

Complaint

IN THE MATTER OF

BRISTOL-MYERS SQUIBB COMPANYCONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4076; File No. 0010221, 0110046, 0210181
Complaint, April 14, 2003--Decision, April 14, 2003*

This consent order addresses practices used by Respondent Bristol-Myers Squibb Corporation (“BMS”) with respect to generic versions – that is, versions that contain the same active ingredients as, and are bioequivalent to, their brand-name counterparts – of three of its major drug products, including BuSpar, used to treat persistent anxiety; Taxol, used to treat cancers of the ovaries, breasts and lungs, and AIDS-related Kaposi’s sarcoma; and Platinol, used in chemotherapy to treat various forms of cancer. The order, among other things, prohibits the respondent from seeking to list the ‘365 patent relating to BuSpar in the Orange Book – in relation to any New Drug Application (“NDA”) in which the active ingredient is buspirone – and restricts the extent to which the respondent can attempt to enforce the ‘365 patent. The order also prohibits the respondent from seeking to enforce, or collecting royalties on, any patent covering any BMS paclitaxel drug product sold as of October 2002. In addition, the order prohibits the respondent from taking any action to obtain or maintain a statutory 30-month stay on Food and Drug Administration approval with respect to an Abbreviated New Drug Application (“ANDA”) that references BuSpar or Taxol. The order also prohibits the respondent from securing Orange Book listings that are contrary to the statutes and regulations governing such listings, such as listing patents in the Orange Book that do not actually claim the drug products at issue. In addition, the order prohibits the respondent from triggering a 30-month stay when the patent at issue is listed after the filing of any ANDA referencing the NDA. The order also prohibits the respondent from making false and misleading statements to the FDA that are material to the approvability or sale of a generic version of a BMS brand-name drug product, unless BMS has a reasonable belief that the statement is neither false nor misleading; from asserting any objectively baseless patent infringement claim; and from seeking to enforce a patent that BMS knows is invalid, unenforceable, or not infringed. In addition, the order prohibits the respondent from being a party to an agreement, with an ANDA filer who has received anything of value, to settle a patent infringement claim, or to refrain from the sale of the ANDA product during litigation of a patent infringement claim, unless, among other provisos, the respondent, pursuant to a request for an advisory opinion, receives a response from the Commission that the agreement would not raise issues under Section 5 of the Federal Trade Commission Act.

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For the Commission: *Gary H. Schorr, Randall David Marks, Bradley S. Albert, Ellen Connelly, Seth Silber, George Bellack, David Dudley, Steve Vieux, Matthew Odette, Andrew Ginsberg, Tim Abbott, Jerod Klein, Natasha Moskvina, Suzanne Michel, David R. Pender, Jeffrey W. Brennan, Chul Pak, Anne R. Schenof, Roberta S. Baruch, Malcolm B. Coate, Louis Silvia, Jr., and Mary T. Coleman.*

For the Respondent: *Evan R. Chesler, Richard J. Stark, and Elizabeth L. Grayer, Cravath, Swaine, & Moore.*

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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.

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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

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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.

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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

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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

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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.

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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.

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**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.

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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

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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.

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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,

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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

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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

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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

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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,

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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";

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- (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

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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

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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.

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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.

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**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.

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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

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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/m² 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

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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/m², 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/m² to 265 mg/m², 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

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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/m² 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/m²,” 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

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higher dosage amounts of 190 mg/m² and 230 mg/m² 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/m², falling within the range of 135-175 mg/m² 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/m² 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

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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.

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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.

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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

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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.

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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%.

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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.

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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

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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."

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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.

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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.

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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

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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.

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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

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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 to 132.
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.

Complaint

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 fourteenth day of April, 2003, issues its Complaint.

Decision and Order

DECISION AND ORDER

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

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

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

1. Respondent BMS is a corporation organized, existing, and doing business under and by virtue of the laws of the state of

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Delaware, with its office and principal place of business located at 345 Park Avenue, New York, N.Y. 10154.

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

ORDER

I.

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

- A. “Respondent BMS” means Bristol-Myers Squibb Company, its directors, officers, employees, agents and representatives, predecessors, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by Bristol-Myers Squibb Company, and the respective directors, officers, employees, agents and representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “180-day Exclusivity Period” means the period of time established by 21 U.S.C. § 355(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355 *et seq.*).
- D. “6-Hydroxy-Metabolite of Buspirone” means 6-hydroxy-8-[4-[4-(2- pyrimidinyl)-piperazinyl]-butyl]-8-azaspiro[4.5]-7,9-dione.
- E. “30-Month Stay” means the period of time, established by 21 U.S.C. § 355(j)(5)(B)(iii), during which the FDA may not grant final approval to an ANDA.

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- F. “AB-rated Generic Version” means an ANDA found by the FDA to be bioequivalent to the Referenced Drug Product, as defined under 21 U.S.C. § 355(j)(8)(B).
- G. “Agreement” means anything that would constitute an agreement under Section 1 of the Sherman Act, 15 U.S.C. § 1, or Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.
- H. “ANDA” means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j).
- I. “ANDA Filer” means a person who has filed or submitted an ANDA with the FDA.
- J. “ANDA First Filer” means the person whom the FDA determines is and remains entitled to, or eligible for, a 180-day Exclusivity Period that has not expired.
- K. “ANDA Product” means the product to be manufactured under the ANDA that is the subject of the Patent Infringement Claim.
- L. “Applicable Law” means the statutes and regulations governing Orange Book listings, including, but not limited to, 21 U.S.C. § 355(b)(1) and (c)(2) and 21 C.F.R. § 314.53(b) and (c).
- M. “Drug Product” means a finished dosage form (e.g., tablet, capsule, or solution), as defined in 21 C.F.R. § 314.3(b), that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.
- N. “Encourage” means suggest, advise, pressure, induce, attempt to induce, prompt, or otherwise influence.

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- O. “Exclusive License” means a license of intellectual property that (a) restricts the right of the licensor to license the intellectual property to other persons, (b) reduces the incentives of the licensor to license the intellectual property to other persons, or (c) grants to the licensee the right to enforce the intellectual property rights against other persons.
- P. “Expiration Date” means 180 days after the date that the ANDA First Filer commences commercial marketing of (1) the ANDA Product, (2) the Reference Drug Product, or (3) any other AB-Rated Generic Version of the Reference Drug Product.
- Q. “FDA” means the United States Food and Drug Administration.
- R. “Listing Information” means any statement or information of any type provided to the FDA in furtherance of the listing or continued listing of any patent in the Orange Book, however communicated or recorded and regardless of the subject matter, including, but not limited to, any factual or legal subject matter.
- S. “Material Patent Information” means any statement or information of any type, however communicated or recorded, regardless of the subject matter, that is material to patentability, as defined in 37 C.F.R. § 1.56(b).
- T. “NDA” means a New Drug Application, as defined under 21 U.S.C. § 355(b), including all changes or supplements thereto which do not result in the submission of a new NDA.
- U. “NDA Holder” means: (1) the person that received FDA approval to market a Drug Product pursuant to an NDA, (2) a person owning or controlling the ability to enforce

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the patent(s) listed in the Orange Book in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licensees, licensors, successors, and assigns of each of the foregoing.

- V. “Orange Book” means the FDA publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations.”
- W. “Patent Infringement” means infringement of any patent or of any filed patent application, extension, reissue, renewal, division, continuation, continuation in part, reexamination, patent term restoration, or patents of addition and extensions thereof.
- X. “Patent Infringement Claim” means any allegation, whether threatened or included in a complaint filed with a court of law, that an ANDA Filer’s ANDA or ANDA Product may infringe any U.S. patent held by, or exclusively licensed to, the NDA Holder of the Reference Drug Product.
- Y. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- Z. “PTO” means the United States Patent and Trademark Office.
- AA. “Reference Drug Product” means the Drug Product identified by the ANDA Filer as the Drug Product upon which the ANDA Filer bases its ANDA.

