UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

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

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act, 15 U.S.C. § 45, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that respondent Bristol-Myers Squibb Company ("BMS") has violated and violates Section 5 of the Federal Trade Commission ("FTC") Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues this complaint, stating its charges in that respect as follows:

I. Nature of the Case

1. This matter concerns BMS's continuing pattern of anticompetitive conduct that delayed the entry of generic drugs capable of competing with BMS's lucrative branded drug monopolies: BuSpar, Taxol, and Platinol. When threatened with imminent generic competition to these branded drug franchises – which collectively garnered nearly $2 billion a year in revenues – BMS acted in a predatory fashion to forestall those competitive threats. BMS knew that generic entry would decimate its sales, and that any delay in such entry would be highly profitable for BMS, but very costly for consumers.

2. Over the course of the past decade, BMS engaged in a series of anticompetitive acts across the BuSpar, Taxol, and Platinol product lines. Among other things, BMS: paid a would-be generic competitor millions of dollars to abandon its patent challenge and agree to withhold competition until patent expiry; misled the United States Food and Drug Administration ("FDA") about the scope, validity, and enforceability of its patents and abused FDA regulations to block generic entry; breached its duty of candor and good faith before the Patent and Trademark Office ("PTO") while pursuing patent applications purportedly related to the branded BMS products; and filed objectively baseless patent infringement lawsuits in federal court against would-be generic competitors. BMS's pattern of conduct evidences a scheme to abuse competitive and government processes for the purpose of maintaining its branded drug monopolies. As a result of these anticompetitive acts, BMS thwarted low-cost generic competition to these monopolies

for many months or years, forcing consumers to overpay by hundreds of millions of dollars for vital prescription drug products.

II. Respondent Bristol-Myers Squibb Company

3. BMS is a for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business at 345 Park Avenue, New York, N.Y. 10154. Among other things, BMS is engaged in the discovery, development, manufacturing, and distribution of prescription pharmaceutical products (including BuSpar, Taxol, and Platinol) and other consumer healthcare products. For the year 2001, BMS's total net sales worldwide were approximately $19.4 billion, and its total net U.S. sales were approximately $13.1 billion.

4. BuSpar is a brand-name prescription drug containing buspirone hydrochloride ("buspirone") as its active pharmaceutical ingredient. In 1986, BMS obtained FDA approval to market BuSpar for the management of anxiety disorders or short-term relief of the symptoms of anxiety. In 2000, the last full year before FDA approval of generic buspirone products, BMS's U.S. BuSpar sales were over $600 million. With entry of generic buspirone in the U.S. market in late March 2001, BMS's U.S. BuSpar sales declined by more than 50% for the remainder of the year.

5. Taxol is a brand-name prescription drug containing paclitaxel as its active pharmaceutical ingredient. In 1992, BMS obtained FDA approval to market Taxol for the treatment of ovarian cancer. Subsequently, Taxol was approved to treat breast and lung cancers and AIDS-related Kaposi's sarcoma. Prior to generic entry in 2000, BMS's annual U.S. Taxol sales were over $1 billion. Within the first year of entry of generic paclitaxel, BMS's sales dropped by almost 50%.

6. Platinol and Platinol-AQ are brand-name prescription drugs containing cisplatin as their active pharmaceutical ingredient. BMS received FDA approval to market Platinol and Platinol-AQ (collectively "Platinol") for the treatment of various forms of cancer in 1978 and 1988, respectively. Prior to generic entry in 1999, BMS's annual U.S. Platinol sales were about $100 million. Within the first year of generic entry, BMS's U.S. sales dropped by almost 50%.

III. Jurisdiction and Interstate Commerce

7. BMS is, and at all relevant times herein has been, a corporation within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

8. BMS's general business activities, including the unfair methods of competition alleged below, are "in or affecting commerce" within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

IV. Statutory and Regulatory Background

9. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 271(e), commonly known as "Hatch-Waxman," requires FDA approval before a company may market or sell a pharmaceutical product in the United States. To obtain approval to make and sell a new (or branded) drug, a company must file a new drug application ("NDA") with the FDA.

10. A generic drug is one that the FDA has found to be "bioequivalent" to a branded drug. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate, and extent to which, the products are absorbed in the human body under similar experimental conditions, when administered at the same dose. *See* Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(8)(B).

11. Hatch-Waxman establishes a procedure for a branded-drug company to identify to prospective generic competitors all patents that it believes claim the branded drug. It also establishes a process for a branded-drug company to address potential claims of patent infringement against the manufacturer of a proposed generic product.

12. The FDA makes public the patents identified by branded-drug companies as claiming a given product in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," which is commonly referred to as the "Orange Book."

13. The FDA views its role in listing patents in the Orange Book as purely ministerial, because it has neither the expertise nor the resources to resolve complex patent coverage issues. Consequently, the FDA does not scrutinize a party's bases for listing patents in the Orange Book, as long as all the information required by statute has been submitted. Should one company challenge the validity of the NDA holder's Orange Book listing, the FDA requests only that the NDA holder provide written confirmation that the patent is properly listed.

14. To obtain approval to make and sell a generic version of a branded drug, a company can file an Abbreviated New Drug Application ("ANDA") with the FDA. With its ANDA, the generic drug applicant must provide certification to the FDA with respect to each patent listed in the Orange Book relating to the branded drug.

15. This certification must make one of the following statements: (I) no patent information on the drug product that is the subject of the ANDA has been submitted to FDA; (II) the patent has expired; (III) the patent will expire on a particular date; or (IV) the patent is invalid or will not

be infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a Paragraph IV Certification.

16. Upon making a Paragraph IV Certification, the generic applicant must provide notice of that certification to the branded-drug company and to the owner of each patent listed in the Orange Book for the branded drug product that the ANDA references. This notice must include a detailed statement of the factual and legal basis for the ANDA applicant's opinion that the patent is not valid or will not be infringed by marketing of the generic product.

17. Hatch-Waxman contains provisions that govern the timing of FDA approval of generic applications containing a Paragraph IV Certification, based on whether and when a patent infringement suit is initiated. If neither the patent holder nor the branded-drug company files a patent infringement suit against the generic drug applicant within 45 days of receipt of notification of a Paragraph IV Certification, then the FDA approval process may proceed. Upon final FDA approval of the ANDA, the generic applicant is free to market its product.

18. If, however, the patent owner or branded drug company files a patent infringement suit against the generic drug applicant within the 45-day period, then final FDA approval of the ANDA is automatically stayed until the earliest of: (a) patent expiration; (b) a final court determination of non-infringement or patent invalidity; or (c) the expiration of a 30-month period from the time the patent holder receives notification of a Paragraph IV Certification. This 30-month period, which effectively is an automatic statutory injunction to final FDA approval of an ANDA, is commonly referred to as the "30-month stay."

