ATTACHMENT 4

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

ORDER AND STIPULATED INJUNCTION

I.

IT IS ORDERED that for the purposes of this 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 or which becomes a party to the Settlement Agreement to which this Order and Stipulated Injunction is attached.

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:

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, 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. 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.

C. 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.

D. 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, annually thereafter for five (5) years 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. 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 _____, 2003;[1] and

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

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[1]This Order and Stipulated Injunction (Attachment 4) shall be interpreted consistently with the Federal Trade Commission's Order and, except for BMS's specific obligations to the Plaintiff States as set forth in this Attachment 4, to the extent that this Attachment 4 is materially inconsistent with the Federal Trade Commission's Order, the Federal Trade Commission's Order shall govern.

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 or federal 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 this Order and Stipulated Injunction shall terminate ten (10) years from the date this Order becomes final.

_____
Date

_____
Hon. John G. Koeltl
United States District Court Judge