from the shelves. Using the market's expected internal rate of return for Merck, I calculate the expected profits from future Vioxx sales. I then use data on financial effects to show how the market value of Merck reflects their probability of winning legal cases concerning Vioxx.

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I. INTRODUCTION

Merck and Co., Inc. withdrew Vioxx from the market in September 2004 after a study was published stating Vioxx increased the risk of cardiovascular events after long-term use.[1] There have been many legal cases from Vioxx patients that have affected Merck since the drug's removal from the market. This study uses an event-study format to find the market effects of the removal of Vioxx from the shelves. I observe that the market reacted completely and immediately to the announcement of Merck's decision, along with all other news announcements concerning Merck. Because the market reacted efficiently, the change in the market value of Merck reflects the total damages expected to occur. This information allows the analysis of the withdrawal decision of Merck and the ability to calculate the probability of a Merck victory in the courtroom by backing out total expected costs of the litigation from the data.

The decrease in market value to Merck the day they withdrew Vioxx was $26.8 billion at the market close on September 30, 2004. This includes expected litigation costs as well as direct costs for the recall including shipping and notification fees. Furthermore, a large portion of the loss results from expected profits that were imbedded in the stock price. When Vioxx was withdrawn, Merck had approximately nine more years of patent life left on a drug selling $2.5 billion a year. To accurately find the total expected profits it is necessary to solve the market's expected internal rate of return for Merck.

This study analyzes the timing of the withdrawal and evaluates whether it was a profit-maximizing decision. I also show how the probability of a successful Merck lawsuit changes as new information becomes available. In section two, I look at the incentives to withdraw the drug, and what the timing of the withdrawal means. Section three describes Vioxx and has a brief timeline of Merck's history. Section four discusses the data and details an event study showing the effects of the four main events:

Event One – Merck removes Vioxx from the shelf.
Event Two – *The Wall Street Journal* reports that greater heart risk was known by executives.
Event Three – Merck loses part of their patent rights on Fosamax.
Event Four – FDA issues a release supporting Cox-2 inhibitors

In section five, I use an analysis of internal rate of return, along with the information obtained from the Fosamax patent loss, to estimate the loss in expected profits due to the Vioxx withdrawal. Using these events, I show how they explain the change in probability of Merck winning lawsuits filed against them concerning the drug Vioxx in section six. The last section concludes.

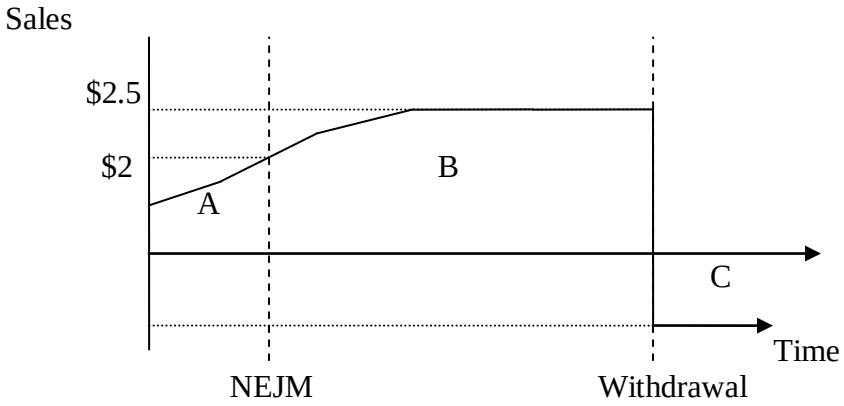
[1] Cardiovascular events are: myocardial infraction (heart attack), unstable angina, cardiac thrombus (blood clot), resuscitated cardiac arrest, sudden or unexpected death, ischemic stroke, and transient ischemic attacks (transient stroke).

II. MERCK'S TIMING

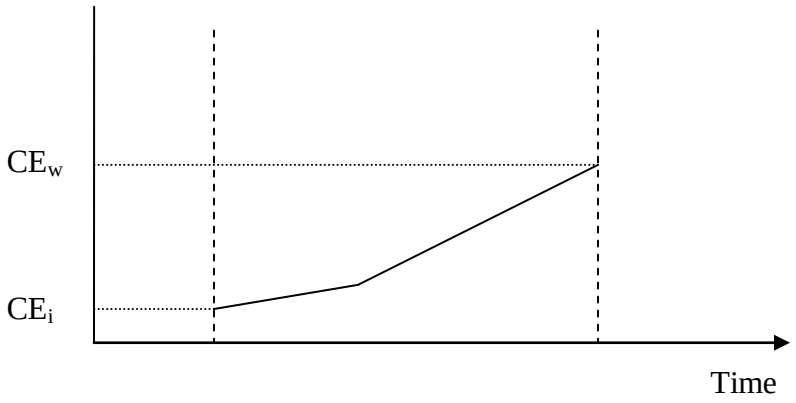
Merck withdrew Vioxx in 2004 when sales were $2.5 billion a year – as opposed to the $2 billion a year sales in 2000. In November of 2000, the *New England Journal of Medicine* published an article stating their VIGOR (Vioxx Gastrointestinal Outcomes Research) study found no significant increase in cardiovascular events. Problems around the article arose when Merck admitted that new data from the same study showed Vioxx did indeed increase the risk of cardiovascular events. Merck claimed that the information was revealed too late in the process to correct the article. If it was too late to re-write the article, there were still two other options available, they could have withdrawn the article (or drug) completely or written a rebuttal in the following issue. From this point forward Merck was making the decision to continue selling the drug, to release the information, or withdraw the drug. Merck choose not to publish this information, making the withdrawal of Vioxx a shock to the market on September 30, 2004.

