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

COMMISSIONERS: Timothy J. Muris, Chairman
Sheila F. Anthony
Mozelle W. Thompson
Orson Swindle
Thomas B. Leary

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| In the Matter of<br><br>**BRISTOL-MYERS SQUIBB COMPANY,**<br>a corporation. | Docket No. C- |

## DECISION AND ORDER

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices by Respondent Bristol-Myers Squibb Company ("Respondent BMS" or "Respondent"), and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in Commission Rule § 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent BMS is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 345 Park Avenue, New York, N.Y. 10154.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

## ORDER

### I.

**IT IS ORDERED** that for the purposes of this Order, the following definitions shall apply:

A. "Respondent BMS" means Bristol-Myers Squibb Company, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Bristol-Myers Squibb Company, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.

B. "Commission" means the Federal Trade Commission.

C. "180-day Exclusivity Period" means the period of time established by 21 U.S.C. § 355(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355 *et seq*.).

D. "6-Hydroxy-Metabolite of Buspirone" means 6-hydroxy-8-[4-[4-(2- pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione.

E. "30-Month Stay" means the period of time, established by 21 U.S.C. § 355(j)(5)(B)(iii), during which the FDA may not grant final approval to an ANDA.

F. "AB-rated Generic Version" means an ANDA found by the FDA to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § 355(j)(8)(B).

G. "Agreement" means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1, or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

H. "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).

I. "ANDA Filer" means a person who has filed or submitted an ANDA with the FDA.

J. "ANDA First Filer" means the person whom the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period that has not expired.

K. "ANDA Product" means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.

L. "Applicable Law" means the statutes and regulations governing Orange Book listings, including, but not limited to, 21 U.S.C. § 355(b)(1) and (c)(2) and 21 C.F.R. § 314.53(b) and (c).

M. "Drug Product" means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

N. "Encourage" means suggest, advise, pressure, induce, attempt to induce, prompt, or otherwise influence.

O. "Exclusive License" means a license of intellectual property that (a) restricts the right of the licensor to license the intellectual property to other persons, (b) reduces the incentives of the licensor to license the intellectual property to other persons, or (c) grants to the licensee the right to enforce the intellectual property rights against other persons.

P. "Expiration Date" means 180 days after the date that the ANDA First Filer commences commercial marketing of (1) the ANDA Product, (2) the Reference Drug Product, or (3) any other AB-Rated Generic Version of the Reference Drug Product.

Q. "FDA" means the United States Food and Drug Administration.

R. "Listing Information" means any statement or information of any type provided to the FDA in furtherance of the listing or continued listing of any patent in the Orange Book, however communicated or recorded and regardless of the subject matter, including, but not limited to, any factual or legal subject matter.

S. "Material Patent Information" means any statement or information of any type, however communicated or recorded, regardless of the subject matter, that is material to patentability, as defined in 37 C.F.R. § 1.56(b).

T. "NDA" means a New Drug Application, as defined under 21 U.S.C. § 355(b), including all changes or supplements thereto which do not result in the submission of a new NDA.

U. "NDA Holder" means: (1) the person that received FDA approval to market a Drug Product pursuant to an NDA, (2) a person owning or controlling the ability to enforce the patent(s) listed in the Orange Book in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

V. "Orange Book" means the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations."

W. "Patent Infringement" means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, or patents of addition and extensions thereof.

X. "Patent Infringement Claim" means any allegation, whether threatened or included in a complaint filed with a court of law, that an ANDA Filer's ANDA or ANDA Product may infringe any U.S. patent held by, or exclusively licensed to, the NDA Holder of the Reference Drug Product.

Y. "Person" means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.

Z. "PTO" means the United States Patent and Trademark Office.

AA. "Reference Drug Product" means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.

BB. "Relinquish" includes, but is not limited to, abandoning, waiving, or relinquishing.

CC. "Sale of Drug Products" means the sale of Drug Products in or affecting

commerce, as commerce is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

DD. "Taxol" means any paclitaxel drug product as BMS sold it as of October 1, 2002, including, but not limited to, active ingredient and formulation.

EE. "Taxol Patent" means one or more of (i) U.S. Patent No. 5,670,537, (ii) U.S. Patent No. 5,641,803, or (iii) any other U.S. patent claiming Taxol as a composition of matter, or any method of using Taxol.

