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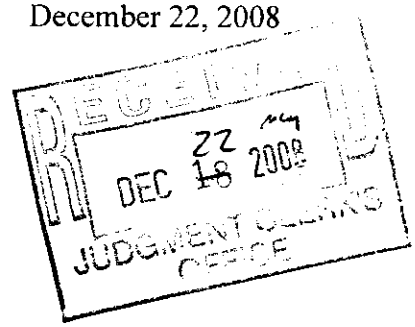
December 22, 2008



BY HAND DELIVERY

Hon. John G. Koeltl
United States District Judge
United States District Court
for the Southern District of New York
500 Pearl Street
New York, NY 10007

***In re Buspirone Antitrust Litigation*,**
Case No. 01 CV 11401, MDL 1410, MDL 1413

Dear Judge Koeltl:

This is to request that the Court order the entry of the enclosed Stipulation and attached exhibits in the case captioned above.

In the *Buspirone* case, the Plaintiff States and Territories (the "States") sued Bristol-Myers Squibb, alleging anticompetitive conduct that delayed cheaper generic competition to its branded drug Buspar. The litigation was resolved in 2003 with a $100 million monetary payment to the States and entry of an order and stipulated injunction (the Order), signed by this Court on November 14, 2003.

After a thorough investigation, the States have concluded that BMS violated the *Buspirone* Order, which, by its terms, does not expire until 2013. Plaintiff States and BMS have resolved their dispute in this regard by entering into a Letter Agreement (Stipulation Ex. A). The Letter Agreement provides for a monetary payment to the States. The Letter Agreement further provides that BMS will not oppose the State's Application for entry of the Amended Revised Order and Stipulated Injunction (Stipulation Ex. B). The Application describes the basis for the

States' conclusion that BMS violated the original injunction. The States believe that the filing of the Stipulation and Exhibits in the public record will be an effective deterrent to future violations of court-ordered injunctions.

Respectfully,

Elinor R. Hoffmann
Assistant Attorney General, Antitrust
Liaison Counsel for the States

cc: Lorin L. Reisner

Enclosures

COPY

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE BUSPIRONE ANTITRUST LITIGATION

Case No.
01 CV 11401
MDL 1410
MDL 1413

STIPULATION AND ORDER

Plaintiff States and Defendant Bristol-Myers Squibb Company ("BMS") hereby stipulate and agree, subject to and in accordance with the Letter Agreement attached as Exhibit A, that BMS will not oppose Plaintiff States' Application to Amend the Order and Stipulated Injunction in the above-referenced matter (attached as Exhibit B) and consents to the entry of the Amended Order and Stipulated Injunction. BMS neither admits nor denies the content of the Application.

By: _____
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Debevoise & Plimpton LLP
919 Third Avenue
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212-909-6000
Attorneys for Defendant BMS

By: _____
Elinor R. Hoffmann
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New York State
Attorney General's Office
120 Broadway, 26th Floor
New York, New York 10271
(212) 416-8280
Attorneys for Plaintiff State of New York

Liaison Counsel for the Plaintiff States

So Ordered: _____

United States District Judge

Exhibit A

STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL

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120 BROADWAY
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December 1, 2008

Lorin L. Reisner
Debevoise & Plimpton, LLP
919 Third Avenue
New York, NY 10022

Re: Letter Agreement

Dear Lorin:

This letter memorializes the agreement between the Plaintiff States listed in Att. A (the "States") and Bristol-Myers Squibb Company ("BMS") regarding the States' allegations that BMS failed to comply with the decrees entered in *In re Buspirone Antitrust Litigation*, Case No. 01 CV 11401, MDL 1410, MDL 1413 (S.D.N.Y.) ("*Buspirone*"), and *State of Ohio v. Bristol-Myers Squibb Co.*, 1:02-CV-01080 (D.D.C.EGS) ("*Taxol*") (collectively, the "Orders").

Background

In *Buspirone* and *Taxol*, BMS agreed to settlements aggregating $150 million, and consented to the entry of stipulated Orders directing injunctive relief. Among other things, each Order imposes conditions on BMS's entry into agreements settling patent infringement claims, requires BMS to make specific notifications to the States regarding such agreements, and requires BMS to file annual compliance reports with the States. The Orders terminate on April 14, 2013.

In March 2006, BMS's agreement with generic drug manufacturer Apotex, Inc. to settle patent infringement claims regarding BMS's branded pharmaceutical, Plavix, triggered BMS's notification obligations under the Orders. BMS submitted the March

2006 agreement to the States, and the States timely refused to approve the agreement. In May 2006, BMS submitted a revised agreement to the States for approval, and the States once again refused to approve the agreement.

The States contend that BMS failed to comply with the Orders because BMS submitted a materially inaccurate and incomplete agreement to the States in May 2006, and submitted materially inaccurate and incomplete compliance reports to the States in 2007 and 2008. In June 2007, BMS pled guilty to two counts of making false statements to the Federal Trade Commission relating to the submission of the same May 2006 agreement to the FTC.