Figure 1, Timing of Withdrawal

1:



2:



In the above charts (figure 1), NEJM is the date the *New England Journal of Medicine* published results from the VIGOR study, while Withdrawal is September 30, 2004, the date Merck withdrew Vioxx. The top graph (1) shows the yearly sales of Vioxx from the FDA[2] approval date (May 1999) to the withdrawal date (September 2004). After

[2] FDA is the U. S. Food and Drug Administration, more information about the FDA can be found at FDA.gov.

that date, the negative value represents the potential loss in brand name capital caused by Merck's actions. The bottom graph (2) shows the expected number of cardiovascular events caused by the use of Vioxx. Cardiovascular events increase over time; longer usage causes increased risk. The graph shows no risk up to the point of the NEJM article, because up to that point, no risk was known.[3]

Section A, the area below the profit line before the NEJM publication (in part 1 of figure 1), shows the profits that Merck made from selling Vioxx before any knowledge of cardiovascular events (CE) were known. Because CE became known to Merck at the point of the NEJM, Merck had the choice to continue to market the drug or retract the publication and withdraw the drug at that time. When Merck found that Vioxx caused an increase in CE, there were an initial number of people already affected by the drug (CE_i), and the number of events continued to increase until the drug was withdrawn from the market (CE_w). As you can see with part 2 of figure 1, as Merck continues to sell Vioxx, the number of cases of CE increase.

To determine why Merck waited to withdraw Vioxx until 2004, it is necessarily to compare the profits they received by keeping the drug on the market against the costs of doing so. To look at those numbers, I compare area B's present value to area C's present value. Area B is the profit between the NEJM and the Withdrawal date. Area C is the loss in brand name capital after the withdrawal, along with all legal costs incurred, or expected to occur, at the time of the withdrawal.

Because quality of a drug is hard to signal, companies try to signal the quality of their product through investments in brand names. Klein and Leffler (1981) argue that a company's investment in brand names and trademarks provide implicit guarantees to consumers of quality products. The idea that brand names are a quality assurance device is supported by Klein, Crawford, and Alchian (1978), Jarrell and Peltzman (1985), Chalk (1986 and 1987), Benjamin and Mitchell (1989) and Mitchell and Maloney (1989). The reason for establishing brand names is that it is not possible for companies to repeatedly fool their consumers about the quality of a product. Although a consumer could be fooled once, they would not be fooled again, and thus the investment in the brand name would be lost. It was this loss in brand name capital that Merck risked by keeping Vioxx on the market.

[3] It is important to note that when drug companies perform statistical analyses, there is a lag between people taking the drug and when they begin to show side effects. An example of the way in which more information becomes available over time is available in the graph in appendix A, Figure A, found at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1151271.

III WHAT IS VIOXX?

Vioxx (rofecoxib) is a prescription medicine that is a Cox-2 (cyclooxygenase-2) selective inhibitor, nonsteroidal anti-inflammatory drug (NSAID). It is used to relieve the pain and inflammation of osteoarthritis and rheumatoid arthritis in adults and is also used to manage short-term pain and treat menstrual pain and migraine headaches. The largest competitors to Vioxx are Pfizer's Celebrex and Bextra and Schering-Plough's Remicade.[4] Alternatives to these Cox-2 selective inhibitors (Vioxx, Bextra, Celebrex and Remicade) are nonselective inhibitors, such as naproxen and ibuprofen.[5]

Vioxx was launched in the United States in 1999 and has been marketed in more than 80 countries. In some countries, the product is marketed under the trademark Ceoxx. Worldwide sales of Vioxx were $2.5 billion in 2003. At that time, Vioxx was the third largest seller within Merck, following Zocor and Fosamax. This represented 11 percent of the $22.5 billion of total sales for Merck in 2003.

On September 30, 2004, Merck voluntarily withdrew Vioxx from sale. This came after another study, which was a three-year study called APPROVe (Adenomatous Polyp Prevention Vioxx), was conducted on the drug concluding that subjects taking 25 mg of Vioxx had a higher chance of cardiovascular events, such as heart attack and stroke, than those taking a placebo. The increased health risks were occurring 18 months after the Vioxx treatment started.[6]

"Merck has always believed that prospective, randomized, controlled clinical trials are the best way to evaluate the safety of medicines. APPROVe is precisely this type of study – and it has provided us with new data on the cardiovascular profile of Vioxx," said Peter S. Kim, Ph.D., president of Merck Research Laboratories. "While the cause of these results is uncertain at this time, they suggest an increased risk of confirmed cardiovascular events beginning after 18 months of continuous therapy. While we recognize that Vioxx benefited many patients, we believe [the removal of Vioxx from the market] is appropriate."[7]

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[4] Bextra has also been removed from the market.

[5] Examples of these are Advil and Motrin (ibuprofen) and Aleve (naproxen). Note: Tylenol (acetaminophen) is not considered a NSAID. Other Cox-2 selective inhibitors that came later are Merck's Arcoxia and Novartis' Prexige. A detailed explanation of Vioxx and Cox-2 inhibitors can be found in Appendix A of a longer draft of this paper (found at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1151271).

[6] APPROVe was a multi-center, randomized, placebo-controlled, double-blind study to determine the effect of 156 weeks (three years) of treatment with Vioxx on the recurrence of neoplastic polyps of the large bowel in patients with a history of colorectal adenoma. The trial enrolled 2,600 patients and compared Vioxx 25 mg to a placebo. The trial began enrollment in 2000.

[7] From the "Statement Issued by Dr. Peter S. Kim at the FDA Advisory Committee Meeting" on February 17, 2005.

Selective Time Line of Merck[8]

May 20, 1999	FDA approves Vioxx. (Closing price of Merck: $72.25, which is a one-day increase of 2.48%)
Nov. 23, 2000	VIGOR, which was designed to find the side effects of Vioxx, such as stomach ulcers and bleeding, is published in *The New England Journal of Medicine*.
Apr. 11, 2002	Merck revises the Vioxx label to include precautions about cardiovascular risk cited in the VIGOR trial.[9]
Sept. 30, 2004	Merck voluntarily removes Vioxx from the shelves. (Event One)
Nov. 1, 2004	*The Wall Street Journal* reports that Merck executives were worried in the mid-to-late 1990's that Vioxx would show greater heart risk than cheaper painkillers. (Event Two)
Jan. 28, 2005	The US Court of Appeals in Washington rules that the company will lose its patent on the osteoporosis drug Fosamax by 2008. (Event Three)
Feb 18, 2005	The FDA releases an announcement saying they believe that the Cox-2 inhibitors' benefits outweigh the increased chance of a cardiovascular event caused by the drugs. (Event Four)

