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

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Plaintiffs,

v.

BRISTOL-MYERS SQUIBB CO.,

DANBURY PHARMACAL, INC., and

WATSON PHARMA, INC.

Defendants.

STATES' FOURTH AMENDED COMPLAINT

The States and Commonwealths of 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, and Wisconsin, and the District of Columbia (collectively "Plaintiff States" or "States"), by and through their Attorneys General, allege as follows:

I. SUMMARY OF COMPLAINT

1. BuSpar® is a brand-name prescription drug containing buspirone hydrochloride as its active pharmaceutical ingredient. Since 1986, BuSpar® has been manufactured and sold by Defendant Bristol-Myers Squibb Co. ("BMS") as a medication for treating patients suffering from generalized anxiety disorder. In 2000, BMS had over $709 million in BuSpar® sales.

2. As described below, on December 2, 1994, BMS entered into an agreement with Schein Pharmaceutical, Inc. (now on information and belief Watson Pharma, Inc.) and Danbury Pharmacal, Inc. (collectively the "Schein Entities" or "Schein") (the "Schein Agreement"). As a result of this illegal agreement, BMS was able to prevent the entry of generic competitors and illegally maintain its monopoly in the United States over the sale of buspirone hydrochloride-based prescription drug products ("buspirone").

3. In addition, as set forth in the allegations below, BMS engaged in fraud in order to unlawfully maintain its monopoly for buspirone in the United States, by improperly submitting U.S. Patent No. 5,150,365 ("the '365 patent") for listing in a publication of the United States Food and Drug Administration ("FDA"), the "Approved Drug Products with

Therapeutic Equivalence Evaluations," commonly known as the "Orange Book," and by misrepresenting that the '365 patent covered a method of using BuSpar®. BMS's unlawful conduct caused the FDA to withhold final approval of several applications by other drug manufacturers to market generic buspirone.

4. As a result of BMS's and the Schein Entities' unlawful actions, generic competition in the sale of buspirone was foreclosed, causing consumers and governmental entities to lose the substantial cost savings that generic entry would have produced.

5. Plaintiff States seek a finding that BMS's and the Schein Entities actions violated federal and state antitrust laws, consumer protection laws, unfair competition laws and other related state laws; a permanent injunction preventing BMS from listing the '365 patent in the Orange Book; other permanent injunctive relief; civil penalties; and damages and other relief for injuries sustained as a result of BMS's and the Schein Entities violations of law.

II. PARTIES

6. BMS is a Delaware corporation with its principal place of business at 345 Park Avenue, New York, N.Y. BMS, through its divisions and subsidiaries, manufactures and distributes prescription drugs (including BuSpar®), consumer healthcare products, medical devices, and beauty care products. For the year 2000, BMS's total net sales worldwide were approximately $18.2 billion.

7. Watson Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey. On information and belief, Watson Pharma formerly transacted business under the name Schein Pharmaceuticals, Inc.

8. Danbury Pharmacal, Inc. is a Delaware corporation with its principal place of business in Carmel, New York.

9. The States bring this action by and through their Attorneys General, in a statutory, equitable and/or common law capacity: (a) in their sovereign capacities, as representatives of, and/or as *parens patriae* on behalf of, or for the benefit of, natural persons under federal or state law; (b) as common law *parens patriae* in their sovereign capacities on behalf of their respective states' general economies; and (c) in their proprietary and/or sovereign capacities, which may include state departments, bureaus, agencies, political subdivisions, and other instrumentalities as purchasers (either directly, indirectly, or as assignees) or as purchasers under medical or pharmaceutical reimbursement programs, of BuSpar®.

III. JURISDICTION

10. The Court has jurisdiction of this action under Sections 1 & 2 of the Sherman Act, 15 U.S.C. §§ 1, 2, and Sections 4, 4C, 12 & 16 of the Clayton Act, 15 U.S.C. §§ 15, 15c, 22 and 26, and under 28 U.S.C. §§ 1331, 1337.

11. In addition to pleading violations of federal antitrust law, the States also allege violations of state antitrust, consumer protection and/or unfair competition statutes and related state laws, as set forth below, and seek damages, civil penalties and/or equitable relief under those state laws. All claims under federal and state law are based upon a common nucleus of operative facts, and the entire action commenced by this Complaint constitutes a single case that would ordinarily be tried in one judicial proceeding. This Court has jurisdiction of the non-federal claims under 28 U.S.C. §1367(a), as well as under the principles of supplemental

jurisdiction. Supplemental jurisdiction will avoid unnecessary duplication and multiplicity of actions, and should be exercised in the interests of judicial economy, convenience, and fairness.

12. Venue is proper in this district under Section 12 of the Clayton Act, 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c). BMS is headquartered, and BMS and the Schein Entities transact business in this district. Further, the claims alleged arose, in whole or in part, in this judicial district.

IV. FACTS UNDERLYING THE STATES' CLAIMS

A. New Drug Applications

13. Under the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, a drug manufacturer must obtain approval from the FDA before the manufacturer may lawfully begin selling a new (or pioneer) drug in the United States. 21 U.S.C. § 355(a). In order to obtain FDA approval, the manufacturer must file a New Drug Application ("NDA") demonstrating that the drug is safe and effective for its intended use .

14. An FDA-approved new drug can be covered by one or more patents. A patent grants the owner the right to exclude others from making, using, or selling the claimed product or method for the duration of the patent and any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 (the "Hatch-Waxman Act").

15. An NDA must list all patents that claim the drug, or that claim a method of using the drug, where a claim of patent infringement could reasonably be asserted against an unauthorized manufacturer or seller of the drug. 21 U.S.C. § 355(b).

