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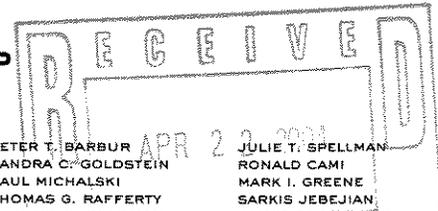
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April 21, 2004

In the Matter of Bristol-Myers Squibb Company
Docket No. C-4076

Dear Mr. Ducore:

In compliance with Paragraph XVII of the Decision and Order (the "Order") in In the Matter of Bristol-Myers Squibb Company, Docket No. C-4076, enclosed please find a verified report setting forth in detail the manner and form in which BMS intends to comply, is complying, and has complied with this Order. I have also forwarded a copy directly to Anne Schenof.

Very truly yours,

Richard J. Stark

Daniel P. Ducore
Bureau of Competition
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, D.C. 20580

Encl.

BY FAX AND FEDERAL EXPRESS

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**UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION**

COMMISSIONERS: Timothy J. Muris, Chairman
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary
Pamela Jones Harbour

In the Matter of

BRISTOL-MYERS SQUIBB COMPANY,
a corporation.

Docket No. C-4076

Bristol-Myers Squibb Company (“BMS”) submits this report in compliance with Paragraph XVII of the Decision and Order served on April 21, 2003 (the “Order”). This report covers the period from June 21, 2003 through April 21, 2004.

Confidential treatment is requested.

1. General

As discussed in BMS’s initial report under the Order, dated June 20, 2003 to ensure compliance with the Order, BMS has taken three actions: (1) implementation of a training program for inside counsel and executives to educate them as to the requirements of the Order; (2) review of existing agreements and Orange Book listings for possible issues; and (3) ongoing review of proposed new agreements and Orange Book listings for compliance with the Order.

BMS intends to repeat the training program in the spring of 2004. BMS also expects to extend the program to cover more individuals.

For the purposes of reviewing agreements and Orange Book listings and proposed new agreements and Orange Book listings, BMS has formed a compliance team, consisting of:

- Linda Willett, Vice President and Deputy General Counsel [senior managing attorney]
- Matthew Blischak, Senior Counsel [responsible for patent litigation]
- David Bonk, Vice President and Associate General Counsel [counsel for R&D, intellectual property, government affairs]
- Thomas Costa, Vice President and Deputy General Counsel [senior managing attorney]
- Charles Linzner, Vice President and Senior Counsel [counsel for licensing and business development]
- Richard Stark, Outside Counsel

The compliance team has continued to review proposed new agreements and new and existing Orange Book listings. The results of the compliance reviews are discussed in the appropriate sections below.

2. Specific Provisions of the Order

a. Paragraph II

BMS has not sought, maintained, certified to or taken any other action in furtherance of the listing or continued listing in the Orange Book of U.S. Patent No. 6,150,365.

b. Paragraph III

BMS has not made any Patent Infringement Claim¹ that a Taxol Patent is infringed by any Drug Product or the use of any Drug Product where the subject of the

¹ Capitalized terms not otherwise defined herein have the meaning assigned to them in the Order.

Patent Infringement Claim is the making, using, selling, offering to sell, or importing of Taxol.

c. Paragraph IV

As of the effective date of the Order, BMS did not have any 30-Month Stay in effect as to any ANDA referencing NDA No. 018731 or NDA No. 020262. No new 30-Month Stay as to any ANDA referencing either NDA has been obtained since the effective date of the Order.

d. Paragraph V

BMS has not made any Patent Infringement Claim regarding U.S. Patent 6,150,365.

e. Paragraph VI

BMS is continually reviewing its Orange Book listings and BMS has not sought, maintained, certified to, or taken any other action in furtherance of, the listing or continued listing of any patent in the Orange Book where the listing of such patent in the Orange Book violates Applicable Law.

f. Paragraph VII

BMS has not, in connection with any patent listed in the Orange Book under any NDA for which BMS is the NDA Holder, taken any action, or encouraged any other person to take any action, that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA approval of any ANDA referencing such NDA under any of the circumstances specified in Paragraph VII.A-F of the Order.

The following litigations where BMS is the “NDA Holder” (as defined in the Order) and a 30-Month Stay of FDA approval of an ANDA is in effect are pending:

<u>Action</u>	<u>NDA</u>	<u>ANDA</u>	<u>Patents in Suit</u>
<u>Bristol-Myers Squibb Company & E.R. Squibb & Sons, LLC v. Andrx Pharmaceuticals, LLC & Andrx Pharms., Inc., C.A. 03-cv-62283 (S.D. Fla.)</u>	19-915 Monopril (fosinopril sodium)	76-620	U.S. Patent No. 5,006,344
<u>Bristol-Myers Squibb Company & E.R. Squibb & Sons, LLC v. Andrx Pharms., LLC & Andrx Pharms., Inc., C.A. 03-cv-60703 (S.D. Fla.)</u>	19-915 Monopril (fosinopril sodium)	76-620	U.S. Patent No. 5,006,344
<u>Bristol-Myers Squibb Company & E.R. Squibb & Sons, LLC v. Andrx Pharms., LLC & Andrx Pharms., Inc., C.A. 03-CV-62283 (S.D. Fla.)</u>	20-286 Monopril HCT (fosinopril sodium/ hydrochlorothiazide combination product)	76-608	U.S. Patent No. 5,006,344
<u>Bristol-Myers Squibb Company & E.R. Squibb & Sons, LLC v. Andrx Pharms., LLC & Andrx Pharms., Inc., C.A. 03-CV-60703 (S.D. Fla.)</u>	20-286 Monopril HCT (fosinopril sodium/ hydrochlorothiazide combination product)	76-608	U.S. Patent No. 5,006,344
<u>Bristol-Myers Squibb Company & Research Corp. Techn., Inc. v. Pharmachemie B.V., C.A. No. 01-cv-3751 (D.N.J.)</u> <u>Bristol-Myers Squibb Company & Research Corp. Techn., Inc. v. Pharmachemie, B.V., C.A. No. 02-cv-1270 (D.N.J.)</u>	19-880 Paraplatin (carboplatin)	76-162 76-292	U.S. Patent No. 4,657,927 ²

