UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

In re: Buspirone Patent Litigation	)	MDL Docket No. 1410 (JGK)
In re: Buspirone Antitrust Litigation	)	

MEMORANDUM OF LAW OF *AMICUS CURIAE* THE FEDERAL TRADE COMMISSION IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

WILLIAM E. KOVACIC [WK-0681]
General Counsel

SUSAN A. CREIGHTON [SC-9427]
Deputy Director, Bureau of Competition

JEFFREY W. BRENNAN [JB-5037]
Assistant Director, Bureau of Competition

R. TED CRUZ [RC-1558]
Director, Office of Policy Planning

DONALD S. CLARK [DC-8829]
JOHN T. DELACOURT [JD-1432]
SIMON A. STEEL [SS-6573]
Attorneys

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
phone: (202) 326-3683
fax: (202) 326-3548

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SUMMARY

In its motion to dismiss, defendant Bristol-Myers Squibb Co. ("BMS") asserts immunity from the antitrust laws, under *Eastern R. Pres. Conf. v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961) ("*Noerr*"), and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965), for its actions in filing with the Food and Drug Administration ("FDA") information on U.S. Patent No. 5,150,365 ("the '365 patent") for listing in the FDA's Orange Book. In making this the basis for a motion to dismiss for failure to state a cause of action under Fed. R. Civ. P. 12(b)(6), BMS asserts that even if the allegations of the complaint are true, it enjoys antitrust immunity. In essence, BMS claims that a pharmaceutical company is at liberty, as a matter of antitrust law, to monopolize a market by means of falsely asserting to the FDA that a new patent claims its approved branded drug, despite knowing that the patent does not, in fact, claim the drug and hence does not meet the statutory criteria for listing in the Orange Book.

Under its regulations and longstanding practice, the FDA does not scrutinize patent listings in the Orange Book for accuracy, and instead takes a wholly ministerial role in maintaining the Orange Book. Moreover, at least one court has held that a potential generic rival whose entry into the market is blocked by an erroneous listing has no private right of action to compel removal of that listing. Therefore, the necessary implication of BMS's position is that neither the FDA nor courts enforcing the antitrust laws can provide any remedy if a pharmaceutical company fraudulently abuses the regulatory procedures of the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), in order to wrongfully extend a drug product's monopoly beyond its lawful limits, to the substantial detriment of consumers.

A ruling in BMS's favor would potentially give a branded drug manufacturer an almost

unlimited ability to stifle generic competition, a result that could cost American consumers billions of dollars annually and would be plainly at odds with Congress's intent, in enacting the Hatch-Waxman Act, to "make available more low cost generic drugs." H.R. Rep. No. 98-857 (Part I), 98th Cong., 2d Sess. 14 (1984). As an agency charged by Congress with enforcing federal antitrust laws, and with substantial experience in competition issues specific to the pharmaceutical industry, the Federal Trade Commission ("FTC") considers such a potential outcome to be a matter of grave concern.

BMS's assertion of antitrust immunity is, however, legally meritless. The *Noerr* doctrine immunizes genuine *petitioning* activity directed at persuading government bodies to adopt a particular course of action. Orange Book filings, even when made properly, are decidedly not "petitions." Rather, they are mechanical, informational filings that do not trigger any exercise of legal or discretionary judgment by the FDA and do not call for any agency decision-making. FDA's role in receiving and publishing Orange Book information is simply ministerial. As such, Orange Book filings are akin to tariff filings, which have consistently been held not to constitute immunized *Noerr* petitioning.

Orange Book filings likewise cannot reasonably be analogized to the limited category of conduct – principally pre-litigation threat letters – that some courts have held may be immunized from Sherman Act liability as "incidental" to a clear form of petitioning. Unlike threat letters, Orange Book filings are remote and distinct from litigation; they are *pro forma* communications with the FDA, not adversary communications with a prospective litigant. Nor are they necessary for, or normally attendant upon, patent infringement litigation. A patent holder can bring the same infringement suit, for the same claims, at the same time, regardless of whether its patents

are listed in the Orange Book.

Finally, even if, contrary to the above, Orange Book filings could be characterized as "petitioning," plaintiffs appear to have alleged abuse of the petitioning process sufficient to invoke the "misrepresentation" and "sham" exceptions to *Noerr* immunity.

STATEMENT OF INTEREST

It is the statutory mission of the FTC to protect consumers. The Commission enforces, *inter alia*, Section 5 of the Federal Trade Commission Act, which prohibits "unfair methods of competition." 15 U.S.C. § 45. Health-related products and services currently account for approximately 15 percent of gross domestic product,[1] including $131.9 billion in expenditures for retail outpatient prescription drugs in the year 2000.[2] The Hatch-Waxman Act is designed to increase the flow of new pharmaceuticals into the marketplace by carefully balancing two public policy objectives: encouraging vigorous competition from generic drugs, and maintaining incentives to invest in the development of innovator drugs. Consumer benefits from generic competition have been dramatic. For example, a Congressional Budget Office report estimated that, in 1994 alone, consumers saved $8-10 billion on prescription drugs sold at retail pharmacies by purchasing generic drugs instead of their branded counterparts.[3]

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[1] *See Federal Trade Commission Enforcement and Programmatic Priorities*: Hearings Before the Subcomm. on Commerce, Trade, and Consumer Protection of the House Energy and Commerce Comm., 107th Cong. (2001) (statement of Timothy J. Muris, Chairman of the Federal Trade Commission) <http://www.ftc.gov/os/2001/11/muris011107.htm>.

[2] *See* National Institute for Health Care Management Research and Educational Foundation, *Prescription Drug Expenditures in 2000: The Upward Trend Continues* at 2 (May 2001) <http://www.nihcm.org>.

