

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

¹⁶ *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.

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.*