

For Release

Bristol-Myers Squibb to Pay \$2.1 Million Penalty for Failure to Disclose Agreement Involving Substantial Payments to Delay Entry of a Generic Version of the Drug Plavix

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Drug maker Bristol-Myers Squibb Company (BMS) will pay \$2.1 million – the largest fine allowed by law – for failing to inform the Federal Trade Commission of agreements reached with Apotex, Inc., regarding potential generic competition to its blockbuster drug Plavix. BMS's conduct violated a 2003 FTC Order and the Medicare Modernization Act, which requires that certain drug company agreements be accurately reported to both the Commission and the U.S. Department of Justice (DOJ). The complaint alleges that BMS failed to disclose that, as part of a patent settlement in which Apotex agreed not to launch its generic version of Plavix for several years, BMS also orally stated, among other things, that it would not compete with Apotex during the first 180 days after Apotex did market its new generic drug.

The Commission's complaint and order announced today stem from a 2003 FTC Order settling charges that BMS had entered into agreements with potential generic drug manufacturers to delay their entry into the market, in exchange for payments from BMS. The 2003 Order required BMS to submit certain future drug settlement agreements to the FTC for review. The Medicare Modernization Act also requires that certain drug agreements be filed with both the FTC and the DOJ.

In May 2007, BMS paid \$1 million to settle a criminal complaint brought by the DOJ that it had lied to the agency about its Plavix agreement with Apotex, and the company also has settled several related state actions.

In filing its complaint, the first-ever brought for violations of the Medicare Modernization Act reporting requirements, the Commission stressed that the primary goal of the Act is to ensure that parties provide a complete description of the agreements they are reporting. The Medicare Modernization Act requires that unwritten understandings be described in writing and provided to the Commission along with written agreements.

"The FTC takes seriously the knowing failure of any company to comply with Commission Orders," said Acting Bureau of Competition Director David P. Wales. "Firms submitting required filings with the FTC have an absolute obligation to be forthright and complete. The material omission in this case went to the very core of the FTC's concerns. Filing firms must understand that they can't reach oral understandings and simply omit them from their required MMA filings. Otherwise, the very goal of the MMA would be undermined. This case, and the significant civil penalty BMS is required to pay, should serve as an important reminder of that."

Case Background. In 2006 BMS proposed to resolve a patent dispute with Apotex Inc., involving Apotex's efforts to introduce a generic version of BMS's blockbuster drug Plavix. As required by the FTC's Order, BMS submitted the proposed agreement to the FTC and filed it in accordance with the Medicare Modernization Act as well, as did Apotex. While reviewing the proposal, FTC identified a provision in which BMS agreed not to launch an "authorized generic" version of Plavix for six months, while Apotex would be the exclusive seller of the generic version of the drug. BMS's agreement not to launch an authorized generic could be worth a significant amount to Apotex because it would make Apotex's product the only generic available during those first 180 days.

When questioned by the Commission, BMS withdrew its filing, renegotiated its deal with Apotex, and refiled the revised agreement with the agency. In its revised filing, BMS did not disclose that it had indicated to Apotex that it would, in fact, not launch an authorized generic.

When Apotex refiled the revised agreement with the Commission, it stated in a cover letter that BMS had made certain oral representations in addition to the written agreement, including, among other things, the discussion about not launching an authorized generic. At that point, the FTC's staff requested BMS to certify under oath that the filed agreement represented the totality of the understandings between the parties. BMS did, and Apotex separately submitted additional exhibits and declarations consistent with its earlier position.

Faced with these conflicting certified statements, the FTC alerted the DOJ's Antitrust Division, which convened a grand jury to investigate. Ultimately, on June 11, 2007, BMS entered a plea of guilty to two counts of perjury for, among other things, failing to disclose that it had indicated to Apotex that it would not launch an authorized generic. BMS subsequently paid \$1 million in criminal fines, the maximum amount for the two counts.

While BMS's guilty plea to DOJ's criminal charges was not a required piece of the FTC's case against the company, it removed any question about whether the firm could be held accountable for violating both the original FTC Order and the requirements of the law. Accordingly, the FTC demanded that BMS address its civil violations as well.

The \$2.1 million civil penalty announced today represents the total statutory penalty available for BMS's civil violations during the period of its most culpable conduct – when it allowed its proposed settlement agreement to remain "open" for review at the FTC and pending under the Medicare Modernization Act, despite failing to include the critical fact that it had made oral representations to Apotex that were contrary to the written agreement.

The Commission vote approving the complaint and consent order in settlement of the court action was 4-0. It was filed in the U.S. District Court for the District of Columbia on March 26, 2009.

NOTE: The Commission authorizes the filing of a complaint when it has "reason to believe" that the law has been or is being violated, and it appears to the Commission that a proceeding is in the public interest. The complaint is not a finding or ruling that the defendants actually have violated the law.

NOTE: Stipulated final judgments and orders are for settlement purposes only and do not constitute an admission by the defendants of a law violation. Consent judgments have the force of law when signed by the judge.

Copies of the documents related to this matter are available from the FTC's web site at <http://www.ftc.gov> and the FTC's Consumer Response Center, Room 130, 600 Pennsylvania Avenue, N.W., Washington, DC 20580. The FTC's Bureau of Competition works with the Bureau of Economics to investigate alleged anticompetitive business practices and, when appropriate, recommends that the Commission take law enforcement action. To inform the Bureau about particular business practices, call 202-326-3300, send an e-mail to antitrust@ftc.gov, or write to the Office of Policy and Coordination, Room 394, Bureau of Competition, Federal Trade Commission, 600 Pennsylvania Ave, N.W., Washington, DC 20580. To learn more about the Bureau of Competition, read "Competition Counts" at <http://www.ftc.gov/competitioncounts>.

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(BMS-Plavix.final.wpd)

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