

Bristol Myers Squibb: Patents, Profits, and Public Scrutiny

Abstract

This case discusses challenges faced by Bristol-Myers Squibb during the tenure of former CEO Peter Dolan, including an accounting scandal and a patent protection dispute involving Plavix, a drug that contributes 30% of the company's global revenue.

“All The World's A Stage”

Bob Zito let out a deep breath as he hung up the phone in his office. It was 11:07am on Saturday morning, and the weather was perfect for the first college football game day of the season. He opened his office window to let in the brisk autumn air of September 2, 2006, and tried to relax for the first time in what felt like weeks. His corporate counsel had called to tell him that the U.S. District Court for the Southern District of New York had just granted Bristol-Myers Squibb a preliminary injunction against the Canadian generic drug producer Apotex. Zito leaned back in his chair, thankful for the breathing space. In the past month alone, Apotex's generic version of Bristol-Myers' Plavix had siphoned off almost 75 percent of the \$4-billion annual market for the blockbuster blood thinner. Many pharmacies had already stocked up multiple months' worth of the product, but this injunction would prevent Apotex from shipping any more of the generic until the patent-protection question was resolved.

Zito was grateful for the temporary respite, which he hoped to use to construct and implement a corporate communication strategy to help the embattled pharmaceutical giant. Such a strategy would have to be comprehensive and incredibly detailed, addressing the widely-publicized Apotex negotiation scandal, the potential loss of patent protection (and revenues) for the company's best-selling drug, and the looming dismissal of Bristol-Myers' CEO, while simultaneously steering attention away from the company's past ethical troubles. Zito opened his laptop and checked the time. With a sigh, he resigned himself to the fact that he wasn't likely to make it home in time to watch the game.

The History of Bristol-Myers Squibb

Bristol-Myers Squibb is the leading worldwide provider of anti-cancer therapies, as well as a leader in the discovery and development of innovative treatments to fight heart disease, stroke, and infectious diseases including HIV/AIDS. Its areas of specialization include most of the pharmaceutical spectrum, from oncology to cardiovascular disease to infectious diseases (including HIV/AIDS) and mental illness. The company enjoys a distinguished history: in the early 1960s Bristol-Myers produced its first anti-cancer medicine (still in use today), while the 1980s witnessed Squibb market the first of an important new class of medications, called ACE inhibitors, for the treatment of hypertension. In 1989 these two companies joined forces in one of the largest mergers in corporate history. During the 1990s, Bristol-Myers Squibb brought to

market the first medicine specifically designed for the treatment of HIV/AIDS, as well as a breakthrough therapy “hailed as the most important cancer medication in 20 years.”¹**Bristol-Myers.** In 1887, William McLaren Bristol and John Ripley Myers invested \$5,000 into a failing drug manufacturing firm located in Clinton, New York. The company was officially incorporated on December 13, 1887, and in May 1898 changed its name to the Bristol, Myers Company (a hyphen would replace the comma when the company became a corporation in 1899).

The partners strove to grow the business in a challenging environment, maintaining two rules above all: an insistence on high quality products and the maintenance of the firm’s good financial standing at all costs. With these two priorities in mind, Bristol-Myers became profitable for the first time in 1900, and from 1903 to 1905 saw a tenfold increase in sales. Bristol-Myers was transformed from a regional to a national company, soon to become an international one. With the company’s products being sold in 26 countries, gross profits topped \$1 million for the first time in 1924. At the same time, “the shares held by John Myers’s heirs became available for sale, triggering a series of moves that in 1929 turned Bristol-Myers into a publicly held company, listed on the New York Stock Exchange.”² Subsequent business decisions saw Bristol-Myers take over smaller, well-managed pharmaceutical firms in a strategy of growth through judicious acquisition that has continued to this day.³

Squibb. Edward Robinson Squibb founded his pharmaceutical company in 1858, headquartered in Brooklyn, New York. He dedicated Squibb to the production of “consistently pure medicines”, a cause that claimed his lifelong interest. In 1906, six years after Edward Squibb’s death, Congress passed the Pure Food and Drugs Act. As related in company lore, the law still stands as the triumph of his lifelong crusade for safe, reliable pharmaceutical products.⁴In 1921, Squibb adopted a slogan that reflected the ideals of its founder: "The priceless ingredient in every product is the honor and integrity of its maker." The company enjoyed respectable growth, and the company expanded into South America and Europe. Squibb International was incorporated in 1946, and built manufacturing facilities in Mexico, Italy and Argentina. Squibb researchers made a significant breakthrough in 1975 with the creation of Capoten®, the first of a brand-new class of antihypertensive agents called ACE inhibitors.