19. The first ANDA filer to submit a Paragraph IV Certification for a branded drug product receives a period of market exclusivity, commonly referred to as "the 180–day Exclusivity Period," during which it is the exclusive generic drug rival to the branded drug. This 180–day Exclusivity Period begins after the earlier of the date on which (1) the first ANDA filer begins commercial marketing of its generic version of the drug, or (2) a court finds the patents claiming the brand name drug are invalid or not infringed.

V. The Benefits of Generic Competition

20. Although therapeutically equivalent to their branded counterparts, generic drugs are typically sold at substantial discounts from the price of the referenced branded drug. The first generic drug to enter the market often does so at a price 25 percent or more below that of the branded product. As additional generic drugs enter the market, generic drug prices continue to fall, often to less than 50% of the branded drug's price.

21. Because of these large price advantages, government officials and private purchasers have adopted policies to encourage or require pharmacists to substitute a generic drug for its

branded counterpart. Many third-party payers of prescription drugs (e.g., managed care plans, Medicaid programs), encourage or insist on the substitution of generic drugs in lieu of their branded counterparts, whenever possible.

22. As a result of this price difference and the ease of substitution, within the first year of generic entry, generic drug competition promptly causes a significant adverse impact on the branded drug's market share, unit sales, and dollar sales.

23. Generic drug competition generates large savings for consumers. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8-10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the brand name product.

VI. BMS's Anticompetitive Campaign to Maintain its BuSpar Monopoly

24. The FDA approved BuSpar on September 29, 1986. At that time, two patents protected the product – U.S. Patent No. 3,976,776 ("the '776 patent") and U.S. Patent No. 4,182,763 ("the '763 patent"). The '776 patent, which expired in August 1993, stated, in pertinent part, that buspirone's tranquilizing effects were similar to those achieved with chlorpromazine, a tranquilizer used to treat anxiety. The '763 patent, which expired on November 21, 2000, claimed a method for using buspirone to treat anxiety.

A. BMS's Unlawful Agreement with Schein Pharmaceutical, Inc.

25. On December 2, 1994, BMS entered into an agreement with Schein Pharmaceutical, Inc. ("Schein") and Danbury Pharmacal, Inc. ("Danbury") settling patent infringement litigation concerning the '763 patent (the "Schein Agreement"). As a result of the Schein Agreement, BMS paid a would-be competitor to abandon its challenge to a BMS patent to maintain its monopoly in the United States over the sale of buspirone until expiration of the '763 patent.

26. In August 1992, Schein filed an ANDA with the FDA containing a Paragraph IV Certification, asserting 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. Schein served BMS with timely notice of its Paragraph IV Certification.

27. BMS sued Schein and its subsidiary, Danbury, for patent infringement in the United States District Court for the Southern District of New York. Because BMS filed its suit within 45 days of receiving Schein's notice of its Paragraph IV Certification, the FDA was precluded from approving Schein's ANDA for up to 30 months.

28. During the patent litigation, Schein filed a motion for summary judgment, asserting that the '763 patent was invalid because its invention was anticipated by the '776 patent. In opposing Schein's motion for summary judgment, BMS 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.

29. On June 30, 1993, the District Court granted Schein's summary judgment motion, finding BMS's '763 patent to be invalid. The District Court found that both the '776 patent's plain language and BMS's own submission to the FDA in 1972 demonstrated that the invention claimed in the '763 patent was anticipated by the earlier patent. 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."

30. BMS appealed the District Court's ruling to the United States Court of Appeals for the Federal Circuit. The Federal Circuit acknowledged 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 the case to the District Court for trial.

31. Faced with the substantial risk that the '763 patent – the only remaining patent claiming BuSpar – would be found invalid, BMS, on December 2, 1994, entered into an agreement with Schein to settle their patent litigation. Pursuant to this agreement, BMS paid Schein $72.5 million in four yearly installments between 1995 and 1998. In return, Schein agreed to refrain from competing with any generic bioequivalent version of BuSpar until the '763 patent's expiration, which occurred nearly six years later.

32. BMS also sought and obtained agreement from Schein to take steps that would help BMS maintain the perception that the '763 patent was valid and enforceable, thereby bolstering BMS's ability to deter any other potential generic drug entrant from challenging its validity. Specifically, Schein agreed:

    (a) to acknowledge that the '763 patent was valid and enforceable;

    (b) to withdraw its Paragraph IV Certification challenging the validity of the '763 patent and to submit a Paragraph III Certification, certifying that it seeks ANDA approval to manufacture and sell its buspirone product only upon the '763 patent's expiration;

(c) to submit, along with BMS, a stipulated order 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";

(d) not to disclose the Schein Agreement's existence or the terms therein, or share information concerning the '763 patent or the litigation related to the patent with any third party;

(e) not to aid or assist others in the purchase, manufacture, use, or sale of buspirone; and

(f) to cooperate with BMS in any legal actions, motions to quash, or motions for a protective order in the event that anyone sought to compel Schein to disclose the Schein Agreement's existence or information about the terms therein.

33. The Schein Agreement enabled BMS to maintain its BuSpar monopoly by eliminating Schein as a potential generic drug rival from the time of the agreement on December 2, 1994, until expiration of the '763 patent on November 21, 2000.

B. BMS's Efforts to Extend its Monopoly by Providing to the FDA False and Misleading Listing Information Concerning the '365 Patent

34. After successfully implementing its strategy through the Schein Agreement to keep would-be generic competitors off the market until expiration of the '763 patent in 2000, BMS developed a scheme to continue to thwart generic competition once the '763 patent expired. BMS sought issuance from the PTO of a new patent, and obtained the patent just as ANDA filers were poised to market and sell their generic buspirone products in competition with BuSpar. BMS submitted false and misleading information to the FDA to cause the FDA to list the new patent in the Orange Book, thereby preventing the FDA from granting final approval to the ready-to-market manufacturers of generic buspirone products.

35. By November 21, 2000, the day on which the '763 patent expired, the FDA had granted tentative approval to more than ten ANDA filers to sell generic buspirone. Schein (which Watson Pharmaceuticals, Inc. ("Watson") acquired in August 2000) was the first ANDA filer on two dosage strengths – the 5 mg and 10 mg products; Mylan Pharmaceuticals, Inc. ("Mylan") was the first filer on the 15 mg product; and Par Pharmaceuticals, Inc. was the first filer on the 7.5 mg product. Upon '763 patent expiry, each such ANDA filer would have received final FDA approval and the 180-day exclusivity period for the dose(s) for which they were first to file ANDAs. Following the exclusivity period, the other ANDA filers with

tentative approval would have received final approval and been eligible to market their generic buspirone products.

36. As the '763 patent's expiry date approached, the first ANDA filers prepared to bring their products to market. Mylan, for example, had a fleet of trucks loaded with its generic buspirone product ready for shipment to customers, and ultimate sale to consumers, beginning on November 22, 2000.

