The company consulted a lawyer who indicated that products liability lawsuits were probable should there be injuries or adverse health consequences associated with the use of the heaters. Strict liability in tort would in all likelihood be the applicable liability standard, so the company could be held liable even if an injury were due to foreseeable misuse by a consumer. The costs to the company included the cost of liability insurance, legal and court costs, and the management time required by the cases. These costs could be reduced by adding more safety features to the model. The lawyer had investigated the cost of insurance and roughly estimated that insurance costs plus legal fees might be as much as $55 per unit for the lowest priced model and $10 per unit for the safest model given the estimated sales. The lawyer also estimated that the purchasers of the lowest-cost heaters were less likely to file lawsuits in the event of an injury because they were less familiar with the legal process.

The likelihood of an injury associated with a heater was difficult to estimate, but the company's engineers gave a ballpark estimate of one in a million of a manufacturing defect resulting in a death or a permanent disability from a fire. They estimated that the likelihood of a fire death from misuse was approximately five in one hundred thousand with the least expensive model over the life of the heater and four in a million with the most expensive model. The lawyer asked the engineers for estimates associated with each safety feature, but so far they had provided only two estimates. They estimated that adding electric spark ignition to the least expensive model would reduce the probability of a death by 50 percent, whereas electric wick adjustment would reduce the probability of a death by less than 2.5 percent. ■

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Preparation Questions

1. How should California Space Heaters reason about its responsibility for the safety of its heaters and their use?
2. What safety features should be incorporated into the heaters? Should electric spark ignition be incorporated? Electric wick adjustment? What criteria should be used for those decisions?
3. What other actions should be taken in the design or marketing of the heaters?
4. How should prices be set; that is, on what cost basis?

Patent Games: Plavix

In 2001 Apotex, a Canadian manufacturer of generic drugs, filed an application with the U.S. Food and Drug Administration (FDA) to market clopidogrel bisulfate as a generic version of the world's second–best-selling drug, Plavix, an anticlotting drug. Sanofi-Aventis, the French pharmaceutical giant, held a composition of matter patent on Plavix, but Apotex claimed that the 1989 Sanofi patent was invalid because the ingredient clopidogrel bisulfate could be inferred from an earlier 1985 patent that had expired. Sanofi-Aventis argued that the later patent was valid and would not expire until 2012.[51] In 2002 Sanofi-Aventis filed a patent infringement lawsuit in federal court, claiming that the patent provided it with exclusive rights to produce and market Plavix. Plavix was marketed in the United States by Bristol-Myers Squibb, and U.S. sales were $3.5 billion in 2005 with worldwide sales of over $6 billion. Plavix was the best-selling of Bristol-Myers Squibb's drugs and was crucial to the success of the company.

Apotex was a privately held generics producer located in Toronto, Canada, and its CEO, Richard Sherman, was known as an aggressive risk taker. Sherman said, "They say I stalk my prey. I say I don't ever shy away from a fight."[52] He added, "The system is being screwed up by greedy people who see this big pot to be split, and they have no interest in consumers, who get screwed by paying more than they should for medications they need." He referred to the payments that drug makers made to keep generic drugs off the market as "poison pills." Sherman had a net worth of $3.7 billion, according to *Forbes* magazine.

The FDA approved Apotex's version of Plavix in January 2006. The approval allowed Apotex to market the drug at its own risk. That is, if it marketed the drug and lost the patent infringement case, it could be liable for damages. Apotex had invested millions of dollars to construct production facilities and began to produce clopidogrel bisulfate in late 2005.

Bristol-Myers Squibb and Sanofi-Aventis learned that Apotex had built an inventory of clopidogrel bisulfate, and with a trial on the merits of the patent infringement lawsuit scheduled for June 2006, they initiated settlement negotiations with Apotex. On March 21 the three companies reached an agreement granting Apotex the right to market its generic drug in September 2011, eight months before the patent on Plavix would expire.

[51] *Wall Street Journal*, September 2, 2006.

[52] *Ottawa Citizen*, August 19, 2006.

The agreement gave Apotex a six-month period before the companies could offer their own generic. Bristol-Myers Squibb and Sanofi-Aventis also agreed to pay Apotex at least $40 million if the agreement were approved and a $60 million break-up fee if the agreement were rejected on antitrust grounds. In a required disclosure, Sanofi-Aventis and Bristol-Myers Squibb stated that there was a significant risk that the agreement would not receive antitrust approval. The trial on the patent infringement lawsuit was postponed pending approval of the agreement.