IV DATA AND METHODOLOGY

For this study, I use stock market data on the daily returns for fifteen stocks in the drug industry and two proxies for the market for one year before and after each event date. The proxies used are the Value-Weighted Index (VWI, value weighted stocks from NYSE, AMEX, and NASDAQ stock markets) and the Standard and Poor's 500 index (S&P). The AMEX Pharmaceutical Index (API, ticker DRG) includes the following fifteen stocks, which are the pharmaceutical stocks analyzed in this paper.[10]

[8] A detailed timeline can be found in the longer working paper at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1151271

[9] The VIGOR study found that of the 4047 patients taking rofecoxib, 111 had cardiovascular events (2.7%), while of the 4029 patients taking naproxen 50 had cardiovascular events (1.2%). This shows patients taking Vioxx had 2.2 times greater chance of having a cardiovascular event than patients taking naproxen. This is a RR (relative risk) of 2.22 and a RD (risk difference) of 44%, found in Mukherjee, Nissen, Topol (2001).

[10] In 2006, Merck was the seventh largest company by market capitalization in the API, but before the withdrawal, Merck was fifth largest in the API and the second largest in terms of drug sales.

Table 1 – Drugs in the API (AMEX Pharmaceutical Index):

Merck & Co	MRK
Pfizer, Inc	PFE
Johnson & Johnson	JNJ
GlaxoSmithKline plc Adr	GSK
Sanofi-Aventis Ads	SNY
Amgen Inc	AMGN
AstraZeneca Ads	AZN
Abbott Laboratories	ABT

Wyeth	WYE
Lilly (eli)	LLY
Bristol-Myers Squibb	BMY
Schering-Plough	SGP
Teva Pharm Indus Adr	TEVA
Forest Labs	FRX
King Pharmaceuticals	KG

I use daily close prices from the CRSP dataset (the Center for Research in Security Prices) and daily holding period returns. These are used to find the movement of stock prices as well as movement relative to the market.

Event Study

Following event-study methodology, I use a zero-one dummy variable to see if there is evidence of abnormal stock movements during a given event window.

$$R_t = \alpha + \beta R_{mt} + \gamma D_t + \varepsilon_t \qquad (1)$$

I regress the daily stock price returns on the market returns. R_t is the return to Merck (or the other drug stocks in the API) at time *t*, and R_{mt} is the market's return at the same date. D_t is a dummy variable that will take the value of one during the event window and zero the rest of the time. This methodology directly tests for any market effects to Merck, or any of the other companies, during the events in this study. Any significant effect on the term γ shows an abnormal return during that event window. Because γ is the parameter of interest, I only report the coefficient and t-statistic on these, and not the α and β which show Merck's average movement with the rest of the market.

The null hypothesis on γ is that the stock has no abnormal return over the event window. If γ is statistically different from 0, then the market had a reaction to the event; if γ is not statistically different from 0, the event had no effect on that stock's price. To determine whether all information is captured the day of the event, or is dispersed over a multiple-day period, I use event-study windows both including the event and excluding the event. This is informative because if γ is significant when the event date is included, but not significant when the event day is excluded, it symbolizes that full information was captured the day of the event.

I use a three-day event study (table 2) four different ways.[11] Two include the event day, the other two do not. Two will test before the event, with and without the event day, and two will test after the event, with and without the event date. The four event-study setups are shown below.

[11] Five, seven, and ten day windows have also been tested with similar results.

Table 2 – Event-study format for three-day event studies. Data is for one year before and after the event date, ten days are show for simplicity.

Date																				
20	21	22	23	24	25	26	27	28	29	30	1	2	3	4	5	6	7	8	9	10
September											October									
0	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0
Merck event one, three-day dummy including day of event																				
0	0	0	0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0
Merck event one, three-day dummy without day of event																				
0	0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0
Merck event one, three-day dummy before the event including event date																				
0	0	0	0	0	0	0	1	1	1	0	0	0	0	0	0	0	0	0	0	0
Merck event one, three-day dummy before the event without event date																				

In addition to the three-day event study I also test one and three months before and after the event (excluding the event date). Significant results after the event reveals if the company is correcting itself from an 'over/under-reaction' (Hirshleifer 2001). Significant results in the months before it shows whether information was acted upon before the announcement was public. I look at the month-long studies with caution, as events in this study tend to occur closely to one another, causing some overlap in the dates analyzed. I conduct the procedure for all fifteen stocks; each regressed against both indices using data for one year before and after the event.[12]

Event One

Merck announced that it would remove Vioxx from the shelf September 30, 2004. It was a surprise announcement, as the only publicly available information about Vioxx was the VIGOR study. This study lead to a label change warning about cardiovascular risk. No other information about the drug was released before the withdrawal, making the announcement a shock to the market.

The announcement was made public after the markets closed September 29, 2004. The first event in this study looks at the effects of Merck's removal of Vioxx from the shelves. To do this, I look at the change from the close of the market on September 29, 2004 to the close of the market on September 30, 2004. I look at the close because although a lot of information was revealed in the opening price on September 30 ($33.40), the change in price to the close that day allows investors to react to all information about the removal.

[12] All these charts have been compiled, please contact author for the regression output.

Table 3 – Event One, the change in price the day Merck removed Vioxx from the shelves, Sept 29, 2004 close to Sept 30, 2004 close.

Market Ticker	Close (9/29/04)	Close (9/30/04)	Percent Change
Merck & Co	45.07	33.00	-26.80%
Pfizer, Inc	30.18	30.60	1.40%
Johnson & Johnson	57.03	56.33	-1.20%
Amgen Inc*	57.99	56.81	-2.00%
Lilly (eli)	61.85	60.05	-2.90%
Schering-Plough	18.50	19.06	3.00%
Teva Pharm Indus Adr*	26.48	25.95	-2.00%
King Pharmaceuticals	12.14	11.94	-1.60%
S & P 500	1114.8	1114.58	-0.02%

* - There was a change in shares outstanding during these days (the shares used are from the later date, as the change was expected). For brevity only companies with an overnight percent change greater than 1% are included.

Table 4 – Event One, the change in market capitalization the day Merck removed Vioxx from the shelves, Sept 29, 2004 close to Sept 30, 2004 close.