The States and BMS have negotiated a resolution with respect to the States' contention, pursuant to which BMS acknowledges responsibility for making incomplete and false statements to the States, agrees to a monetary payment to the States, and agrees to the entry of a stipulated revised Order in each of the *Buspirone* and *Taxol* cases. The operative terms of the agreement follow:

Agreement

1. Acknowledgement

Prior to the time that BMS submitted the revised proposed settlement agreement to the Liaison Counsel for the Plaintiff States on May 30, 2006 and submitted its Annual Compliance Reports on April 20, 2007 and April 21, 2008, a former BMS senior executive made oral representations to Apotex for the purpose of causing Apotex to conclude that BMS would not launch an authorized generic in the event that the parties reached a final revised settlement agreement. These representations by the former officer of BMS were not disclosed to the State Liaison Counsel at the time of the submission of the final revised settlement agreement and subsequent Annual Compliance Report dated April 20, 2007. The failure to disclose this information to the State Liaison Counsel at the time of the submission of the final revised settlement agreement operated as incomplete and therefore false statements to the States. The Company acknowledges its responsibility for the conduct of its former senior officer and for the failure to disclose this information to the States.

2. Payment

In resolving the alleged violations of the Orders, upon the Courts' entry of the Amended Orders referred to below, BMS will pay the States a monetary settlement, inclusive of penalties, fines and investigative fees and expenses, in the amount of $1,100,000.00. The States shall allocate the funds among themselves. The Attorney General of each State shall use its share of the funds consistently with his/her state laws for any of the following purposes:

1) payment of attorneys' fees and costs;

2) antitrust or consumer protection law enforcement;

3) deposit into a state antitrust or consumer protection revolving or trust fund; or

4) as otherwise provided by state law.

3. Amended Orders

BMS consents to the filing and entry of the Amended Orders, in the form of Exhibits attached as A and B. By way of summary only, the Amended Orders:

1. Extend BMS's annual filing requirements pursuant to paragraph XVII of the Orders for an additional five years from April 21, 2008, for a total of ten years.

2. Require that all such annual compliance reports be accompanied by a certification under oath that the compliance report is accurate, complete, and does not omit any information that is material to a review of the report by the States.

3. Require that BMS's notifications pursuant to Paragraphs X, XII, XIV, XV and XVI of the Orders be accompanied by a certification under oath that the notifications are accurate, complete, and do not omit any information that is material to the review of the notifications by the States.

4. Require that, for any violation of the Amended Orders, BMS shall pay to the Plaintiff States a civil penalty of $11,000 per violation with each day of a continuing violation constituting a separate violation. Any violation of the Amended Orders shall extend BMS's notification requirements pursuant to Paragraphs X, XII, XIV, XV, and XVI of the Orders for an additional five years from April 21, 2013, for a total of fifteen years.

4. Filing of Application

BMS will execute an appropriate stipulation stating that it does not oppose an application filed by the States in each of the *BuSpirone* and *Taxol* proceedings that seeks entry of the Amended Orders subject to and in accordance with this Letter Agreement. BMS agrees that it will not publicly contest or contradict the statements set forth in this Letter Agreement. Nothing in this paragraph shall affect BMS' testimonial obligations or its right to take legal or factual positions in defense of litigation or other legal proceedings. BMS shall be deemed to have neither admitted nor denied the content of the

Motions or other applications of the Plaintiff States to Amend the Orders and Stipulated Injunctions.

5. Release

Upon the Courts' entry of the Amended Orders: (a) the States shall be deemed to have released, and to have agreed not to pursue further, any enforcement, regulatory or other claims against BMS, its subsidiaries and affiliates, or any of their former or current officers, directors, employees, agents or representatives relating to the proposed 2006 settlements of the patent infringement litigation between BMS and Apotex concerning Plavix; and (b) any pending investigations relating to the proposed 2006 settlements by the States shall be deemed closed with respect to BMS, its subsidiaries and affiliates, and any of their former or current officers, directors, employees, agents or representatives.

Please confirm our agreement by signing and returning to us a duplicate original of this Letter Agreement.