Bristol-Myers Squibb was operating under a 2003 consent decree with the Federal Trade Commission (FTC) and state attorneys general pertaining to attempts to delay the entry of generic versions of two of its drugs—Taxol and BuSpar. Under the consent decree the FTC and the state attorneys general had to approve any Bristol-Myers Squibb arrangements that could be anticompetitive. The agreement with Apotex was submitted to the regulators for review. The FTC had expressed opposition to agreements that restricted the introduction of generic drugs. On May 5 the state attorneys general told the three companies that they would not approve the agreement, and the FTC also was said to be opposed. The FTC was reportedly concerned about the break-up fee and the six-month period before Bristol-Myers Squibb and Sanofi-Aventis could begin marketing their own generic drug.

After the agreement was rejected, Bristol-Myers Squibb CEO Peter R. Dolan sent executive vice president Dr. Andrew G. Bodnar to Toronto to negotiate a modified agreement that would satisfy the regulators. The modified agreement was submitted on May 26 to the FTC and state attorneys general. It did not include the six-month period and allowed Apotex to license and manufacture a generic version of Plavix in June 2011.

Apotex said that in addition to the modified agreement submitted to the FTC and the state attorneys general, Bodnar had made two oral agreements with Sherman that had been in the original agreement but were not in the modified agreement. One was that Bristol-Myers Squibb and Sanofi-Aventis would not market its own generic version of Plavix until Apotex's generic had been on the market for six months. The other was that Bristol-Myers Squibb and Sanofi-Aventis would pay Apotex the $60 million break-up if the modified agreement were rejected by the government.

One provision retained in the modified agreement was that Bristol-Myers Squibb and Sanofi-Aventis could not file for an injunction to stop generic sales of clopidogrel until five days after a sales launch. The modified agreement also limited damages to 50 percent of Apotex's sales of the generic if it launched the drug and the modified agreement were rejected and Apotex lost the patent infringement case.[53] These provisions were to remain valid even if the agreement were rejected by the government.

Robert S. Silver, an attorney for Apotex, demanded payment of the $60 million break-up fee after regulators rejected the initial agreement. On May 27 one day after the modified agreement had been concluded, Dr. Bodnar sent an e-mail message to Sherman stating, "You explicitly assured me that you would not initiate such action at this point and would wait until matters had resolved themselves. Unless Silver immediately withdraws his demand, I will consider myself not bound by any restriction as to this issue to which I am bound by agreement with you."[54]

On July 26 Federal Bureau of Investigation agents raided Bristol-Myers Squibb's headquarters, including the office of CEO Dolan, as the Antitrust Division of the U.S. Department of Justice began a criminal investigation of the agreement. The investigation was initiated at the request of the FTC. Bristol-Myers Squibb commented that it "believes that all of its conduct relating to the proposed Plavix settlement has been entirely appropriate and coordinated throughout with senior outside counsel."

The state attorneys general indicated that they would not accept the modified agreement, and the FTC indicated that it was not satisfied with the modifications. This rejection and the provisions of the agreement that remained valid gave Apotex an opportunity to market clopidogrel with only limited risk.

Apotex launched its generic drug on August 8. Sherman said, "There should be no mistaking that our decision to launch a generic version of this blockbuster product at risk is a testament to our commitment to patients, consumers, and taxpayers." The drug had an expiration date of nearly two years, so drug distributors could buy large quantities and sell it out of inventory. Apotex had talked with the major drug distributors prior to launching its sales, and they had expressed eagerness to purchase the drug, since they had mandates to obtain drugs at the lowest possible cost. Medco Health Solutions and other pharmacy benefits companies purchased the generic, and Rite Aid said it would have the generic on its shelves in a day. Apotex charged $124 for a 30-day supply, compared to a price of $148 for Plavix. Bristol-Myers Squibb was reported to be offering rebates. Verispan LLC, which provided information on prescription sales, reported that Apotex's generic drug had 60.2 percent of total prescriptions written and 74 percent of new prescriptions for the week ending August 18.[55]

Surprised by Apotex's flooding the market, Sanofi-Aventis responded by filing a lawsuit in federal court seeking an injunction to halt the sales. Prior to the first

[53] *Wall Street Journal*, September 2, 2006.