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- BB. “Relinquish” includes, but is not limited to, abandoning, waiving, or relinquishing.
- CC. “Sale of Drug Products” means the sale of Drug Products in or affecting commerce, as commerce is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- DD. “Taxol” means any paclitaxel drug product as BMS sold it as of October 1, 2002, including, but not limited to, active ingredient and formulation.
- EE. “Taxol Patent” means one or more of (i) U.S. Patent No. 5,670,537, (ii) U.S. Patent No. 5,641,803, or (iii) any other U.S. patent claiming Taxol as a composition of matter, or any method of using Taxol.
- FF. “Use Patent” means a patent claiming an indication, dosage regimen, method of administration, or other condition of use.

II.

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

III.

IT IS FURTHER ORDERED that Respondent BMS shall not:

- A. Make a Patent Infringement Claim that a Taxol Patent is infringed by any Drug Product or the use of any Drug Product where the subject of the Patent Infringement

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Claim is the making, using, selling, offering to sell, or importing of Taxol; or

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

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

IV.

IT IS FURTHER ORDERED that Respondent BMS shall not take any action, or Encourage any other person to take any action, that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA approval of any ANDA referencing:

- A. NDA No. 018731 (BuSpar); or
- B. NDA No. 020262 (Taxol).

V.

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

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VI.

IT IS FURTHER ORDERED that Respondent BMS shall not seek, maintain, certify to, or take any other action in furtherance of, the listing or continued listing of any patent in the Orange Book where the listing of such patent in the Orange Book violates Applicable Law.

VII.

IT IS FURTHER ORDERED that Respondent BMS shall not, in connection with any patent listed in the Orange Book under any NDA for which Respondent BMS is the NDA Holder, take any action, or Encourage any other person to take any action, that initiates, maintains, or causes to be initiated or maintained, a 30-Month Stay of FDA approval of any ANDA referencing such NDA where:

- A. The patent is listed in the Orange Book under such NDA after the filing of any ANDA referencing such NDA;
- B. Respondent BMS, in obtaining the patent before the PTO, engaged in inequitable conduct as that term is judicially construed in the context of patent litigation;
- C. Respondent BMS provided Listing Information that is false or misleading;
- D. Respondent BMS provided Listing Information to the FDA and Material Patent Information to the PTO, where Respondent BMS cannot show that, at the time the statements were made, it had a reasonable belief that the Material Patent Information and the Listing Information were both accurate. A violation of this subparagraph VII.D can be established without the Commission proving whether it is the Listing Information or the Material Patent Information that is inaccurate;

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- E. The patent is a Use Patent, and at the time of its Orange Book listing, such patent did not claim an approved use of the Drug Product specified in the NDA referenced by such ANDA; or
- F. The patent claims (1) a composition of matter that is a metabolite of an active ingredient listed in the NDA referenced by such ANDA, and/or (2) a method of use of such a metabolite.

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

- (1) the patent listed in the Orange Book contains a claim or portion of a claim distinct from those identified in paragraph VII.E and VII.F (“Additional Claim”);
- (2) an Orange Book listing based on the Additional Claim does not violate Applicable Law; and
- (3) so long as BMS maintains a Patent Infringement Claim that the ANDA Filer infringes the Additional Claim.

VIII.

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

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

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IX.

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

- A. Assert any fraudulent or objectively baseless claim, or otherwise engage in sham litigation for the purpose of injuring an ANDA Filer rather than to obtain a favorable outcome to the Patent Infringement Claim.
- B. Enforce or seek to enforce any patent that it knows is invalid, unenforceable, or not infringed.

X.

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

XI.

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

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

XII.

IT IS FURTHER ORDERED that Respondent BMS shall cease and desist, directly or indirectly, in connection with the Sale of Drug Products, from being a party to any Agreement resolving or settling a Patent Infringement Claim in which:

- A. An ANDA Filer receives anything of value; and
- B. The ANDA Filer agrees not to research, develop, manufacture, market, or sell, the ANDA Product for any period of time.

PROVIDED, HOWEVER, that nothing in this Paragraph XII shall prohibit:

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

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- (c) Respondent BMS has notified the Commission, as described in Paragraph XVI.
- (2) Respondent BMS from resolving or settling a Patent Infringement Claim after the Commission, in response to a request by Respondent BMS for an advisory opinion pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. § 1.2, determines that the settlement Agreement would not raise issues under Section 5 of the Federal Trade Commission Act.
- (3) Respondent BMS, without notice to the Commission, from seeking relief unilaterally from a court, including but not limited to, applying for permanent injunctive relief, or seeking to extend or reduce a 30-month stay pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

XIII.

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

- A. Could be approved for sale by the FDA pursuant to an ANDA; and
- B. Is neither the subject of any written claim or allegation of Patent Infringement nor the subject of a written representation from the ANDA Filer's counsel that the Drug Product would be the subject of such a claim or allegation if disclosed to the NDA Holder.

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XIV.

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

- A. One party is an NDA Holder and the other party is the ANDA First Filer for the Reference Drug Product; and
- B. The ANDA First Filer is prohibited by such Agreement from Relinquishing, or is subject to a penalty, forfeiture, or loss of benefit, if it Relinquishes its right to the 180-day Exclusivity Period.

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

- (1) Within twenty (20) days of entering into the Agreement, the ANDA First Filer commences commercial marketing of the ANDA Product, the Reference Drug Product, or any other AB-rated Generic Version of the Reference Drug Product;
- (2) One of the following two conditions has been satisfied:
 - (a) the 180-day Exclusivity Period, if any, has been triggered by the commercial marketing required by proviso subparagraph (1) above, and has begun to run with respect to the ANDA Product; or
 - (b) within ten (10) days of the commercial marketing of a Drug Product other than the one subject to the ANDA, the ANDA First Filer has notified the FDA, in

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writing, that it will Relinquish any and all eligibility for, and entitlement to, a 180-day Exclusivity Period, if any, for the ANDA Product, beyond the Expiration Date; and

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

XV.

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

- A. The parties do not agree to dismiss the litigation;
- B. The NDA Holder provides anything of value to the alleged infringer; and
- C. The ANDA Filer agrees to refrain during part or all of the course of the litigation from selling the ANDA Product, or any Drug Product containing the same active chemical ingredient as the ANDA Product.

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

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

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- (2) Respondent BMS has notified the Commission, as described in Paragraph XVI, at least thirty (30) days prior to submitting the stipulation for a preliminary injunction;
- (3) Respondent BMS does not oppose any effort by the Commission to participate, in any capacity permitted by the court, in the court's consideration of any such action for preliminary relief; and
- (4) One of the following two conditions apply:
 - (a) the court issues an order and the parties' agreement conforms to said order; or
 - (b) the Commission, in response to a request by Respondent BMS for an advisory opinion, pursuant to Section 1.2 of the Commission Rules of Practice, 16 C.F.R. § 1.2, determines that entering into the stipulation would not raise issues under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

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

XVI.

IT IS FURTHER ORDERED that:

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

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- (1) The docket number and caption name of this Order;
 - (2) A statement that the purpose of the Notification Letter is to give the Commission prior notification of a proposed Agreement as required by this Order;
 - (3) Identification of the parties involved in the proposed Agreement;
 - (4) Identification of all Drug Products involved in the proposed Agreement;
 - (5) Identification of all persons, to the extent known, who have filed an ANDA with the FDA (including the status of such application) for any Drug Product containing the same chemical entity(ies) as the Drug Product(s) involved in the proposed Agreement;
 - (6) A copy of the proposed Agreement;
 - (7) Identification of the court, and a copy of the docket sheet, for any legal action which involves either party to the proposed Agreement and relates to any Drug Product(s) containing the same chemical entity(ies) involved in the Agreement; and
 - (8) All documents which were prepared by or for any officer(s) or director(s) of Respondent BMS for the purpose of evaluating or analyzing the proposed Agreement, *provided that* documents subject to a valid claim of privilege or work product need not be produced pursuant to this provision, but shall be identified in a log.
- B. Respondent BMS shall submit the Notification Letter to the Secretary of the Commission at least thirty (30) days prior to consummating the proposed Agreement (“First

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Waiting Period”). If Respondent BMS so requests, the Commission shall keep the Notification Letter and accompanying information and documents confidential to the extent provided by law.