Bristol-Myers Squibb (BMS). Bristol-Myers merged with Squibb in 1989, creating a global leader in the health care industry. The merger created what was then the world’s second-largest pharmaceutical enterprise. BMS core products include: Videx (1991), Monopril (1991) and Pravachol (1991, expanded usage granted in 1995 by the FDA), TAXOL Injection (1991), Glucophage (1993), Avapro (1997), Plavix (1997), Excedrin (1998), Sustiva capsules (2001), Coumadin Crystalline (2001), Abilify (2002), Reyataz (2004), Orenicia (2005), EMSAM transdermal (2006), SPRYCEL (2006), and ATRIPLA (2006). Bristol-Myers Squibb received the National Medal of Technology in December 1998, an award widely respected as America’s highest honor for technological innovation. The company received outstanding recognition "for extending and enhancing human life through innovative pharmaceutical research and development, and for redefining the science of clinical study through groundbreaking and hugely complex clinical trials that are recognized models in the industry."⁵BMS attempts to act as a good global corporate citizen and live the ideals of its founders through its outreach programs.

In 1999, the company announced Secure the Future, a \$100 million commitment to advance HIV/AIDS research and community outreach programs in five southern African countries. In 2000, BMS and four other pharmaceutical companies and international agencies joined the UNAIDS "Drug ACCESS Initiative," which aims to make antiretroviral medicines and therapies widely available in African countries that have developed a coherent national AIDS strategy. As part of the program, the company offered to lower the prices of HIV/AIDS medicines in those countries by 90 percent. More recently, Bristol-Myers Squibb took its access efforts a step further, offering HIV/AIDS drugs below cost in Africa. The company is also ensuring that its patents do not prevent inexpensive HIV/AIDS therapy in Africa.⁶BMS had 2005 revenues of approximately \$19 billion, with profits of \$3 billion. This is a -7.6% decrease and 25.6% increase, respectively, on 2004 results.⁷ R&D expenditures in 2005 were \$2.7 billion, up 10% from 2004. This included \$2.5 billion in payments for in-licensing and development programs. The first quarter of 2006 saw \$750 million spent on R&D, up 22% from the previous year.

BMS is determined to retain its position as a leader in drug development. Current strategies include: in-house development and collaboration, the acquisition of smaller dynamic pharmaceutical companies, the divestiture of non-core assets (including the May 2005 sale of BMS' Oncology Therapeutics Network distribution business, as well as the divestiture of the US and Canadian Consumer Medicines business to Novartis).

BMS' forecast for the future is cautiously optimistic. New BMS blockbuster drugs may strengthen the company's financial position. In the first half of 2003 two major drugs were approved: Abilify, an antipsychotic, and Reyataz, the first once-daily protease inhibitor for the treatment of HIV/AIDS. The FDA also granted limited clearance to Erbitux, the sidelined cancer drug that BMS developed in conjunction with ImClone. Analysts at SunTrust Robinson Humphrey estimated that Erbitux sales could peak at more than \$700 million. These promising drugs signal a potential new beginning for the company. Morningstar projects an average revenue growth rate of 3 percent through 2007. However, generic challengers continue to enter the market at a steady pace, and there is the constant threat of competition from the large drug developers (Merck, Novartis, and Pfizer) in BMS's core territories. If the first quarter is a trend indicator, 2006 will be more profitable for BMS: the company reported a 34% increase in first-quarter profit to \$714 million, helped by higher sales of heart and blood-pressure drugs, and a \$200 million gain from the sale of assets. Erbitux sales were \$413 million for the year up 58%. Plavix, Abilify, and Reyataz sales were up 15%, 54% and 68% respectively – definitely a bright spot for the company. Nevertheless, revenues were up only 3% to \$4.7 billion, while the average U.S. pharmaceutical industry revenues rose 7% to \$2.1 billion.⁸ In February 2001, *Fortune* magazine named Bristol-Myers Squibb "America's Most Admired Pharmaceutical Company." One month later, Peter R. Dolan, a 13-year veteran of the company, succeeded Charles A. Heimbold, Jr., as chief executive officer.⁹

Peter R. Dolan

Peter R. Dolan was born on January 6, 1956, in Salem, Massachusetts. He received his BA from

Tufts University in 1978, and his MBA from Dartmouth College in 1980. He began his career at General Foods from 1983-1987, but by 1988 had transferred to Bristol-Myers Squibb as Vice-President of Marketing.

Dolan served as president of the Mead Johnson Nutritional Group from 1995-1996. Under his direction, the company opened related manufacturing facilities in four countries and international sales climbed to 40 percent of the corporation's revenue by 1996.