FF. "Use Patent" means a patent claiming an indication, dosage regimen, method of administration, or other condition of use.

**II.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not seek, maintain, certify to, or take any other action in furtherance of, the listing or continued listing in the Orange Book of U.S. Patent No. 6,150,365 in connection with any NDA where the active ingredient is buspirone.

**III.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not:

A. Make a Patent Infringement Claim that a Taxol Patent is infringed by any Drug Product or the use of any Drug Product where the subject of the Patent Infringement Claim is the making, using, selling, offering to sell, or importing of Taxol; or

B. Receive royalties or other fees from another person pursuant to a license of a Taxol Patent to make, use, sell, offer to sell, or import Taxol.

*PROVIDED, HOWEVER*, nothing in this paragraph shall preclude BMS from engaging in the conduct described in this Paragraph in connection with a Taxol Patent claiming a method of using Taxol in combination with another oncological active ingredient or a composition of matter patent claiming Taxol in combination with another oncological active ingredient.

**IV.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not take any action, or Encourage 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:

A. NDA No. 018731 (BuSpar); or

B. NDA No. 020262 (Taxol).

**V.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not make a Patent Infringement Claim that U.S. Patent No. 6,150,365 is infringed by any Drug Product, or the use of any Drug Product, that contains the active ingredient buspirone, unless the Drug Product also contains the 6-Hydroxy-Metabolite of Buspirone and the Patent Infringement Claim is based on the 6-Hydroxy-Metabolite of Buspirone.

**VI.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not seek, maintain, certify to, or take 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.

**VII.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not, in connection with any patent listed in the Orange Book under any NDA for which Respondent BMS is the NDA Holder, take any action, or Encourage 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 where:

A. The patent is listed in the Orange Book under such NDA after the filing of any ANDA referencing such NDA;

B. Respondent BMS, in obtaining the patent before the PTO, engaged in inequitable conduct as that term is judicially construed in the context of patent litigation;

C. Respondent BMS provided Listing Information that is false or misleading;

D. Respondent BMS provided Listing Information to the FDA and Material Patent Information to the PTO, where Respondent BMS cannot show that, at the time the statements were made, it had a reasonable belief that the Material Patent Information and the Listing Information were both accurate. A violation of this subparagraph VII.D can be established without the Commission proving whether it is the Listing Information or the Material Patent Information that is inaccurate;

E. The patent is a Use Patent, and at the time of its Orange Book listing, such patent did not claim an approved use of the Drug Product specified in the NDA referenced by such ANDA; or

F. The patent claims (1) a composition of matter that is a metabolite of an active ingredient listed in the NDA referenced by such ANDA, and/or (2) a method of use of such a metabolite.

*PROVIDED, HOWEVER,* it shall not be a violation of either Paragraph VII.E or VII.F if the following three conditions are met:

(1) the patent listed in the Orange Book contains a claim or portion of a claim distinct from those identified in paragraph VII.E and VII.F ("Additional Claim");

(2) an Orange Book listing based on the Additional Claim does not violate Applicable Law; and

(3) so long as BMS maintains a Patent Infringement Claim that the ANDA Filer infringes the Additional Claim.

**VIII.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not make any statements to the FDA that are (1) false and misleading; and (2) material to either the approvability of an ANDA referencing an NDA for which BMS is the NDA Holder, or the sale of any product pursuant to such ANDA.

*PROVIDED, HOWEVER,* it shall not be a violation of Paragraph VIII if, at the time the statement was made, Respondent BMS had a reasonable belief that the statement was neither false nor misleading.

**IX.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not, in connection with a Patent Infringement Claim:

A. Assert any fraudulent or objectively baseless claim, or otherwise engage in sham litigation for the purpose of injuring an ANDA Filer rather than to obtain a favorable outcome to the Patent Infringement Claim.

B. Enforce or seek to enforce any patent that it knows is invalid, unenforceable, or not infringed.

**X.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not, without providing prior written notification to the Commission in the manner described in Paragraph XVI ("Notification"), acquire from another person a patent or an Exclusive License to a patent if Respondent BMS seeks or secures the patent's listing in the Orange Book for an NDA which has received FDA approval. For purposes of this Paragraph X only, the term acquire shall exclude the assignment or license of patents to Respondent BMS pursuant to an agreement existing at the time the NDA received FDA approval.

