UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION
WASHINGTON, D.C. 20580

Office of the Secretary

PUBLIC RECORD VERSION

May 24, 2004

Mr. Richard J. Stark, Esq.
Cravath, Swaine & Moore LLP
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019-7475

Re: *In the Matter of Bristol-Myers Squibb Company, Docket No. C-4076*

Dear Mr. Stark:

On April 12, 2004, Bristol-Myers Squibb Company ("BMS"), pursuant to the requirement of the second proviso to Paragraph XII of the above-referenced order ("Order") that it obtain from the Commission an advisory opinion related to specified settlements, submitted its proposed agreement with Teva Pharmaceuticals USA, Inc. ("Teva") to settle their litigation over the validity of BMS's patent for the drug Carboplatin. Specifically, as relevant to the proposed settlement, Paragraph XII and its proviso prohibits BMS from:

> . . . being a party to any Agreement resolving or settling a Patent Infringement Claim in which:
>
> A. An ANDA Filer receives anything of value; and
>
> B. The ANDA Filer agrees not to research, develop, manufacture, market, or sell, the ANDA Product for any period of time.
>
> *PROVIDED, HOWEVER*, that nothing in this Paragraph XII shall prohibit:
>
> . . .
>
> (2) Respondent BMS from resolving or settling a Patent Infringement Claim after the Commission, in response to a request by Respondent BMS for an advisory opinion . . . determines that the settlement Agreement would not raise issues under Section 5 of the Federal Trade Commission Act.

This Order provision arose from BMS conduct that included an agreement to settle certain patent litigation by paying the alleged infringer millions of dollars for the alleged purpose of eliminating competition from a generic drug. Paragraph XII of the Order therefore bars, unless an applicable proviso applies, such payments to an ANDA filer in exchange for an agreement not to market its product for some period of time.

According to BMS, the proposed settlement with Teva that is the subject of this request for an advisory opinion will be entered into to resolve an ANDA patent litigation concerning the drug Carboplatin and U.S. Patent No. 4,657,927 (the "'927 patent"),[1] in which the U.S. Court of Appeals for the Federal Circuit vacated and remanded a district court determination on summary judgement that the '927 patent was not invalid.[2] BMS has filed a motion for a rehearing en banc. BMS has also informed the Commission that, although the '927 patent expired on April 14, 2004, the dispute with Teva is not moot, because BMS has filed with the Food and Drug Administration ("FDA") for pediatric exclusivity, which, if granted, would result in an additional six months of exclusivity ("exclusivity period') for BMS. No company therefore could enter the Carboplatin for Injection market prior to the expiration of the exclusivity period, i.e., until October 14, 2004. The parties are, however, uncertain whether a final determination that the '927 patent is invalid would affect the exclusivity period, and that uncertainty has led the parties to reach the proposed settlement.

The terms as proposed provide that BMS and Teva agree to dismiss the litigation and that as of June 24, 2004, BMS will appoint, and qualify under BMS's NDAs, Teva (or its designee) as a distributor of Carboplatin for Injection.[3] Morever, Teva has the option to purchase [redacted] its requirements of BMS's NDA drugs from June 24, 2004, until [redacted], in exchange for sharing its profits with BMS. Finally, upon expiration of the exclusivity period, on October 14, 2004, Teva may begin to sell its ANDA drugs and cease to purchase the BMS NDA drugs.

Unlike the settlement that led to entry of the Order, in which BMS allegedly paid the generic challenger to defer entry beyond the date that would represent an otherwise reasonable

---

[1] Memorandum Opinion and Order, *Bristol-Myers Squibb Company and Research Corporation Technologies, Inc. v. Pharmachemie, B.V.*, C.A. No. 01-3751 (MLC) (D.N.J. July 29, 2002).

[2] Decision, *Bristol-Myers Squibb Company and Research Corporation Technologies, Inc. v. Pharmachemie B.V.*, Appeal No. 03-1077 (Fed. Cir. Mar. 17, 2004).

[3] *See* NDA 20-452 (ready to use forms); NDA 19-880 (lyophilized (freeze-dried forms)).

litigation compromise,[4] this settlement does not involve a payment to Teva in exchange for Teva's agreement not to enter the market. Thus, we presume that the entry date, three months prior to the expiration of the exclusivity period, reflects a reasonable assessment of BMS's and Teva's respective litigation positions.

The settlement agreement provides no mechanism for BMS to share supracompetitive profits with Teva. Teva earns profits only by competing. Because Teva's payments to BMS likely will reduce Teva's profits, Teva will have the incentive to bring its ANDA drug products to the market as soon as possible after the exclusivity period. Importantly, the settlement agreement does not prevent Teva from marketing its own product under its ANDA at any time after October 14, 2004. Even while selling BMS's products, Teva retains the ability and incentive to price independently.

The Commission therefore has determined that the proposed agreement between BMS and Teva to settle the aforementioned litigation concerning the drug Carboplatin and the '927 patent does not raise issues under Section 5 of the Federal Trade Commission Act, and accordingly, BMS may enter the proposed settlement.

By direction of the Commission.

Donald S. Clark
Secretary

SEAL:

[4] *See also Opinion of the Commission, In the Matter of Schering-Plough Corporation et al.*, Docket No. 9297