[3] Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry* (July 1998) <http://www.cbo.gov>. The

The Commission has developed significant expertise regarding the pharmaceutical industry and has brought a number of antitrust enforcement actions affecting both the branded and generic pharmaceutical industries.[4] The Commission is also conducting an industry-wide study of generic drug competition, designed to provide a more complete picture of how generic competition has developed under the Hatch-Waxman Act.[5] In addition, the staff of the FTC's Bureau of Economics has recently released an in-depth report on competition issues in the pharmaceutical industry,[6] and the Commission staff has twice commented to the FDA concerning the specific issue of Hatch-Waxman Act implementation.[7]

CBO noted in particular that the Hatch-Waxman Act had "greatly increased the number of drugs that experience generic competition and, thus, contributed to an increase in the supply of generic drugs." *Id.*

[4] *See, e.g., FTC v. Mylan Laboratories, Inc. et al*., 62 F. Supp. 2d 25 (D.D.C. 1999); *In the Matter of Hoechst Marion Roussel, Inc.; Carderm Capital L.P.; and Andrx Corporation*, Docket No. 9293 (FTC May 8, 2001) (consent order); *In the Matter of Abbott Laboratories*, Docket No. C-3945 (FTC May 22, 2000) (consent order); *In the Matter of Geneva Pharmaceuticals, Inc.*, Docket No. C-3946 (FTC May 22, 2000) (consent order); *In the Matter of Roche Holding Ltd.*, 125 F.T.C. 919 (1998) (consent order); *In the Matter of Ciba-Geigy Ltd*., 123 F.T.C. 842 (1997) (consent order); *In the Matter of Hoechst AG*, 120 F.T.C. 1010 (1995) (consent order). For a discussion of FTC pharmaceutical enforcement actions, *see FTC Antitrust Actions in Health Care Services and Products* <http://www.ftc.gov/bc/healthindex.htm>.

[5] *See* 65 Fed. Reg. 61334 (Oct. 17, 2000); 66 Fed. Reg. 12512 (Feb. 27, 2001).

[6] Bureau of Economics Staff Report, Federal Trade Commission, *The Pharmaceutical Industry: A Discussion of Competitive and Antitrust Issues in an Environment of Change* (Mar. 1999) <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

[7] *FDA: Citizen Petition*, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Mar. 2, 2000) <http://www.ftc.gov/be/v000005.pdf>; *FDA: 180-Day Marketing Exclusivity for Generic Drugs*, Comment of the Staff of the Bureau of Competition and of Policy Planning of the Federal Trade Commission Before the Food and Drug Administration (Nov. 4, 1999) <http://www.ftc.gov/be/v990016.htm>.

The *Noerr-Pennington* issues that defendant's motion raises plainly have significance extending well beyond the scope of this particular lawsuit. The instant proceeding has direct relevance to the Commission. Indeed, the Commission currently has several open investigations inquiring into whether actions by pharmaceutical companies of the very type alleged here may constitute "unfair method[s] of competition" in violation of Section 5 of the Federal Trade Commission Act. Because the Court's ruling on the motion may have implications for numerous Commission investigations and potential antitrust enforcement proceedings, and because the Commission's views may be relevant to the Court's disposition of the motion, the Commission respectfully requests to be heard as *amicus* and to be allowed to participate at oral argument if and when the Court considers the motion.

ARGUMENT

I. THE FILING OF PATENT INFORMATION FOR LISTING IN THE ORANGE BOOK IS NOT "PETITIONING"

The First Amendment includes among its enumerated rights the "right of the people . . . to petition the Government for a redress of grievances." In *Noerr*, the Supreme Court determined that, in enacting the Sherman Act – and its proscriptions against contracts, combinations, or conspiracies in restraint of trade and against monopolistic acts – Congress did not intend to "invade these freedoms."[8] Accordingly, the Court held that the Sherman Act did not extend to a

[8] 365 U.S. at 138, 144 (1961). Because of the view it took of "the proper construction of the Sherman Act," the Court found it unnecessary to consider, *inter alia*, the defendant railroads' "contention that the activities complained of were constitutionally protected under the First Amendment . . . ." *Id.* at 132 n.6; *accord, e.g.*, *In re Airport Car Rental Antitrust Litig.*, 474 F. Supp. 1072, 1083 (N.D. Cal. 1979) ("In *Noerr*, the Supreme Court strongly suggested that its exemption was the result of statutory construction."). Four years later, in *Pennington*, the Court extended *Noerr*'s reach to concerted action before the Executive Branch and, seven years after that, to joint petitioning before courts in *California Motor Transp. Co. v. Trucking Unlimited*,

joint effort among several rival railroads to lobby Congress for legislation that would insulate the railroads from competition by trucking firms.

Not all communications addressed to the government, however, constitute "petitioning" immunized from Sherman Act liability under *Noerr*. *See* 1 Phillip Areeda & Herbert Hovenkamp, Antitrust Law ¶ 210 (1999). Black's Law Dictionary defines a "petition" as "[a] written address, *embodying an application or prayer* from the person or persons preferring it, to the power, body, or person to whom it is presented, *for the exercise of his or their authority* in the redress of some wrong, or the grant of some favor, privilege, or license." Black's Law Dictionary 1145 (6th ed. 1990) (emphasis added). As the *Noerr* Court itself noted, legitimate petitioning activity is by its nature "directed toward *obtaining governmental action.*" 365 U.S. at 140 (emphasis added). *See also* Raymond Ku, *Antitrust Immunity, the First Amendment and Settlements: Defining the Boundaries of the Right to Petition*, 33 IND. L. REV. 385, 404 (2000) ("Valid petitioning is defined as a formal or informal attempt to *persuade* an independent government decision maker consistent with the rules of the political forum in question"; if no such attempt is made, immunity does not attach regardless of whether the criteria for a "sham" are met.) (emphasis added).