37. BMS, however, had already begun implementing its strategy to maintain its BuSpar monopoly beyond expiration of the '763 patent. On August 5, 1999, BMS filed patent application 09/368,842 ("the '842 application") with the PTO. This application claimed treatment of anxiety through two inventions: (1) the use of 6-Hydroxy-Metabolite of buspirone; and (2) the use of buspirone to create the metabolite. A metabolite is a new molecule created when an existing pharmaceutical agent, such as buspirone, breaks down in the body.

38. On August 9, 1999, BMS requested expedited treatment of its patent application. The PTO required BMS to choose between the two claimed inventions identified in the '842 application to qualify for expedited treatment. BMS decided to pursue the second claimed invention, involving the use of buspirone to create the metabolite.

39. On December 13, 1999, the PTO rejected the '842 application, in part because BMS had been making and selling BuSpar to treat anxiety in the United States for more than one year prior to the filing date, rendering this claimed invention unpatentable. BMS did not respond to the PTO's rejection of the '842 application and eventually abandoned it.

40. On January 18, 2000, BMS filed divisional application 09/484,161 ("the '161 application") with the PTO, containing claims directed to the use of the 6-Hydroxy-Metabolite of buspirone, but not to the use of buspirone itself.

41. On June 6, 2000, BMS filed four continuation-in-part ("CIP") applications. Two of these applications, 09/588,221 ("the '221 application") and 09/588,222 ("the '222 application"), like the '161 application, claimed only the use of the 6-Hydroxy-Metabolite of buspirone. The other two applications, 09/588,220 ("the '220 application") and 09/588,223 ("the '223 application"), claimed the use of buspirone to create the metabolite.

42. On September 8, 2000, the PTO rejected the two CIP applications that concerned the use of buspirone (the '220 and '223 applications), for the same reason that it had previously rejected the '842 application - *i.e.*, because BMS had been making and selling BuSpar to treat anxiety in the United States for nearly 14 years. With these rejections, the PTO had rejected all three BMS applications covering the use of buspirone to create the metabolite.

43. On September 12-13, 2000, the PTO rejected BMS's remaining applications – the '161 divisional application and the '221 and '222 CIP applications – because they contained identical or overlapping claims. On September 22, 2000, BMS abandoned the '161 and '222 applications, and asked the PTO to reconsider its rejection of the '221 application. The PTO agreed to do so. The '221 application, which eventually matured into U.S. Patent No. 6,150,365 ("the '365 patent"), claimed only the use of the 6-Hydroxy-Metabolite of buspirone, and not the use of buspirone itself.

44. On October 2, 2000, the PTO issued a Notice of Allowability for the '221 application. Thereafter, on October 5, 2000, BMS filed a petition to expedite the issuance of the patent, asserting that, "[i]n order to maintain its product position in what becomes a highly competitive market, assignee requires issuance of this patent prior to *November 22, 2000*" (emphasis in original). This is the date on which generic drug competition was poised to begin and erode BMS's monopoly profits for BuSpar.

45. Hours before the '763 patent's term was set to expire, on November 21, 2000, the PTO issued the '365 patent to BMS. The sole claim in the '365 patent concerns the use of the 6-Hydroxy-Metabolite of buspirone. It does not recite any use of buspirone itself. The '365 patent states:

> 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 [the 6-Hydroxy-Metabolite of buspirone] or pharmaceutically acceptable acid addition salt or hydrate thereof.

46. Upon issuance of the '365 patent, BMS issued a press release stating the patent covers "a method of use of a metabolite produced by the administration of [buspirone]." Internal BMS documents also referred to the '365 patent as a patent for a buspirone metabolite.

47. Hours after the PTO issued the '365 patent, BMS submitted information to the FDA for listing the '365 patent in the Orange Book. As part of this submission, BMS declared that the '365 patent "is a method-use patent covering, among other things, a *method of using BuSpar* for all of its approved indications" (emphasis added). BMS submitted this information even though it knew that the patent covered only a method of using a metabolite, and not a method of using buspirone itself.

48. Various generic buspirone manufacturers thereafter 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 Hatch-Waxman.

49. At least one generic company, Par, filed a Paragraph IV Certification, but did not notify BMS of its certification. Because Par failed to notify BMS of its Paragraph IV Certification, BMS's listing of the '365 patent, in and of itself, prevented FDA approval of Par's generic buspirone ANDA.

50. BMS's '365 patent did not meet the statutory requirements for listing a patent in the Orange Book. Such requirements are set forth at 21 U.S.C.§§ 355 (c)(1) and (c)(2). The '365 patent was not properly listable because it (1) does not claim BuSpar or a method of using BuSpar, and (2) is not one with respect to which a claim of patent infringement could reasonably be asserted against someone selling BuSpar.

51. Following the FDA's listing of the '365 patent in the Orange Book, some of the ANDA filers who had been prevented from selling their generic buspirone products provided copies of BMS's press release to the FDA. One of the ANDA filers also asserted to the FDA 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, and therefore could not be listed in the Orange Book.

52. Thereafter, on November 30, 2000, the FDA asked BMS 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 informed BMS that it considered the '365 patent "provisionally listed" pending BMS's submission of an additional declaration.

53. On December 4, 2000, BMS provided the declaration, sworn by Richard P. Ryan, BMS's in-house patent counsel, stating that "[the '365 patent] issued by the United States Patent and Trademark Office on November 21, 2000 contains a claim for the approved uses of buspirone hydrochloride." BMS's declaration was false. In reality, the patent pertained to a use of the 6-Hydroxy-Metabolite of buspirone, and not to any use of buspirone itself.

54. BMS's sworn declaration to the FDA further represented that the '365 patent's sole claim was:

> a method for ameliorating an undesirable anxiety state comprising the direct administration of 6-hydroxy-buspirone 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.

This representation was also false, because the actual patent claim does not refer to any use of the buspirone prodrug.

55. BMS's representations to the FDA that the '365 patent "contains a claim for the approved uses of buspirone hydrochloride" directly contradicted its representations to the PTO in prosecuting the patent. BMS knew that the PTO had already rejected three previous applications in which BMS claimed a use of buspirone, for the reason that BMS had been making and selling buspirone to treat anxiety in the United States for many years. The PTO had allowed only the '365 patent claim, which recited a use of the 6-Hydroxy-Metabolite of buspirone.

56. Moreover, during its unsuccessful effort to obtain a patent claiming a use of buspirone, BMS specifically distinguished that claimed use from the currently approved method of using buspirone. For example, BMS told the PTO that:

(a) the method of oral administration of buspirone claimed by the invention "improves upon and differs from the known standard of oral administration of buspirone";

(b) "[t]he improved method is directly counter to the past method of orally administering buspirone";

(c) the method of administration claimed by the patent "is in contradiction to currently accepted methods of administration";

(d) "dosing instructions should be changed to conditions favoring enzymatic production of [the metabolite]"; and

(e) "instead of dosing buspirone at mealtimes, the dosing should occur about two hours or more before or after a meal."