C. If the Notification Letter is provided pursuant to:

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

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

XVII.

IT IS FURTHER ORDERED that Respondent BMS shall file a verified written report within sixty (60) days after the date this Order becomes final, annually thereafter for five (5) years on the

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anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, setting forth in detail the manner and form in which Respondent BMS intends to comply, is complying, and has complied with this Order. Respondent BMS shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order. As to Paragraph VII of this Order, this description shall identify all ANDAs subjected to a 30-Month Stay of FDA approval, and as to each of these 30-Month Stays, a description of BMS's efforts to comply with Paragraph VII of this Order.

XVIII.

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

XIX.

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

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

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

XX.

IT IS FURTHER ORDERED that this Order shall terminate on April 14, 2013.

By the Commission.

Analysis

Analysis to Aid Public Comment

The Federal Trade Commission has accepted for public comment an agreement and proposed consent order with Bristol-Myers Squibb Corporation (BMS). The proposed consent order would settle charges that BMS engaged in a series of unlawful acts to delay competition from generic versions of three of its major drug products. The proposed consent order has been placed on the public record for 30 days to receive comments by interested persons. The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by BMS that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

The complaint charges that BMS engaged in a series of anticompetitive acts over the past decade to obstruct the entry of low-cost generic competition to three highly profitable BMS prescription drug products: BuSpar, an anti-anxiety agent; and two anti-cancer drugs, Taxol and Platinol. According to the complaint, when confronted with imminent competition to these drugs through generic entry, BMS undertook a course of conduct that includes: paying a would-be competitor \$72.5 million to abandon its challenge to a BMS patent and stay off the market until the patent expired; abusing Food and Drug Administration (FDA) regulations to block generic entry; making false statements to the FDA in connection with listing patents in the Orange Book; engaging in inequitable conduct before the U.S. Patent and Trademark Office (PTO) to obtain patents; and filing baseless patent infringement suits. As a result, the complaint alleges, consumers were forced to incur hundreds of millions of dollars in additional costs to obtain vital prescription drug products.

The proposed order is designed to remedy the pattern of unlawful conduct charged in the complaint and prevent recurrence of such conduct, while maintaining BMS's ability to engage in legitimate activities that may promote innovation and benefit consumers.

Background

The proposed consent order rests in substantial part on charges that BMS abused governmental processes to delay generic competition to three of its highly successful prescription drug products and, in particular, that it misused the regulatory scheme established by Congress to expedite the approval of generic drugs.

A generic drug is a pharmaceutical product that contains the same active ingredients as its brand-name counterpart and is “bioequivalent” to the branded drug, that is, the FDA has determined there is no significant difference in the rate and extent of absorption of the two products. Generic drugs typically are sold at substantial discounts from the branded drug’s price. A Congressional Budget Office report estimates that purchasers saved \$8-10 billion on prescriptions at retail pharmacies in 1994 by purchasing generic drugs instead of the brand-name product.¹

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the “Hatch-Waxman Act,” to facilitate the entry of lower-priced generic drugs, while maintaining incentives for companies to invest in research and development of new drugs. A company seeking approval from the FDA to market a new drug must file a New Drug Application (NDA) demonstrating the safety and efficacy of its product. To receive FDA approval to market a generic version of a branded drug, a company files an Abbreviated New Drug Application (ANDA) demonstrating that its product is bio-equivalent to its branded counterpart, but need not provide independent data on safety and efficacy.

The Hatch-Waxman Act established certain rights and procedures that apply when a company seeks approval from the

¹ Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* xiii, 13 (July 1998).

Analysis

FDA to market a generic product prior to the expiration of a patent or patents relating to the branded drug upon which the generic is based. An NDA applicant is required to submit to the FDA information on certain types of patents relating to the approved drug. The FDA lists the approved drug and its related patents in a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly known as the “Orange Book.” If the PTO grants a patent relating to an approved drug after the NDA has been approved, and the NDA holder submits it for listing in the Orange Book, then the FDA will list it as well.

The listing of patents in the Orange Book plays a substantial role in the timing of FDA approval of generic drugs. As part of the ANDA process, the ANDA filer must certify to the FDA regarding its generic product and any patents listed in the Orange Book that claim the reference branded drug. If the ANDA filer seeks approval before the expiration of all listed patents, it must: (1) file what is known as a “Paragraph IV certification,” declaring that the patents listed in the Orange Book either are invalid or will not be infringed by the manufacture, use, or sale of the drug products for which the ANDA is submitted; and (2) notify the patent holder of the filing of the certification. If the holder of patent rights files a patent infringement suit within 45 days of the notification, FDA approval to market the generic drug is automatically stayed for 30 months, regardless of the merits of the suit, unless before that time the patent expires or a court holds that the patent is invalid or not infringed.

Not all patents are eligible for listing in the Orange Book and the special statutory 30-month stay that the Hatch-Waxman Act provides. The statute provides for listing only if: (1) the patent “claims the drug . . . or a method of using such drug” and (2) the patent is one “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture,

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use, or sale of the drug.”² In the case of patents not eligible for listing in the Orange Book, a branded firm still can sue a generic company for patent infringement, but under ordinary federal litigation procedures and without the benefit of an automatic 30-month stay. To prevent sale of the generic product before conclusion of the suit in such cases, a branded firm must obtain a preliminary injunction, which requires that it demonstrate a likelihood of success on the merits, among other factors.

Although Orange Book listings have significant legal and competitive implications, it is private parties, rather than the FDA, that in practice determine whether patents are listed. The FDA has repeatedly stated that its role in patent listings is solely ministerial and that it lacks the resources and expertise to scrutinize patent information in the Orange Book. Even when a generic applicant disputes a patent listing, the FDA merely asks the NDA holder to confirm that the listed patent information is correct. Unless the NDA holder itself withdraws or amends its listed patent information, the FDA will not remove the patent listings from the Orange Book.³ Thus, as one court has stated, “the FDA’s listing should not create any presumption that [a] patent was correctly listed.”⁴ In addition, the Federal Circuit has held that generic applicants have no right to bring a declaratory judgment action to challenge an NDA holder’s Orange Book

² 21 U.S.C. §§ 355(b)(1); 355(c)(2); 355(j)(7)(A)(iii) (2003).

³ See, e.g., *American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) (recognizing that the FDA “has refused to become involved in patent listing disputes, accepting at face value the accuracy of NDA holders’ patent declarations and following their listing instructions”).

⁴ *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 10 F. Supp. 2d 446, 456 (D.N.J. 1998).

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listing as improper.⁵ As long as the patent remains listed, the brand-name company can continue to benefit from the availability of an automatic 30-month stay of FDA approval of ANDAs, by initiating a patent suit against generic applicants.

The Commission's recent study, *Generic Drug Entry Prior to Patent Expiration* (July 2002), examined the potential for abuse of the Hatch-Waxman process for Orange Book listings and 30-month stays.⁶ The data received by the Commission showed that brand-name companies are increasingly listing in the Orange Book, and suing on, multiple patents, and that these are frequently patents that have been listed after an ANDA has been filed. If patents issued to the brand-name company are listed before the generic applicant files its ANDA, then a brand-name company's suit on those patents will generate a single 30-month stay, even though multiple patents are at issue in the litigation. If the patent is obtained and listed after the generic applicant has filed its ANDA, however, then the brand-name company can obtain an additional 30-month stay (which may be consecutive to or overlap the first 30-month stay) following a generic applicant's certification that it does not infringe the later-issued patent. The FTC Study found that for drugs for which there were multiple 30-month stays, the additional delay of FDA approval (beyond the first 30 months) ranged from four to 40 months. The FTC Study also found that later-issued patents frequently raise listability or validity concerns. Of the eight drug products involving later-issued patents identified in the study, all four that had been adjudicated were found invalid or not infringed. Of the eight drug products involving later-issued patents identified in the study,

⁵ See *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001).