In the instant case, defendant engaged in two separate acts, only one of which constituted "petitioning." It is perfectly clear under the case law that the filing of a lawsuit constitutes *Noerr* petitioning (unless it loses its immunity under the "misrepresentation" or "sham" exceptions). It is equally clear that defendant's earlier filing of the '365 patent with the FDA was *not* "petitioning" under *Noerr*. Faced with these two separate acts, and the prospect of significant

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404 U.S. 508 (1972).

antitrust liability for the allegedly fraudulent FDA listing, defendant gamely attempts to conflate both acts throughout its memoranda, repeatedly framing the issue in terms of the follow-on litigation alone. *See, e.g.*, Memorandum in Support of Bristol-Myers Squibb Company's Motion to Dismiss ("Def. Mem.") at 13 ("The issue here really comes down to whether or not BMS's patent infringement suits are sham litigation."); Reply Memorandum in Support of Bristol-Myers Squibb Company's Motion to Dismiss ("Def. Reply Mem.") at 1 ("The entire issue of *Noerr-Pennington* . . . turns on one question: whether BMS's assertion of the '365 patent is objectively baseless.").

To the critical question of whether the *Orange Book filing* was *Noerr* petitioning, defendant tellingly devotes a total of two footnotes in its 35 pages of legal argument. *See* Def. Mem. at 12 n.10; Def. Reply Mem. at 5 n.7. Neither footnote is persuasive.

"Petitioning" is, by its very essence, an effort to convince the government to *do* something. Defendant implicitly recognizes this: "From start to finish, BMS has done nothing but seek the benefit of government *actions*." Def. Mem. at 12 (emphasis added). Simply put, with respect to the Orange Book listing, there was no discretionary government decision or action for which defendant was "petitioning." Rather, defendant's filing was informational and mechanical (not argumentative) and the FDA's listing was ministerial (not adjudicatory or discretionary).

The Second Circuit case on point is *Litton Systems v. American Tel. & Tel. Co.*, 700 F.2d 785 (2d Cir. 1983), *cert. denied*, 464 U.S. 1073 (1984). In that case, the Court of Appeals addressed the antitrust significance of a tariff filed by AT&T with the Federal Communications Commission, which required the use of an AT&T interface device to connect non-AT&T

telephone equipment into the Bell System network. The Court of Appeals premised its *Noerr* analysis on "the Supreme Court's repeated admonition that antitrust exemptions are to be countenanced only where 'there is a plain repugnancy between the antitrust and regulatory provisions.'" *Id.* at 807 (quoting *Gordon v. New York Stock Exchange, Inc.*, 422 U.S. 659, 682 (1975) (quoting *United States v. Philadelphia National Bank*, 374 U.S. 321, 350 (1963))) (internal quotation marks omitted). Because the tariff filings at issue there were mechanical and the FCC's consideration of them ministerial, the Second Circuit concluded they did not amount to "petitioning" under *Noerr*:

> AT&T erroneously assumes that a mere *incident* of regulation – the tariff filing requirement – is tantamount to a request for governmental action akin to the conduct held protected in *Noerr* and *Pennington*. But in this case, as in *Continental Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 707 (1962), the *Noerr-Pennington* doctrine is "plainly inapposite" because AT&T was "engaged in private commercial activity, no element of which involved seeking to procure the passage or enforcement of laws." . . . AT&T cannot cloak its actions in *Noerr-Pennington* immunity simply because it is required, as a regulated monopoly, to disclose publicly its rates and operating procedures.

Id. at 807 (emphasis in the original).

Other circuits have consistently agreed that ministerial tariff filings are not protected by *Noerr*. *See, e.g., Ticor Title Ins. Co. v. FTC*, 998 F.2d 1129, 1138 (3d Cir. 1993) (a collective rate filing is not a petition), *cert. denied*, 510 U.S. 1190 (1994); *City of Kirkwood v. Union Elec. Co.*, 671 F.2d 1173, 1181 (8th Cir. 1982) (utility rate filings are not petitions; tariff filings "may not be used as pretext to achieve otherwise unlawful results"), *cert. denied*, 459 U.S. 1170 (1983); *New England Motor Rate Bureau*, 112 F.T.C. 200, 284 (1989) (joint applications to regulators for tariff changes are not petitions), *vacated on other grounds*, 908 F.2d 1064 (1st Cir.

1990); 1 Areeda & Hovenkamp ¶ 210 (collecting cases).[9]

Orange Book filings are like tariff filings in two critical respects. First, patent information filing is a purely mechanical process, involving only the formulaic provision of data, not advocacy or the expression of "grievances." An NDA filer need do nothing more than include in its application "the patent number and the expiration date" of any patent claiming the drug or a method of using the drug that is the subject of the NDA, together with a supporting

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[9] *Accord In re Wheat Rail Freight Rate Antitrust Litig*., 579 F. Supp. 517, 537-38 (N.D. Ill. 1984) ("Though the [ICC] may reject a tariff on its own initiative or at the request of a third party, the filing of a tariff itself cannot be considered a 'petition' to the government." Therefore, such a tariff filing is not immune under *Noerr*.), *aff'd mem*., 759 F.2d 1305 (7th Cir. 1985), *cert. denied*, 476 U.S. 1158 (1986). *See also Columbia Steel Casting Co. v. Portland Gen. Elec. Co*., 111 F.3d 1427, 1446 (9th Cir. 1996) ("Applying to an administrative agency for approval of an anticompetitive contract is not lobbying activity within the meaning of the *Noerr-Pennington* doctrine."), *cert. denied*, 523 U.S. 1112 (1998); *United States v. Southern Motor Carriers Rate Conf., Inc.*, 672 F.2d 469, 477 (5th Cir. 1982) (*Noerr* immunity extends to "joint efforts of the bureaus to secure [State] legislation or commission regulation permitting collective ratemaking procedures . . . ," but not to "collective action to determine the rates which the bureaus desire the commission to approve . . ."), *modified en banc on other grounds*, 702 F.2d 532 (1983), *rev'd on other grounds*, 471 U.S. 48 (1985).