Market Ticker	Shares Outstanding In Billions	Market Cap (9/29/04)	Market Cap (9/30/04)	Gain (loss) Sept. 30, 2004 in Billions of Dollars
Merck & Co	2.22	100	73.22	-26.78
Pfizer, Inc	7.55	227.88	231.05	3.17
Johnson & Johnson	2.97	169.27	167.19	-2.08
Amgen Inc*	1.27	73.65	72.15	-1.5
Lilly (eli)	1.13	69.93	67.89	-2.04
			API Sum:	-29.61

* - There was a change in shares outstanding during these days (the shares used are from the later date, as the change was expected). For brevity only companies with a gain (loss) greater than $1 billion are included.

Recall that the largest competitors to Vioxx are Pfizer's Bextra and Celebrex, Schering-Plough's Remicade, and nonselective inhibitors, such as naproxen and ibuprofen. A shift in profits from Vioxx to the competition will occur only if the market believes the danger is an isolated problem with Vioxx and not all Cox-2 selective inhibitors. If this increased chance of cardiovascular events is thought to be caused by all

Cox-2 drugs, then the market will worry that Pfizer and Schering-Plough will also be battling lawsuits in the near future.[13]

Visible from the one-day price changes (table 3), the large drop in Merck brought only a small increase in Pfizer and small losses in Johnson & Johnson, Lilly, and Amgen (table 4). At the time of the withdrawal, Merck had 2.2 billion shares outstanding, meaning that the $12.07 overnight loss to the stock price represents a market value loss to Merck of $26.8 billion. That same day, Pfizer had an increase of $3.2 billion and Schering-Plough had an increase of $0.8 billion, while Johnson & Johnson lost $2.1 billion, Lilly lost $2 billion, and Amgen lost $1.5 billion. The net loss to the fifteen drug stocks that day was $29.6 billion (the overnight loss was $16 billion). This loss represents the total expected loss to these fifteen drug companies due to Merck's decision to remove Vioxx from the shelves. At first thought, the $2.8 billion difference between Merck's loss and the drug industry's loss captures the expected loss to the rest of the industry from the effects of the Cox-2 inhibitors. Before exploring that idea, let's first see if indeed the market captured all information that day.

Table 5 – Event One, three-day study including event day and without event day: September 30, 2004

Company Name	(Event One With Day)		(Event One Without Day)	
	VWI	S&P	VWI	S&P
Merck & Co	-0.081 (7.71)**	-0.081 (7.76)**	0.002 (0.16)	0.001 (0.13)
Pfizer, Inc	0.007 (1.04)	0.007 (1.04)	0.003 (0.43)	0.003 (0.37)
Johnson & Johnson	-0.002 (0.44)	-0.002 (0.49)	0.003 (0.71)	0.003 (0.64)
Amgen Inc	-0.009 (1.12)	-0.009 (1.11)	-0.002 (0.26)	-0.002 (0.3)
Lilly (eli)	-0.007 (0.89)	-0.007 (0.9)	0.006 (0.83)	0.006 (0.79)
Schering-Plough	-0.006 (0.71)	-0.006 (0.71)	-0.015 (1.87)	-0.015 (1.93)

* significant at 5%; ** significant at 1%, Absolute value of t statistics in parentheses. Select list shown. No other pharmaceutical companies have a significant impact. A full list can be found at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1151271.

Seen in the regression output above (table 5), Merck is significant when the event day is included, but not significant when the event day is not included. Merck is also the only company that moves statistically different from the market, showing that all information about the withdrawal occurred the day of the event and that Merck is the only company that was significantly affected by the event. Results hold when looking at the three days leading up to the event. This event study was also done for one and three

[13] Evidence later revealed that all Cox-2 selective drugs have risks. Companies with this type of drug are dealing with similar lawsuits and have had to change their labels to include warnings of heart risk.

months before and after the event.[14] This reveals two pieces of information. First the day of the event captured all information and second, there is no evidence of insider trading.

Although Pfizer and Schering-Plough are the two largest competitors, neither company had a significant change in price over the sample period (nor are any companies other than Merck). This shows that their movement is not abnormal from the market movements; therefore, their gains that day were not necessarily due to the Vioxx announcement. This can occur because there are two contradictory pressures on the prices of Vioxx's competitors. One is that they will increase sales making up for Vioxx's lost sales, while the other is the chance that all Cox-2 inhibitors could increase cardiovascular events. Because of this, the price changes expected to Pfizer and Shering-Plough are ambiguous.

Other Events

The same event-study format is used for all four of the events in this study. The effects of the first event, when Vioxx was withdrawn from market, were fully captured the day of the event and the same was found with the other three events as well. The second event occurred while the markets were closed, while the other events all occurred while the market was open. I compare the one-day price change to see what effect that event had on Merck's market capitalization.

The second event was when the *Wall Street Journal* published an article claiming that Merck executives had knowledge of the increased risk of cardiovascular events well before they withdrew the drug. Because this information can be used against Merck in the legal cases, the drop in Merck's value will reflect a decrease in Merck's ability to win cases. This event caused Merck's stock price to decrease by 9.7 percent (or $6.72 billion).

The third event had no direct effects on the lawsuits filed against Vioxx, but can be used as a proxy to estimate the profit loss from Vioxx's expected sales. This event marks when Merck lost the last ten years of patent life of Fosamax, their second-largest-selling drug. Teva Pharmaceuticals challenged Merck for patent infringement, and the US Court of Appeals voted that Merck infringed on the patent. Merck lost the rights for an exclusive patent to Fosamax in February 2008, when it was initially set to expire in February 2018. [15]

The last event (event four) was on February 18, 2005 when a FDA panel voted to allow sales of Cox-2 inhibitors, despite their increased risk of cardiovascular events. They voted in favor of Celebrex (31-1), Bextra (17-13), and Vioxx (17-15). The event has a direct effect on the market's expectations of Merck's ability to win lawsuits; they are expected to win more cases because the FDA supports the sale of their drug. Merck increased 13 percent during the day of this announcement (table 6).

[14] For brevity these regressions can be found online at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1151271, in a longer draft of the paper.

