

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.<sup>10</sup> 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.<sup>11</sup> The Orange Book

<sup>10</sup> *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).

<sup>11</sup> 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*