In *MCI Communications Corp. v. AT&T*, 708 F.2d 1081, 1153 (7th Cir.), *cert. denied*, 464 U.S. 891 (1983), the Court of Appeals considered, *inter alia*, a jury finding "that AT&T filed tariffs [covering interconnections between interstate long distance carriers regulated by the FCC and local telephone operating companies regulated by state agencies] in bad faith with state utility commissions as an act in willful maintenance of its monopoly position," and AT&T's claim that the filings were immune from antitrust scrutiny because they simply constituted "petitioning of the government." While the court suggested in *dicta* that "activities such as state tariff filings are immune from antitrust liability where their purpose is to influence government action," it later noted that "[s]ince *Noerr-Pennington* is designed to protect the right to petition the government to take some action, *Noerr-Pennington* might not apply if a tariff filing is only a *pro forma* publication perhaps required by law and not an exercise of the right to *petition* the government . . . ." The court further noted that it did not in any event need to reach this issue "given [its] conclusion that these filings, even if 'petitions' to which *Noerr-Pennington* applied, were, in any event, 'sham.'" *Id.* at 1155 n.114.

declaration.[10] Similarly, when a holder of an approved NDA secures a new patent, it need only provide the FDA with the same type of patent information within 30 days after the patent is issued.[11] In either circumstance, the submitter is neither requesting governmental action nor expressing a political opinion, and this "essentially procedural aspect of regulation . . . cannot [support an antitrust exemption]." *Litton Sys.*, 700 F.2d at 807.[12]

Second, the FDA's review of pre-listing submissions, and subsequent listing of patents in the Orange Book, are purely ministerial, not involving discretionary judgment or adjudication. Explicitly, the FDA does not purport to evaluate the propriety of patent listings,[13] and will not change patent information in the Orange Book "[u]nless the NDA holder withdraws or amends its patent information."[14] As the D.C. Circuit recently explained,

[t]he FDA, pursuant to longstanding practice and its own regulations, and based on its

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[10] 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(c).

[11] 21 U.S.C. § 355(c)(2).

[12] *Cf. Noerr*, 365 U.S. at 138 (protected petitioning involves "solicitation of governmental action with respect to the passage and enforcement of laws"); Ku, *Antitrust Immunity*, 33 IND. L. REV. at 417, 422 (equating protected petitioning with "an effort to persuade an independent government decision-maker through the presentation of facts and arguments," and noting that purely private settlements are not *Noerr*-protected "because they are in fact the antithesis of efforts to solicit government action").

[13] *See* 59 Fed. Reg. 50338, 50343 (1994)*; accord Abbott Laboratories v. Novopharm Ltd.*, 104 F.3d 1305, 1307 n.1 (Fed. Cir. 1997) ("[t]he FDA must accept as true the patent information supplied by the patentee"). Indeed, the FDA has consistently maintained that it has neither the resources nor the expertise to resolve patent issues. *See* 54 Fed. Reg. 28872, 28910 (1989) (preamble to proposed regulations); 59 Fed. Reg. at 50345 (cols. 2, 3) (preamble to final regulations in which FDA rejected two comments that asserted that "FDA should ensure that patent information submitted to the agency is complete and applies to a particular NDA").

[14] 21 C.F.R. § 314.53(f); *accord American Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1080 (D.C. Cir. 2001) ("*American Bioscience II*").

> acknowledged lack of expertise and resources, 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.

American Bioscience II, 269 F.3d at 1080.[15] In other words, as the court elaborated, the FDA's Orange Book listing, rather than being an exercise of judgment or discretion, is purely "ministerial." *Id.* at 1084. The ministerial nature of the FDA's role in listing patents in the Orange Book is further evident in the rule that such listings create no presumption that the patent has been listed correctly. *See Ben Venue Laboratories, Inc. v. Novartis Pharmaceutical Corp.*, 10 F. Supp. 2d 446, 456 (D.N.J. 1998). *See also Watson Pharm., Inc. v. Henney*, No. S 00-3516, 2001 U.S. Dist LEXIS 2477 at *7 (D. Md. Jan. 18, 2001) (describing the FDA's role in Orange Book listing as "very limited [and] ministerial") (Attachment 1).

The distinction between ministerial government acts and exercises of judgment and discretion reflects in part the reality that, with the former, there is little check on the truth or falsity of parties' representations, whereas with the latter, the government decisionmaker can assess veracity and weigh those statements in accordance with the public interest. Under *Noerr*, it is both the nature of the submission (informational or attempting to persuade) and the nature of the governmental agency's review (discretionary or ministerial) that determine whether a given communication constitutes "petitioning."[16] Thus, while advocacy in a political or adjudicatory

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[15] *Cf. Woods Exploration & Producing Co. v. Aluminum Co. of America*, 438 F.2d 1286, 1295 (5th Cir. 1971) (*Noerr* provides no immunity for gas producers' filings with Railroad Commission where Commission has "no opportunity . . . [to] supervis[e] or verif[y]" filings and instead "must rely on the truthfulness" of producers), *cert. denied*, 404 U.S. 1047 (1972).

[16] *See Noerr*, 365 U.S. at 138 (protected petitioning involves "solicitation of governmental action with respect to the passage and enforcement of laws"); *see also Litton*, 700 F.2d at 807-08 (contrasting a "mere incident of regulation" with "a 'request' for government action or an 'expression' of political opinion"); *cf.* Gregory A. Mark, *The Vestigial Constitution: The History*

context is deemed petitioning; informational filings in ministerial contexts are not.[17]

Indeed, the FCC's review of the tariff filings in *Litton* was far less ministerial than the FDA's review of Orange Book filings. There, the FCC did engage in some substantive review of those filings, but, as the Second Circuit concluded,

> [t]he fact that the FCC might ultimately set aside a tariff filing does not transform AT&T's independent decisions as to how it will conduct its business into a "request" for governmental action or an "expression" of political opinion. Similarly, the FCC's failure to strike down a tariff at the time of its filing does not make the conduct lawful, particularly where, as in this case, the agency specifically declines to rule on a tariff's legality.