[15] Fosamax (alendronate) is a once–a-week drug used to treat osteoporosis in women after menopause and to reduce the chances of having a hip or spinal fracture. Treatment has been shown to increase the bone mass in both women and men with osteoporosis with as little as three months treatment. Fosamax tablets can be taken as both a treatment and as prevention. Fosamax alters the cycle of bone formation and breakdown in the body, which is called a bisphosphonates.

Table 6 –all four events, the stock price change when the event occurs:

	Withdrawal of Vioxx	*The Wall Street Jorunal* Report	US Court of Appeals ruling	FDA announces support for Cox-2 inhibitors
Event #	One	Two	Three	Four
Date	9/29-30/2004	10/29-11/1/2004	1/27-28/2005	2/17-18/2005
Company	%Δ	%Δ	%Δ	%Δ
Merck & Co	-26.80%	-9.70%	-10.10%	13.00%
Pfizer, Inc	1.40%	-0.50%	-1.30%	6.90%
Johnson & Johnson	-1.20%	0.10%	0.60%	0.10%
Amgen Inc	-2.00%	-2.00%	-0.50%	-0.60%
Lilly (eli)	-2.90%	0.40%	-3.60%	-1.00%
Schering-Plough	3.00%	-2.70%	-0.70%	1.10%
Teva Pharmaceuticals	-2.00%	-3.30%	2.20%	1.80%
King Pharmaceuticals	-1.60%	-2.80%	0.80%	1.70%

The second event increased Merck's aggregate amount lost to $33.5 billion, while the FDA panel vote decreased the total amount back to $25.2 billion. Because event three did not have a direct effect on the Vioxx lawsuits, the $7 billion lost that day was not seen as part of the aggregate loss, but rather a reflection of the present discounted value of a Merck Patent loss of ten years. All of the events in the event study show that Merck moves significantly when the event is included, but insignificantly when the event is not included.

V PATENT LOSS

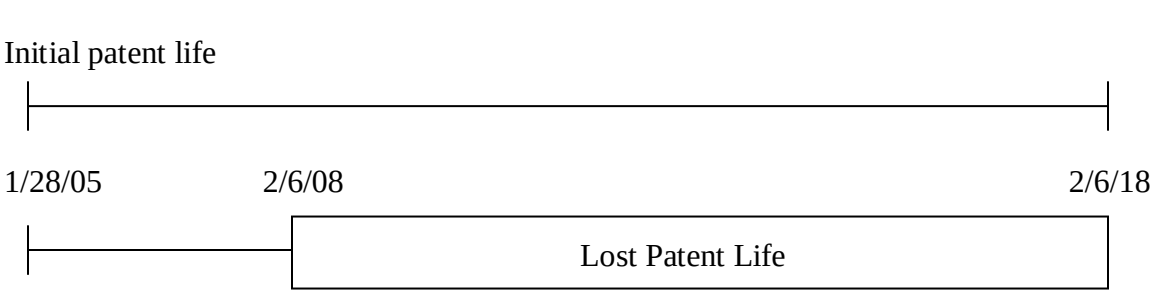
When Merck withdrew Vioxx from the market in 2004, it was selling $2.5 billion a year world wide. The patent on Vioxx was set to expire on December 24, 2013, giving it approximately nine more years of patent life at the time it was removed from the market. This represents nine years of profits, along with any additional sales that could have been made after the patent expired, that Merck will no longer receive.

The third event in the study showed that the market efficiently reflected the lost value to Merck when the patent of Fosamax was set to expire in February 2008, instead of when it was originally set to expire in February 2018.[16] This decision was made by the

[16] This is not actually a loss of patent to Merck, but rather a patent that is "…unenforceable due to findings of invalidity. Merck did not lose 10 years of patent term, regarding the one weekly dosing of Fosamax, rather, their patent was held to be invalid over a prior art reference (that means they cannot exclude others from making, selling or using the subject matter of the patent claims…)." Email correspondence from the USPTO (Mary Till) July 13, 2006. More information about the USPTO can be found USPTO.com.

US Court of Appeals on January 28, 2005. This natural event allows the opportunity to examine the value (or return) to a Merck patent.

Figure 2 Fosamax Patent Loss:



The gap between the initial patent life and the remaining patent life is equal to the change in value found that day, the $7 billion loss on January 28, 2005 (Figure 2). This means the market value of the last ten years of Merck's patent on Fosamax is $7 billion (b). With the years lost in patent and current sales of the drug, an internal rate of return (IRR) can be calculated. To find the IRR, I solve:

$$\$7b = \sum_{0=i}^{13} \left(\frac{profits}{(1+r)^i}\right) - \sum_{0=i}^{3} \left(\frac{profits}{(1+r)^i}\right) \qquad (2)$$

where *profits* represents the expected profits of the drug during each year. Knowing the value of profits allows *r* to be solved for, which gives the IRR.

In "Safety, Patent Issues Weigh on Big Pharma" published in Forbes by Peter Kang on January 28, 2005, the sales of Fosamax were expected to be $3.6 billion.[17] Although the expected sales are $3.6 billion dollars, the market only reacts to profits. In 2005, Merck's gross margin on sales was 76%. This is the best available measure of profit for Merck, or any of its drugs, thus the expected profits are $2.7 billion.

Although Merck lost the patent rights on Fosamax, they can still sell the drug after their patent expires. Research has been conducted to examine what happens to the price of a drug when its patent expires. Because price can change in any direction – up, down, or remain constant – it is the remaining market share of the drug that reveals more information. Grabowski and Vernon (1992) and Caves, Whinston, and Hurwitz (1991) show that in the first year of patent loss a drug's market share will decrease by 20 to 30 percent. The following year's market share falls by 30 to 50 percent, and by the third year out, it will have lost a total of 80 percent of its market share. This assumes the number of generics is greater than 5. With Fosamax sales of $3.2 billion in 2005, ranking it in the top 20 for total sales, it safe to say generics will be entering the market as soon as the patent expires.

Accounting for this information, in addition to equation 2, Merck has an IRR of 13.2%. Because both Fosamax and Vioxx were in the same stage of sales, having gone

[17] The sales in 2005 were actually $3.2 billion, but the day the event occurred, the market expectation was $3.6 billion.

through the growth faze and plateaued, along with similar time left on their patent life, this IRR can be used for both drugs. When Vioxx was withdrawn sales were $2.5 billion a year, of which $2 billion were profits (the gross margin was 80% in 2003). With this IRR the total loss of profits from the withdrawal of Vioxx is $11.5 billion.