57. BMS's statements to the PTO are irreconcilable with BMS's sworn declaration to the FDA on December 4, 2000, that the '365 patent "contains a claim for the approved uses of buspirone hydrochloride." Nonetheless, consistent with its ministerial approach to Orange Book listings, the FDA did not review the propriety of BMS's sworn declaration. Instead, the FDA thereafter deemed the '365 patent listed in the Orange Book as of November 21, 2000. The FDA expressly noted that it listed the patent solely on the basis of BMS's declarations that the patent met the requirements for listing, and that it did not make an independent determination regarding the '365 patent's scope and coverage.

58. BMS obtained an Orange Book listing of the '365 patent only because it provided false and misleading information to the FDA concerning the scope and coverage of the '365 patent. BMS knew that its representations to the FDA – to the effect that the '365 patent claimed a method of using buspirone – were false and misleading. BMS made these misrepresentations purposely and intentionally, to obtain wrongfully an Orange Book listing of the '365 patent.

Through its wrongful listing in the Orange Book of the '365 patent, BMS illegitimately acquired the ability to trigger a 30-month stay, thereby delaying entry of generic buspirone, and depriving consumers of lower prices and other benefits of competition.

C. BMS Files Objectively Baseless Patent Infringement Lawsuits

59. Following the listing of the '365 patent in the Orange Book, BMS filed patent infringement lawsuits against ANDA filers who had notified BMS of their Paragraph IV Certifications with respect to the '365 patent. These lawsuits were objectively baseless because, with respect to these competitors' ANDAs, the '365 patent could not be both valid and infringed. Were the patent claim interpreted to cover the currently-approved uses for which the generic applicants submitted their ANDAs, then the patent necessarily would be invalid, because those uses had been known long before BMS applied for the patent. Indeed, the United States District Court for the Southern District of New York granted summary judgment in favor of Mylan and Watson in BMS's patent infringement actions against these companies. The court found that Mylan's and Watson's ANDAs did not infringe the '365 patent, and determined that BMS's proposed construction of the '365 patent claim – which would have been needed to support an infringement holding – would render the patent invalid.

60. The intent and effect of BMS's multiple patent infringement lawsuits was to prevent generic buspirone manufacturers from marketing their products for as long as possible, through wrongful triggering of the 30-month stay.

D. The FDA De-lists the '365 Patent and Generic Entry Belatedly Occurs

61. On November 30, 2000, Mylan filed a lawsuit against BMS and the FDA in the U.S. District Court for the District of Columbia requesting, among other things, the issuance of an injunction ordering de-listing of the '365 patent from the Orange Book. On March 14, 2001, the District Court granted Mylan's motion for a preliminary injunction, 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. BMS and the FDA both complied with the Order. Shortly thereafter, Mylan, Watson, and Par launched their respective generic buspirone products into the marketplace.

62. Mylan, Watson, and Par entered the market substantially later than they would have absent BMS's anticompetitive acts. As a consequence, consumers suffered substantial economic detriment by paying monopoly prices for an unjustifiably extended period.

63. Because they were the first to submit Paragraph IV Certifications, Mylan, Watson, and Par were each entitled to the 180-day Exclusivity Period for certain dosages of generic buspirone. Each entered the market with prices substantially below BuSpar's price. Once the 180-day

Exclusivity Period ended, other firms launched additional generic buspirone products, and generic buspirone prices declined even further. BMS's anticompetitive acts, therefore, not only delayed the entry of Mylan, Watson, and Par, but also that of these other firms. BMS's exclusionary conduct denied consumers timely access to the lower prices that result when multiple generic competitors compete in the market.

E. BMS Had Monopoly Power in the Relevant Market of Buspirone Sold in the United States

64. The relevant product market in which to assess the anticompetitive effects of BMS's conduct concerning BuSpar is the market for buspirone products, which consists of BuSpar and generic bioequivalent versions of BuSpar.

65. Entry of generic buspirone products significantly and immediately decreased BMS's BuSpar sales and market share, and led to a substantial reduction in the average market price paid for buspirone products. Before generic entry, BMS's U.S. BuSpar sales were over $600 million. In the year after generic entry, BMS's U.S. BuSpar sales declined by more than 50%.

66. Because of this competitive relationship between BuSpar and its generic bioequivalent drug rivals, such products comprise a distinct relevant product market for antitrust purposes. Other therapeutic agents can be used to treat anxiety, but the presence of these therapeutic agents is not sufficient to prevent the anticompetitive effects from BMS's conduct.

67. The relevant geographic market in which to assess the anticompetitive effects of BMS's conduct concerning BuSpar is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

68. At all times relevant to this complaint, and until March 2001, when generic buspirone manufacturers finally overcame BMS's anticompetitive efforts to keep their products off the market, BMS's share of the relevant market was 100%.

69. At all times relevant to this complaint, FDA processes, as well as BMS's exclusionary acts, restricted entry into the relevant market and protected BMS's monopoly.

VII. BMS's Anticompetitive Campaign to Maintain its Taxol Monopoly

A. The National Cancer Institute's Discovery of Taxol

70. Paclitaxel is a naturally occurring substance that has anti-cancer properties. BMS has marketed a paclitaxel product in the U.S. under the brand name Taxol since December 1992.

71. In the late 1980s, researchers at the United States National Cancer Institute ("NCI") discovered and developed paclitaxel anti-cancer properties. Prior to any involvement by BMS, the U.S. government spent more than $32 million to develop economically feasible techniques to extract paclitaxel from yew tree bark and to create a clinically acceptable formulation for treating cancer.

72. In 1991, pursuant to the Federal Technology Transfer Act, 15 U.S.C. § 3710a, *et seq.*, the NCI and BMS entered into a cooperative research and development agreement ("'CRADA") for the development of (a) a paclitaxel-based drug to treat refractory ovarian cancer and (b) alternative sources of paclitaxel. The CRADA gave BMS exclusive use of existing and future data necessary for FDA approval of paclitaxel, and exclusive access to the NCI's Investigative New Drug registration. In return, the CRADA required BMS to investigate and establish alternative sources of paclitaxel, develop supplies of paclitaxel, supply formulated paclitaxel for government sponsored clinical trials and compassionate distribution, assist in those trials for eighteen months, and prepare and file an NDA.

B. BMS Seeks to Patent Taxol Despite Knowing That it Was Not Patentable and Despite Public Statements That Taxol Had No Patent Protection

73. In 1990, BMS understood that paclitaxel was not patentable as either a composition of matter or as an anti-tumor agent in view of prior public use, public knowledge, and written publications regarding the drug.

74. On July 29, 1991, a subcommittee of the United States House of Representatives held a hearing on several issues associated with BMS's agreements with the NCI regarding Taxol. Responding to a concern expressed by the subcommittee that the "agreements offer no protection to cancer patients from price gouging," BMS told Congress that Taxol "has no patent protection. Thus, the degree of market protection typically available to new pharmaceutical products is lacking in this case."

75. On July 22, 1992, BMS filed an NDA seeking approval to market Taxol for the treatment of ovarian cancer. On December 27, 1992, the FDA approved BMS's application, triggering, pursuant to Hatch-Waxman, 21 U.S.C. § 355(c)(3)(D)(ii), an automatic, five-year period during which BMS had the exclusive right to market a paclitaxel product in the United States.