16. Once the NDA is approved, the FDA lists all patents claiming the approved drug in the Orange Book. *See* 21 U.S.C. § 355(j)(7)(a)(iii).

17. Pursuant to 21 U.S.C. § 355(c)(2), when a brand-name drug manufacturer is issued a new patent that claims a drug or method of its use, the brand-name manufacturer must supplement its NDA listing within 30 days of issuance. Upon certification by the brand-name manufacturer that such a patent has been issued, the FDA lists the new patent in a supplement to the Orange Book. The FDA has a long-standing, publicly announced policy of accepting at face value the accuracy of patent information it receives from a patent holder.

B. Generic Drugs

i. Definition

18. A generic drug is one that has been approved by the FDA as bioequivalent to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.

19. Generic drugs are usually priced substantially below their brand-name drug bioequivalents. Typically, the first generic drug to be sold is priced at a percentage discount off the brand-name drug price, and even steeper price reductions occur as more generic versions enter the market. The beneficiaries of this competition are prescription drug purchasers, including both consumers and third-party payors/reimbursers.

20. A brand-name drug generally loses substantial market share to generic competition within a relatively short time after a generic bioequivalent is introduced to the market. Often, consumers covered by third-party payor plans switch to a generic bioequivalent. Third-party payors encourage their members to use generic drugs by, among other things, reducing co-payments for members who receive generics. Many uninsured prescription drug

purchasers (cash payors) switch from brand-name to generic drugs in order to obtain the lower price.

21. In some states, a pharmacist is required by law to dispense the generic version of a drug unless the prescribing physician has specifically indicated on the prescription "dispense as written" ("DAW"), or a similar instruction, the wording of which varies slightly from state to state.

ii. Abbreviated New Drug Applications ("ANDAs") For Generic Drugs

22. One of Congress's principal goals in enacting the Hatch-Waxman Act was to facilitate generic competition by streamlining the process by which manufacturers of generic drugs receive regulatory approval to bring their products to market. Under Hatch-Waxman, a company may seek expedited FDA approval to market a generic version of a brand-name drug with an approved NDA by filing an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. § 355(j). An ANDA filer relies on the safety and efficacy data already filed with the FDA by the brand-name manufacturer.

23. In its ANDA, a generic manufacturer must certify one of the following: (i) no patent for the generic bioequivalent has been filed with the FDA ("Paragraph I Certification"); (ii) the patent for the brand-name drug has expired ("Paragraph II Certification"); (iii) the patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date ("Paragraph III Certification"); or (iv) the patent for the brand-name drug is invalid or will not be infringed by the generic company's proposed product ("Paragraph IV Certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

24. Pursuant to a Paragraph III Certification, the Hatch-Waxman Act allows ANDA applicants to perform all necessary testing, to submit an application for approval, and to receive tentative approval before the relevant patents covering the brand-name pioneer drug expire. Upon the patent's expiration and receipt of FDA final approval, the generic drug companies may market their generic versions of the brand-name drug. Prior to the Hatch-Waxman Act, a generic applicant could not engage in any research that infringed upon any patents claiming any aspect of the brand-name drug; the approval process could not even begin until the patents had expired.

25. Pursuant to the Hatch-Waxman Act, after a generic manufacturer files its Paragraph IV Certification with the FDA, it must then provide notice of the Paragraph IV Certification to the brand-name manufacturer, along with an explanation as to the reasons why it believes that its generic drug either does not infringe upon the patent or the patent is invalid. If the brand-name manufacturer brings a patent infringement suit against the generic manufacturer within 45 days of its receiving this notice, under the Hatch-Waxman Act, the FDA's approval of the ANDA is automatically stayed for 30 months, or until there is a final decision in the patent case finding the patent either invalid or not infringed, whichever occurs first.

C. BMS's and the Schein Entities' Unlawful, Anticompetitive Acts

i. The "Schein Agreement"

26. In 1976, BMS received U.S. Patent No. 3,976,776 ("the '776 patent"). The '776 patent stated, in pertinent part, that the tranquilizing effects of buspirone were similar to those achieved with chlorpromazine, a tranquilizer used to treat anxiety. Notwithstanding the issuance of the '776 patent, in 1978, BMS filed another patent application to cover the use of buspirone to

treat anxiety. In 1980, as a result of this new patent application, BMS received U.S. Patent No. 4,182,763 ("the '763 patent"), which claimed a method for using buspirone to treat anxiety. BMS obtained FDA approval to market Buspar® in 1986.

27. In August, 1992, the Schein Entities filed an ANDA containing a Paragraph IV Certification with the FDA. Simultaneously, the Schein Entities served BMS with notice of its Paragraph IV Certification. The Schein Entities asserted that the '763 patent was invalid and unenforceable, because it claimed a use anticipated in the previously issued '776 patent, *i.e.*, using buspirone to treat anxiety.

28. Pursuant to the Hatch-Waxman Act, BMS sued the Schein Entities for patent infringement in the Southern District of New York. Because BMS's suit was filed within 45 days of its receipt of Schein's notice, the FDA was precluded from approving Schein's ANDA for 30 months unless, during this 30-month period, the patent infringement suit was resolved in Schein's favor.

29. During the course of the litigation, Schein filed a motion for summary judgment. In this motion, Schein asserted that the '763 patent was invalid, because its invention was anticipated by the '776 patent. On June 30, 1993, the District Court granted Schein's summary judgment motion and held that the '776 patent, in fact, had disclosed buspirone's anti-anxiety effects. *Bristol-Myers Squibb Co. v. Danbury Pharmacal, Inc.,* 825 F. Supp. 58 (S.D.N.Y. 1993).