Very truly yours,

Office of the NYS Attorney General (on behalf of the States)

By _____

~~Jay L. Himes~~
~~Bureau Chief~~

Elinor R. Hoffmann
Assistant Attorney General

Antitrust Bureau
120 Broadway, Suite 26C
New York, NY 10271

AGREED: Bristol-Myers Squibb Company

Date: 2/1/08

By: _____
Name: SANDRA LEUNG
Title: SVP, General Counsel + Secretary

Attachment A

Alabama	Indiana	Montana	Rhode Island
Alaska	Illinois	Nebraska	South Carolina
Arizona	Iowa	Nevada	South Dakota
Arkansas	Kansas	New Hampshire	Tennessee
California	Kentucky	New Mexico	Texas
Colorado	Louisiana	New Jersey	Utah
Connecticut	Maine	New York	Vermont
Delaware	Maryland	North Carolina	Virginia
District of Columbia	Massachusetts	North Dakota	Washington
Florida	Michigan	Ohio	West Virginia
Georgia	Minnesota	Oklahoma	Wisconsin
Hawaii	Mississippi	Oregon	Wyoming
Idaho	Missouri	Pennsylvania	

Exhibit B

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

IN RE BUSPIRONE ANTITRUST LITIGATION	**Case No.** **01 CV 11401** **MDL 1410** **MDL 1413**

APPLICATION OF PLAINTIFF STATES TO AMEND ORDER AND STIPULATED INJUNCTION

Plaintiff States, by their Attorneys General, submit this unopposed Application to amend the Order and Stipulated Injunction entered by this Court on November 14, 2003 (the "Order") in *In re Buspirone Antitrust Litigation*, Case No. 01 CV 11401, MDL 1410, MDL 1413 (S.D.N.Y.) ("Buspirone"). The Plaintiff States represent as follows:

I.

JURISDICTION OF THE COURT

1. This Court has jurisdiction under the All Writs Act, 28 U.S.C. § 1651, and under its inherent powers to enforce the Order.

II.
BMS' NOTIFICATION AND ANNUAL REPORTING OBLIGATIONS UNDER THE COURT'S ORDER

2. Defendant Bristol-Myers Squibb Company ("BMS") is a Delaware corporation, with its corporate headquarters at 345 Park Avenue, New York, NY 10154. In this case Plaintiff States, as well as private plaintiffs, alleged that BMS unlawfully aintained its monopoly over the drug BuSpar. In resolving the matter, BMS agreed to

maintained its monopoly over the drug BuSpar. In resolving the matter, BMS agreed to pay Plaintiff States nearly $100 million and consented to injunctive measures. On November 14, 2003, this Court entered the Order and accompanying Settlement Agreement to which the Plaintiff States and BMS had agreed.

3. The Federal Trade Commission ("FTC") brought a separate proceeding against BMS for the same alleged anticompetitive conduct, and its consent order contains injunctive provisions parallel to those found in the Order.

4. Paragraph XII of the Order imposes conditions on BMS's entry into agreements settling patent infringement claims. Among other things, Paragraph XII permits BMS to enter into some such agreements, provided that "BMS has notified Liaison Counsel for the Plaintiff States . . . and Liaison Counsel for the Plaintiff States have not notified BMS of any objection to the proposed Agreement, resolution or settlement within 30 days." Order, ¶ XII B. (2). Paragraph XVI of the Order prescribes the process and method by which BMS must give notice of agreements subject to Paragraph XII. BMS's obligations under these notice provisions continue for the Order's entire ten-year term.

5. Paragraph XVII of the Order further requires BMS to file annually with Liaison Counsel for the Plaintiff States verified written reports "setting forth in detail the manner and form in which BMS intends to comply, is complying and has complied with this Order." BMS's obligation to file annual reports pursuant to Paragraph XVII continued for five years from April 21, 2003.

6. BMS has parallel notification and filing requirements with respect to the FTC order. Independent of that consent order, BMS also is required to notify the FTC of certain patent infringement litigation settlement agreements under the Medicare Modernization Act of 2003 (the "MMA").

III.

THE PATENT LITIGATION THAT TRIGGERED BMS'S NOTIFICATION REQUIREMENTS UNDER THE COURT'S ORDER

The Drug Plavix

7. Plavix is a brand name pharmaceutical drug prescribed to reduce risks of thrombotic events, such as heart attacks and strokes, for patients who have recently suffered such events or who have arterial disease or acute coronary symptoms. The Food and Drug Administration ("FDA") approved Plavix for sale in the United States in November 1997.

8. Sanofi-Synthelabo, a subsidiary of Sanofi-Aventis (collectively, "Sanofi"), holds the approved new drug application ("NDA") 20-839 for Plavix, whose active ingredient is clopidogrel bisulfate. Sanofi obtained the patent claiming clopidogrel bisulfate on July 11, 1989. The Plavix patent, or "'265 patent," expires on November 17, 2011.

The Defendant BMS and Apotex, its Generic Competitor

9. BMS participates in the sale and marketing of Plavix, through an exclusive license that Sanofi has granted to the Bristol-Myers Squibb Sanofi Pharmaceuticals

Holding Partnership (the "Partnership"). In 2007, worldwide sales of Plavix exceeded $5 billion.

10. Apotex Inc. is a privately held Canadian company with worldwide facilities for the research, development, manufacture and marketing of pharmaceuticals. It is headquartered in Toronto, Canada. Apotex Inc. conducts business in the United States through Apotex Corporation, a wholly-owned subsidiary. Apotex Inc. and Apotex Corporation are referred to as "Apotex."