76. On August 3, 1992, notwithstanding BMS's statements to Congress that the protection "typically available to new pharmaceutical products is lacking" for Taxol, BMS filed a patent application in the PTO related to Taxol.

77. On December 3, 1992, while prosecuting a patent application for methods of administering Taxol, BMS told the House subcommittee that "near-term generic competition for TAXOL is a certainty because TAXOL is not a patented product. This absence of patent protection means that BMS only has protection against Abbreviated New Drug Applications (ANDAs) filings for five years from the date of approval as provided under the Hatch-Waxman Act."

C. BMS Procures Two Taxol Patents Through Inequitable Conduct

78. BMS's five-year, exclusive right to sell Taxol, pursuant to 21 U.S.C. § 355(c)(3)(D)(ii), expired on December 27, 1997. Thereafter, absent exclusionary acts by BMS, generic paclitaxel rivals would have faced no regulatory stay on obtaining FDA approval to enter the market. BMS, however, succeeded, through exclusionary acts, in obtaining two patents that delayed generic competition to Taxol.

79. On June 24, 1997, the PTO issued to BMS U.S. Patent No. 5,641,803 ("the '803 patent"), and on September 23, 1997, it issued to BMS U.S. Patent No. 5,670,537 ("the '537 patent"). The claims of the '803 patent cover administering 135-175 mg/m^2 of Taxol to a patient over a period of about three hours. The claims of the '537 patent additionally require that the patient receive premedication, before Taxol is administered, to reduce hypersensitivity reactions.

80. When pursuing a patent, an applicant has a duty of candor and good faith in dealing with the PTO. This duty includes a requirement to disclose all information, of which the applicant is aware, that a reasonable patent examiner would find material in determining patentability. The failure to satisfy this duty is inequitable conduct that renders the patent unenforceable.

81. Because the NCI funded the discovery and initial development of paclitaxel as an anti-cancer drug, much of the research relating to Taxol was in the public domain and thus the results of that research were unpatentable. To obtain FDA approval of its NDA, BMS relied on several studies in the public domain to show that Taxol was safe and effective. To obtain the patents, however, BMS needed to demonstrate to the PTO that its claimed method of administering Taxol differed from those methods used in the prior studies, including those on which it had earlier relied in seeking approval of its NDA. In prosecuting the '537 and '803 patents, BMS represented to the PTO that such differences existed, by failing to disclose, or by misrepresenting, to the PTO information that a reasonable patent examiner would find material in determining patentability.

82. Prior to entering the CRADA with BMS, the NCI sponsored clinical trials of Taxol, including Phase I trials designed to examine Taxol's safety. Researchers published the results of the Phase I trials in several articles. One of these articles – a 1986 article by Kris et al., *Phase I Trial Of Taxol Given As A 3-Hour Infusion Every 21 Days*, 70 Cancer Treatment Reports, Vol. 70, No. 5, pp. 605-607 (May 1986) ("*Kris*") – reported on the results of a Phase I trial conducted at Sloan-Kettering Hospital in New York. The trial involved giving Taxol as a 3-hour intravenous infusion every 21 days, in doses ranging from 15 to 230 mg/m^2, to 17 patients suffering from various forms of cancer. Another article reporting on the results of another Phase I trial was a 1987 article by Donehower et al., *Phase I Trial of Taxol In Patients With Advanced Cancer*, Cancer Treatment Reports, Vol. 71, No. 12, pp. 1171-1177 (December 1987) ("*Donehower*"). Dosages in that trial varied from 15 mg/m^2 to 265 mg/m^2, administered over either one or six hours.

83. BMS's 1992 pursuit of its NDA before the FDA relied on the *Donehower* and *Kris* studies as providing evidence of safety and efficacy. While pursuing the '537 and '803 patents before the PTO, however, BMS argued that *Donehower* and *Kris* did not provide evidence of safety and efficacy – statements directly contrary to those BMS made to the FDA. BMS's statements to the PTO concerning the *Donehower* and *Kris* references were material misrepresentations of those references. BMS more accurately depicted the two reports in its statements to the FDA while pursuing the Taxol NDA.

84. In a report on the *Donehower* trials submitted in support of its NDA, BMS told the FDA that *Donehower* taught that, based on a promising showing of efficacy, an entire broad-based Phase II (efficacy) study should be undertaken. In contrast, BMS told the PTO that *Donehower* failed to suggest that Taxol as administered was effective or that further study of the relevant duration periods was warranted.

85. In a report on the *Kris* trials, submitted in support of its NDA, BMS told the FDA that doses of Taxol up to 160 mg/m^2 administered over a three-hour period "were well tolerated with no severe toxicity." BMS also told the FDA that the results in *Kris* indicated that further investigation of Taxol was warranted. In contrast, BMS told the PTO that *Kris* demonstrated that administering Taxol over a three hour period "would be unduly hazardous."

86. BMS made its statements to the PTO concerning the *Donehower* and *Kris* references in a declaration signed by Dr. Renzo Carretta, a BMS scientist who co-authored BMS's reports to the FDA concerning *Donehower* and *Kris*. BMS's and Dr. Carretta's statements to the FDA are irreconcilable with their false and misleading statements to the PTO.

87. BMS also deliberately failed to disclose to the PTO material prior art, as reported in O'Connell, et al., "*Phase I Trial of Taxol Given as a Three Hour Infusion Every Three Weeks*," published at 26 Proceedings of AACR, 169 (1985) ("*O'Connell*"). This 1985

abstract reports the results of a Phase I trial of Taxol and states that "for doses up to 160 mg/m^2," Taxol "can be safely given as a 3 hour infusion every 3 weeks." The *O'Connell* reference is a preliminary report of the complete trial reported in Kris, which added higher dosage amounts of 190 mg/m^2 and 230 mg/m^2 to the dosages reported in *O'Connell*. Research observed hypersensitivity reactions only at the higher dosages observed in *Kris*.

88. *O'Connell* was material because it demonstrated that doses up to 160 mg/m^2, falling within the range of 135-175 mg/m^2 recited in BMS's claims, could be safely administered over three hours. This finding was consistent with BMS's position before the FDA, but was inconsistent with BMS's argument before the PTO that available prior art taught that three-hour infusions of paclitaxel in the claimed ranges of 135-175 mg/m^2 were "unsafe" and "would be unduly hazardous." The PTO would likely have given this argument less weight had BMS disclosed *O'Connell*.

89. In making false and misleading material statements to the PTO concerning *Donehower* and *Kris*, and by failing to disclose the material *O'Connell* reference, BMS breached its duty of candor and good faith in dealing with the PTO, and therefore engaged in inequitable conduct.