**XI.**

**IT IS FURTHER ORDERED** that Respondent BMS shall not, with respect to any patent for which BMS acquires a non-exclusive license from another person (the "Acquisition"), assist in, advise regarding, or act so as to affect in any manner the licensor's or any other person's (1) enforcement of the patent with respect to an ANDA, (2) licensing of the patent to an ANDA Filer with respect to an ANDA, or (3) determination of royalties or other fees paid for the patent by an ANDA Filer with respect to an ANDA.

*PROVIDED, HOWEVER*, nothing in this paragraph shall prohibit Respondent BMS from engaging in the conduct described in this Paragraph with respect to any ANDA filed with the FDA after the Acquisition, unless such ANDA references the same NDA as an ANDA filed with the FDA before the Acquisition.

**XII.**

**IT IS FURTHER ORDERED** that Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, 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:

(1) A resolution or settlement of a Patent Infringement Claim in which:

(a) Respondent BMS is the NDA Holder;

(b) The value received by the ANDA Filer, in the resolution or settlement of the Patent Infringement Claim, is no more than (1) the right to market the ANDA Product prior to the expiration of the patent that is the basis for the Patent Infringement Claim, and (2) the lesser of the NDA Holder's expected future litigation costs to resolve the Patent Infringement Claim or $2 million; and

(c) Respondent BMS has notified the Commission, as described in Paragraph XVI.

(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 pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. § 1.2, determines that the settlement Agreement would not raise issues under Section 5 of the Federal Trade Commission Act.

(3) Respondent BMS, without notice to the Commission, from seeking relief unilaterally from a court, including but not limited to, applying for permanent injunctive relief, or seeking to extend or reduce a 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

**XIII.**

**IT IS FURTHER ORDERED** that, when Respondent BMS makes a Patent Infringement Claim in which Respondent BMS is the NDA Holder, Respondent BMS shall cease and desist, in connection with the Sale of Drug Products, from being a party to any Agreement in which the ANDA Filer agrees to refrain from researching, developing, manufacturing, marketing, or selling any Drug Product that:

A. Could be approved for sale by the FDA pursuant to an ANDA; and

B. Is neither the subject of any written claim or allegation of Patent Infringement nor the subject of a written representation from the ANDA Filer's counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

## XIV.

**IT IS FURTHER ORDERED** that Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products with respect to which Respondent BMS is an NDA Holder for the Reference Drug Product(s), from being a party to any Agreement in which:

A. One party is an NDA Holder and the other party is the ANDA First Filer for the Reference Drug Product; and

B. The ANDA First Filer is prohibited by such Agreement from Relinquishing, or is subject to a penalty, forfeiture, or loss of benefit, if it Relinquishes its right to the 180-day Exclusivity Period.

*PROVIDED, HOWEVER*, that nothing in this Paragraph shall prohibit any Agreement if and only if the following three conditions are all met:

(1) Within twenty (20) days of entering into the Agreement, the ANDA First Filer commences commercial marketing of the ANDA Product, the Reference Drug Product, or any other AB-rated Generic Version of the Reference Drug Product;

(2) One of the following two conditions has been satisfied:

(a) the 180-day Exclusivity Period, if any, has been triggered by the commercial marketing required by proviso subparagraph (1) above, and has begun to run with respect to the ANDA Product; or

(b) within ten (10) days of the commercial marketing of a Drug Product other than the one subject to the ANDA, the ANDA First Filer has notified the FDA, in writing, that it will Relinquish any and all eligibility for, and entitlement to, a 180-day Exclusivity Period, if any, for the ANDA Product, beyond the Expiration Date; and

(3) Respondent BMS has notified the Commission, as described in Paragraph XVI.