Sanofi-Synthelabo v. Apotex Inc., 02 CV 255 (SHS) (S.D.N.Y.)

11. In November 2001, Apotex filed an Abbreviated New Drug Application ("ANDA") with the FDA, seeking approval to sell a generic form of the active ingredient in Plavix, clopidogrel bisulfate, before Sanofi's '265 patent expired in 2011.

12. On March 21, 2002, in response to Apotex's ANDA filing, BMS and Sanofi sued Apotex in the Southern District of New York alleging that, under the Hatch-Waxman Act, 21 U.S.C. § 355 *et seq.*, Apotex's ANDA filing constituted patent infringement ("the Patent Litigation"). Apotex counterclaimed, alleging that the '265 patent was invalid. On June 19, 2007, the Honorable Sidney H. Stein ruled that the patent was valid. *Sanofi-Synthelabo v. Apotex, Inc.*, 492 F. Supp. 2d 353 (S.D.N.Y. 2007). Apotex appealed the decision to the Federal Circuit. That appeal is pending.

IV.

THE FIRST PROPOSED SETTLEMENT OF THE PATENT LITIGATION

13. Beginning at least as early as January 2006 and continuing into March 2006, BMS and Apotex negotiated the possible settlement of the Patent Litigation.

14. On March 17, 2006, BMS and Apotex signed a settlement agreement (the "March Agreement"). Under the March Agreement, Apotex was granted a license to manufacture and sell its generic version of Plavix as of September 17, 2011 – two months before the Plavix '265 patent was due to expire on November 17, 2011. The March Agreement further provided that the license would be exclusive for a period of six months, and stated that BMS was precluded from launching an authorized generic version of Plavix during that six-month period.

15. Pursuant to Paragraphs XII and XVI of the Order, BMS was required to notify the Liaison States of the March Agreement, and BMS could not consummate the March Agreement until 30 days after it had submitted the notice, provided that the Plaintiff States did not make a request for additional information within those 30 days.

16. BMS submitted the March Agreement to the States for review under the Order, as well as to the FTC for review under its separate order. Thereafter, outside counsel for BMS met with representatives of the States and the FTC at the FTC's offices in Washington. At the meeting, the States and the FTC expressed objections to three provisions in the March Agreement: (a) the provision prohibiting BMS from launching an authorized generic version of Plavix during Apotex's exclusive license period; (b) the provision requiring that BMS make a payment to Apotex of $60 million if there was a

"regulatory denial" as defined in the March Agreement by June 30, 2006 (the "break-up fee provision"); and (c) the provision requiring BMS to compensate Apotex if BMS's Plavix sales did not reach specified minimum annualized levels in the three months preceding Apotex's market entry in accordance with the March Agreement ("market guarantee provision").

17. On May 5, 2006, Meredyth Andrus, then Assistant Attorney General for Maryland, advised BMS's outside counsel that the Plaintiff States

> "decline to affirmatively approve the [March] Agreement as that term is used in the definition of 'Regulatory Denial' in . . . the Agreement, nor will the [Plaintiff States] provide written notice that we do not object, as required in . . . the Agreement."

V.

THE REVISED AGREEMENT

18. After the Plaintiff States declined to approve the March Agreement, BMS and Apotex negotiated a revised settlement agreement (the "Revised Agreement"). The principal negotiations for the Revised Agreement took place during face-to-face meetings in Apotex's offices in Toronto, one of which was held on May 12, 2006. Andrew Bodnar, BMS's Senior Vice President, Strategy and Medical and External Affairs, was BMS's only in-person representative at the Toronto meetings. Dr. Bodnar, who reported directly to BMS's then CEO, also was on the BMS management Executive Committee, which reported to the BMS Board of Directors. Barry Sherman, CEO of Apotex and an owner of the privately held company, represented Apotex at the Toronto meetings. Two other officers of Apotex, Mr. Kaye and Mr. Baxter, participated in a portion of the May

12 meeting. Evan Chesler, a partner in the New York law firm of Cravath, Swaine & Moore and outside counsel for BMS, participated in part of the meetings by telephone.

19. During the May 12 meeting, the parties discussed the Plaintiff States' and FTC's unwillingness to approve a settlement agreement that included a provision precluding BMS from launching an authorized generic. During that same meeting, Dr. Bodnar made statements to Apotex for the purpose of causing Apotex to conclude that BMS would not launch an authorized generic if the parties reached a revised settlement embodying agreement on other matters.

20. Dr. Bodnar's oral representations to Apotex resulted in an understanding that BMS would not launch an authorized generic version of Plavix in the event that the parties reached a final revised settlement.

21. Dr. Bodnar met with Mr. Sherman again in Toronto on May 24, 2006. At this meeting, the parties reached an agreement on the remaining terms of the Revised Agreement, subject to review of a final draft of the written agreement.