⁶ Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (July 2002), available at <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>.

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three involve the BMS products that are the subject of the complaint here.⁷

The Challenged Conduct

The complaint makes the following allegations:

A. BuSpar

BuSpar is used to treat persistent anxiety, a condition affecting an estimated 10 million Americans. BMS began selling BuSpar in 1986, and by 2000, the year before a generic version became available, BuSpar sales in the United States were over \$600 million.

The complaint charges that BMS first entered into an unlawful patent settlement agreement, in which it agreed to pay a potential generic competitor over \$70 million to withhold its generic version of BuSpar from the market until BMS's patent expired, and then provided false and misleading information to the FDA to induce the FDA to list a later patent on BuSpar in the Orange Book, one that did not meet either of the statutory requirements for listing. Additionally, the complaint alleges that BMS filed baseless patent infringement suits against generic applicants on BuSpar.

The settlement agreement arose out of patent litigation that BMS filed after Schein Pharmaceutical, Inc. submitted an ANDA for generic buspirone hydrochloride (buspirone), the active ingredient in BuSpar. Schein filed a Paragraph IV certification with the FDA in 1992, contending that BMS's '763 patent was invalid, because it claimed a use of buspirone that had been anticipated by an earlier BMS patent. BMS's suit triggered a 30-month stay on FDA approval of Schein's ANDA, which would have expired in early 1995.

⁷ *Generic Drug Study* at 39-40, 48-50.

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In December 1994, BMS entered into an agreement with Schein to settle their patent litigation. Pursuant to that agreement, BMS agreed to pay Schein \$72.5 million over the next four years, and Schein agreed to refrain from marketing its ANDA product or any other generic version of BuSpar (regardless of whether such product would infringe BMS's patent), until the '763 patent expired. Schein also agreed to acknowledge the validity of the '763 patent, to refrain from assisting others in challenging the '763 patent or in developing generic buspirone, and to take other steps to help BMS protect its patent from another challenge to its validity.

Anticipating expiration of its '763 patent in November 2000, BMS filed a new patent application with the PTO in 1999, involving the use of buspirone to create the metabolite of buspirone (a metabolite is the new molecule created when a pharmaceutical agent breaks down in the body). The PTO, however, repeatedly rejected BMS's efforts because BMS had been making and selling BuSpar to treat anxiety in the United States for nearly 14 years. Only after BMS finally requested a patent that claimed solely the use of the metabolite of buspirone – not the use of buspirone itself – and only hours before the '763 patent was due to expire, did the PTO issue what became known as the '365 patent. BMS promptly submitted the '365 patent information to the FDA for listing in the Orange Book.

BMS's '365 patent did not meet either of the statutory requirements for listing a patent in the Orange Book, because it does not claim BuSpar or a method of using BuSpar, and it is not a patent with respect to which a claim of patent infringement could reasonably be asserted against someone selling BuSpar. Although BMS knew that it had only obtained a patent claiming a method of using a metabolite, it nonetheless submitted a declaration to the FDA affirming that the '365 patent claimed a method of using BuSpar, in order to list the patent in the Orange Book. Furthermore, BMS intentionally made an additional false and misleading statement after ANDA filers on BuSpar asserted to the FDA that the '365 patent did not meet the criteria for listing in

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the Orange Book. The FDA asked BMS to provide a declaration that the '365 patent contains a claim for an approved use of buspirone. BMS responded with a declaration expressly affirming that the '365 patent does in fact claim the approved uses of buspirone, a statement that was false and directly contradicted representations BMS made to the PTO to obtain the '365 patent. Consistent with its ministerial approach to Orange Book listings, the FDA simply accepted BMS's statements and deemed the '365 patent listed in the Orange Book as of November 21, 2000. In so doing, FDA noted that it listed the patent solely on the basis of BMS's declarations that the patent met the requirements for listing and did not make any independent determination regarding the '365 patent's scope and coverage.

The complaint charges that 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 an improper 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.

Generic competition to BuSpar occurred only after the '365 patent was removed from the Orange Book in March 2001, following the decision by the district court in *Mylan Pharmaceuticals, Inc. v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001), ordering BMS to seek de-listing.⁸ This competition occurred substantially later than it would have absent BMS's anticompetitive acts. As a consequence, consumers suffered

⁸ The Federal Circuit later reversed this ruling on jurisdictional grounds. *Mylan Pharms., Inc. v. Thompson*, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001) (holding no private right of action under the Federal Food, Drug, and Cosmetic Act to seek de-listing).

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substantial economic detriment by paying monopoly prices for an unjustifiably extended period.

The complaint also charges that the patent infringement suits BMS brought against ANDA filers for infringement of the ‘365 patent were objectively baseless and filed without regard to their merits. The ‘365 patent could not be both valid and infringed. If the patent claim were interpreted to cover the currently-approved uses for which the generic applicants submitted their ANDAs – necessary to demonstrate that the ANDA products infringed – then the patent necessarily would be invalid, because those uses had been known long before BMS applied for the patent. A court later so found on summary judgment.⁹ The intent and effect of BMS’s suits, the complaint states, was to wrongfully trigger the 30-month stay as a means of preventing generic buspirone manufacturers from marketing their products.

B. Taxol

Taxol is used to treat cancers of the ovaries, breasts and lungs, and AIDS-related Kaposi’s sarcoma. The drug’s active ingredient, paclitaxel, is a naturally-occurring substance whose anticancer properties were discovered and developed by scientists at the National Cancer Institute (NCI). In 1991, the NCI gave BMS the exclusive right to use existing and future data for FDA approval of paclitaxel, and BMS obtained FDA approval to market Taxol in 1992. Prior to generic entry in 2000, BMS’s annual Taxol sales in the United States were over \$1 billion.

The complaint charges that BMS used many of the same strategies to obstruct generic competition to Taxol that it used with BuSpar: improperly listing patents in the Orange Book (three patents in the case of Taxol); and abusing the regulatory

⁹ *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002); *In re Buspirone Antitrust Litig.*, 183 F. Supp.2d 363, 376 (S.D.N.Y. 2002)..

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process through the filing of misrepresentations. In addition, the complaint alleges that BMS entered into an unlawful agreement with another firm for the purpose of furthering its effort to obtain another 30-month stay on FDA approval of generic versions of Taxol.

In 1992, although it told a Congressional committee that “near-term generic competition for TAXOL is a certainty,” because Taxol was not a patented product, BMS in fact was actively pursuing a patent application before the PTO on Taxol. In prosecuting that patent application before the PTO, BMS made representations that were directly contrary to what it had previously told the FDA in seeking approval of its NDA for Taxol.

To obtain FDA approval of its NDA, BMS had relied on several studies in the public domain to show that Taxol was safe and effective. 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, so the results of that research were unpatentable. To obtain a patent, BMS had to demonstrate to the PTO that its claimed method of administering Taxol differed from the methods used in those prior studies.

BMS told the PTO that certain studies (ones it had relied on to obtain FDA approval for Taxol) did not provide evidence of safety and efficacy, and thus made various statements about the studies that are directly contrary to those BMS made to the FDA. In addition, BMS also deliberately failed to disclose to the PTO material prior art. In making false and misleading material statements to the PTO and by failing to disclose material prior art, BMS breached its duty of candor and good faith in dealing with the PTO. BMS therefore engaged in inequitable conduct, rendering the two patents that resulted (the ‘537 and ‘803 patents) unenforceable.

