

"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."<sup>2</sup> 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.<sup>3</sup> Thus, as one court has stated, "the FDA's listing should not create any presumption that [a] patent was correctly listed."<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup>

### 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

<sup>3</sup> 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").

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

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

<sup>6</sup> 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>.

<sup>7</sup> *Generic Drug Study* at 39-40, 48-50.

<sup>2</sup> 21 U.S.C. 355(b)(1); 355(c)(2); 355(j)(7)(A)(iii) (2003).