A large assumption is made to arrive at this IRR: calculations assume the market expected Merck to win the Fosamax case with certainty, which is risky because the case was known before there was the Fosamax ruling. There was a positive probability that Merck could lose the case before the ruling came out, so it is important to check the sensitivity of this IRR.

Sensitivity of Fosamax patent loss

When Merck lost ten patent years from their drug Fosamax the market capitalization decreased by $7 billion. This loss is due to their loss in the patent, but the loss in profits may be more than the $7 billion if the expected probability of Merck losing the case is greater than zero. I look at the value of the loss in patent for variations in the probability of Merck's victory in this case.

As the expected probability of victory of the Fosamax case falls, the amount lost due to the expected profits on Fosamax increases.

Table 7 – Sensitivity test for Merck's probability of victory on Fosamax patent case:

Expected Probability of Victory	Actual Patent loss Valuation	Change the day of announcement
100%	7.01	7.01
90%	7.78	7.01
80%	8.76	7.01
70%	10.01	7.01
60%	11.68	7.01
50%	14.02	7.01
40%	17.53	7.01
30%	23.37	7.01

The actual loss and change the day of announcement are in billions of dollars

To see how this changes the IRR and the expected loss in profits to Vioxx, I use the numbers from table 7, and equation 2 (controlling for sales off patent). The result is table 8:

Table 8 – Sensitivity test for Merck's probability of victory on Fosamax patent case:

Expected Probability of Victory	Value of Patent	IRR	Loss to Vioxx
100	7.01	13.24%	11.48
90	7.78	11.87%	12.31
80	8.76	10.38%	13.37
75	9.33	9.6%*	14.01
70	10.01	8.74%	14.80
60	11.68	6.90%	16.94
50	14.02	4.80%	20.70
40	17.53	2.34%	31.26
30	23.37	-0.67%	

* - CAPM estimate of IRR for Merck

Using the CAPM (Sharpe 1964) framework, the expected probability of victory was actually 75 percent and not 100 percent, as suggested by my initial calculation of IRR. This means the loss of profits due to the withdrawal of Vioxx was $14.01 billion. Because the probability is unknown to the market, I use the CAPM estimate for the loss in profits, giving an IRR of 9.6%, which is a $14.01 billion loss from the withdrawal.

VI PROBABILITY OF MERCK VICTORY

The market value (MV) of Merck, at any given point in time, is equal to the discounted expected future cash flows (φ) of the company.

$$MV = \sum_{t=0}^{\infty} \varphi_t \tag{3}$$

However there were also costs to the recall.

$$MV = \sum_{t=0}^{\infty} \varphi_t - \theta - \rho - (\omega * \sigma) \tag{4}$$

One of the costs that Merck has to deal with is the direct cost (θ) of the recall. These direct costs, according to Merck's 2005 Annual Report's financial section, are the costs of recalling the previously sold products ($491.6 million), loss of current inventory ($93.2 million), and the costs to undertake the withdrawal ($141.4 million). This leaves the total direct cost of recall at $726.2 million, which is $552.6 million post tax.[18] The markets estimate of θ, the day the announcement, is not available. I assume the market's estimation was close to the after-tax cost of the recall, or $552.6 million.

In addition to the direct legal costs, Merck has to pay fixed legal costs (ρ) and marginal legal costs (ω). Fixed legal costs consist of the initial gathering of data on the

[18] From Merck's 2005 annual report.

case and the creation of a legal team. The marginal cost of litigation will be the lawyer and any other marginal costs representing the firm at each court case, multiplied by the number of cases heard (σ).[19]

The additional, and arguably largest, cost of the recall is the expected payout for all cases lost. The expected total payout will be the payout awarded for any given litigation (ξ) multiplied by the number of cases (δ) and the probability of losing each individual case (γ).[20]

$$E\,[\text{total payout}] = \xi * \delta * \gamma \tag{5}$$

Merck also loses its ability to sell Vioxx, both under patent and after patent expiry. The expected profits ($E[\pi]$) will also be taken out of the market value.

$$MV = \sum_{t=0}^{\infty} \varphi_t - \theta - \rho - (\omega * \sigma) - (\xi * \delta * \gamma) - E[\pi] \tag{6}$$

The change in the market value is equal to the difference in the market value before the recall (MV_b) and the market value after the announcement (MV_a). Thus the change in the market value (Δ MV) is:

$$\Delta \text{ MV} = MV_b - MV_a$$

or

$$\Delta \text{ MV} = \sum_{t=0}^{\infty} \varphi_t - \left(\sum_{t=0}^{\infty} \varphi_t - \theta - \rho - (\omega * \sigma) - (\xi * \delta * \gamma) - E[\pi] \right)$$

$$= \theta + \rho + (\omega * \sigma) + (\xi * \delta * \gamma) + E[\pi] \tag{7}$$

The significant change in market value (Δ MV) was a loss of \$26.8 billion the day Merck recalled Vioxx. In addition, the direct costs were \$552.6 million (m) and the total loss in profits was \$14.01 billion, based on estimates from the previous patent loss section.

$$\$26.8 \text{ b} = 552.6 \text{ m} + \rho + (\omega * \sigma) + (\xi * \delta * \gamma) + \$14.01 \text{ b}$$

Thus,

$$\$12.24 \text{ b} = \rho + (\omega * \sigma) + (\xi * \delta * \gamma) \tag{8}$$

At the time of the withdrawal, it was estimated that Merck would have to face nearly 10,000 cases.

$$\$12.24 \text{ b} = \rho + (\omega * \sigma) + (\gamma * 10{,}000 * \xi) \tag{9}$$

[19] The cost is for the litigation of each lawsuit. Markets tend to react negatively to companies that settle rather then taking it to court. Because of this, and Merck's stated confidence in their ability to win cases, I assume all cases will go to trial.

[20] The probability of loss is used here because Merck will only have to pay a plaintiff (PŁ) if Merck loses the case.