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Because BMS knew that the ‘537 and ‘803 patents were obtained through inequitable conduct before the PTO, it could not reasonably believe that the patents were enforceable or consequently that they were listable under the FDA’s Orange Book regulations. Nevertheless, BMS promptly submitted the patents to the FDA for listing in the Orange Book. Furthermore, after a number of generic pharmaceutical manufacturers filed ANDAs with Paragraph IV certifications, BMS brought patent infringement suits – based on patents it knew it had obtained through inequitable conduct – that triggered Hatch-Waxman’s automatic 30-month stay provision, insulating Taxol from potential generic drug competition for that period.

Finally, BMS improperly listed a third patent in the Orange Book and thereby obtained the ability to trigger the Hatch-Waxman provision for another 30-month stay as a result of a conspiracy with American Bioscience, Inc. (ABI). Shortly after the 30-month stays that BMS had obtained from its unlawful listings of the ‘537 and ‘803 patents expired, but before any ANDAs for generic paclitaxel obtained FDA approval, BMS and ABI agreed on the terms of an option to license ABI’s ‘331 patent. The agreement provided that ABI would receive royalties based on a significant percentage of BMS sales of Taxol, an arrangement that would be highly profitable to ABI if BMS continued to enjoy protection from generic competition to Taxol.

BMS submitted the ‘331 patent to the FDA for listing in the Orange Book, but it could not have reasonably believed 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. BMS knew of material 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.

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C. Platinol

Platinol is used in chemotherapy to treat various forms of cancer. BMS began selling Platinol in 1978 and Platinol-AQ in 1988, and annual United States sales of its Platinol products were \$100 million by 1998. Platinol's active pharmaceutical ingredient is cisplatin.

Regarding Platinol, the complaint alleges that, as with BuSpar and Taxol, BMS wrongfully submitted a patent for listing in the Orange Book to obtain an unwarranted 30-month stay on FDA approval of competing generic products. By 1996, BMS's patent protection for its Platinol products was running out, and four would-be generic rivals were poised to enter with their lower-cost, bioequivalent products. Facing likely generic competition to its Platinol monopoly for the first time, BMS, which held an exclusive license to cisplatin, and the licensor decided to amend a patent application then pending at the PTO – an application that had been initially filed more than two decades earlier, in 1970. In October 1996 – just two months before BMS's other Platinol patents were to expire – the PTO issued the '925 patent based on this amended application. BMS promptly submitted this new patent for listing in the Orange Book. This listing, coupled with BMS's initiation of a patent infringement lawsuit in federal court against each generic cisplatin applicant, triggered an automatic statutory 30-month stay on FDA approval of the generic applications.

According to the complaint, BMS could not have reasonably believed that the '925 patent was valid, and its listing of the patent in the Orange Book was not made in good faith to comply with FDA regulations. In fact, in October 1999, a district court ultimately found, by clear and convincing evidence, that the '925 patent was invalid for obviousness-type double patenting, a ruling that the Federal Circuit later upheld. As a result of BMS's wrongful listing of the '925 patent, consumers were deprived, for about two years, of the benefits of a lower-priced generic alternative to BMS's branded cisplatin products.

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Competitive Analysis

The complaint alleges that the relevant product markets in which to assess the competitive effects of BMS's conduct are:

buspirone-based products (BuSpar and generic bioequivalent versions of BuSpar);

paclitaxel-based products (Taxol and generic bioequivalent versions of Taxol); and

cisplatin-based products (Platinol and generic bioequivalent versions of Platinol).

In each market, according to the complaint, entry of a lower-priced generic version of BMS's product resulted in a significant, immediate decrease in the sales of the BMS product and led to a significant reduction in the average price for products in the relevant market. Conversely, the complaint states that the availability of other therapeutic agents for the conditions that BuSpar, Taxol, and Platinol treat was not sufficient to prevent the effects from BMS's conduct. As a result of this competitive relationship between each of the three BMS branded products and its generic bioequivalents, each of these groups of products comprises a distinct relevant product market for purposes of analyzing the challenged conduct here.

According to the complaint, the relevant geographic market in which to assess the competitive effects of BMS's conduct is the United States, given 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 such as those at issue here occur on a nationwide basis.

The complaint alleges that, prior to the entry of generic versions of its BuSpar, Taxol, and Platinol products, BMS had monopoly power in each of the three relevant antitrust markets. BMS is charged with engaging in acts that willfully maintained its

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monopolies in buspirone, paclitaxel, and cisplatin products, thereby violating Section 5 of the FTC Act. In addition, the complaint charges that BMS agreed with Schein to settle patent litigation by paying Schein not to compete until the patent expired, and agreed with ABI to wrongfully list ABI's '331 patent, and challenges those agreements as acts of monopolization and as unreasonable restraints of trade in violation of Section 5.

Exclusionary conduct by a monopolist that is reasonably capable of significantly contributing to the maintenance of the firm's dominance gives rise to substantial competitive concerns.¹⁰ The conduct alleged in the complaint creates such concerns.

By listing patents in the Orange Book that did not meet the statutory requirements for such listings, BMS, according to the complaint, acquired the ability to trigger the Hatch-Waxman 30-month stay provision on FDA approval of competing generic products. An NDA with monopoly power has an incentive to make improper listings to protect its monopolies. In addition, NDA holders have the ability to make wrongful listings because the FDA does not police listings to ensure they meet regulatory requirements prior to publishing them in the Orange Book.¹¹ The Orange Book listing scheme established by Congress assumes and requires that NDA holders act in good faith in listing patents.

¹⁰ *Barry Wright Corp. v. ITT Grinnell Corp.*, 724 F.2d 227, 230 (1st Cir. 1983) (Breyer, J.) (citing 3 P. Areeda & D. Turner, *Antitrust Law*, ¶ 626 at 83 (1978)); see also *Aspen Skiing Co. v. Aspen Highlands Skiing Co.*, 472 U.S. 585, 596 n.20 (1985); *Lorain Journal Co. v. United States*, 342 U.S. 143, 154 n.7 (1951).

¹¹ As a recent court decision expressly recognized, "[t]he duty to ensure that the Orange Book only lists patents that actually claim approved drugs . . . lies with NDA holders." *Purepac Pharm. v. Thompson*, 2002 WL 31840631, at *5 (D.D.C. Dec 16, 2002).

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Listings that are not based on a reasonable, good faith belief that the patent is listable thus cannot be justified on grounds that the NDA holder was merely complying with Hatch-Waxman listing regulations.¹² The complaint alleges for each of the challenged listings that BMS lacked a reasonable belief that the patents were listable, and that it listed the patents to block generic competition, not in good faith compliance with FDA regulations.

Indeed, the complaint charges that BMS misled the FDA about the scope, validity, and enforceability of its patents. In listing the ‘365 patent on BuSpar, the complaint alleges, BMS intentionally made false and misleading statements to the FDA to obtain a wrongful Orange Book listing. Similarly, the charges concerning two of the Taxol patents (the ‘537 and ‘803 patents) involve allegations that BMS submitted the patents for listing knowing that it had engaged in inequitable conduct before the PTO, deliberately making misleading statements and concealing material prior art, as part of a scheme to abuse Hatch-Waxman processes and thereby extend its monopoly in paclitaxel. Under well-established patent law, inequitable conduct in obtaining a patent makes the patent unenforceable.¹³ But the Orange Book listing scheme is susceptible to opportunistic behavior. The NDA holder can exploit the listing scheme by obtaining patents and listing them in the Orange Book to block FDA approvals of

¹² See, e.g., *Southern Pac. Communications Co. v. AT&T*, 740 F.2d 980, 1009 (D.C. Cir. 1984) (AT&T’s conduct in meeting regulations governing its obligations for interconnecting other long distance carriers with its local service network can only be justified if it “is reasonable and if AT&T actually made its decision at the time in good faith on that basis rather than solely on the basis of competitive considerations.”).