30. In opposing Schein's motion for summary judgment, BMS had relied on expert affidavits stating that in 1969, when the '776 patent application had been filed, the buspirone uses described in the patent would have been interpreted to cover only anti-psychotic effects, and not anti-anxiety effects. The District Court found that these affidavits did not give rise to a

disputed issue of material fact, because the expert affidavits were contradicted by statements BMS had made to the FDA in 1972, in the course of attempting to secure FDA approval, as well as by the plain language of the '776 patent itself. Specifically, the District Court concluded that "[i]n face of this clear evidence that the invention covered exactly what the plain meaning of the language suggests, plaintiffs' submissions of expert affidavits that ask the Court to ignore the plain language of the patent do not create an issue of fact precluding summary judgment." 825 F. Supp. at 62.

31. BMS appealed the District Court's ruling to the United States Court of Appeals for the Federal Circuit. *Bristol-Myers Squibb Co., et al. v. Danbury Pharmacal, Inc.,* 26 F. 3d 138, 33 U.S. P.Q. 2d 1539, 1994 U.S. App. Lexis 7461 (Fed. Cir. 1994). The Federal Circuit agreed that the expert affidavits on which BMS relied in opposing summary judgment "conflicted with statements made by Bristol-Myers to the FDA and with other evidence relied on by the district court." Nevertheless, the Federal Circuit held that the expert affidavits were sufficient to raise disputed issues of fact. For this reason, the Federal Circuit vacated the grant of summary judgment and remanded to the District Court for trial.

32. While BMS had succeeded in obtaining a reversal of the grant of summary judgment, it was still faced with the prospect of putting on a case in which its principal witnesses were paid experts retained specifically for the litigation who would be impeached by BMS's own statements to the FDA. For this reason, BMS knew that at trial Schein's challenge to the validity of the '763 patent was extremely likely to succeed. Schein was also aware that it was quite likely to win the trial.

33. To avoid its probable loss at trial, BMS entered into an illegal agreement with Schein which had the purpose and effect of foreclosing Schein as a generic competitor. BMS

agreed to make annual payments to Schein over a term of four years, beginning with $5 million dollars due in 1995, $12.5 million in 1996, $25 million in 1997, and $30 million in 1998, for a total of $72.5 million

34. In return, Schein agreed and acknowledged that the '763 patent was valid and enforceable, that the manufacture, use or sale of buspirone would infringe the '763 patent, and agreed not to engage in the purchase, manufacture, use or sale of a generic version of buspirone.

35. Schein also agreed to take steps calculated to conceal any indication of the likely invalidity of the '763 patent and to create an appearance of the validity of the patent which would deter any other potential entrant from challenging that validity. Indeed, both BMS and Schein implicitly recognized in the Schein Agreement that, having agreed not to compete, their joint interest was in deterring any such challenge and any competitive entry. They noted, in the "Background Statement" of the Schein Agreement, that "the parties' calculations and estimates of their respective expenses, damages, or profits would be made uncertain by the filing of litigation by a third party challenging the validity and/or enforceability of the '763 patent."

36. Specifically, Schein agreed to do the following:

- To join in submitting to the District Court a stipulation of dismissal in a form that would "insure that the presumption of validity of the '763 patent remains intact and that BMS retains the full power to enforce the '763 patent to the same extent as though the Litigation had never commenced."
- To convert its ANDA for the '763 patent from a Paragraph IV Certification to a Paragraph III Certification.
- Not to share with any third parties any information concerning the '763 patent or the litigation.

• Not to disclose the facts or terms of the settlement agreement to any parties and to cooperate with BMS to oppose disclosure of the agreement by means of legal process.

37. Absent the Schein Agreement, Schein would likely have begun selling a generic version of buspirone, because it was likely to have prevailed in the litigation and/or because it would have been economically rational and preferable for BMS to grant Schein a license to sell a generic version of BuSpar® for a royalty rather than risk the losses it would have suffered if the '763 patent were declared invalid. The Agreement therefore resulted directly in the unlawful extension of BMS's monopoly power and the exclusion of generic competition until November 21, 2000, at 11:59 p.m., when the '763 patent expired.

ii. BMS's Fraud On The FDA

38. On September 29, 1998, Mylan Laboratories, Inc. ("Mylan"), the nation's largest generic drug manufacturer, submitted an ANDA to the FDA for a generic version of buspirone tablets. Mylan's ANDA contained a Paragraph III Certification stating that it would not market its generic product until the expiration of BMS's '763 patent. The FDA granted tentative approval of Mylan's ANDA, with final approval contingent only on the expiration of BMS's patent on November 21, 2000. Anticipating that BMS's patent would expire, Mylan and Danbury, which also had a pending Paragraph III Certification for buspirone, prepared to bring their generic buspiorone to market. Mylan's activities included loading its trucks and otherwise preparing to ship its product beginning at 12:00 a.m. on November 22, 2000.

39. On August 5, 1999, BMS filed patent application 09/368,842 ("the '842 application") with the U.S. Patent and Trademark Office ("PTO"). This application's claim was for the treatment of anxiety through 1) the systemic administration of metabolite BMY 28674

and 2) the systemic administration of a prodrug of the metabolite (e.g., buspirone).

40. A "metabolite" is created when a chemical introduced into the body interacts with other chemicals inside the body during a process known as metabolism. In the case of buspirone, from at least 1989, several metabolites had been identified as occurring in humans after ingesting buspirone, including the metabolite BMY 28674. A "prodrug" is a chemical that is metabolized in the body and becomes (at least in part) an active pharmaceutical agent. In the case of the metabolite BMY 28674, the prodrug is buspirone. BMS did not claim to have invented BMY 28674. The '842 application however, and subsequent patent applications, claim that BMS was the first to discover that administering metabolite BMY 28674 to a patient could treat anxiety.