700 F.2d at 807-08. *A fortiori*, an FDA filing subjected to even more circumscribed and ministerial review cannot be considered "petitioning" protected under *Noerr*.[18]

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and Significance of the Right to Petition, 66 FORDHAM L. REV. 2153, 2173 (1998) (as developed in English law and known to the Framers, "[a] petition was a communication that, 1) had to be addressed to an authority such as the King, 2) had to state a grievance, and, 3) had to pray for relief").

[17] For example, misrepresentations on an individual's tax return are not protected "petitioning" under *Noerr*, but arguing to an elected Representative or to a court that one's taxes are too high (or that a given expense should be deductible) would be.

[18] In contrast, neither of these characteristics – (1) a purely mechanical, information-providing content to the filing, or (2) an absence of judgment or discretion on the part of the government agency – has been present in recent cases in which *Noerr* immunity was held to apply. Rather, *Noerr* cases typically involve efforts to persuade or negotiate with the government to promulgate statutes or regulations, enter into agreements, or engage in law enforcement actions – *i.e.*, appeals to the substantive judgment or discretion of a government agent. *See, e.g., A.D. Bedell Wholesale Co. v. Philip Morris, Inc.*, 263 F.3d 239, 252 (3d Cir. 2001) (upholding district court's holding that tobacco companies' successful negotiations with state governments to enter the Multistate Settlement Agreement and secure implementing state legislation were *Noerr* protected), *cert. denied*, __ U.S. __ (Jan. 7, 2002); *Hallco Environmental, Inc. v. Comanche County Board of County Commissioners*, 1998-1 Trade Cas. (CCH) ¶ 72,175, at 82,138 (10th Cir. June 10, 1998) (efforts by a number of individuals to persuade a county board and its commissioners to establish landfill regulations under a state solid waste management act); *Massachusetts School of Law at Andover, Inc. v. American Bar Association*, 107 F.3d 1026, 1038 (3d Cir.) (efforts by the ABA to convince states to prohibit graduates of unaccredited law

II. ORANGE BOOK FILINGS ARE NOT "INCIDENTAL" TO SUBSEQUENT PATENT INFRINGEMENT LITIGATION

In the event that the Court concludes that Orange Book filing does not constitute "petitioning," BMS urges the Court to adopt the position that filing is "incident[al]" to petitioning. *See* Def. Mem. at 12 n.10; Def. Reply Mem. at 5 n.7. This latter contention is equally unpersuasive. Patent listings in the Orange Book result from mechanical informational filings calling for ministerial action, rather than the exercise of judgment, by the FDA. Furthermore, they share little in common with other conduct held to be "incidental" to petitioning, such as the transmittal of pre-litigation threat letters.

A number of courts have found a limited category of pre-litigation conduct to be "incidental" to petitioning and so protected by *Noerr*. Those cases have generally involved a *threat* to litigate a specific claim against a specific party. *See Glass Equip. Dev., Inc. v. Besten, Inc.*, 174 F.3d 1337, 1343-44 (Fed. Cir. 1999); *McGuire Oil Co. v. Mapco, Inc.*, 958 F.2d 1552, 1558-60 (11th Cir. 1992); *CVD, Inc. v. Raytheon Co.*, 769 F.2d 842, 851 (1st Cir. 1985); *Coastal States Marketing, Inc. v. Hunt*, 694 F.2d 1358, 1366-67 (5th Cir. 1983); *Barq's Inc. v. Barq's*

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schools from taking the bar examination), *cert. denied*, 522 U.S. 907 (1997); *PTI, Inc. v. Philip Morris Inc.*, 100 F. Supp. 2d 1179, 1193 (C.D. Cal. 2000) ("activities involved with the negotiation, execution, and attempts to implement the [tobacco litigation] MSA, the Qualifying Statute, and the Model Act"); *Modesto Irrigation District v. Pacific Gas & Elec. Co.*, 61 F. Supp. 2d 1058, 1062, 1070-73 (N.D. Cal. 1999) (utility's petition to the Federal Energy Regulatory Commission for a declaration that it was not obligated to supply power to another firm); *Omega Homes, Inc. v. City of Buffalo*, 4 F. Supp. 2d 187, 193-94 (W.D.N.Y. 1998) (successful lobbying efforts to secure an exclusive contract to build a low-income housing development), *aff'd*, 171 F.3d 755 (2d Cir.), *cert. denied*, 528 U.S. 874 (1999); *Ehlinger & Assocs. v. Louisiana Architects Ass'n*, 989 F. Supp. 775, 784-85 (E.D. La.) (efforts to influence a state board that selected architects for state projects), *aff'd*, 167 F.3d 537 (5th Cir. 1998); *Association of Minority Contractors & Suppliers v. Halliday Properties, Inc.*, 1998-2 Trade Cas. (CCH) ¶ 72,250, at 82,575-78 (E.D. Pa. 1998) (efforts to convince city council to initiate a lawsuit to dissolve a local redevelopment authority).

Beverages, Inc., 677 F. Supp. 449, 452-53 (E.D. La. 1987). Such conduct is closely related to litigation: it announces an intent to litigate specific claims against specific parties; it is typically communicated between the prospective parties to the suit; it is a normal part of the litigation process; it makes the litigation process itself work better by providing notice that may lead to a settlement or an adjustment of conduct that makes the process less costly for all involved; its deterrent or remedial effects are directly dependent on the merits of the litigation; and it is often an essential part of the process of petitioning effectively, inasmuch as the remedies sought by the petitioner often include treble damages for willful infringement for which notice – typically in the form of a threat letter – is a legal requirement. A pre-litigation threat letter has been found to be immune as incidental to the petitioning process because it is often a normal aspect of the process of litigating effectively and in good faith:

> Given that petitioning immunity protects joint litigation, it would be absurd to hold that it does not protect those acts reasonably and normally attendant upon effective litigation. The litigator should not be protected only when he strikes without warning. If litigation is in good faith, a token of that sincerity is a warning that it will be commenced and a possible effort to compromise the dispute.