D. BMS Wrongfully Submits Unenforceable Patents For Orange Book Listing

90. Upon obtaining the '537 and '803 patents, BMS promptly submitted them to the FDA for listing in the Orange Book. BMS obtained the patents by inequitable conduct, however, rendering such patents unenforceable. Because of this inequitable conduct, BMS could not reasonably believe that the patents were listable under the FDA's Orange Book regulations.

91. Beginning on July 30, 1997, a number of generic pharmaceutical manufacturers filed ANDAs with the FDA for generic paclitaxel products and provided BMS with notice of Paragraph IV Certifications, claiming that the '803 and '537 patents were invalid or not infringed by their ANDAs.

92. Within 45 days of receiving the notices, BMS filed suit in the United States District Court for the District of New Jersey against these generic manufacturers – including IVAX Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., and Bedford Laboratories – alleging infringement of the '803 and '537 patents. In so doing, BMS triggered Hatch-Waxman's automatic 30-month stay provision, insulating Taxol from potential generic drug competition over that period.

93. On March 2, 2000, the District Court granted in part motions for summary judgment that the asserted claims of the '803 and '537 patents were invalid. The Court found that those claims were anticipated by *Kris* – one of the articles BMS misrepresented to the PTO. The United States Court of Appeals for the Federal Circuit affirmed the District Court rulings on invalidity

as to all of the appealed claims of the ‘803 patent, and four of the appealed six claims of the ‘537 patent, indicating skepticism about the validity of the remaining two '537 patent claims.

E. BMS’s Agreement with ABI to Extend its Taxol Exclusivity

94. The 30-month stays that BMS obtained from its unlawful listings of the ‘537 and ‘803 patents ended in June 2000. Shortly after those stays expired, but before any ANDAs for generic paclitaxel obtained FDA approval, BMS conspired with American Bioscience, Inc. (ABI) to list improperly a third patent in the Orange Book – ABI’s U.S. Patent No. 6,096,331 (the “‘331 patent”) – and thereby triggered again Hatch-Waxman’s 30-month stay provision, and thus continued the BMS monopoly in the market for paclitaxel-based drugs.

95. In July 2000, BMS and ABI agreed on the terms of an option to license the ‘331 patent, whereby if BMS licensed the ‘331 patent, then ABI would receive royalties based on a significant percentage of BMS sales of Taxol. This license was nominally “non-exclusive,” but ABI would have no incentive to license the ‘331 patent to anyone except BMS. If ABI also licensed the patent to BMS’s generic competitors, then their entry at a lower price would have dramatically reduced BMS’s Taxol sales and the royalties ABI would otherwise obtain from licensing the patent solely to BMS.

96. The PTO issued the ‘331 patent to ABI on August 1, 2000. Most of the ‘331 patent’s claims cover a drug similar to paclitaxel, but which differs from BMS’s Taxol NDA, and thus those claims are not a basis for listing. The few remaining claims relate to Taxol, because they simply cover administering specified dosages of Taxol, generally over specified time periods. These claims, if they were valid, could have provided a basis for listing the ‘331 patent in the Orange Book.

97. On August 1, BMS submitted the ‘331 patent to the FDA for listing in the Orange Book; later that day BMS withdrew the listing information. At all relevant times, BMS could not reasonably believe that the relevant claims of the ‘331 patent were valid, or consequently that the ‘331 patent should be listed in the Orange Book as claiming Taxol. In particular, BMS was well aware of the *O'Connell*, *Kris*, and *Donehower* references, which disclosed administering the claimed doses of Taxol prior to the '331 patent's earliest filing date of March 26, 1993. As with BMS’s ‘803 and ‘537 patents, these references were prior art that invalidated the relevant claims of the ‘331 patent. Moreover, BMS’s own experience with the sale and use of Taxol prior to that date invalidated the relevant claims of the ‘331 patent.

98. ABI filed suit against BMS on August 11, 2000 (the “listing suit”) in the United States District Court for the Central District of California, alleging that BMS purportedly refused to list the ‘331 patent, and that such refusal was contrary to federal law. That same day, in rapid succession, BMS and ABI agreed to stipulate to entry of a temporary restraining order (TRO)

under which BMS agreed to list the '331 patent in the FDA Orange Book, the District Court entered the requested order, and BMS again filed the '331 patent for listing in the Orange Book. The TRO provided that the parties would act to de-list the '331 patent if ABI failed to justify the entry of a preliminary injunction. This listing triggered the Hatch-Waxman requirement that ANDA filers certify to the patent.

99. On August 28, 2000, the FDA tentatively approved IVAX's pending ANDA for generic Taxol. In the absence of the Orange Book listing of the '331 patent, the FDA would have given final approval to IVAX's ANDA on that date.

100. The District Court held that ABI did not merit a preliminary injunction and dismissed the listing suit on September 7, 2000. The District Court orally advised the parties that its order would, consistent with the TRO, require them to take steps to delist the '331 patent. That day, ABI filed a lawsuit against IVAX (the "infringement suit"), alleging that its ANDA infringed the '331 patent. One day later, BMS, knowing that the court hearing the listing suit was about to order it to take actions to delist the '331 patent, informed the FDA of the infringement suit and claimed that the lawsuit barred the FDA from approving all pending ANDAs for thirty more months. The court hearing the infringement suit eventually found, on summary judgment, that all claims of the '331 patent asserted against IVAX for generic Taxol were invalid.

101. On September 11, 2000, BMS again submitted the '331 patent to the FDA for Orange Book listing. On September 14, 2000, the court hearing the listing suit ordered BMS to "use its best efforts to cause the delisting of [the] '331 patent from the Orange Book." On September 14, 2000, to comply with that order, BMS sent a letter to the FDA (1) asking for withdrawal of its August 11 listing of the '331 patent, but only "to the extent it was compelled" by the order, and (2) maintaining that it did not withdraw its earlier listing of the '331 patent and thus that a 30-month stay barred final FDA approval of the IVAX ANDA. Despite these efforts by BMS to maintain an invalid Orange Book listing, the FDA granted IVAX final approval of its ANDA on September 15, 2000, allowing IVAX to market its generic Taxol product.

102. In part because of BMS's conduct, IVAX did not ship its product until October 23, 2000, and the quantities then shipped were smaller than they likely would have been if BMS had not listed the '331 patent. For 180 days thereafter, IVAX was the only generic manufacturer permitted to market generic Taxol because of the Hatch-Waxman 180-day exclusivity period. This exclusivity period would not have existed absent the improper listing of the '537 and '803 patents, because there would have been no patent against which an ANDA applicant could have filed a Paragraph IV certification. Mylan, Bedford, and Abbott later entered with their generic Taxol products, further enhancing price competition.

103. BMS paid ABI $3.5 million to extend its option to license the '331 patent until December 31, 2000. But, as soon as generic paclitaxel products entered the market, despite BMS's and

ABI's effort to use the patent to delay such competition, the patent no longer offered any value to BMS, and BMS did not exercise the option so as to avoid compensating ABI further.