Merck established approximately $675 million in reserve to cover the initial and future legal costs over Vioxx.[21] I assume this is an accurate, and known, estimate at the time of the removal.[22]

$$\rho + (\omega * \sigma) = 675 \text{ m}$$

So,

$$12.24 \text{ b} = 675 \text{ m} + (\xi * 10{,}000 * \gamma) \qquad (10)$$

or

$$11.56 \text{ b} = (\xi * 10{,}000 * \gamma)$$

In order to solve for γ, it is necessary to determine the expected litigation payout (ξ). The first cases heard had large payouts; however payouts tend to fall over time. Also, given that those individuals with the highest risk of cardiovascular events are individuals who are older, the economic value of life will also tend to be lower. Because of these, a good estimate of the litigation cost is $5 million.[23] Thus,

$$11.56 \text{ b} = (5 \text{ m} * 10{,}000 * \gamma) \qquad (11)$$

$$23.1\% = \gamma$$

Using this information, Merck's probability of loss, for any given case, is 23.1 percent, making the probability that Merck will win a case 76.9 percent.

Because the expected payout per case can vary (see sensitivity test below), I look at the relative probability change. As long as the expected payout is the same for all cases, the percentage change will capture the relative change in the expected outcome.

After *The Wall Street Journal* announced that Merck executives knew about the increased cardiovascular events in the mid-to-late 1990's their probability of successful litigation decreased by 13.4 percent (or a 13.5% change in the probability) to 63.5 percent. However, when the FDA announced its support of Cox-2 inhibitors, despite their increased heart risk, Merck's probability of success increased by 16.7 percent (or a 28.5 percent change) to 79.2 percent (Figure 3).

[21] The amount was set at the withdraw date.

[22] They have since increased this amount, but they also increased the expected number of cases simultaneously.

[23] I used $5 million as the expected payout. This number can be debated greatly, and it is hard to tell what the expected payout would be per case when this event occurred. I use this number because we have to look at the economic value of life. And although the people taking these drugs are older, thus have a lower economic value of life, juries will also be handing out punitive damages. With these two elements combined, I believe $5m is a good estimate of the average payout expected. However, because I use the relative probability change as each event occurs, this payout will only affect the initial starting point.

Figure 3 Expected Probability of Merck Victory

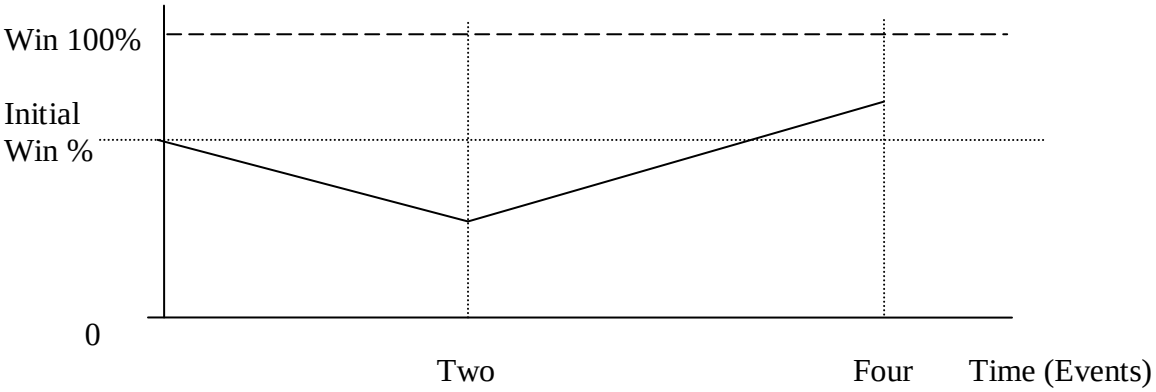


Table 9 – Sensitivity Analysis, what happens when the assumptions change?

	Baseline	Δ E[π]	Δ Legal Cost	Δ Payout
$(1-\gamma)$	76.9%	71.9%	78.7%	90.9%
E[π]	$14.01 billion	$11.0 billion	$14.01 billion	$14.01 billion
Legal Cost	$675 million	$675 million	$1.6 billion	$675 million
Payout	$5 million	$5 million	$5 million	$10 million

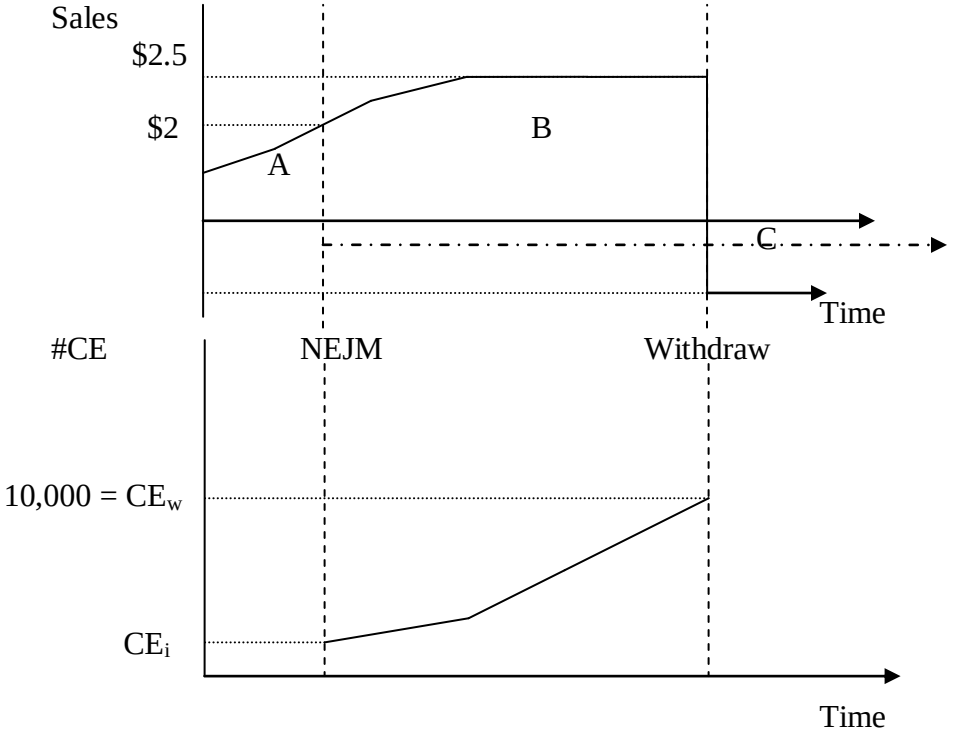
As you can see from table 9 above, the payout per case has the largest effect on changing the probability outcome, which is addressed in table 10. For this reason, I solve for the relative probability change; this gives an accurate estimate of the change in probability given any starting expected probability of victory.

