

listing scheme established by Congress assumes and requires that NDA holders act in good faith in listing patents. Listings that are not based on a reasonable, good faith belief that the patent is listable thus cannot be justified on grounds that the NDA holder was merely complying with Hatch-Waxman listing regulations.<sup>12</sup> The complaint alleges for each of the challenged listings that BMS lacked a reasonable belief that the patents were listable, and that it listed the patents to block generic competition, not in good faith compliance with FDA regulations.

Indeed, the complaint charges that BMS misled the FDA about the scope, validity, and enforceability of its patents. In listing the '365 patent on BuSpar, the complaint alleges, BMS intentionally made false and misleading statements to the FDA to obtain a wrongful Orange Book listing. Similarly, the charges concerning two of the Taxol patents (the '537 and '803 patents) involve allegations that BMS submitted the patents for listing knowing that it had engaged in inequitable conduct before the PTO, deliberately making misleading statements and concealing material prior art, as part of a scheme to abuse Hatch-Waxman processes and thereby extend its monopoly in paclitaxel. Under well-established patent law, inequitable conduct in obtaining a patent makes the patent unenforceable.<sup>13</sup> But the Orange Book listing scheme is susceptible to opportunistic behavior. The NDA holder can exploit the listing scheme by obtaining patents and listing them in the Orange Book to block FDA approvals of generic rivals for 30 months, even when the NDA holder does not reasonably expect the patents to ultimately hold up in court.

Finally, with respect to two other patents (ABI's '331 patent on Taxol and the '925 patent on Platinol), the complaint alleges that BMS submitted the listings while fully aware of facts and law that made the patents invalid. Although the Hatch-Waxman Paragraph IV certification process contemplates that some patents that are listed may ultimately be found invalid or unenforceable, it does not contemplate

NDA holders listing a patent without a reasonable belief that the patent meets the listing requirements in order to use the 30-month stay provision as a weapon against generic rivals. Moreover, the pattern of conduct that BMS is charged with having engaged in reinforces the charge that BMS acted with an intent to abuse the listing process to extend its monopolies in all three drugs.

BMS's alleged initiation of baseless lawsuits to trigger the 30-month stay provision and inflict competitive harm through the process, rather than through the outcome, of the suit likewise amounts to exclusionary conduct to maintain BMS's monopoly in buspirone products.

Two of BMS's challenged acts were taken in concert with other firms, and the complaint challenges these acts both as monopoly maintenance and as agreements that unreasonably restrain trade in violation of Section 5. First, BMS's settlement with Schein, in which BMS is alleged to have agreed to pay its potential competitor in the buspirone market to withhold competition until patent expiration, eliminated the only potential generic threat to BuSpar for the entire patent period. Such action not only would have deprived consumers of the potential, albeit uncertain, competition from Schein, but also would have given BMS time to implement what the complaint charges was a further strategy to obstruct competition to BuSpar, obtaining and wrongfully listing the '365 patent. The complaint alleges that the settlement agreement has no legitimate justification, harms consumers, and is unlawful.

BMS's agreement with ABI to list ABI's '331 patent likewise involves charges of an unjustified agreement to obstruct generic competition and share monopoly profits. As set forth in the complaint, for both parties, the value of the patent license that ABI agreed to sell to BMS lay in its ability to trigger a 30-month stay under Hatch-Waxman: Delayed generic entry would protect BMS's revenues, and the terms of the option to license meant that ABI would receive more in royalty payments from BMS if BMS continued to hold a monopoly in paclitaxel products.

Because most of the acts challenged in this matter involve use of governmental processes, the complaint also affirmatively pleads that BMS's conduct is not immune from antitrust liability under the Noerr-Pennington doctrine, which protects private parties' petitioning for governmental action. First, BMS's Orange Book submissions of five patents (one on BuSpar, three on

Taxol, and one on Platinol) cannot qualify for Noerr immunity because they do not constitute petitioning behavior. As the court in *In re Buspirone Antitrust Litigation*, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002), observed in rejecting BMS's claim of Noerr protection, Orange Book filings involve no petitioning because the FDA merely accepts the NDA holder's representations and exercises no intervening judgment. In addition, Orange Book filings are not entitled to Noerr protection as conduct incidental to petitioning by means of a patent infringement suit. The fact that infringement litigation triggers a statutory delay in FDA approval does not render the Orange Book listing incidental to the litigation. An NDA holder can bring an infringement suit regardless of whether its patents are listed in the Orange Book. Id. at 372.<sup>14</sup> Furthermore, BMS's filings and other statements to the FDA are alleged to involve knowing and material misrepresentations, and would therefore fall outside the protection of the Noerr doctrine for that reason as well.

The challenged settlement agreement between BMS and Schein likewise is neither petitioning nor the kind of action incidental to petitioning that the Noerr doctrine immunizes.<sup>15</sup>

Second, with respect to challenged BMS actions that do involve petitioning of government (for example, the patent infringement suits involving BuSpar), the complaint alleges that BMS's actions fall outside the protections of the Noerr doctrine. Regarding the lawsuits, the complaint alleges that they were objectively baseless and brought to injure a competitor through the process, rather than the outcome, of the litigation. As a result, they satisfy the two-part test for the sham litigation exception to Noerr set forth in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc.*, 508 U.S. 49 (1993).

Finally, the logic and policy underlying the Supreme Court's decision in *California Motor Transport Co. v. Trucking Unlimited*, 404 U.S. 508 (1972), which held a pattern of filings undertaken without regard to their merits to be outside the protections of Noerr, supports the application of a pattern exception for BMS's alleged pattern of conduct across its buspirone, paclitaxel, and cisplatin products, and

*Pharm. v. Thompson*, 2002 WL 31840631, at \*5 (D.D.C. Dec 16, 2002).

<sup>12</sup> See, e.g., *Southern Pac. Communications Co. v. AT&T*, 740 F.2d 980, 1009 (D.C. Cir. 1984) (AT&T's conduct in meeting regulations governing its obligations for interconnecting other long distance carriers with its local service network can only be justified if it "is reasonable and if AT&T actually made its decision at the time in good faith on that basis rather than solely on the basis of competitive considerations.").

<sup>13</sup> *Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co.*, 324 U.S. 806 (1945).

<sup>14</sup> See also Memorandum of Law of *Amicus Curiae* Federal Trade Commission in Opposition to Defendant's Motion to Dismiss (Jan. 8, 2002) in *In re Buspirone Antitrust Litig.*, 185 F.Supp. 2d 363 (S.D.N.Y. 2002), available at <http://www.ftc.gov/os/2002/01/busparbrief.pdf>.

<sup>15</sup> See *Andrx Pharms. v. Biovail Corp. Int'l*, 256 F.3d 799, 817-19 (D.C. Cir. 2001).