F. BMS Had Monopoly Power in the Relevant Market of Paclitaxel-based Drugs Sold in the United States

104. The relevant antitrust product market in which to assess the anticompetitive effects of BMS's conduct concerning Taxol is the market for paclitaxel-based drugs, which consists of Taxol and generic versions of Taxol.

105. Entry of generic Taxol significantly decreased BMS's Taxol sales and market share, and led to a significant reduction in the average market price paid for paclitaxel-based drugs. Before generic entry, BMS's U.S. Taxol sales were $1.1 billion. In the year after generic entry, BMS's U.S. Taxol sales fell about 50% to $545 million.

106. Because of this competitive relationship between Taxol and its generic bioequivalent drug rivals, such products comprise a distinct relevant product market for antitrust purposes. Other therapeutic agents can be used to treat cancer, but the presence of these therapeutic agents is not sufficient to prevent the anticompetitive effects from BMS's conduct.

107. The relevant geographic market in which to assess the anticompetitive effects of BMS's conduct is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

108. At all times relevant to this complaint, and until October 23, 2000, when generic paclitaxel manufacturers finally overcame BMS's anticompetitive efforts to keep their products off the market, BMS's share of the relevant market was 100%.

109. At all times relevant to this complaint, FDA processes, as well as BMS's exclusionary acts, restricted entry into the relevant market and protected BMS's monopoly.

VIII. BMS's Anticompetitive Campaign to Maintain its Platinol Monopoly

A. BMS Wrongfully Submits the Invalid '925 Patent for Orange Book Listing

110. BMS distributes two cisplatin products (known by the brand names Platinol and Platinol-AQ) which are used in chemotherapy to treat various forms of cancer. BMS received FDA approval for Platinol in 1978 and Platinol-AQ in 1988.

111. By 1995, two patents protected BMS's cisplatin products from final FDA approval of competing generic versions: U.S. Patent Nos. 4,177,263 ("the '263 patent") and 4,339,437 ("the '437 patent"). Each patent claimed a method of treating tumor cells by administering a solution containing cisplatin or other platinum-based compounds. Each patent also claimed priority to, or the benefit of the filing date of, a patent application filed on April 20, 1970. BMS became the exclusive licensee to cisplatin in 1977, in an agreement with Research Corporation Technologies, Inc. ("RCT").

112. On May 26, 1995, the first ANDA-filer submitted its application seeking approval to market a generic cisplatin. Later that year, three other firms also filed ANDAs for generic cisplatin. Each applicant included what is referred to as a Paragraph III Certification, stating that it did not seek FDA approval for its generic product until the expiration of the '263 and '437 patents, which was to occur on December 4, 1996.

113. BMS thus faced potential competition from ANDA filers for the first time. BMS and RCT had a substantial interest in maintaining the cisplatin monopoly. In October 1995, the parties amended a continuation application at the PTO that claimed priority to the same 1970 application that led to the '263 and '437 patents. In April 1996, they told the PTO that the amendment claimed platinum complexes, including cisplatin, which purportedly had additional features not recited in the earlier '263 and '437 patents – i.e., that the complexes were to be "protected from light."

114. As early as 1967, however, it was well known from an article published by the inventors of what became U.S. Patent No. 5,562,925 ("the '925 patent"), that platinum complexes such as cisplatin were light sensitive, and that such complexes should be maintained in the dark. Nonetheless, the applicants asserted that the "claims of the present application [i.e, for the '925 patent] are . . . patentably distinguished," simply because the phrase "'protected from light' is not recited in connection with the methods claimed" in the '263 and '437 patents.

115. On October 8, 1996, the PTO issued the '925 patent. This patent matured from the tenth application in a series of continuation applications based on the original 1970 application. The '925 patent issued less than two months before expiration of the '263 and '437 patents, which would have permitted the FDA to grant final approval to the existing ANDAs.

116. Upon issuance of the '925 patent, BMS promptly submitted the patent to the FDA for listing in the Orange Book in connection with its Platinol products. As a result, the FDA was no longer permitted to grant final approval to any of the pending generic cisplatin ANDAs upon expiration of the '263 and '437 patents in December 1996. Instead, pursuant to Hatch-Waxman, the generic applicants were required to submit a new certification to the FDA concerning this newly listed patent. Each of the generic applicants submitted a Paragraph IV Certification, asserting that their respective ANDAs did not infringe the '925 patent or that the '925 patent was invalid.

117. In response to these Paragraph IV Certifications, BMS filed patent infringement lawsuits against each generic applicant, alleging that the applicants' proposed generic versions of Platinol would infringe the '925 patent. These patent infringement suits were consolidated in the United States District Court for the District of New Jersey. By July 1997, at least three generic applicants had received tentative FDA approval for their generic cisplatin products. By filing these lawsuits, however, BMS triggered Hatch-Waxman's 30-month stay provision, preventing the FDA from granting final approval to each of the ANDAs until as late as July 1999.

118. On July 16, 1999, following expiration of the 30-month stay, American Pharmaceutical Partners – the first generic applicant to submit its Paragraph IV Certification with respect to the '925 patent, and thus the company eligible for the Hatch-Waxman 180-day Exclusivity Period – received final FDA approval.

119. On October 21, 1999, the District Court presiding over the consolidated patent infringement litigation found, by clear and convincing evidence, that the '925 patent was invalid for obviousness-type double patenting in light of the previously granted '263 and '437 patents. Based on controlling Federal Circuit precedent, and the prior art, which demonstrated that certain platinum complexes, including cisplatin, underwent chemical changes when exposed to light, the District Court concluded that "the '925 patent is an obvious modification of the '263 and '437 patents."

120. In November 1999, almost three years after expiration of the two unchallenged BMS patents, APP finally began selling to consumers its generic version of cisplatin.

121. On March 23, 2001, the Federal Circuit affirmed the District Court's ruling that the '925 patent was invalid, finding that the "'protected from light' language provides no distinguishing structure to the claim," amounting to nothing more than a "direction for care," and thus "cannot be a basis for distinguishing the composition claims over the prior method claims."

122. BMS did not reasonably and in good faith believe that the '925 patent was, in fact, valid. The "protected from light" language upon which BMS based its patent claim is nothing more than a "direction for care" that adds no distinguishing structure to the composition. Moreover, it had been reported as early as 1967 that platinum complexes including cisplatin were sensitive to the light, and no effort was made to claim patentability for the "protection from light" feature for nearly three decades thereafter – and not until generic entry against BMS's monopoly was imminent.

B. BMS Had Monopoly Power in the Relevant Market of Cisplatin Sold in the United States

123. The relevant antitrust product market in which to assess the anticompetitive effects of BMS's conduct is the market for cisplatin-based products, which consists of Platinol and generic bioequivalent versions of Platinol.

124. Entry of generic bioequivalent versions of Platinol resulted in a significant, immediate decrease in the sales of branded Platinol, and led to a significant reduction in the average market price paid for Platinol and its generic bioequivalents. Before generic entry, BMS's U.S. Platinol sales were about $100 million. In the year after generic entry, BMS's U.S. Platinol sales fell about 50% to $50 million.