22. BMS and Apotex executed the Revised Agreement on May 25 and 26, 2006, respectively. BMS submitted the Revised Agreement to the States on May 30, 2006 for review under Paragraphs XII and XVI of the Order. BMS also submitted the Revised Agreement to the FTC pursuant to its separate order.

23. BMS's May 30 notification to the States did not include any mention of any oral representation, side agreement or other understanding regarding BMS's willingness to refrain from launching an authorized generic during the period of Apotex's

exclusive license. BMS and Apotex, however, had reached such an arrangement as a result of Bodner's representations during the May 12, 2006 meeting in Toronto.

24. On July 5, 2006, counsel for Apotex faxed to Meredyth Andrus, representing the States, materials that included a declaration of Barry Sherman and appended exhibits. Among these materials was "Exhibit A," a cover letter dated June 5, 2006, that Robert Silver, one of Apotex's outside counsel, had sent to the FTC on behalf of Apotex pursuant to the MMA. The June 5th letter stated that, in addition to the written Revised Agreement submitted to the FTC (and the States), BMS had committed to Apotex that no authorized generic would be launched during Apotex's period of exclusivity if the FTC approved the Revised Agreement.

25. On June 12, 2006, BMS submitted a certification to the FTC, signed by Dr. Bodnar and BMS's outside counsel, stating that BMS had not made any representation, commitment or promise to Apotex that was not included in the written Revised Agreement (the "BMS Certification"). The BMS Certification did not disclose any oral representation, side agreement or understanding regarding the launch of an authorized generic that occurred during the May 12 meeting in Toronto. The FTC provided a copy of the BMS Certification to the States. On June 28, 2006, Ms. Andrus notified BMS's outside counsel that, pursuant to Paragraph XVI(C)(1) of the Orders, the States were requesting additional information from BMS for the purpose of reviewing the Revised Agreement. In the same letter, Ms. Andrus also advised BMS's counsel that in the course of their review the States intended to rely on the Certification dated June 12.

26. On May 30, 2007, following a criminal investigation of the BMS/Apotex settlement negotiations, the United States Department of Justice issued an Information charging that BMS: (1) knowingly and willfully concealed and failed to disclose to the FTC a material fact and made a materially false, fictitious and fraudulent representation by failing "to disclose certain information ... that was material to the FTC" when it submitted the Revised Agreement to the FTC on May 30, 2006; and (2) knowingly and willfully made a materially false, fictitious and fraudulent statement and representation by failing to disclose in the certification filed with the FTC on June 12, 2006 information that was material to the FTC.

27. BMS entered a Plea Agreement with the Department of Justice on May 31, 2007 and pled guilty in open court on June 11, 2007 to violations of 18 U.S.C. §1001.

VI.

PLAINTIFF STATES CONTEND THAT BMS VIOLATED THE ORDER

28. Plaintiff States contend that BMS violated Paragraphs XII and XVI of the Order by failing to disclose to the States in its submission on May 30, 2006 the oral representation, side agreement or other understanding that Dr. Bodnar and Mr. Sherman reached on or about May 12, 2006 regarding BMS's refraining from launching an authorized generic during the period of Apotex's exclusive license under the Plavix Patent.

29. Moreover, pursuant to Paragraph XVII of the Order, BMS was required to file a verified report within 60 days after April 23, annually "setting forth in detail the

manner and form in which BMS intends to comply and is complying" with the Order. Although BMS filed reports with the states on April 20, 2007 and April 21, 2008, BMS did not mention in those reports the oral representation, side agreement or other understanding that Dr. Bodnar and Mr. Sherman reached on or about May 12, 2006 regarding authorized generics. The States contend that the reports therefore were incomplete and inaccurate.

30. BMS's failure to provide complete and accurate information, as required by the Order, materially interfered with the States' opportunity to assess the competitive impact of BMS's agreement with Apotex, a potential competitor, as the Order contemplated that the States would do. BMS's conduct thus impaired the effectiveness of a material provision of the Court's Order.

VII.

RELIEF SOUGHT

Plaintiff States and BMS have entered into a Letter Agreement in which BMS has agreed to pay Plaintiff States a monetary settlement and has agreed to modifications of the Order. BMS also has agreed not to oppose this Application and has consented to the entry of the Stipulated Amended Order, attached as Exhibit 1. Accordingly, Plaintiff States respectfully request that this Court enter the attached Stipulated Amended Order

Dated: New York, New York
December 22, 2008

ANDREW M. CUOMO

Attorney General of the State of New York

Elinor R. Hoffmann
Sarah M. Hubbard
Assistant Attorneys General
Antitrust Bureau
New York State Dep't of Law
120 Broadway, Suite 26C
New York, NY 10271
212-416-8269

Liaison Counsel for the States

Exhibit 1

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re: Buspirone Antitrust Litigation	Case Number 01 CV 11401 MDL 1410 MDL 1413 Judge: Hon. John G. Koeltl

AMENDED REVISED ORDER AND STIPULATED INJUNCTION

I.