Dolan was named CEO in February 2001 and made Chairman of the Board in 2002. He was infamous within the company for setting “Big Hairy Audacious Goals”, such as his 2001 promise to double BMS revenues within five years. He would come to regret that particular statement, as 2002 sales totaled \$18.1 billion, down 1% from 2000.

Robert Zito and BMS Corporate Communications

Robert T. Zito joined Bristol-Myers Squibb as Chief Communications Officer (CCO) in June 2004. Zito received his BA in English from Fairfield University and is a 1998 Ellis Island Medal of Honor recipient.¹⁰ He is responsible for implementing external and internal communications initiatives, as well as developing a long-term corporate strategic communications plan for BMS. He oversees all aspects of communication and public relations for the company, including corporate brand management, advertising, media relations, employee and policy communications, executive prep and communications, creative services and community affairs.¹¹

Before accepting his current position with BMS, Zito was the EVP of Communications at the New York Stock Exchange, where he was responsible for developing and building the NYSE’s brand. He has also worked as VP of Corporate Communications at Sony (North America), VP of CN Communications, and as an account executive at the public relations firm of Hill and Knowlton.¹²

What is Plavix?

Plavix was a FDA-approved anti-platelet daily medication that reduced the risk of heart attack, stroke or vascular death in patients with established peripheral arterial disease (PAD).¹³ The drug had also been shown to reduce occurrences of peripheral artery disease and stroke. Plavix was brought to market through a partnership between Bristol-Myers Squibb and French drug maker Sanofi-Aventis, the world’s third largest pharmaceutical company and the largest in Europe.

Plavix Function

Clot formation is a natural defense mechanism of the body that protects excessive bleeding in the case of an injury. When the skin is cut, particles in human blood called platelets bond together to form a clot. Clot formation can also be triggered by the rupture of plaque, which is a buildup of cholesterol and other materials in the walls of the arteries. When platelets clump together on

or near the plaque, they can form a clot that may limit or completely stop the flow of blood to various parts of the body. If a clot forms in an artery leading to the heart, heart-related chest pain or a heart attack may occur. If a clot forms in an artery leading to the brain, it can cause a stroke. Plavix prevents platelets from sticking together and forming clots, which keeps blood flowing and helps protect against future heart attack or stroke.

Plavix Revenues

Plavix 2005 global sales were \$5.9-billion, up more than 15% from 2004.¹⁴ According to Pharmaceutical Business Revenue and Data Monitor, sales were expected to peak at \$6-billion in 2011, when the Plavix patent was expected to expire. Bristol-Myers Squibb total 2005 revenues were \$19.2-billion; Plavix sales thus represented 30% of the company's total revenues.

Pharmaceutical Industry

The global pharmaceutical sales market in 2005 was \$565-billion, growing at an estimated 7% per year.¹⁵ Generic competition is currently the principal threat to branded drug makers. Between 2006 and 2010, at least 70 innovative brand-name drugs are expected to go off-patent in the United States. 19 of these drugs are "blockbusters," meaning that they have annual sales of more than \$1-billion. This accounts for \$45-billion in revenues, or roughly 8% of the global market.¹⁶

Generic Drug Competition

A generic drug may be comparable to a brand name drug in dosage form, strength, performance characteristics and intended use. Brand name drug patents are usually protected for 20 years from the date of the patent submission.¹⁷ The patent protects the drug manufacturer that incurred the costs of researching, developing and marketing the drug. Once a drug's patent has expired, any other drug company may release a generic version. Generic drugs tend to be drastically cheaper than brand-name drugs, with prices ranging from 20-70 percent of the brand-name version.

FDA Approval: Brand Name and Generic Drugs

All new drugs must be approved for human use by the United State Food and Drug Administration. The approval process includes laboratory, animal and human testing. Human testing is completed in three phases and may include data collected from thousands of patients. It is not uncommon for a drug to take as long as eight years to be approved.¹⁸ Generic drugs must also obtain FDA approval. However, generic drugs may take advantage of an abbreviated process wherein they do not have to submit the generic drug for animal or human tests, as the drug's safety and effectiveness were already established in the initial clinical trials.