² The 30 month stay as to ANDA 76-162 has expired. The one Paragraph IV challenger, Pharmachemie, is still barred by an injunction. Also, BMS applied for pediatric exclusivity.

<u>Bristol-Myers Squibb Company & Kvorin Pharm. Co., Ltd. v. Teva Pharms., USA, Inc., & Teva Pharm. Indus., Ltd., C.A. 04-cv-02312 (S.D.N.Y.)</u>	21-061 (gatifloxacin sesquihydrate)	76-950	U.S. Patent No. 4,980,470
<u>Sanofi-Synthelabo, Sanofi-Synthelabo, Inc., & Bristol-Myers Squibb Pharms. Holding Partnership v. Apotex Corp., C.A. No. 02-cv-2255 (S.D.N.Y.)</u>	20-839 (Plavix)	76-274	U.S. Patent No. 4,847,265
<u>Sanofi-Synthelabo, Sanofi-Synthelabo, Inc., & Bristol-Myers Squibb Pharms. Holding Partnership v. Dr. Reddy's Labs., Inc., C.A. No. 02-cv-3672 (S.D.N.Y.)</u>	20-839 (Plavix)	76-273	U.S. Patent No. 4,847,265

BMS has reviewed each of the above-listed litigations, and none of the circumstances listed in Paragraph VII.A-F of the Order applies in any of the actions.

g. Paragraph VIII

BMS has made no statements to the FDA prohibited by Section VIII of the Order.

h. Paragraph IX

BMS has not, in connection with a Patent Infringement Claim, asserted any fraudulent or objectively baseless claim, or otherwise engaged in sham litigation for the purpose of injuring an ANDA Filer rather than to obtain a favorable outcome to the Patent Infringement Claim. Since the effective date of the Order, BMS has not, in connection with a Patent Infringement Claim, enforced or sought to enforce any patent that it knows is invalid, unenforceable, or not infringed.

i. Paragraphs X-XI

The BMS compliance team has reviewed proposed new licensing agreements to ensure compliance with Paragraphs X-XI. On August 27, 2003, BMS notified the Commission of a proposed agreement under Paragraphs X and XVI. By

letter dated September 9, 2003, the Commission granted early termination of the waiting period for the licensing agreement as described. BMS has not otherwise acquired any patents or Exclusive Licenses within the scope of Paragraph X of the Order.³

BMS has not entered into any non-exclusive licenses to patents that are listed or listable in the Orange Book or would otherwise be relevant to the enforcement of Paragraph XI of the Order.

BMS has, from time to time, entered into a number of agreements that include patent licensing provisions, but which, BMS respectfully submits, are not covered by Paragraphs X-XI of the Order and are not relevant to enforcement of the Order.

However, if additional information is required, the staff is invited to contact Richard J. Stark at Cravath, Swaine & Moore LLP, Worldwide Plaza, 825 Eighth Avenue, New York, NY 10019, (212) 474-1000. These agreements are of the following three types:

(1) From time to time, BMS licenses in research materials and research tools (e.g., compounds, genetic materials, data, assay technology). Such license agreements often include non-exclusive licenses under patents covering such materials and tools and may include options to exclusively license certain patents (which options would typically be exercised in the event that a commercial product were developed).

(2) From time to time, BMS also enters into "material transfer agreements", under which research materials are provided to outside entities, such as universities. Such agreements typically include provisions that would grant BMS a non-exclusive license in the event that the outside entity's research resulted in a patent and often include provisions that would grant BMS an option to take an exclusive license to such patents.

(3) From time to time, BMS also enters into service, funded research and/or feasibility and similar agreements under which outside parties conduct certain activities (e.g., manufacture materials, evaluate improved

³ This statement is not intended to cover filings of patent applications by BMS employees or the issuance of new patents to employees or under agreements existing at the time an NDA received FDA approval, which are not within the scope of Paragraph X.

manufacturing processes, conduct various types of research activities, etc.). Such agreements typically include provisions that grant BMS exclusive and/or non-exclusive licenses to the outside entity's platform technologies used in performing the services and grant BMS exclusive and/or non-exclusive licenses in the event the outside entity's activities result in a patent or other intellectual property.

j. Paragraphs XII-XV

BMS did not have any agreements in effect as of the effective date of the Order of the types that are prohibited by Paragraphs XII-XV of the Order. BMS has not entered any agreements after the effective date of the Order that are prohibited by Paragraphs XII-XV of the Order. On April 12, 2004, BMS submitted a proposed agreement to the FTC for review under Section XII, subsection (2) of the Order.

Dated: April 21, 2004

Respectfully submitted,

CRAVATH, SWAINE & MOORE LLP

by


Richard J. Stark
A member of the firm

Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
(212) 474-1000

Verification

The foregoing is true and correct to the best of my knowledge, information
and belief.



John L. McGoldrick
Executive Vice President and General
Counsel, Bristol-Myers Squibb Company