Table 10 – Initial probability outcomes as expected payout changes:

Expected Payout	Probability of Win
$3 million	62%
$5 million	77%
$10 million	88%
$20 million	94%

Should Merck have withdrawn when they did?

Figure 4 Timing of Withdrawal:



Merck was selling $2.5 billion dollars a year of Vioxx and lost $26.8 billion from the announcement. Fourteen billion dollars of that was a loss in expected profits, which left $12.8 billion dollars as the total cost of cases Merck was expected to face. Although it's not possible to separate out, the costs (C) include both the total loss of brand name capital as well as expected litigation costs (Figure 4). If Merck made the right decision, C will be smaller than area B (where area B is the total amount of sales from Vioxx from late 2000 until late 2004). Using the same internal rate of return from earlier to discount forward (9.6%), the value of sales over the period was $13.1 billion. Using a profit margin of 80%, the actual amount made in profits is $10.5 billion. From this information Merck lost more over the time period than they gained in profit, suggesting the choice to keep Vioxx on the market was (ex-post) a poor one. It would have been a better financial choice to have withdrawn the drug when the NEJM was published.

VII CONCLUSIONS

Using an event-study format I show that the market reacts immediately, without any evidence of over/under-reaction, to all four events: the Vioxx withdrawal, *The Wall Street Journal* announcement, the Fosamax patent loss, and the FDA vote. With that information, I am able to calculate the loss to Merck by looking at their market capitalization change when any particular event occurs. I find that when Merck removed Vioxx from the shelves, there was a loss in market value of $26.8 billion. After *The Wall*

Street Journal published an article stating that Merck executives knew that Vioxx increases the risk of cardiovascular events since the mid-to-late 1990's, the market value of Merck fell another $6.7 billion. This gave the company a total loss of $33.5 billion. When Merck initially withdrew Vioxx from the shelves, there was an expected probability of 76.9 percent that Merck would win a lawsuit filed against it, but when the information was released by *The Wall Street Journal*, their probability of winning a lawsuit decreased to 63.5 percent. Even more information was revealed when the FDA announced its support of Cox-2 inhibitors which decreased the total loss of Merck to $25.2 billion, giving them a 79.2 percent probability of victory.

Although the loss in market capitalization is large, the expected loss to the company is not entirely due to legal issues. When Merck removed Vioxx from the shelves it eliminated its third largest drug from the market, at $2.5 billion a year. In removing Vioxx from sale, it also took away a large profit-making drug from the company. To find the loss in value to the company due to profit loss, I use the drug Fosamax to find an internal rate of return for the company. I find that the market gives a 9.6 percent internal rate of return to Merck's drugs, allowing an estimation of profit loss from the removal of Vioxx to reach $14.01 billion.

The change in probability of Merck winning cases can be observed in the market. The probability initially falls with *The Wall Street Journal* report, but increases when the FDA votes in favor of Cox-2 drugs. I find that Merck's decision to withdraw in September 2004, rather than 2000, seems to have been, ex-post, the wrong financial decision. However, there are other possible reasons that Merck may have wanted to keep Vioxx on the market. They could have known the situation was inevitable, and wanted to use their information to acquire companies, through stock purchase, at a stock price that was artificially high. They may have also anticipated not paying out the total amount of the lawsuits. It has been announced that Merck is trying to settle all outstanding lawsuits for $4.85 billion. If this goes through, then this would make the decision to stay on the market the correct one.

WORKS CITED

Benjamin, Daniel K. and Mark L. Mitchell. (1989) "Quality-Assuring Price Premia: Classic Evidence from the Real Thing." Working Paper, *Securities and Exchange Commission*.

Caves, Richard; Whinston, Michael; Hurwitz, Mark. (1991) "Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry". *Brookings Papers on Economic Activity*. 1-66

Chalk, Andrew. (1986) "Market Forces and Commercial Aircraft Safety: The Case of the DC-10". *Economic Inquiry*. January, p 43-60

Chalk, Andrew. (1987) "Market Forces and Commercial Aircraft Safety". *Journal of Industrial Economies*. September, p 61-82

Grabowski, Henry and Vernon, John (1992) "Brand Loyalty, Entry, and Price Competition in Pharmaceuticals after the 1984 Drug Act". *The Journal of Law and Economics*. October. 331-350

Hirshleifer, David. (2001) "Investor Psychology and Asset Pricing". *The Journal of Finance*, Vol. 56, No. 4, Papers and Proceedings of the Sixty-First Annual Meeting of the American Finance Association, New Orleans, Louisiana, January 5-7, pp. 1533-1597

Jarrell, Gregg and Peltzman, Sam (1985) "The Impact of Product Recalls on the Wealth of Sellers". *Journal of Political Economiy* Vol. 93

Klein, Benjamin; Crawford, Robert G; Alchian, Armen A. (1978) "Vertical Integration, Appropriable Rents, and the Competitive Contracting Process". *Journal of Law and Economics*. Vol. 21 October, p 297-326

Klein, Benjamin and Leffler, Keith B. (1981) "The Role of Market Forces in Assuring Contractual Performance". *Journal of Political Economy*. Vol. 81

Mitchell, Mark and Maloney, Michael. (1989) "Crisis in the Cockpit? The Role of Market Forces in Promoting Air Travel Safety". *The Journal of Law and Economics*. October 1989, p 329-355

Mukherjee, Debabrata; Nissen, Steven; and Topol, Eric. (2001) "Risk of Cardiovascular Events Associated With Selective Cox-2 Inhibitors". *Journal of the American Medical Association*. August 22/29, Vol. 286.

Till, Mary. (2006) "Question on Patent Loss". E-mail correspondence. July 12, 2006.