## XV.

**IT IS FURTHER ORDERED** that, in any instance where Respondent BMS is a party to a Patent Infringement Claim in which it is the NDA Holder, Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement in which:

C. The parties do not agree to dismiss the litigation;

D. The NDA Holder provides anything of value to the alleged infringer; and

C. The ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

*PROVIDED, HOWEVER*, such an Agreement is not prohibited by this Order when entered into in conjunction with a joint stipulation between the parties that the court may enter a preliminary injunction pursuant to Rule 65 of the Federal Rules of Civil Procedure, Fed. R. Civ. P. 65, if:

(1) Together with the stipulation for a preliminary injunction, Respondent BMS provides the court the proposed Agreement, as well as a copy of the Commission's complaint and order in this matter;

(2) Respondent BMS has notified the Commission, as described in Paragraph XVI, at least thirty (30) days prior to submitting the stipulation for a preliminary injunction;

(3) Respondent BMS does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and

(4) One of the following two conditions apply:

(a) the court issues an order and the parties' agreement conforms to said order; or

(b) the Commission, in response to a request by Respondent BMS for an advisory opinion, pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. § 1.2, determines that entering into the stipulation

would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

*PROVIDED, HOWEVER*, nothing in this Paragraph XV shall be interpreted to prohibit or restrict the right of Respondent BMS unilaterally to seek relief from the court (including but not limited to, applying for preliminary injunctive relief or seeking to extend, or reduce, the 30-Month Stay).

**XVI.**

**IT IS FURTHER ORDERED** that:

A. Respondent BMS shall notify the Commission as required by Paragraphs X, XII, XIV, and XV in the form of a letter ("Notification Letter") submitted to the Secretary of the Commission, which shall contain the following information:

(1) The docket number and caption name of this Order;

(2) A statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;

(3) Identification of the parties involved in the proposed Agreement;

(4) Identification of all Drug Products involved in the proposed Agreement;

(5) Identification of all persons, to the extent known, who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;

(6) A copy of the proposed Agreement;

(7) Identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and

(8) All documents which were prepared by or for any officer(s) or director(s) of Respondent BMS for the purpose of evaluating or analyzing the proposed Agreement, *provided that* documents subject to a valid claim of privilege or

work product need not be produced pursuant to this provision, but shall be identified in a log.

B. Respondent BMS shall submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement ("First Waiting Period"). If Respondent BMS so requests, the Commission shall keep the Notification Letter and accompanying information and documents confidential to the extent provided by law.

C. If the Notification Letter is provided pursuant to:

(1) Paragraph XII, representatives of the Commission may make a written request for additional information or documentary material (as if the request were within the meaning of 16 C.F.R. § 803.20) prior to expiration of the First Waiting Period. If such a request for additional information is made, Respondent BMS shall not execute the proposed Agreement until expiration of thirty (30) days following complete submission of such additional information or documentary material ("Second Waiting Period"). Receipt by the Commission from Respondent BMS of any notification, pursuant to this Paragraph XVI, is not to be construed as a determination by the Commission that any action described in such notification does or does not violate this Order or any law enforced by the Commission.

(2) Paragraphs X, XIV or XV, Respondent BMS may execute the proposed Agreement upon expiration of the First Waiting Period.

D. Early termination of the Waiting Periods in this Paragraph XVI may be requested from the Director of the Commission's Bureau of Competition.

## XVII.

**IT IS FURTHER ORDERED** that Respondent BMS shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent BMS intends to comply, is complying, and has complied with this Order. Respondent BMS shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order. As to Paragraph VII of this Order, this description shall identify all ANDAs subjected to a 30-Month Stay of FDA approval, and as to each of these 30-Month Stays, a description of BMS's efforts to comply with Paragraph VII of this Order.

**XVIII.**

**IT IS FURTHER ORDERED** that Respondent BMS shall notify the Commission at least thirty (30) days prior to any proposed change in Respondent BMS such as dissolution, assignment, sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries, or any other change in Respondent BMS that may affect compliance obligations arising out of this Order.

**XIX.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order and subject to any legally recognized privilege or immunity, and upon written request with reasonable notice to Respondent BMS, Respondent BMS shall permit any duly authorized representative of the Commission:

A. Access, during office hours and in the presence of counsel, to all facilities, and to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession or under its control relating to compliance with this Order; and

B. To interview officers, directors, employees, agents, and other representatives of Respondent BMS, who may have counsel present, regarding such compliance issues.

**XX.**

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the date this Order becomes final.

By the Commission.

Donald S. Clark
Secretary

SEAL:

ISSUED: