

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.<sup>19</sup> 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),<sup>20</sup> 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 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 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

<sup>20</sup> 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.

<sup>19</sup> Generic Drug Study at iii-iv, 40, 48-54.