McGuire Oil, 958 F.2d at 1560; *see also Outboard Marine Corp. v. Pezetel*, 474 F. Supp. 168, 174 (D. Del. 1979); *Clairol, Inc. v. Boston Discount Center of Berkley, Inc.*, 1976 U.S. Dist. LEXIS 13139 at *16 (E.D. Mich.), *aff'd on other grounds*, 608 F.2d 1114 (6th Cir. 1979) (Attachment 2).

In a similar vein, the Second Circuit has described signal strength challenges under the Satellite Home Viewer's Act ("SHVA") as analogous to pre-litigation threat letters and so conceivably *Noerr*-protected. In *Primetime 24 Joint Venture v. National Broadcasting Co.*, 219 F.3d 92 (2d Cir. 2000), the court held that signal-strength challenges by TV networks to satellite

providers' assertions of mandatory copyright licensing rights could be (absent abuse) *Noerr*-protected, finding that such challenges served the same role as pre-litigation threat letters. *Id.* at 100. Like pre-litigation threat letters, SHVA challenges provided specific notice to a specific party that specific conduct by that party is alleged to violate the challenger's rights. They were, in short, "a litigation skirmish in miniature," *id.*, and for that reason protected together with the litigation which they preceded.

An Orange Book filing, by contrast, is plainly *not* a miniature, preliminary version of *Noerr*-protected litigation. Unlike a litigation threat letter, an Orange Book listing is made to the world in general; and it is made without regard to, and often in the complete absence of, any potentially adversary party. An Orange Book filing is a communication with the government purporting to describe a property right – akin to registration of a trademark or title to land – not a communication with an adversary asserting an infringement. Indeed, the obligation to list a patent in the Orange Book arises without regard to whether there is, or ever will be, another company that seeks to manufacture the drug claimed in the NDA. For patents that have issued by the time the NDA is filed, the obligation to list arises with the filing of the NDA; for subsequently issued patents, the patent must be listed within 30 days of its issuance. 21 U.S.C. §§ 355(b)(1), (c)(2)**.** The listing thus often will arise years before any potential competitor has emerged; and, indeed, sometimes there will *never* be another company seeking to make the claimed drug. Moreover, the statutory obligation to list encompasses patents owned by persons other than the NDA holder – *i.e.*, circumstances in which even if subsequent patent infringement suit may occur, the person filing the Orange Book listing will not be a party to such litigation. Given the significant attenuation between Orange Book filings and potential future litigation,

fraudulent conduct undertaken in compliance with regulatory obligations under the FDA cannot properly be characterized as "incidental" to hypothetical future litigation that may or may not arise against unknown parties who may or may not appear.

Moreover, an Orange Book filing is not merely separated in time and made without regard to the identity of any particular adversary. It also relates to a *different subject matter* from subsequent patent litigation. An Orange Book filing makes a representation about the relationship between a particular patent and the branded drug that is the subject of the NDA – that is, between the patent and the *NDA holder's product*. A patent infringement claim, by contrast, concerns the relationship between a particular patent and the *ANDA filer's product*. The listing of a patent in the Orange Book accordingly does not mean that an ANDA filer infringes the patent; an Orange Book listing might be proper even though a patent litigation claim would not be, and vice versa. In short, an Orange Book filing bears little resemblance to the "litigation skirmishes in miniature" that have been protected as "incidental" to litigation. Unlike threat letters and SHVA challenges, which are between the same parties, involve the same claims, and arise immediately before the protected litigation, Orange Book filings are unrelated in time, different in subject matter, and made to the world in general. To find such conduct "incidental" to litigation would be a dramatic, and unwarranted, extension of existing precedent.

BMS nonetheless asserts that Orange Book filings should be deemed "incidental" to litigation because, BMS claims, listing in the Orange Book is required in order to take advantage of 35 U.S.C. § 271(e)(2), which permits commencement of an infringement action at the time an

ANDA is filed.[19] Otherwise, BMS contends, it would have had to wait until the ANDA filer actually made, used, or sold the allegedly infringing drug under 35 U.S.C. §271(a). *See* Def. Mem. at 12 n.10 (Orange Book listing "was a necessary predicate to the filing of [its] patent suits against Mylan and Watson under 35 U.S.C. § 271(e)(2)").

There are, however, several difficulties with BMS's argument. To begin with, the hypothesized distinction between the timing of an action under §§ 271(a) and 271(e)(2) appears to be entirely irrelevant on the facts of this case. Given the conduct alleged here – namely, that Mylan and Danbury had manufactured sizeable quantities of the allegedly infringing product, presumably subsequent to multiple offers to sell, and even had their trucks loaded and ready to go – it would appear that BMS could have brought the same suit, alleging the same claims, at the same time, under either § 271(a) or § 271(e)(2). The Orange Book listing accordingly was not "necessary" in any respect to BMS's filing of the current litigation.