[54] *New York Times*, August 18, 2006.

[55] AFX.COM, September 1, 2006.

hearing on the lawsuit, Apotex's lawyers advised Sherman to disclose the oral agreements, and on August 17, 2006 Apotex filed a statement in federal court revealing the oral agreements. Bristol-Myers Squibb said that the side agreements had been suggested by Sherman and that they had refused. Bristol-Myers Squibb held that there were no oral agreements.

After Apotex began shipping its generic, Sherman said in an interview, "I thought the FTC would turn [the modified agreement] down, but I didn't let on that I did. But they seemed blind to it."[56] He also commented, "They couldn't see that maybe certain things were going to end them up in prison."[57] Sherman's belief that the modified agreement would be rejected was supported by a July 7 letter to three U.S. senators in which Sherman wrote, "I must comment on the well-publicized perception that Apotex has entered into an anticompetitive settlement with Sanofi/Bristol-Myers Squibb concerning clopidogrel (Plavix). That perception is incorrect. Apotex has negotiated only to remove barriers to immediate launch. To achieve that objective, we entered into a somewhat bizarre arrangement that will enable immediate launch, if and when the FTC refuses to approve a settlement."[58]

At the hearing on the lawsuit seeking an injunction, attorneys for Bristol-Myers Squibb claimed that failure to issue an injunction would "kill future clinical efforts." Federal judge Sidney Stein granted a preliminary injunction, halting sales on August 31. Judge Stein wrote that Sanofi-Aventis "clearly established a likelihood of success on the merits." The judge, however, refused to order Apotex to recall the product it had already shipped, and Bristol-Myers Squibb was required to post a $400 million bond to compensate Apotex if it won the lawsuit. Apotex had asked for a $4 billion bond and said that the amount of the bond was "grossly inadequate." Apotex filed with the U.S. Court of Appeals for an emergency stay of the injunction,[59] and the U.S. Court of Appeals rejected the appeal, ending Apotex's foray. Analysts estimated that Apotex had shipped several hundred million dollars worth of clopidogrel.

In 2005 Bristol-Myers Squibb and the U.S. Attorney in New Jersey had reached a deferred-prosecution agreement in a case involving charges of conspiracy to commit securities fraud relating to an accounting scandal. Under the agreement Bristol-Myers Squibb agreed to exemplary conduct for two years and supervision by an independent federal monitor, retired judge Frederick B. Lacey, appointed by the court. The U.S. attorney asked Lacey to examine the Apotex affair, and Lacey conducted a review. In September 2006 Lacey told the Bristol-Myers Squibb board of directors that CEO Dolan should be fired. The board promptly did so. Bristol-Myers Squibb's share price had fallen 60 percent since Dolan was appointed CEO in 2001. ■

Preparation Questions

1. Why did Bristol-Myers Squibb and Sanofi-Aventis seek a settlement rather than let the patent infringement case go to trial?
2. Should Bristol-Myers Squibb and Sanofi-Aventis have attempted to pay Apotex to prevent it from launching a generic version of Plavix?
3. Was Sherman's strategy that of a shrewd business executive? Did Sherman act ethically in his strategy?
4. Should the FTC and the state attorneys general have rejected the agreements?
5. Did Bristol-Myers Squibb likely violate the deferred-prosecution agreement?

[56] *Wall Street Journal*, September 2, 2006.
[57] *New York Times*, August 15, 2006.
[58] *New York Times*, August 15, 2006.
[59] The judge stated that the claims of an oral side agreement were not affecting his decision "as of now."

Obesity and McLawsuits

In 2001 New York trial lawyer Samuel Hirsch filed a liability lawsuit against McDonald's alleging that his 5-feet 10-inch, 272-pound client had become obese from eating at McDonald's and other fast-food restaurants. The man had continued to eat at fast-food restaurants despite two heart attacks. After dropping that lawsuit, Hirsch represented two obese teenagers who claimed to have eaten at McDonald's regularly for several years and to have developed obesity-related illnesses.

Hirsch was advised by professor John Banzhaf of the George Washington University Law School, whose students had earlier filed a lawsuit against McDonald's for claiming that its french fries were fried in vegetable oil when they were also par-fried in beef fat at the potato processing plant.[60] The case was settled in 2002

[60] The Daily Buzz, www.foodservice.com, March 12, 2004.