IT IS ORDERED that for the purposes of this Amended Order and Stipulated Injunction, the following definitions shall apply:

A. "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. "Plaintiff States" means the Litigating Plaintiff States and any State or Commonwealth which is a party to the Settlement Agreement.

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.

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. "Litigating Plaintiff States" means: Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin and the District of Columbia.

T. "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).

U. "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.

V. "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.

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

X. "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.

Y. "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.

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

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

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

CC. "Relinquish" includes, but is not limited to, abandoning, waiving, or releasing.

DD. "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.

EE. "State Liaison Counsel" or "Liaison Counsel for the Plaintiff States" means the Attorneys General of the States of Florida, Maryland, New York, Ohio and Texas.

FF. **Provision FF. intentionally omitted**

GG. **Provision GG. intentionally omitted**

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

II.

IT IS FURTHER ORDERED that 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.

Provision III. intentionally omitted.

IV.

IT IS FURTHER ORDERED that 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. **Provision IV.B. intentionally omitted.**

V.

IT IS FURTHER ORDERED that 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 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 BMS shall not, in connection with any patent listed in the Orange Book under any NDA for which 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. 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. BMS provided Listing Information that is false or misleading;

D. BMS provided Listing Information to the FDA and Material Patent Information to the PTO, where 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 Plaintiff States 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 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, BMS had a reasonable belief that the statement was neither false nor misleading.

IX.

IT IS FURTHER ORDERED that 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 BMS shall not, without providing prior written notification to the Plaintiff States in the manner described in Paragraph XVI ("Notification"), acquire from another person a patent or an Exclusive License to a patent if 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 BMS pursuant to an agreement existing at the time the NDA received FDA approval.

XI.

IT IS FURTHER ORDERED that 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 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 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) 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) BMS has notified the Plaintiff States, as described in Paragraph XVI.

(2) BMS from resolving or settling a Patent Infringement Claim if BMS has notified Liaison Counsel for the Plaintiff States as described in Paragraph XVI, and Liaison Counsel for the Plaintiff States have not notified BMS of any objection to the proposed Agreement, resolution or settlement within 30 days.

(3) BMS, without notice to the Plaintiff States, 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 BMS makes a Patent Infringement Claim in which BMS is the NDA Holder, 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 BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products with respect to which 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) BMS has notified the Plaintiff States, as described in Paragraph XVI.

XV.

IT IS FURTHER ORDERED that, in any instance where BMS is a party to a Patent Infringement Claim in which it is the NDA Holder, 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:

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

B. 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, BMS provides the court the proposed Agreement, as well as a copy of the Plaintiff States' complaint and order in this matter;

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

(3) BMS does not oppose any effort by the Plaintiff States 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) BMS has notified Liaison Counsel for the Plaintiff States as described in Paragraph XVI and Liaison Counsel for the Plaintiff States have not notified BMS of any objection to the proposed Agreement within 30 days.

PROVIDED, HOWEVER, nothing in this Paragraph XV shall be interpreted to prohibit or restrict the right of 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. BMS shall notify Liaison Counsel for the Plaintiff States as required by Paragraphs X, XII, XIV, and XV in the form of a letter ("Notification Letter"), 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 Plaintiff States 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 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. Accompanying the Notification Letter, BMS shall submit a certification under oath that the Notification Letter is accurate, complete, and does not omit any information that is material to review by the Plaintiff States.

C. BMS shall submit the Notification Letter to Liaison Counsel for the Plaintiff States at least thirty (30) days prior to consummating the proposed Agreement ("First Waiting Period"). If BMS so requests, the Plaintiff States shall keep the Notification Letter and accompanying information and documents confidential to the extent provided by law.

D. If the Notification Letter is provided pursuant to:

(1) Paragraph XII, Liaison Counsel for the Plaintiff States may make a written request for additional information or documentary material prior to expiration of the First Waiting Period. If such a request for additional information is made, 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 Liaison Counsel for the Plaintiff States from BMS of any notification, pursuant to this Paragraph XVI, is not to be construed as a determination by the Plaintiff States that any action described in such notification does or does not violate this Order or any law enforced by the Plaintiff States.

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

E. Early termination of the Waiting Periods in this Paragraph XVI may be requested from Liaison Counsel for the Plaintiff States.

XVII.

IT IS FURTHER ORDERED that BMS shall file a verified written report within sixty (60) days after the date this Order becomes final, and annually thereafter through termination of this Order on the anniversary of the date this Order becomes final, and at such other times as Liaison Counsel for the Plaintiff States may by written notice require, setting forth in detail the manner and form in which BMS intends to comply, is complying, and has complied with this Order. 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. Accompanying the compliance report, BMS shall submit a certification under oath that the report is accurate, complete, and does not omit any information that may be material to review by the Plaintiff States. If, following review of BMS's compliance reports, Liaison Counsel for the Plaintiff States conclude that additional information is needed, upon reasonable notice to BMS, Liaison Counsel for the Plaintiff States may serve interrogatories on BMS regarding any matters contained in this Order, which BMS shall answer within 30 days of receipt.