Second, BMS's suggestion that otherwise unrelated conduct is protected under *Noerr* because it affects – at most – only the *timing* of litigation, proves far too much. To our knowledge, only one court has adopted BMS's interpretation of § 271(e)(2). Notably, however, that case itself emphasized that the unavailability of § 271(e)(2) did not alter the litigant's ability to secure the same effective relief under § 271(a). *See Abbott Laboratories v. Zenith Laboratories, Inc.*, 1995 WL 117984 at *12 (N.D. Ill. Mar. 16, 1995) ("[D]ismissal of Plaintiff's § 271(e)(2)(A) claim does not leave Plaintiff without a remedy as Plaintiff can bring a patent

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[19] 35 U.S.C. § 271(e)(2) provides in relevant part: "It shall be an act of infringement to submit (A) an application under section 505(j) [the ANDA provisions] of the Federal Food, Drug and Cosmetic Act or described in section 505(b)(2) [provisions allowing "paper NDAs"] of such Act for a drug claimed in a patent or the use of which is claimed in a patent."

infringement claim pursuant to 35 U.S.C. § 271(a) if and when Defendant proceeds to manufacture and sell its new generic form of Hytrin.") (Attachment 3).[20] Indeed, it would be highly anomalous for BMS to claim that the difference between the two provisions is an important one, if, as BMS claims, listing in the Orange Book is required to bring a § 271(e)(2) claim. As discussed earlier, *it is unilaterally within the control of the NDA holder which patents are listed in the Orange Book*, and many patents can affect a given drug yet not be owned by the NDA holder. If other patent holders are dependent on the NDA holder to decide whether they can bring a claim under § 271(e)(2), it would be striking indeed for BMS to claim that Congress intended to leave this right within the unilateral control of another firm.

In fact, however, BMS's argument suffers from an even more fundamental difficulty: its interpretation of § 271(e)(2) finds no support in the plain language of the provision. The referenced provision merely indicates that submission of an ANDA "for a drug claimed in a patent or the use of which is claimed in a patent" constitutes grounds for an infringement action. It makes no reference, either express or implied, to the Orange Book listing process. Rather, under the terms of § 271(e)(2), the filing of an ANDA makes a patent infringement suit ripe if the generic drug for which the ANDA is filed infringes a patent, *irrespective* of whether the patent concerned is listed in the Orange Book or whether a Paragraph IV certification has been, or should have been, filed.

The only court to interpret § 271(e)(2) as BMS suggests – the Northern District of Illinois in *Abbott Laboratories* – was, we would respectfully submit, in error. There the court appears to

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[20] *Cf. Glaxo Group Ltd. v. Apotex, Inc.*, 130 F. Supp. 2d 1006, 1009 n.4 (N.D. Ill. 2001) (agreeing in *dicta* with *Abbott Laboratories*' holding, but declining to reach the issue because plaintiff sought the same effective relief under § 271(a)).

have been motivated principally by a policy concern,[21] that NDA holders not withhold patents from the Orange Book in hopes of surprising ANDA filers with subsequent litigation. However, that concern does not justify grafting a new requirement onto the otherwise straightforward statutory text of § 271(e)(2): "It shall be an act of infringement to submit an [ANDA] for a drug claimed in a patent or the use of which is claimed in a patent." Had Congress intended to do so, it would not have been difficult to have written: "It shall be an act of infringement to submit an ANDA for a drug claimed in a patent *that has been filed with the FDA under § 355(b)(1).*" Moreover, actual practice in the intervening years suggests that the underlying policy concern is unlikely to have substantial real world consequences: given the substantial economic advantages to NDA holders of having patents listed in the Orange Book – namely, the automatic 30-month stay provision halting FDA approval of competing ANDAs – there are very few incentives for NDA holders to deliberately withhold validly listable patents (which, indeed, they are required to list under § 355(b)).

Not only is BMS's contention contrary to the plain language of § 271(e)(2), but, as suggested earlier, it makes little sense within the framework of the statute. For example, suppose

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[21] In addition, the court looked to *dicta* in the Supreme Court's decision *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), that § 271(e)(2) created "a highly artificial act of infringement that consists of submitting an ANDA or paper NDA *containing the fourth type of certification*" (emphasis added). But the Court in *Eli Lilly* was not addressing the question of whether § 271(e)(2) required an Orange Book listing, which had not been briefed, argued, or even considered. Rather, the Court was addressing the reach of § 271(e)(1)'s broad immunity from infringement liability for research conducted in the process of submitting an ANDA. Its passing mention of § 271(e)(2) described the usual circumstance in which a suit proceeds (where there is a Paragraph IV certification) but did not state or even imply that this is the *only* circumstance where a suit may lie. And it would be doubtful, to say the least, that Justice Scalia's opinion for the Court in *Eli Lilly*, which relied heavily on the plain language of § 271(e)(1), was meant to foreclose the same reliance on the plain language of § 271(e)(2) on an issue the Court was not there considering.

that party A filed an NDA, party B held a related patent, and party C filed an ANDA potentially infringing on B's patent. If A refused to list B's patent (a not unlikely occurrence, *see American Bioscience II*, 269 F.3d at 1080-81), it would be a very odd conclusion that A's malfeasance foreclosed B from enforcing his patent against C's infringement. The much more natural inference would be that § 271(e)(2) in fact means what it says – that submitting an ANDA for "a drug claimed in a patent" constitutes infringement, so B can sue for C's submission.

In any event, the fact remains: if BMS had not made its allegedly false Orange Book filing, it could nonetheless have brought all the lawsuits it brought, for exactly the same claims, at exactly the same time it brought them. It could have done so under § 271(a), or under the plain terms of § 271(e)(2), *irrespective of any Orange Book listing*.

To be sure, Orange Book listing has substantial relevance *within the FDA process*, and that process is brought to a halt if subsequent infringement litigation ensues. But the fact that infringement litigation triggers a statutory delay in FDA approval does not render listing incidental *to the litigation*. The "30-month stay" is not a "stay" in the ordinary sense: it is not ordered by a court, enforced by contempt authority, or issued after a preliminary hearing assessing, *inter alia*, likelihood of success on the merits.[22] Rather, it is an automatic delay in the *regulatory process of the FDA* to approve a generic drug as safe and effective for public consumption. That process is wholly unrelated to any patent litigation, does not affect the patent litigation, and so cannot be deemed "incidental" to that litigation.[23]

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[22] In fact, precisely such a remedy remains available in infringement litigation irrespective of whether a patent is listed in the Orange Book.