125. Because of this competitive relationship between Platinol and its generic bioequivalent drug rivals, such products comprise a distinct relevant product market for antitrust purposes. Other therapeutic agents can be used to treat cancer, but the presence of these therapeutic agents is not sufficient to prevent the anticompetitive effects from BMS's conduct.

126. The relevant geographic market in which to assess the anticompetitive effects of BMS's conduct regarding Platinol is the United States. The FDA's elaborate regulatory process for approving drugs for sale in the United States, and the fact that the marketing, sales, and distribution of pharmaceuticals occur on a nationwide basis, establish the boundaries of the geographic market.

127. At all times relevant to this complaint, BMS had 100% of the sales in the United States market for Platinol and its generic bioequivalents.

128. At all times relevant to this complaint, FDA processes, as well as BMS's exclusionary acts, restricted entry into the relevant market and protected BMS's monopoly.

IX. The Anticompetitive Effect of BMS's Conduct

129. As a result of BMS's conduct as alleged herein, consumers were deprived, for a substantial period of time, of the benefits of lower-priced competition.

130. The purpose and effect of BMS's actions was to block generic drug products from entering the relevant markets for BuSpar, Taxol, and Platinol. Had generic competition occurred sooner, consumers would have been free to substitute – and, to a significant extent, would have substituted – a lower-priced, therapeutically equivalent, generic drug for the higher-priced BMS brand-name drug.

131. BMS's anticompetitive actions are not justified by any countervailing efficiencies or legitimate business reasons.

X. BMS's Conduct is Not Immune Under the *Noerr-Pennington* Doctrine

132. BMS is not shielded from antitrust liability pursuant to the *Noerr-Pennington* doctrine for numerous reasons as a matter of law and as a matter of fact including, but not limited to, the following: (i) Many of BMS's acts do not constitute "petitioning" behavior, including its entry into unlawful, anticompetitive agreements with Schein and ABI, and its wrongful submission for the Orange Book listing of the '365, '537, '803, '331 and '925 patents; (ii) BMS initiated and maintained objectively baseless "sham" litigation against its generic competitors; and (iii) BMS made misrepresentations or materially false and misleading statements to the PTO and FDA. In addition, the course of conduct alleged herein constitutes a pattern of abusive filings made without regard to the merits that used administrative and judicial processes (as opposed to the outcome of those processes) as an anticompetitive weapon. This pattern of abusive filings with respect to its buspirone, cisplatin, and paclitaxel-based drugs falls outside any petitioning privilege under the *Noerr-Pennington* doctrine.

XI. Violations Alleged

COUNT 1 - Agreement in Restraint of Trade on BuSpar

133. The Commission realleges paragraphs 1 to 33; 64 to 69; and 129 to 132.

134. The agreement between BMS and Schein, under which BMS paid Schein not to compete with any generic buspirone product until expiration of the '763 patent, unreasonably restrained competition and is, therefore, an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S. C. § 45.

COUNT 2 - Monopolization of BuSpar

135. The Commission realleges paragraphs 1 to 69 and 129 to 132.

136. At all times relevant to this complaint, BMS had monopoly power in the market for buspirone products in the United States.

137. BMS willfully maintained its BuSpar monopoly by: (a) entering into an unlawful, anticompetitive agreement with Schein, pursuant to which it paid Schein millions of dollars to stay off the market with its generic buspirone product; (b) providing false and misleading information to the FDA in order to cause the FDA to list the '365 patent in the Orange Book and withhold approval for generic buspirone products; (c) wrongfully submitting the '365 patent for Orange

Book listing without a reasonable good faith belief that the '365 patent met the statutory listing requirements; and (d) initiating and maintaining objectively baseless lawsuits against generic buspirone competitors, without regard to the merits of said lawsuits. By these acts, among others, BMS excluded competition and willfully maintained its BuSpar monopoly based not on the strength and scope of its patents, but rather by abusing competitive and government processes, including by strategically gaming the Hatch-Waxman 30-month provision to block FDA approval for any generic version of BuSpar.

138. BMS's monopolization raised substantial barriers to entry into the relevant market and gave BMS the power to exclude competition, thereby depriving consumers of the benefits of lower-priced generic competition.

139. BMS's acts and practices described above are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

COUNT 3 - Monopolization of Taxol

140. The Commission realleges paragraphs 1 to 23; 70 to 109; and 129 to 132.

141. At all times relevant to this complaint, BMS had monopoly power in the market for paclitaxel-based drugs in the United States.

142. BMS willfully maintained its Taxol monopoly by: (a) securing the '537 and '803 patents through inequitable conduct at the PTO and wrongfully submitting them for Orange Book listing without a reasonable good faith belief that the patents were, in fact, enforceable and thus met the statutory listing requirements; and (b) conspiring with ABI to cause the FDA to list the '331 patent in the Orange Book without a reasonable good faith belief that the relevant claims of the patent were valid and thus met the statutory listing requirements. By these acts, among others, BMS excluded competition and willfully maintained its Taxol monopoly based not on the strength and scope of its patents, but rather by abusing competitive and government processes, including by strategically gaming the Hatch-Waxman 30-month provision to block FDA approval for any generic version of Taxol.

143. BMS's monopolization raised substantial barriers to entry into the relevant market and gave BMS the power to exclude competition, thereby depriving consumers of the benefits of lower-priced generic competition.

144. BMS's acts and practices described above are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

COUNT 4 – Agreement in Restraint of Trade on Taxol

145. The Commission realleges paragraphs 1 to 23; 94 to 109; and 129 to 132.

146. The agreement between BMS and ABI, under which BMS agreed to list the '331 patent without a reasonable good faith belief that said patent was valid and listable, unreasonably restrained competition, and is therefore an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S. C. § 45.

COUNT 5 - Monopolization of Platinol

147. The Commission realleges paragraphs 1 to132.

148. At all times relevant to this complaint, BMS had monopoly power in the market for Platinol in the United States.

149. BMS acted willfully maintain its Platinol monopoly. It did so by wrongfully submitting the invalid '925 patent for Orange Book listing without a reasonable good faith belief that the '925 patent – which issued from a 26-year old application, and just two months prior to expiration of the existing Platinol patent protection – was in fact valid. By this act, among others, BMS excluded competition and willfully maintained its Platinol monopoly based not on the strength and scope of its patent, but rather by abusing government processes, including by strategically gaming the Hatch-Waxman 30-month provision to block FDA approval for any generic version of Platinol.

150. BMS's monopolization raised substantial barriers to entry into the relevant market and gave BMS the power to exclude competition, thereby depriving consumers of the benefits of lower-priced generic competition.

151. BMS's acts and practices described above are anticompetitive in nature and tendency, and constitute an unfair method of competition in violation of Section 5 of the FTC Act, 15 U.S.C. § 45.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this _____ day of _____, 2003, issues its Complaint.

By the Commission.

Donald S. Clark
Secretary

ISSUED:

SEAL