¹³ *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806 (1945).

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generic rivals for 30 months, even when the NDA holder does not reasonably expect the patents to ultimately hold up in court.

Finally, with respect to two other patents (ABI's '331 patent on Taxol and the '925 patent on Platinol), the complaint alleges that BMS submitted the listings while fully aware of facts and law that made the patents invalid. Although the Hatch-Waxman Paragraph IV certification process contemplates that some patents that are listed may ultimately be found invalid or unenforceable, it does not contemplate NDA holders listing a patent without a reasonable belief that the patent meets the listing requirements in order to use the 30-month stay provision as a weapon against generic rivals. Moreover, the pattern of conduct that BMS is charged with having engaged in reinforces the charge that BMS acted with an intent to abuse the listing process to extend its monopolies in all three drugs.

BMS's alleged initiation of baseless lawsuits to trigger the 30-month stay provision and inflict competitive harm through the process, rather than through the outcome, of the suit likewise amounts to exclusionary conduct to maintain BMS's monopoly in buspirone products.

Two of BMS's challenged acts were taken in concert with other firms, and the complaint challenges these acts both as monopoly maintenance and as agreements that unreasonably restrain trade in violation of Section 5. First, BMS's settlement with Schein, in which BMS is alleged to have agreed to pay its potential competitor in the buspirone market to withhold competition until patent expiration, eliminated the only potential generic threat to BuSpar for the entire patent period. Such action not only would have deprived consumers of the potential, albeit uncertain, competition from Schein, but also would have given BMS time to implement what the complaint charges was a further strategy to obstruct competition to BuSpar, obtaining and wrongfully listing the '365 patent. The complaint alleges that the settlement agreement has no legitimate justification, harms consumers, and is unlawful.

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BMS's agreement with ABI to list ABI's '331 patent likewise involves charges of an unjustified agreement to obstruct generic competition and share monopoly profits. As set forth in the complaint, for both parties, the value of the patent license that ABI agreed to sell to BMS lay in its ability to trigger a 30-month stay under Hatch-Waxman: Delayed generic entry would protect BMS's revenues, and the terms of the option to license meant that ABI would receive more in royalty payments from BMS if BMS continued to hold a monopoly in paclitaxel products.

Because most of the acts challenged in this matter involve use of governmental processes, the complaint also affirmatively pleads that BMS's conduct is not immune from antitrust liability under the *Noerr-Pennington* doctrine, which protects private parties' petitioning for governmental action. First, BMS's Orange Book submissions of five patents (one on BuSpar, three on Taxol, and one on Platinol) cannot qualify for *Noerr* immunity because they do not constitute petitioning behavior. As the court in *In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002), observed in rejecting BMS's claim of *Noerr* protection, Orange Book filings involve no petitioning because the FDA merely accepts the NDA holder's representations and exercises no intervening judgment. In addition, Orange Book filings are not entitled to *Noerr* protection as conduct incidental to petitioning by means of a patent infringement suit. The fact that infringement litigation triggers a statutory delay in FDA approval does not render the Orange Book listing incidental to the litigation. An NDA holder can bring an infringement suit regardless of whether its patents are listed in the Orange Book. *Id.* at 372.¹⁴ Furthermore, BMS's filings and other statements to the

¹⁴ See also Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss (Jan. 8, 2002) in *In re Buspirone Antitrust Litig.*, 185 F.Supp. 2d 363 (S.D.N.Y. 2002), available at <http://www.ftc.gov/os/2002/01/busparbrief.pdf>.

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FDA are alleged to involve knowing and material misrepresentations, and would therefore fall outside the protection of the *Noerr* doctrine for that reason as well.

The challenged settlement agreement between BMS and Schein likewise is neither petitioning nor the kind of action incidental to petitioning that the *Noerr* doctrine immunizes.¹⁵

Second, with respect to challenged BMS actions that do involve petitioning of government (for example, the patent infringement suits involving BuSpar), the complaint alleges that BMS's actions fall outside the protections of the *Noerr* doctrine. Regarding the lawsuits, the complaint alleges that they were objectively baseless and brought to injure a competitor through the process, rather than the outcome, of the litigation. As a result, they satisfy the two-part test for the sham litigation exception to *Noerr* set forth in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993).

Finally, the logic and policy underlying the Supreme Court's decision in *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), which held a pattern of filings undertaken without regard to their merits to be outside the protections of *Noerr*, supports the application of a pattern exception for BMS's alleged pattern of conduct across its buspirone, paclitaxel, and cisplatin products, and thus provides a separate reason to reject *Noerr* immunity here. As is reflected in the complaint, the overall course of conduct challenged here constitutes a clear and systematic pattern of anticompetitive misuse of governmental processes, that is, abusive filings undertaken without regard to the merits, in order to use administrative and judicial processes – rather than the outcome of those processes – as a weapon to obstruct competition. Just as the

¹⁵ See *Andrx Pharms. v. Biovail Corp. Int'l*, 256 F.3d 799, 817-19 (D.C. Cir. 2001).

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repeated filing of lawsuits brought without regard to the merits, and for the purpose of using the judicial process (as opposed to the outcome of the process), warrants rejection of *Noerr* immunity, so too do the alleged repeated filing of patents on the Orange Book without regard to their validity, enforceability, or listability; repeated filing of recklessly or deliberately false statements with government agencies; and filing of lawsuits brought with or without regard to the merits, also cause the actions challenged here to fall outside the scope of *Noerr*'s protection.

By issuing the complaint in this matter along with the proposed consent agreement, the Commission finds reason to believe that BMS engaged in the alleged violations of law set forth in the complaint.

The Proposed Order

The proposed order is designed to maintain BMS's incentives to engage in legitimate conduct that could promote innovation, while ensuring protection of consumers through:

prohibitions regarding the listing and enforcement of patents relating to specific BMS products at issue here;

general prohibitions concerning the listing and enforcement of patents; and

prohibitions concerning settlement of patent litigation and other agreements between an NDA holder and an ANDA filer.

Product-Specific Provisions

Paragraphs II through V directly address complaint charges concerning BMS's unlawful conduct regarding patents relating to BuSpar and Taxol. The proposed order does not provide similar specific relief for Platinol, because the only unexpired Platinol patent was conclusively held invalid.

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The complaint alleges that the ‘365 patent relating to BuSpar does not cover any uses of buspirone, and a district court has so held.¹⁶ Accordingly, to prevent future abusive listing of the ‘365 patent,¹⁷ Paragraph II bars BMS from seeking to list the ‘365 patent in the Orange Book in relation to any NDA in which the active ingredient is buspirone. This provision will prevent BMS from seeking to list the ‘365 patent in connection with another buspirone product, for example a new dosage strength or formulation of BuSpar, as well as with its current BuSpar NDA.

The limitation on attempts to enforce the ‘365 patent is similar, but allows for the possibility that BMS might in the future have a legitimate claim of infringement. Thus, Paragraph V bars BMS from seeking to enforce the ‘365 patent against a product, or use of a product, that contains buspirone, except that such enforcement is permitted if the drug product in question also contains the metabolite that is the subject of the ‘365 patent (the 6-Hydrodroxy-metabolite of Buspirone) and the infringement claim is based on that metabolite.¹⁸ Should such a case arise, BMS would not obtain an automatic 30-month stay on FDA

¹⁶ *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 359 (S.D.N.Y. 2002).

¹⁷ In March 2001, a district court ordered BMS to seek de-listing of the patent. *Mylan Pharms., Inc. v. Thompson*, 139 F. Supp. 2d 1 (D.D.C. 2001). The Federal Circuit later reversed this ruling. *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323, 1329-33 (Fed. Cir. 2001) (holding no private right of action under the Food, Drug, and Cosmetic Act to seek de-listing). By that time, generic buspirone had entered the market, and BMS did not seek to re-list the ‘365 patent.