41. In the course of reviewing the '842 application, the patent examiner concluded that the claim consisted of two distinct inventions: systemic administration of the metabolite BMY 28674 (including its salts and hydrates) and systemic administration of the prodrug form of BMY 28674 (buspirone). The patent examiner required BMS to choose one of the two inventions for continued prosecution in the '842 application. In response, BMS elected to amend its claim in the '842 application to continue prosecution of the prodrug invention, and added a second claim that specifically recited the systemic administration of buspirone.

42. On December 13, 1999, the PTO rejected the prodrug claim in the '842 application, stating that, among other things, the use of buspirone for the treatment of anxiety is prior art, and that the fact that buspirone becomes the metabolite inside the body is an unpatentable inherent quality.

43. On January 18, 2000, BMS filed divisional application 09/484,161 ("the '161 application") with the PTO containing a single claim that recited the systemic administration of

the metabolite BMY 28674 to treat anxiety. This was the metabolite claim that BMS had elected not to pursue in the '842 application.

44. On June 6, 2000, BMS filed two continuation-in-part applications: continuation-in-part application 09/588,221 ("the '221 application"), and continuation-in-part application 09/588, 222 ("the '222 application"). Both of these applications contained a metabolite claim identical to the one set forth in the '161 application.

45. Shortly thereafter, on June 9, 2000, BMS expressly abandoned the '842 application. By doing so, BMS relinquished its claim directed to the systemic administration of the prodrug (buspirone).

46. In September 2000, the PTO rejected both the '221 application and the '222 application for double patenting, because the claims of the '221, '222 and '161 applications were identical (each claiming administration of BMY 28674).

47. In response, BMS abandoned both the '161 application and the '222 application. BMS then sought reconsideration of the '221 application, which claimed the systemic administration of the metabolite BMY 28674, and **not** the systemic administration of the prodrug buspirone.

48. On October 2, 2000, the PTO issued a Notice of Allowability concerning the '221 application. On October 5, 2000, BMS filed a petition to expedite the issuance of the patent.

49. Hours before the '763 patent's term was set to expire, on November 21, 2000, the PTO issued to BMS U.S. Patent No. 5,150,365 (the " '365 patent"). The sole claim in the '365 patent is for the systemic administration of the metabolite. The '365 patent claims:

> A process for ameliorating an undesirable anxiety state in a mammal comprising systemic administration to the mammal of an effective but non-toxic anxiolytic dose of [BMY 28674]

or pharmaceutically acceptable acid addition salt or hydrate thereof.

50. BMS immediately notified the FDA that its '365 patent was to be listed in the Orange Book. Its submission to the FDA contained the information required by the FDA's regulations, and included a declaration that the '365 patent "is a method-of-use patent covering, among other things, a method of using BuSpar® for all of its approved indications."

51. As a result of the FDA's receipt of the '365 patent and accompanying declaration, the FDA denied final approval to Mylan's ANDA (and to all other ANDAs) for generic buspirone tablets.

52. On November 21, 2000, BMS also issued a press release stating the '365 patent covers "a method of use of a metabolite produced by the administration of [buspirone]." Mylan and Danbury provided copies of this release to the FDA. The FDA also received correspondence from Danbury, in which Danbury argued that under the Federal Circuit's ruling in *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756 (Fed. Cir. 1997), a patent for a metabolite could not "claim a listed drug" within the meaning of the patent laws.

53. After reviewing the BMS press release and the Federal Circuit's *Hoechst-Roussel* decision, the FDA determined that a patent for a drug's metabolites does not "claim" the listed drug itself. The FDA asked BMS in a November 30, 2000 letter to provide "a declaration that the '365 patent issued by the PTO on November 21, 2000 contains a claim for an approved use of buspirone [the approved drug] that is separate from the claim for 6-hydroxy-buspirone [the metabolite] described in the November 21, 2000 Bristol-Myers Squibb press release." The FDA also asked Mylan and Danbury to submit additional legal analysis "to help the agency determine the impact of this Federal Circuit opinion [*Hoechst-Roussel*] on the patent listing process."

54. On December 4, 2000, BMS submitted a declaration under oath in response to the FDA . In its declaration, BMS stated that the sole claim of the '365 patent was:

> a method for ameliorating an undesirable anxiety state comprising the direct administration of 6-hydroxy-buspirone [the metabolite] ***or oral administration of a prodrug [buspirone] of 6-hydroxy-buspirone such as buspirone hydrochloride*** to provide an effective but non-toxic anxiolytic dose of 6-hydroxy-buspirone.

(emphasis added to language that substantively differs from patent issued by PTO). In the declaration, BMS further stated that its press release was "a short-hand, layperson's description of the patent." In a letter accompanying its declaration, BMS reiterated that "the '365 patent does not simply claim a method of using [the metabolite], but also claims a method of using [buspirone itself]."

55. BMS obtained its Orange Book listing of the '365 patent by fraud. BMS knew that its representations to the FDA that the '365 patent claimed a method of using buspirone itself -- and not only a metabolite -- were false. BMS made these false representations for the purpose and with the intent to improperly obtain an Orange Book listing of the '365 patent. BMS made these fraudulent representations for the purpose of forestalling competition for BuSpar® sales from generic drug manufacturers.