Accounting Irregularities: Dolan's Troubles Begin

On March 10, 2003, just over two years after Dolan's took over as CEO, Bristol-Myers Squibb announced that it had overstated sales by \$2.5-billion over a three-year period. The earnings overstatement was due to Bristol-Myers employing "channel surfing" scheme in which the company used financial incentives that rewarded wholesalers for buying and holding larger prescription drug inventories. The scheme resulted in wholesalers acquiring almost \$2-billion in excess inventories. Bristol-Myers eventually admitted that the incentives were designed to help the company meet its quarterly sales projections.¹⁹

Bristol's accounting troubles continued when former CFO Frederick S. Schiff and former executive vice president Richard J. Lane were indicted and charged with securities fraud for artificially inflating sales through the channel surfing scheme. Schiff and Lane were also charged with signing inaccurate SEC filings and purposely misleading investors through press releases and conference calls that masked the increasing wholesaler drug inventories. Both were asked to leave in 2001.

At the end of the scandal, Bristol-Myers Squibb reduced net sales figures by \$1.4-billion for 2001, \$678-million for 2000, and \$376-million for 1999.²⁰ A total of \$839 million was paid to shareholders harmed by BMS' fraudulent conduct.²¹ The Department of Justice agreed to dismiss criminal complaints against the company if it cooperated with the legal investigation, admitted wrongdoing, and adopted strict internal compliance controls.

Plavix Generic Drug Agreement

In July 2006, BMS announced that the U.S. Justice Department was investigating the company's March 2006 agreement with Canadian generic drug manufacturer Apotex. The agreement was intended to delay the Apotex's release of an inexpensive generic version of Plavix. The investigation led FBI agents to search Dolan's office in New York the day before the announcement was made.

Under the terms of Bristol-Myers' ill-conceived agreement with Apotex, BMS offered Apotex \$40 million to halt production of the generic Plavix until June 1, 2011. This date was five months before the Plavix patent was set to expire.²² Bristol-Myers also agreed not to release its own non-branded Plavix until six months after Apotex began to sell its generic version of the blood thinner. When asked to approve the agreement, the U.S. Federal Trade Commission and state Attorneys General objected to these provisions. They labeled the Bristol-Myers concession anti-competitive because it assured that Apotex would be the sole market vendor of cheap, generic Plavix for at least six months.²³ Bristol-Myers Squibb agreed to remove the anti-competitive provision from the contract. Nevertheless, the Federal Trade Commission began questioning Apotex regarding the revised agreement. During these questioning sessions, Apotex told the federal regulators that Bristol-Myers had given Apotex private assurance that it would not release a general version of Plavix to the market.²⁴ These statements, which contradicted statements made by Bristol-Myers to the FTC, led the Federal Trade Commission to pursue a criminal investigation into the rejected contract.

When the agreement did not receive approval, Apotex quickly introduced its generic version of Plavix (which had obtained FDA approval earlier that year), and the drug became universally available in August 2006. While Plavix cost about \$4 per dose in the US, Apotex priced the generic version at an estimated 10 to 20 percent discount.²⁵ Apotex's generic Plavix quickly gained 75% market share of new prescriptions.²⁶ Within the month, Bristol-Myers Squibb was able to get a United States District Judge to order a temporary injunction halting further sales of the generic Plavix. However, the judge did not order a recall of generic Plavix. The District Court set January 22, 2007 as the start of the patent trial. The Court required Bristol-Myers and Sanofi-Aventis (BMS' Plavix development partner) to post a \$400-million bond to the court. The bond provided security to Apotex in the event that the Court ruled that Apotex had the legal right to sell its generic version of Plavix.

After only one month of generic Plavix competition, BMS was forced to reduce its 2006 earnings forecast by 25%. Bristol-Myers's reduced per share earnings estimate was below the company dividend, meaning that Bristol would be paying more to shareholders than it actually earned.²⁷ Citing the threat of generic competition, Moody's Investor Services downgraded Bristol-Myers' debt from A1 to A2. The BMS Board stated that it still intended to declare its regular 28-cents per share quarterly dividend, but some analysts predicted that the lost Plavix sales would force Bristol-Myers to slash the dividend in half. In sum, over the five years of Dolan's tenure, the stock price of Bristol-Myers Squibb had declined by over 60%.²⁸

The Board Decides to Act

On September 12, 2006, CEO Peter Dolan and General Counsel Richard K. Willard were dismissed by the Bristol-Myers board. Dolan was replaced on an interim basis by James M. Cornelius, a Bristol-Myers director and former executive at Guidant Corporation. The board maintained that it would search both internally and externally for a permanent replacement, but Dolan's firing increased Wall Street speculation that Bristol-Myers would be acquired.

The Uncertain Path Ahead for Bristol-Myers Squibb

As Dolan's rocky tenure came to a close, CCO Zito wondered what he needed to communicate to stakeholders to overcome Bristol-Myers' poor financial projections questionable practices over the past five years. With the threat of acquisition looming larger, Zito began to brainstorm, crafting a communications strategy that would help retain investor, employee and customer confidence in the pharmaceutical giant.

