FEDERAL TRADE COMMISSION

[File Nos. 001 0221, 011 0046, and 021 0181]

Bristol-Myers Squibb Company; Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint that accompanies the consent agreement and the terms of the consent order—embodied in the consent agreement—that would settle these allegations.

DATES: Comments must be received on or before April 7, 2003.

ADDRESSES: Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. Comments filed in electronic form should be directed to: *consentagreement@ftc.gov,* as prescribed below.

FOR FURTHER INFORMATION CONTACT: Susan Creighton or Jeffrey Brennan, FTC, Bureau of Competition, 600 Pennsylvania Avenue, NW., Washington, DC 20580, (202) 326–2946 or 326–3688.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 of the Commission's Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 7, 2003), on the World Wide Web, at *http://www.ftc.gov/os/2003/03/index.htm.* A paper copy can be obtained from the FTC Public Reference Room, Room 130–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580, either in person or by calling (202) 326–2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. Comments filed in paper form should be directed to: FTC/Office of the Secretary, Room 159–H, 600 Pennsylvania Avenue, NW., Washington, DC 20580. If a comment contains nonpublic information, it must be filed in paper form, and the first page of the document must be clearly labeled ''confidential.'' Comments that do not contain any nonpublic information may instead be filed in electronic form (in ASCII format, WordPerfect, or Microsoft Word) as part of or as an attachment to email messages directed to the following email box: *consentagreement@ftc.gov.* Such comments will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice, 16 CFR 4.9(b)(6)(ii)).

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 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

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

''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, 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 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, 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.

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

[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).

[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.*

[7] Generic Drug Study at 39–40, 48–50.

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 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 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 antic-cancer 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 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.

[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).

[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).

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.

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.

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 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

[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*

Continued

listing scheme established by Congress assumes and requires that NDA holders act in good faith in listing patents. 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 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.

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 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

Pharm. v. *Thompson,* 2002 WL 31840631, at *5 (D.D.C. Dec 16, 2002).

[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).

[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.*

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

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 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.

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 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 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

[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.

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 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 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 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 though 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 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

[19] Generic Drug Study at iii–iv, 40, 48–54.

[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 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.

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.

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.

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
- 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 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.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–6078 Filed 3–12–03; 8:45 am]

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[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).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03F–0088]

Ion Beam Applications; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ion Beam Applications has filed a petition proposing that the food additive regulations be amended by increasing