¹⁸ The proposed order defines “Patent Infringement Claim” to include threats of enforcement and other allegations that an ANDA product infringes the NDA holder’s patent.

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approval (because of the bar on listing in Paragraph II), but, like any patent holder, it could seek a preliminary injunction from the court hearing the infringement case.

With respect to Taxol, the proposed order generally bars BMS from seeking to enforce, or collecting royalties on, any “Taxol Patent” if the infringement claim involves the use of “Taxol.” The proposed order defines “Taxol” to be any BMS paclitaxel drug product sold as of October 2002. As a result, this provision would not apply to any new form of Taxol that BMS might develop, and thus it would maintain BMS’s incentives to pursue such innovation. With respect to BMS’s existing Taxol product, however, the proposed order’s bar on enforcement and royalties would apply not only to BMS’s ‘537 and ‘803 patents (patents that the complaint alleges are unenforceable because of inequitable conduct by BMS before the PTO), but also to any other U.S. patent claiming Taxol as a composition of matter or a method of using Taxol (by virtue of the definition of “Taxol Patent” in Paragraph I.EE). Any such patent for the existing Taxol product would almost certainly be invalid, as a result of the sale of Taxol since 1992 and the extensive prior art in the public domain.

Paragraph IV of the proposed order bars BMS from taking any action to obtain or maintain a statutory 30-month stay on FDA approval with respect to an ANDA that references BuSpar or Taxol. There have already been multiple 30-month stays in connection with both of these drugs, and this provision makes it clear that further stays would be improper. At the same time, the proposed order would preserve incentives to innovate by allowing 30-month stays on new NDAs, even if those NDAs are related to BuSpar and Taxol.

General Prohibitions Concerning the Listing and Enforcement of Patents

Because improper Orange Book listings have a significant potential to obstruct competition and harm consumers, the

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proposed order contains general prohibitions designed to deter improper listings and to prevent BMS from triggering the Hatch-Waxman automatic 30-month stay in circumstances that could improperly block generic entry. Thus, the proposed order's Paragraph VI would bar BMS from Orange Book listings that are contrary to the statutes and regulations governing such listings. For example, this provision would prohibit listing patents in the Orange Book that do not actually claim the drug product at issue. This provision is similar to one contained in the consent order issued in *Biovail Corp.*, FTC Dkt. No. C-4060 (Oct. 2, 2002).

In addition, Paragraph VII bars BMS from acting to obtain or maintain a Hatch-Waxman 30-month stay on FDA approval in certain specified situations. Because this provision does not bar Orange Book listings, ANDA filers would continue to get notice through the Orange Book of patents relating to the reference drug. Although the provision prohibits BMS from suing to trigger the automatic 30-month stay, BMS could still bring an infringement suit and avail itself of the procedures available to patent holders generally, including seeking a preliminary injunction against market entry by the generic applicant.

Paragraph VII.A prohibits BMS from triggering a 30-month stay when the patent is listed after the filing of any ANDA referencing the NDA. The Commission's *Generic Drug Study* found that the listing of patents after a generic applicant has filed its ANDA led to substantial delay of FDA approval. The report identified two reasons for this delay. First, "later-issued patents" often enabled the NDA holder to obtain multiple 30-month stays, resulting in an automatic stay period that significantly exceeds 30 months. BuSpar and Taxol involve allegations relating to improper efforts to obtain such additional stays. Second, later-issued patents also typically presented significant questions whether they met the criteria for listing, and, when courts had ruled, the later-issued patents had been found to be invalid or not

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infringed.¹⁹ BuSpar, Taxol, and Platinol all are alleged to have involved improper listings. By eliminating the availability of a 30-month stay on later-issued patents, this provision reduces the rewards for obtaining and listing patents improperly. Moreover, by denying BMS the benefit of the 30-month stay on later-issued patents, the proposed order should reduce BMS's incentives to engage in improper behavior before the PTO and the FDA to obtain and list a patent for the purpose of obtaining an unwarranted automatic 30-month stay. This remedy is consistent with the Commission's recommendation to Congress that, to reduce the possibility of abuse of the 30-month stay provision, an ANDA filer only be subject to a 30-month stay for patents listed in the Orange Book prior to the filing of its ANDA.

Paragraph VII also bars a 30-month stay, regardless of when the patent was listed, if BMS engages in certain types of misconduct in connection with obtaining or listing the patent: inequitable conduct before the PTO in obtaining the patent (VII.B); making a false or misleading statement to the FDA in connection with listing the patent (VII.C); or providing information about the patent to the FDA that is inconsistent with information it provided to the PTO (VII.D). These provisions reflect particular types of unlawful conduct charged in the complaint.

Finally, Paragraph VII would also prevent BMS from obtaining a 30-month stay when it has listed a patent that does not claim an approved use of the drug (VII.E) or when the patent is for a metabolite of an active ingredient listed in the NDA (VII.F). These provisions directly respond to the complaint allegations that BMS obstructed generic competition to BuSpar by listing the '365 patent, which did not comply with the standards for listing in the Orange Book. These provisions would not bar BMS from bringing a patent infringement action triggering a 30-month stay if the action is based on a patent claim that is distinct from those

¹⁹ *Generic Drug Study* at iii-iv, 40, 48-54.

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identified in these two subparagraphs, and the listing of that distinct additional claim does not conflict with regulations governing Orange Book listings.

To ensure that BMS does not seek to obstruct generic competition through false statements to the FDA outside the Orange Book listing context, such as through the citizen petition process, the proposed order also contains a general prohibition on false statements to the FDA. Paragraph VIII bans false and misleading statements to the FDA that are material to the approvability or sale of a generic version of a BMS brand-name drug product, unless BMS had a reasonable belief that the statement was neither false nor misleading.

To address complaint allegations that BMS engaged in sham litigation, the proposed order's Paragraph IX bars BMS from: asserting any patent infringement claim that is objectively baseless; or seeking to enforce a patent that BMS knows is invalid, unenforceable, or not infringed.

Paragraphs X and XI deal with the acquisition of patents, patent licenses, and conduct in connection with such acquisitions or licenses. These two provisions address complaint allegations that, as one part of its unlawful scheme to delay generic competition to Taxol, BMS entered into an unlawful agreement with ABI that BMS acquire a license to and list an invalid ABI patent in the Orange Book to maintain BMS's monopoly in Taxol.

As in *Biovail Corp.*, FTC Dkt. No. C-4060 (Oct. 2, 2002), the proposed order would require BMS to provide notice to the Commission before it acquires a patent, or an exclusive license to a patent (whether exclusive by its terms or otherwise),²⁰ if BMS

²⁰ The definition of "Exclusive License" in Paragraph I.O includes a license that "reduces the incentives of the licensor to license the intellectual property to other persons." This definition reflects that a license may be nominally non-exclusive, but its

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intends to list that patent in the Orange Book. Patents obtained through internal development activities or research joint ventures existing at the time of NDA approval, however, do not present the competitive concerns that the arrangement between BMS and ABI does and are excluded from the proposed order's prior notice requirement.

If BMS acquires a non-exclusive license to a patent, Paragraph XI bars it from participating in enforcement of, licensing of, or setting royalties for, that patent with respect to an ANDA filer. This prohibition applies only to acquisitions that occur after an ANDA referencing the NDA to which the patent relates has been filed. It is intended to ensure that BMS does not attempt to obstruct generic competition by influencing the conduct of the patent holder.

Provisions Concerning Settlement of Patent Litigation and Other Agreements

Paragraphs XII through XV address the challenged settlement agreement between BMS and Schein Pharmaceutical, Inc., concerning generic BuSpar. Schein was acquired by Watson Pharmaceuticals in August 2000, and the Commission has determined that under the circumstances here it is not necessary to seek an order against Watson to ensure effective relief.