With the January 22, 2007 patent trial date approaching rapidly, Zito also knew he had to consider if and how corporate communication could help Bristol-Myers win its patent dispute with Apotex. If Bristol-Myers lost the legal case, it risked losing 30% of its revenues and would forfeit its share of the \$400 million bond set by the U.S. District Court.

Discussion Questions

1. What are the critical issues facing Bristol-Myers Squibb in this case?
2. Who are the key stakeholders in this case? How would a patent case verdict for or against Bristol-Myers Squibb affect the stakeholders?
3. What messages does Zito need to communicate to the stakeholder groups? How should he deliver his message to them?
4. Does Bristol-Myers Squibb need to retain an external firm to help it craft an effective public response to Dolan's firing or the patent dispute?
5. What other actions (if any) should the board take in response to the accounting and patent protection scandals?
6. What mistakes did Dolan make while negotiating with Apotex? What else could he have done to protect the Plavix patent?
7. Can corporate communication play a role in helping Bristol-Myers Squibb win the upcoming patent protection trial? What can Zito and his team do?

¹BMS Official Site: Company History. Last updated: August 2006. Website: <http://www.bms.com/aboutbms/content/data/ourhis.html>

² *Ibid.*

³ *Ibid.*

⁴ *Ibid.*

⁵ *Ibid.*

⁶ Paraphrased from: Bristol-Myers Squibb Homepage. Last updated: August 2006. Website: <http://www.bms.com/aboutbms/content/data/ourhis.html>

⁷ CNN Money.com, Fortune 500 2006 rankings

⁸ Website: <http://www.contractpharma.com/articles/2006/07/bristol-myers-squibb.php>

⁹ Quote from: BMS Official Site: Company History. Last updated: August 2006. Website: <http://www.bms.com/aboutbms/content/data/ourhis.html>

¹⁰ Biography of Robert Zito. Last updated 2006. Website: www.bms.com/news/pressroom/content/data/zito.pdf

¹¹ Biography of Robert Zito. Last updated 2006. Website: www.bms.com/news/pressroom/content/data/zito.pdf

¹² Adapted from *Ibid.*

¹³ Plavix Website (Bristol Myers Squibb). Last updated: 2006. Website: www.plavix.com

¹⁴ S&P Market Insight: Pharmaceuticals Industry Survey

¹⁵ *Ibid.*

¹⁶ Medco Health Solutions Inc. & S&P Market Insight

¹⁷ Generic Drugs: Questions & Answers. Website: http://www.fda.gov/cder/consumerinfo/generics_q&a.htm.

¹⁸ "Solving The Drug Patent Problem." Last updated: May 2, 2002. Website: <http://www.forbes.com/2002/05/02/0502patents.html>.

¹⁹ "Bitter Pill? Bristol-Myers Squibb Off by \$900 Million." Last updated: March 11, 2003. Website: <http://www.cfo.com/printable/article.cfm/3008682?f=options>

²⁰ *Ibid.*

²¹ "Bristol's Former CFO Indicted." Last updated: June 17, 2005. Website: <http://www.cfo.com/article.cfm/4096065?f=related>

²² "Bristol stock hurt by generic Plavix." Last updated: August 8, 2006. Website: <http://money.cnn.com/2006/08/08/news/companies/plavix/index.htm?postversion=2006080812>

²³ "Bristol-Myers Probed For Deceiving U.S. Regulators." Last updated: July 29, 2006. Website: <http://www.investmentsmagazine.com/ManageArticle.asp?C=160&A=17351>

Ibid.

²⁵ “Battle over a Blood Thinner Goes to Court.” Last updated: August 18, 2006. Website:
<http://www.npr.org/templates/story/story.php?storyId=5673477>

²⁶ “Bristol-Myers Ousts CEO Dolan, Willard.” Last updated: September 12, 2006. Website:
<http://www.wtopnews.com/?nid=111&pid=0&sid=909672&page=2>

²⁷ “Bristol-Myers Chief Fired Over Patent Dispute.” Last updated: September 12, 2006.
Website:

<http://www.nytimes.com/2006/09/12/business/13bristolcnd.html?pagewanted=1&ei=5088&en=829899f21a96a8a2&ex=1315713600&partner=rssnyt&emc=rss>

²⁸ “Bristol-Myers CEO Forced Out.” Last updated: September 12, 2006. Website:
http://news.yahoo.com/s/nm/20060912/bs_nm/bristolmyers_dc