56. Based on BMS's declaration, and consistent with the FDA's long-standing policy of accepting at face value the accuracy of such patent declarations, the FDA concluded that the Federal Circuit's ruling in *Hoechst-Roussel* was inapplicable because the '365 patent did not solely claim a metabolite. The FDA informed BMS that the declaration had "adequately responded" to the agency's concerns, and that the '365 patent would, therefore, be deemed to have been listed in the Orange Book on November 21, 2000.

57. After the '365 patent was listed in the Orange Book, various generic manufacturers filed Paragraph IV Certifications with the FDA and provided BMS with notice of these certifications. BMS filed suit against these generic manufacturers within 45 days of receiving the notices. In so doing, BMS triggered the automatic 30-month stay provision of the Hatch-Waxman Act.

58. BMS pursued patent infringement litigation against generic competitors knowing that its '365 patent was invalid, to the extent that it was construed by BMS to claim the administration of buspirone in the form, dosages and uses encompassed in the '763 patent and encompassed in prior art.

59. BMS filed its patent infringement actions knowing the '365 patent cannot support a reasonable claim that a generic version of buspirone would infringe that patent.

60. The specific intent and effect of BMS's multiple infringement lawsuits was to prevent generic manufacturers from marketing their products as long as possible by taking advantage of the full 30-month stay of competition under the Hatch-Waxman provisions.

D. <u>The '365 Patent Should Not Have Been Listed In The Orange Book</u>

61. BMS's '365 patent does not meet the two statutory listing requirements of 21 U.S.C. §§ 355 (c)(1) and (c)(2). Specifically, the '365 patent does not meet either the statutory listing requirement that (1) it "claim the drug" or "a method of using" the drug for which BMS had obtained FDA approval; or that (2) "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the [approved] drug."

i. <u>The '365 Patent Does Not Claim Buspirone or a Method of Using Buspirone</u>

62. The prosecution history of the '365 patent can be summarized as follows: (a) BMS attempted to claim the systemic *administration* of buspirone as a prodrug; (b) the PTO did not allow it; and (c) BMS *abandoned* that claim . The '365 patent is therefore limited to the systemic administration of the metabolite , and does not -- and cannot -- claim BuSpar® or a method of using BuSpar®.

ii. No Buspirone Product Would Infringe the '365 Patent

63. To be properly listed in the Orange Book, the '365 patent must cover the same method of using BuSpar® as is currently approved. The '365 patent, however, expressly disclaims coverage of the administration of buspirone in the manner currently approved. The patent's specification states:

> However, this method of systemic administration of BMY 28674 improves upon and *differs from the known standard method of oral administration of buspirone*.

The patent specification also states that the claimed invention "is in contradiction to currently accepted methods of administration" and "is directly counter to the past method of orally administering buspirone."

64. Thus, according to the '365 patent itself, the use of BuSpar® in accordance with its current labeling would not infringe the '365 patent. The proper claim construction in the '365 patent does not cover the conventional mode of administering buspirone – the method set out in the approved NDA for BuSpar®. Accordingly, the '365 patent does not claim a method of using BuSpar® with respect to which a claim of patent infringement could reasonably be asserted.

65. BMS knowingly submitted false declarations to the FDA so as to list the '365 patent in the Orange Book. By creating new – and impermissible – ways to extend its monopoly, BMS has unlawfully limited the public's access to lower-cost generic buspirone.

E. The Court's Order For BMS to De-List the '365 Patent

66. On November 30, 2000, Mylan filed a lawsuit in the U.S. District Court for the District of Columbia requesting, among other things, an injunction ordering the de-listing of the '365 patent from the Orange Book. On March 14, 2001, Judge Ricardo M. Urbina granted Mylan's motion for a preliminary injunction and ordered BMS to request that the FDA de-list the patent, and further ordered the FDA to grant immediate approval of Mylan's ANDA for its generic buspirone. *Mylan Pharmaceuticals, Inc. v. Thompson,* 139 F. Supp. 2d 1 (D.D.C. 2001). BMS and the FDA both complied with the Order.

67. On October 12, 2001, the United States Court of Appeals for the Federal Circuit reversed the District Court's Order on the grounds that Mylan's action for declaratory judgment was a non-justiciable private attempt to enforce the Federal Food, Drug and Cosmetic Act. *Mylan Pharmaceuticals, Inc. v. Thompson,* 2001 U.S. App. Lexis 21768 (Fed. Cir. 2001). The Federal Circuit did not reach the merits of Judge Urbina's decision that the '365 patent should not have been listed in the Orange Book.

V. RELEVANT MARKETS

68. The relevant product market is the market for the manufacture and sale of buspirone hydrochloride based prescription drugs. The relevant geographic market is the United States (50 states, the District of Columbia, the Commonwealth of Puerto Rico, other U.S. commonwealths, and protectorates).

69. Until the March 14, 2001, U.S. District Court for the District of Columbia Order, BMS's share of the relevant market was 100%. BMS has unlawfully maintained (or unlawfully attempted to maintain) monopoly power in the relevant market.

VI. TRADE AND COMMERCE

70. The activities of BMS and the Schein Entities, including manufacturing, marketing, distributing and selling buspirone prescription drugs, were in the regular, continuous and substantial flow of interstate commerce and have had and continue to have a substantial effect upon interstate commerce.

VII. MARKET EFFECTS

71. The acts and practices of BMS and the Schein Entities have had the purpose or effect, or the tendency or capacity, of restraining competition unreasonably and injuring competition by preventing the entry of generic buspirone.

72. Absent BMS's and the Schein Entities' illegal, anticompetitive conduct, at least one generic competitor would have begun marketing a generic version of buspirone prior to the expiration of the '763 patent.

73. Absent BMS's illegal "Orange Book" listing and associated conduct, upon the expiration of the '763 patent on November 21, 2000, generic competition would have begun on or about November 22, 2001.

74. If a generic competitor had been able to enter the relevant market at either time and compete with BMS, consumers and state entities (payors and reimbursers) would have been

free to substitute -- and, to a significant extent, would have substituted -- a lower-priced generic for the higher-priced brand-name drug.

75. By preventing generic competitors from entering the market, BMS and the Schein Entities have deprived Plaintiff States and their consumers of the benefits of the competition that the federal and state antitrust laws, consumer protection laws and/or unfair competition statutes and related state laws are designed to promote, preserve, and protect.

VIII. INJURY

76. As a direct and proximate result of the unlawful conduct alleged above, the States were not and are not able to purchase, or pay reimbursements for purchases of, buspirone at prices determined by free and open competition. Consequently, they have been injured in their business and property in that, *inter alia,* they have paid more and continue to pay more for buspirone than they would have paid in a free and open competitive market. The States cannot quantify at this time the precise amount of monetary harm which they have sustained, but allege that such harm is substantial. A precise determination of this amount will require discovery from the books and records of BMS, the Schein Entities and third parties.

77. As a direct and proximate result of the unlawful conduct alleged above, consumers in the Plaintiff States were not and are not able to purchase buspirone at prices determined by free and open competition, and consequently have been injured in their business or property in that, *inter alia*, they have paid more and continue to pay more for buspirone than they would have paid in a free and open competitive market. The States cannot quantify at this time the precise amount of monetary harm which their consumers have sustained, but allege that

such harm is substantial. A precise determination of this amount will require discovery from the books and records of BMS, the Schein Entities and third parties.

78. As a direct and proximate result of the unlawful conduct alleged above, the general economies of the States have sustained injury and the States are threatened with further injury to their business and property unless BMS and the Schein Entities are enjoined from its unlawful conduct.

79. As a direct and proximate result of the unlawful conduct alleged above, BMS and the Schein Entities have unjustly profited through inflated profit margins and have thus far retained the illegally obtained profits.

80. BMS's unlawful conduct is continuing and will continue unless the injunctive and equitable relief requested by the Plaintiff States is granted. Plaintiff States do not have an adequate remedy at law.

IX. FRAUDULENT CONCEALMENT

81. The running of any statute of limitations has been tolled by reason of BMS's and Schein's fraudulent concealment. As described above, BMS took affirmative steps, and enlisted the Schein Entities also to take affirmative steps, to keep secret an agreement not to compete between BMS and a potential generic competitor.

82. Until after their entry into this action, the Plaintiff States were unaware of, and could not through due diligence have discovered, the existence or terms of the Schein Agreement. Indeed, BMS designated the Schein Agreement as confidential under the Protective Order, thus making it available to the States only after the filing of their initial complaint.

X. BMS UNLAWFULLY MAINTAINED ITS MONOPOLY FOR BUSPIRONE PRESCRIPTION DRUGS

83. Plaintiff States repeat and reallege every preceding allegation.

84. BMS had a lawful monopoly over sales of BuSpar® as long as the drug was covered by valid, unexpired patents. As described above, BMS willfully engaged in actions designed to extend the time period of its monopoly beyond the lawful boundaries of its patents.

85. BMS entered into an illegal agreement with the Schein Entities with the intent and purpose of preventing generic buspirone from coming to market. In so doing, BMS engaged in an unlawful act of monopoly maintenance.

86. BMS fraudulently induced the FDA to list the '365 patent in the Orange Book based on false certifications that BMS submitted to the FDA, and subsequently engaged in repeated prosecution of baseless, sham patent litigation against its generic competitors. The result of BMS's unlawful conduct was to extend BMS's monopoly beyond the time period permitted by law, thus constituting an unlawful act of monopoly maintenance.

87. In the alternative, by entering into an illegal agreement with the Schein EntitIes and by fraudulently inducing the FDA to list the '365 patent in the Orange Book, and engaging in sham patent litigation, BMS willfully engaged in a single course of unlawful conduct. This conduct, intended to prevent generic buspirone from coming to market, constituted unlawful monopoly maintenance.

88. At all times from 1994 until the entry of generic competition in the market as a result of Judge Urbina's preliminary injunction decision, BMS maintained monopoly power in the relevant markets.

89. BMS illegally maintained its monopoly power in the relevant markets in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

XI. BMS's AND THE SCHEIN ENTITIES UNLAWFUL AGREEMENT PREVENTED GENERIC BUSPIRONE PRODUCTS FROM ENTERING THE MARKET

90. Plaintiff States repeat and reallege every preceding allegation.

91. As described above, BMS entered into an unlawful agreement with the Schein Entities to prevent generic buspirone products from entering the market. As a result of the Schein Agreement, among other things, the Schein Entities dropped a meritorious patent claim against BMS, and BMS paid the Schein Entities $72 million in return for the Schein Entities agreeing not to enter the market.

92. The Schein Agreement served to divide the market for buspirone between two competitors, and thus entering into the agreement constituted a *per se* violation of the antitrust laws.

93. In the alternative, the purpose and effect of the Schein Agreement were to eliminate generic competition for buspirone. The Schein Agreement had no countervailing pro-competitive justifications. For this reason, under a rule of reason analysis, the Schein Agreement constituted a violation of the antitrust laws.

94. BMS's and the Schein Entities unlawful agreement in restraint of trade was in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1.

XII. SUPPLEMENTAL STATE LAW CLAIMS

95. Plaintiff State of Alabama repeats and realleges every preceding allegation.

96. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Code of Alabama, § 8-19-1 *et seq.* (1975).

97. Plaintiff State of Alaska repeats and realleges every preceding allegation.

98. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Alaska Monopolies and Restraint of Trade Act, AS 45.50.562 *et seq.*, and the Alaska Unfair Trade Practices and Consumer Protection Act, AS 45.50.471 *et seq.*

99. Plaintiff State of Arizona repeats and realleges every preceding allegation.

100. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Arizona Uniform State Antitrust Act, A.R.S. §§ 44-1401 *et seq.*

101. Plaintiff State of Arkansas repeats and realleges every preceding allegation.

102. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Arkansas Deceptive Trade Practices Act, Ark. Code Ann., §§ 4-88-101, *et seq.*

103. Plaintiff State of Colorado repeats and realleges every preceding allegation.

104. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Colorado Antitrust Act of 1992, §§ 6-4-101 *et seq.*, Colo. Rev. Stat.

105. Plaintiff State of Connecticut repeats and realleges every preceding allegation.

106. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Connecticut Antitrust Act, Conn. Gen. Stat. § 35-24 *et seq.*, and the Connecticut Unfair Trade Practices Act, Conn. Gen. Stat. § 42-110a *et seq.*

107. Plaintiff State of Delaware repeats and realleges every preceding allegation.

108. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Delaware Antitrust Act, 6 Delaware Code Chapter 21, and Delaware's Deceptive Trade Practices Act, 6 Delaware Code, Chapter 25, *et seq.*

109. Plaintiff District of Columbia repeats and realleges every preceding allegation.

110. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the District of Columbia Antitrust Act, D.C. Code, 2001 Ed. § 28-4501 et. seq., including, without limitation, D.C. Code, 2001 Ed. § 28-4507, pursuant to which plaintiff District of Columbia seeks threefold the damages sustained by natural persons.

111. Plaintiff State of Florida repeats and realleges every preceding allegation.

112. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Florida Antitrust Act of 1980, § 542.15 Florida Statutes, *et seq.*, and the Florida Deceptive and Unfair Trade Practices Act, § 501.201 Florida Statutes, *et seq.*

113. Plaintiff State of Idaho repeats and realleges every preceding allegation.

114. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Idaho Competition Act, Idaho Code Sections 48-101 *et seq.*, and were unconscionable acts or practices in violation of Idaho Code Section 48-603(18) of the Idaho Consumer Protection Act.

115. Plaintiff State of Illinois repeats and realleges every preceding allegation.

116. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Illinois Antitrust Act, 740 ILCS 10/1 *et seq.*

117. Plaintiff State of Iowa repeats and realleges every preceding allegation.

118. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Iowa Competition Act, Iowa Code §§ 553 *et seq.*, the Iowa Consumer Fraud Act, Iowa Code § 714.16, and a claim for unjust enrichment under Iowa common law.

119. Plaintiff State of Kansas repeats and realleges every preceding allegation.

120. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the laws of the State of Kansas, including, without limitation: the Kansas Restraint of Trade Act , Kansas Statutes Annotated 50-101 *et seq.* and its predecessor; the Kansas Consumer Protection Act, Kansas Statutes Annotated 50-101 *et seq.* and its predecessor; the common laws of Kansas including, without limitation: the common law of fraud, unconscionable acts or practices, deceptive acts and practices, unfair methods of competition, and unjust enrichment.

121. Plaintiff Commonwealth of Kentucky repeats and realleges every preceding allegation.

122. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Kentucky Revised Statutes (KRS) 367.175, and the Kentucky Consumer Protection Act, KRS 367.110 *et seq.*

123. Plaintiff State of Louisiana repeats and realleges every preceding allegation.

124. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Louisiana Monopolies Act, Louisiana Revised Statutes (La. R.S.) 51:121 *et seq.* and the Louisiana Unfair Trade and Consumer Protection Act, La. R.S. 51:1405 *et seq.*

125. Plaintiff State of Maine repeats and realleges every preceding allegation.

126. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Maine Revised Statutes Annotated, 10 M.R.S.A. § 1101 *et seq.*, and Maine's Unfair Trade Practices Act, 5 M.R.S.A. '205-A *et seq.*

127. Plaintiff State of Maryland repeats and realleges every preceding allegation.

128. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were, and are in violation of the Maryland Antitrust Act, Md. Com. Law Code Ann. § 11-201 *et seq.*

129. Plaintiff Commonwealth of Massachusetts repeats and realleges every preceding allegation.

130. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Massachusetts Consumer Protection Act, Mass. Gen. L. c. 93A, §§ 1 *et seq.*

131. Plaintiff State of Michigan repeats and realleges every preceding allegation.

132. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Michigan Antitrust Reform Act, MCL 445.771 *et seq.*

133. Plaintiff State of Mississippi repeats and realleges every preceding allegation.

134. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Mississippi Code Annotated § 75-21-1 *et seq.* and Mississippi Code Annotated 75-24-1 *et seq.*

135. Plaintiff State of New Mexico repeats and realleges every preceding allegation.

136. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1 *et*

seq. NMSA (1978) and the New Mexico Unfair Practices Act, N.M. Stat. Ann. §57-12-1 to § 57-12-22 (1978).

137. Plaintiff State of New York repeats and realleges every preceding allegation.

138. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. violate New York General Business Law §§ 340-347, 349 and also constitute fraudulent or illegal acts under New York Exec. Law § 63(12).

139. Plaintiff State of North Carolina repeats and realleges every preceding allegation.

140. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of N.C. Gen. Stat. §§ 75-1, -1.1, -2 and -2.1, and were in knowing violation of law.

141. Plaintiff State of North Dakota repeats and realleges every preceding allegation.

142. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the North Dakota State Antitrust Act, N.D.C.C Sec. 51-08.1-01 *et seq.*, and North Dakota's Consumer Protection Act, N.D.C.C. Sec. 51-15-01, *et seq.*

143. Plaintiff State of Ohio repeats and realleges every preceding allegation.

144. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Ohio's antitrust law, the Ohio Valentine Act, Ohio Rev. Code §§ 1331.01 *et seq.,* Ohio Rev. Code § 109.81, and the common law of Ohio.

145. Plaintiff State of Oklahoma repeats and realleges every preceding allegation.

146. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the laws of the State of Oklahoma, including, without

limitation, the Oklahoma Antitrust Reform Act, 79 O.S. §§ 201 *et seq.*, and the Oklahoma Consumer Protection Act, 15 O.S. §§ 751 *et seq.*

147. Plaintiff State of Oregon repeats and realleges every preceding allegation.

148. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of ORS 646.725, ORS 646.730 and ORS 646.760 of the Oregon Antitrust Act, ORS 646.705 *et seq.*

149. Plaintiff Commonwealth of Pennsylvania repeats and realleges every preceding allegation.

150. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Pennsylvania common law doctrines against monopolies, unreasonable restraint of trade, and unjust enrichment, proceeding under 71 Pennsylvania Stat. Ann. § 732-204(c).

151. Plaintiff Commonwealth of Puerto Rico repeats and realleges every preceding allegation.

152. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of 10 P.R. Laws Ann. §§ 251-276 and 32 P.R. Laws §§ 3341-3344.

153. Plaintiff State of Rhode Island repeats and realleges every preceding allegation.

154. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Rhode Island General Laws §§6-36-5, 6-36-11 and 6-36-12.

155. Plaintiff State of South Carolina repeats and realleges every preceding allegation.

156. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of South Carolina Code of Laws §§ 39-5-10 *et seq.*

157. Plaintiff State of Texas repeats and realleges every preceding allegation.

158. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Texas Business and Commerce Code §15.01 *et seq.*

159. Plaintiff State of Utah repeats and realleges every preceding allegation.

160. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Utah Antitrust Act, Utah Code Ann. Sections 76-10-911 through 76-10-926 (1999 Replacement, as amended), including, without limitation, Utah Code Ann. Sections 76-10-914(1) and 76-10-914(2), and the common law of Utah, including, without limitation, the common law of fraud, unconscionable acts or practices, unfair methods of competition, deceptive acts and practices, and unjust enrichment.

161. Plaintiff State of Vermont repeats and realleges every preceding allegation.

162. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were unfair methods of competition and unfair and deceptive acts and practices in commerce in violation of the Vermont Consumer Fraud Act, 9 Vermont Statutes Annotated, Chapter 63, and the common law of Vermont.

163. Plaintiff State of Washington repeats and realleges every preceding allegation.

164. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of Washington Chapter 19.86 RCW.

165. Plaintiff State of West Virginia repeats and realleges every preceding allegation.

166. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the West Virginia Antitrust Act, W. Va. Code § 47-18-1 *et seq.*, and in violation of the West Virginia Consumer Credit and Protection Act, W. Va. Code § 46A-1-101 *et seq.*

167. Plaintiff State of Wisconsin repeats and realleges every preceding allegation.

168. The aforementioned practices by BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. were in violation of the Wisconsin Trusts and Monopolies Act, Wis. Stats. § 133.03(1) *et seq.*

XIII. RELIEF REQUESTED

Accordingly, the States demand judgment as follows:

1. Adjudge and decree that BMS engaged in conduct in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2;

2. Adjudge and decree that BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. engaged in conduct in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1;

3. Adjudge and decree that BMS, Watson Pharma, Inc., and Danbury Pharmacal, Inc. engaged in conduct in violation of each of the state statutes enumerated in Section XII of this Complaint;

4. Enjoin and restrain, pursuant to federal and state law, BMS, its affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and employees, and all other persons acting or claiming to act on their behalf or in concert with them, from engaging in any conduct and from adopting any practice, plan, program or device having a similar purpose or effect to the anti-competitive actions set forth above, including, but not limited to, asserting to any state or federal regulatory agency, or in any legal preceding, that the '365 patent covers administration of buspirone hydrochloride;

5. Enjoin and restrain pursuant to federal and state law BMS, its affiliates, assignees, subsidiaries, successors and transferees, and the officers, directors, partners, agents and

employees, and all other persons acting or claiming to act on their behalf or in concert with them from entering into any settlement of any patent infringement action brought by them pursuant to the Hatch-Waxman Act against any potential generic competitor which has filed a Paragraph IV certification relating to one of their products without notification to the States;

6. Award to Plaintiff States such other equitable relief, including, but not limited to, restitution and disgorgement, as the Court finds appropriate to redress BMS's and the Schein Entities' violations of state and federal law;

7. Award to the Plaintiff States all damages sustained by and permitted to be recovered by the States (as direct purchasers, assignees of direct purchasers, or as indirect purchasers) and on behalf of, or for the benefit of their consumers, and for all additional damages, penalties and other monetary relief provided by applicable law, including but not limited to treble damages;

8. Award to each Plaintiff State the maximum civil penalties allowed by law;

9. Award to each Plaintiff State its costs of this action, including reasonable attorneys' fees, and where applicable, expert fees; and,

10. Direct such other and further relief as the Court deems just and proper.

XIV. JURY TRIAL DEMAND

Plaintiff States demand a trial by jury, pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, on all issues triable of right by jury.

July 25, 2002

Respectfully submitted,

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