This aspect of the proposed order would essentially prohibit two categories of conduct:

agreements in which the brand-name drug company (the NDA holder) makes payments to a potential generic competitor (an

terms may be such (for example, when royalties paid to the patent holder would be higher if no generic entry occurs) that the patent holder would have no incentive to license the patent to anyone other than the manufacturer of the brand-name drug to which the patent relates.

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ANDA filer) and the ANDA filer agrees not to market its product for some period of time (except in certain limited circumstances); and

agreements between the NDA holder and an ANDA filer in which the generic competitor agrees not to enter the market with a non-infringing generic product, or agrees not to relinquish exclusivity rights.

Paragraph XII of the proposed order covers agreements to resolve patent infringement disputes. It bars agreements wherein (1) the NDA holder makes payments or otherwise transfers something of value to the ANDA filer and (2) the ANDA filer agrees not to market its product for some period of time, subject to two exceptions described below. The ban in Paragraph XII includes not only final settlements of ongoing patent infringement litigation, but also agreements resolving claims of patent infringement that have not resulted in a lawsuit (see definition in Paragraph I.X.). In addition, by virtue of the definition of “Agreement” in Paragraph I.G., the proposed order makes it clear that the prohibition on payments for delayed generic entry would cover such arrangements even if they are achieved through separate agreements (for example, when one agreement resolves the patent infringement dispute and another provides for the payment for delayed entry).

The proposed order prohibits not merely cash payments to induce delayed entry, but, more broadly, agreements in which the NDA holder provides something of value to the potential generic entrant, and the ANDA filer agrees in some fashion not to sell its product. Although the pharmaceutical agreements that the Commission has challenged to date have involved cash payments, a company could easily evade a prohibition on such agreements by substituting other things of value for cash payments. Thus, to protect against a recurrent violation, the proposed order is not limited to cash payments.

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The proposed order would create two exceptions to Paragraph XII's ban on giving value for delayed entry. First, the ban would not apply if the value BMS provided to the ANDA filer was only: (1) the right to market the ANDA product prior to expiration of the patent that it is alleged to infringe; and/or (2) an amount representing BMS's expected future litigation costs, up to a maximum of two million dollars. This exception reflects that a payment limited to the NDA-holder's expected future litigation costs is not likely to result in a later generic entry date than would be expected to occur absent the payment. As a fencing-in provision, the proposed order sets a two-million dollar limit on expected litigation cost payments. In addition, the exception requires that BMS notify the Commission at least 30 days in advance of consummating such an agreement, to allow an assessment of potential harm to competition that could arise as a result of the exclusivity provisions of the Hatch-Waxman Act. Paragraph XVI sets forth a notification process similar to that used for mergers under the Hart-Scott-Rodino Act, which is designed to permit the Commission to obtain additional information when an agreement's potential effect on the triggering of the 180-day exclusivity period may raise competitive concerns.

A second exception addresses the possibility that there might be some agreements that fall within the terms of the prohibition in Paragraph XII that the Commission would not wish to prohibit. Thus, the proposed order includes a mechanism that would permit the Commission to consider and permit such arrangements.

Paragraph XIII prohibits agreements between an NDA holder and an ANDA filer in which the ANDA filer agrees not to develop or market a generic drug product that is not the subject of a claim of patent infringement. The complaint alleges that BMS's settlement agreement with Schein not only barred sale of the ANDA product, but also prohibited marketing of any other generic version of BuSpar, regardless of whether it infringed a BMS patent.

Analysis

The proposed order would also ban agreements in which a first ANDA filer agrees not to relinquish its right to the 180-day exclusivity period provided under Hatch-Waxman (Paragraph XIV). Under a proviso, however, such agreements are permitted in the context of a licensing arrangement if: (1) the first ANDA filer comes to market immediately with a generic version of the reference drug product; (2) the ANDA filer either triggers or relinquishes the 180-day exclusivity period; and (3) BMS complies with the notice requirements of Paragraph XVI. Although a ban on relinquishing exclusivity rights was not part of the challenged settlement agreement between BMS and Schein, such agreements have been used to thwart generic entry and the prohibition of such agreements will help to prevent future unlawful conduct.²¹

Paragraph XV bars agreements that involve payment to an ANDA filer and in which the ANDA filer agrees not to enter the market for a period of time, but the patent infringement litigation continues. As with Paragraph XII's treatment of final settlements, it extends beyond cash payments to cover the NDA holder's providing "anything of value" to the ANDA filer. The proposed order also provides for an exception to the provision on interim settlements if BMS presents the agreement to a court in connection with a joint stipulation for a preliminary injunction, and the following conditions are met:

BMS must provide certain information to the Commission at least 30 days before submitting the joint stipulation to the court, and must also provide certain information to the court along with the joint stipulation;

BMS may not oppose Commission participation in the court's consideration of the request for preliminary injunction; and

²¹ See *Abbott Labs.*, FTC Dkt. No. C-3945 (May 22, 2000); *Geneva Pharms*, FTC Dkt. No. C-3946 (May 22, 2000); *Hoechst Marion Roussel, et al.*, FTC Dkt. No. D.9293 (May 8, 2001).

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Either: (1) the court issues a preliminary injunction and the parties' agreement conforms to the court's order; or (2) the Commission determines that the agreement does not raise issues under Section 5 of the FTC Act.

Notice and Compliance Provisions

The form and timing of the notice that BMS must provide to the Commission under Paragraphs X, XII, XIV, and XV of the proposed order is set forth in Paragraph XVI. In addition to supplying a copy of the proposed agreement at least 30 days in advance of its consummation, BMS is required to provide certain other information to assist the Commission in assessing the potential competitive impact of the agreement. Accordingly, the proposed order requires BMS to identify, among other things, all others known by BMS to have filed an ANDA for a product containing the same chemical entities as the product at issue, as well as the court that is hearing any relevant legal proceedings involving BMS. In addition, BMS must provide the Commission with certain documents that evaluate the proposed agreement.

The proposed order also provides a Hart-Scott-Rodino-type "second request" process in connection with the notice required by Paragraph XII.

The proposed order also contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order and are standard provisions in Commission orders.

The proposed order would expire in 10 years.

Opportunity for Public Comment

The proposed order has been placed on the public record for 30 days in order to receive comments from interested persons. Comments received during this period will become part of the

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public record. After 30 days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make the proposed order final.

The purpose of this analysis is to facilitate public comment on the agreement. The analysis is not intended to constitute an official interpretation of the agreement, the complaint, or the proposed consent order, or to modify their terms in any way.

Complaint

IN THE MATTER OF

**INDIANA HOUSEHOLD MOVERS AND
WAREHOUSEMEN, INC.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS OF
SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4077; File No. 0210115
Complaint, April 25, 2003--Decision, April 25, 2003*

This consent order, among other things, prohibits Respondent Indiana Household Movers and Warehousemen, Inc. – an association organized for and serving its members, which are approximately 70 household goods movers that conduct business within the State of Indiana – from filing tariffs that contain collective intrastate rates. The order also prohibits the respondent from engaging in activities such as exchanges of information that would facilitate member movers in agreeing on the rates contained in their intrastate tariffs. In addition, the order prohibits the respondent from maintaining a tariff committee or agreeing with movers to institute any automatic intrastate rate increases. The order also requires the respondent to cancel all tariffs it has filed that contain intrastate collective rates; to cancel any provisions in its governing documents that permit it to engage in activities prohibited by the order; and to send its members a letter explaining the terms of the order.

Participants

For the Commission: *Dana Abrahamsen, Peggy D. Bayer, Harry Schwirck, Ted Cruz, John Delacourt, Patrick J. Roach, Richard B. Dagen, Joseph Eckhaus, Roberta S. Baruch, John Howell and Mary T. Coleman.*

For the Respondent: *Daniel R. Barney, Scopelitis, Garvin, Light & Hanson, P.C.*

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act (15 U.S.C. § 41, et seq.) and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Indiana Household Movers and Warehousemen, Inc. (hereinafter sometimes referred to as “respondent” or “IHM&W”),