XVIII.

IT IS FURTHER ORDERED that BMS shall notify Liaison Counsel for the Plaintiff States at least thirty (30) days prior to any proposed change in 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 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 BMS, BMS shall permit Liaison Counsel for the Plaintiff States:

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;

B. To interview officers, directors, employees, agents, and other representatives of BMS, who may have counsel present, informally or under oath and on the record, at the Plaintiff States' sole discretion and option, regarding such compliance issues;

C. To share information obtained pursuant to this Order with the Federal Trade Commission and to share information obtained by the Federal Trade Commission pursuant to the Order entered into by BMS and the Federal Trade Commission on April 14, 2003; and

D. To serve interrogatories upon BMS relating to compliance with this Order, which BMS shall answer within 30 days of receipt.

XX.

IT IS FURTHER ORDERED that, for purposes of monitoring, investigating or enforcing compliance by BMS with the terms of this Order, in addition to the provisions above and in addition to each Plaintiff State's authority to monitor, investigate or enforce compliance with this Order pursuant to state law, each Plaintiff State may issue subpoenas or Civil Investigative Demands to non-parties to obtain documents and other information subject to the procedures and confidentiality provisions of the Antitrust Civil Process Act, 15 U.S.C. 1312, et seq. All such subpoenas and CIDs issued to non-parties shall expressly refer to and attach a copy of this Order and Stipulated Injunction.

XXI.

Provision XXI. intentionally omitted.

XXII.

IT IS FURTHER ORDERED that, for any violation of this Order, BMS shall pay to the Plaintiff States a civil penalty of $11,000 per violation, with each day of a continuing violation constituting a separate violation. Any violation of this Order shall extend BMS's notification requirements pursuant to Paragraphs X, XII, XIV, XV, and XVI of this Order, and shall extend the term of this Order, for an additional five years from April 21, 2013, for a total of fifteen (15) years.

XXIII.

IT IS FURTHER ORDERED that this Order and Stipulated Injunction shall terminate ten (10) years from April 14, 2003, unless extended pursuant to paragraph XXII above.

Date

Hon. John G. Koeltl
United States District Court Judge

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re: Buspirone Antitrust Litigation	Case Number 01 CV 11401 MDL 1410 MDL 1413 Judge: Hon. John G. Koeltl

AMENDED REVISED ORDER AND STIPULATED INJUNCTION

I.

IT IS ORDERED that for the purposes of this Amended Order and Stipulated Injunction, the following definitions shall apply:

A. "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. "Plaintiff States" means the Litigating Plaintiff States and any State or Commonwealth which is a party to the Settlement Agreement.

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.

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. "Litigating Plaintiff States" means: Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, Florida, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Carolina, Texas, Utah, Vermont, Washington, West Virginia, Wisconsin and the District of Columbia.

T. "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).

U. "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.

V. "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.

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

X. "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.

Y. "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.

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

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

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

CC. "Relinquish" includes, but is not limited to, abandoning, waiving, or releasing.

DD. "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.

EE. "State Liaison Counsel" or "Liaison Counsel for the Plaintiff States" means the Attorneys General of the States of Florida, Maryland, New York, Ohio and Texas.

FF. **Provision FF. intentionally omitted**

GG. **Provision GG. intentionally omitted**

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

II.

IT IS FURTHER ORDERED that 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.

Provision III. intentionally omitted.

IV.

IT IS FURTHER ORDERED that 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. **Provision IV.B. intentionally omitted.**

V.

IT IS FURTHER ORDERED that 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 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 BMS shall not, in connection with any patent listed in the Orange Book under any NDA for which 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. 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. BMS provided Listing Information that is false or misleading;

D. BMS provided Listing Information to the FDA and Material Patent Information to the PTO, where 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 Plaintiff States 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 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, BMS had a reasonable belief that the statement was neither false nor misleading.

IX.

IT IS FURTHER ORDERED that 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 BMS shall not, without providing prior written notification to the Plaintiff States in the manner described in Paragraph XVI ("Notification"), acquire from another person a patent or an Exclusive License to a patent if 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 BMS pursuant to an agreement existing at the time the NDA received FDA approval.

XI.

IT IS FURTHER ORDERED that 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 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 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) 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) BMS has notified the Plaintiff States, as described in Paragraph XVI.

(2) BMS from resolving or settling a Patent Infringement Claim if BMS has notified Liaison Counsel for the Plaintiff States as described in Paragraph XVI, and Liaison Counsel for the Plaintiff States have not notified BMS of any objection to the proposed Agreement, resolution or settlement within 30 days.

(3) BMS, without notice to the Plaintiff States, 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 BMS makes a Patent Infringement Claim in which BMS is the NDA Holder, 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 BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products with respect to which 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) BMS has notified the Plaintiff States, as described in Paragraph XVI.

