

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

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 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 anticancer 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).