XV.

IT IS FURTHER ORDERED that, in any instance where BMS is a party to a Patent Infringement Claim in which it is the NDA Holder, 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:

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

B. 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, BMS provides the court the proposed Agreement, as well as a copy of the Plaintiff States' complaint and order in this matter;

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

(3) BMS does not oppose any effort by the Plaintiff States 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) BMS has notified Liaison Counsel for the Plaintiff States as described in Paragraph XVI and Liaison Counsel for the Plaintiff States have not notified BMS of any objection to the proposed Agreement within 30 days.

PROVIDED, HOWEVER, nothing in this Paragraph XV shall be interpreted to prohibit or restrict the right of 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. BMS shall notify Liaison Counsel for the Plaintiff States as required by Paragraphs X, XII, XIV, and XV in the form of a letter ("Notification Letter"), 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 Plaintiff States 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 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. Accompanying the Notification Letter, BMS shall submit a certification under oath that the Notification Letter is accurate, complete, and does not omit any information that is material to review by the Plaintiff States.

C. BMS shall submit the Notification Letter to Liaison Counsel for the Plaintiff States at least thirty (30) days prior to consummating the proposed Agreement ("First Waiting Period"). If BMS so requests, the Plaintiff States shall keep the Notification Letter and accompanying information and documents confidential to the extent provided by law.

D. If the Notification Letter is provided pursuant to:

(1) Paragraph XII, Liaison Counsel for the Plaintiff States may make a written request for additional information or documentary material prior to expiration of the First Waiting Period. If such a request for additional information is made, 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 Liaison Counsel for the Plaintiff States from BMS of any notification, pursuant to this Paragraph XVI, is not to be construed as a determination by the Plaintiff States that any action described in such notification does or does not violate this Order or any law enforced by the Plaintiff States.

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

E. Early termination of the Waiting Periods in this Paragraph XVI may be requested from Liaison Counsel for the Plaintiff States.

XVII.

IT IS FURTHER ORDERED that BMS shall file a verified written report within sixty (60) days after the date this Order becomes final, and annually thereafter through termination of this Order on the anniversary of the date this Order becomes final, and at such other times as Liaison Counsel for the Plaintiff States may by written notice require, setting forth in detail the manner and form in which BMS intends to comply, is complying, and has complied with this Order. 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. Accompanying the compliance report, BMS shall submit a certification under oath that the report is accurate, complete, and does not omit any information that may be material to review by the Plaintiff States. If, following review of BMS's compliance reports, Liaison Counsel for the Plaintiff States conclude that additional information is needed, upon reasonable notice to BMS, Liaison Counsel for the Plaintiff States may serve interrogatories on BMS regarding any matters contained in this Order, which BMS shall answer within 30 days of receipt.

XVIII.

IT IS FURTHER ORDERED that BMS shall notify Liaison Counsel for the Plaintiff States at least thirty (30) days prior to any proposed change in 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 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 BMS, BMS shall permit Liaison Counsel for the Plaintiff States:

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;

B. To interview officers, directors, employees, agents, and other representatives of BMS, who may have counsel present, informally or under oath and on the record, at the Plaintiff States' sole discretion and option, regarding such compliance issues;

C. To share information obtained pursuant to this Order with the Federal Trade Commission and to share information obtained by the Federal Trade Commission pursuant to the Order entered into by BMS and the Federal Trade Commission on April 14, 2003; and

D. To serve interrogatories upon BMS relating to compliance with this Order, which BMS shall answer within 30 days of receipt.

XX.

IT IS FURTHER ORDERED that, for purposes of monitoring, investigating or enforcing compliance by BMS with the terms of this Order, in addition to the provisions above and in addition to each Plaintiff State's authority to monitor, investigate or enforce compliance with this Order pursuant to state law, each Plaintiff State may issue subpoenas or Civil Investigative Demands to non-parties to obtain documents and other information subject to the procedures and confidentiality provisions of the Antitrust Civil Process Act, 15 U.S.C. 1312, et seq. All such subpoenas and CIDs issued to non-parties shall expressly refer to and attach a copy of this Order and Stipulated Injunction.

XXI.

Provision XXI. intentionally omitted.

XXII.

IT IS FURTHER ORDERED that, for any violation of this Order, BMS shall pay to the Plaintiff States a civil penalty of $11,000 per violation, with each day of a continuing violation constituting a separate violation. Any violation of this Order shall extend BMS's notification requirements pursuant to Paragraphs X, XII, XIV, XV, and XVI of this Order, and shall extend the term of this Order, for an additional five years from April 21, 2013, for a total of fifteen (15) years.

XXIII.

IT IS FURTHER ORDERED that this Order and Stipulated Injunction shall terminate ten (10) years from April 14, 2003, unless extended pursuant to paragraph XXII above.

Date

Hon. John G. Koeltl
United States District Court Judge