[23] By way of analogy, suppose employee John Doe had an employment contract with employer Acme that specified he could be fired only for cause. Suppose Acme fraudulently altered that

III. EVEN IF ORANGE BOOK FILINGS WERE "PETITIONING" UNDER *NOERR*, THE "MISREPRESENTATION" AND "SHAM" EXCEPTIONS MAY DEPRIVE BMS OF *NOERR* IMMUNITY

Even if the Court were to determine that Orange Book filings are petitioning activity, BMS's conduct would not necessarily be immune from liability under *Noerr-Pennington*. The Commission will leave it to the parties to this case to address the particular fact pattern at issue here, but there are a number of legal principles relevant to *Noerr*, and Orange Book filings generally, that could be helpful to resolution of these complex issues.

First, as the plaintiffs noted in their memorandum, many courts have held that *Noerr* immunity does not extend to knowing and material misrepresentations made in adjudicatory or administrative proceedings. *See, e.g.*, *Kottle v. Northwest Kidney Centers*, 146 F.3d 1056, 1062-63 (9th Cir. 1998) (in adjudicatory or administrative proceedings "guided by enforceable standards subject to review," *Noerr* does not apply if misrepresentations deprived "the entire . . . proceeding of its legitimacy")*; Whelan v. Abell*, 48 F.3d 1247, 1255 (D.C. Cir. 1995) ("the knowing assertion of false claims [to courts and securities regulators] is not protected by *Noerr-Pennington*"). *See also Cheminor Drugs Ltd. v. Ethyl Corp.*, 168 F.3d 119, 124 (3d Cir. 1999) ("a material misrepresentation that affects the very core of a litigant's . . . case will preclude . . . immunity"); *St. Joseph's Hosp. v. Hospital Corp. of America*, 795 F.2d 948, 955 (11th Cir. 1986) ("When a governmental agency . . . is passing on specific certificate applications it is acting judicially. Misrepresentations under these circumstances do not enjoy *Noerr* immunity.").

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contract to insert a provision that being sued necessarily constituted "cause," and then sued Doe and fired him. In that situation, the negative consequence – Doe's being subject to termination – is triggered by the lawsuit, but none would suggest that the employment contract imposing those consequences was somehow "incidental" to the litigation or that Acme's fraud concerning that contract should be immune from liability.

Indeed, the Supreme Court itself has explained that "[m]isrepresentations, condoned in the political arena, *are not immunized when used in the adjudicatory process*." *California Motor Transp.*, 404 U.S. at 513 (emphasis added).[24] Thus, the significant misrepresentations plaintiffs have alleged that BMS made to the FDA, if proven, could defeat *Noerr* immunity.[25]

Moreover, the submission of knowing and willful misrepresentations to the FDA in the Orange Book listing process is quite closely analogous to the submission of intentional misrepresentations to the Patent Office during patent prosecution, which the Supreme Court explicitly held sufficient to support a finding of Sherman Act liability in *Walker Process Equip. Co. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965). The Supreme Court's decision in *Walker Process* gave rise to the "misrepresentation" exception, *see, e.g., Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240, 1260 (9th Cir. 1982), and the reasons that led the Court to recognize an exception to *Noerr* in *Walker Process* would support the same outcome in Orange Book listing cases such as this one.

In both cases, the administrative process is *ex parte*, and potential competitors typically

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[24] Although Orange Book listing is properly characterized as non-petitioning and ministerial, were it to be deemed petitioning it would certainly be closer to "adjudicatory" than to "political." *Cf. Kottle*, 146 F.3d at 1061 (explaining that the critical difference between "adjudicatory" and "political" is whether there are "objective standards" to govern the decision).

[25] In brief, plaintiffs' key allegations appear to be the following: (1) before the PTO, BMS attempted to claim the systematic administration of buspirone as a prodrug and as a metabolite; (2) the PTO did not allow the prodrug claim; (3) BMS therefore elected to abandon that claim and to proceed explicitly on the metabolite alone; and (4) upon receiving the '395 patent on the metabolite (and describing it in a company press release as limited to the metabolite), BMS willfully represented to the FDA that it covered the prodrug as well and secured an improper Orange Book listing to enable a 30-month stay on generic entry. In essence, the allegation is that BMS stated "not X" to the PTO and then "X" to the FDA; both cannot be true. If the application covered the prodrug, BMS's representations to the PTO were false; if it did not, its filings with the FDA were fraudulent.

have no opportunity to challenge the claimant's submission before the patent issuance or listing takes place. The Patent Office has only a limited ability to probe a claimant's factual assertions; the FDA expressly accepts representations regarding the Orange Book at face value. In both proceedings, much of the most critical evidence, including relevant prior art and background of patent claims, lies in the hands of private parties and is not necessarily easily available. And in both instances, the antitrust consequences of the false representation can be severe: in the case of the issuance of a patent, exclusion of a competitor from the invention claimed in the patent; in the case of an Orange Book listing, automatic exclusion from the market for up to 30 months.

In addition, a knowing, material misrepresentation in an Orange Book listing context would also appear to satisfy the "sham" exception to *Noerr*.[26] The "sham" exception "encompasses situations in which persons use the governmental process – as opposed to the outcome of that process – as an anticompetitive weapon." *City of Columbia v. Omni Outdoor Advertising, Inc.*, 499 U.S. 365, 380 (1991). A "sham" petitioner attempts to use the governmental process itself to impose collateral harm on a competitor, such as "impos[ing] expense and delay," *id.*, without regard to the merits.

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[26] The Ninth, D.C., and Federal Circuits have all explicitly recognized a "misrepresentation" exception distinct from the "sham" exception identified by the Supreme Court in *Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.* ("*PRE*"), 508 U.S. 49 (1993). *Kottle*, 146 F.3d at 1060; *Whelan*, 48 F.3d at 1255; *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1071 (Fed. Cir. 1998) ("*PRE* and *Walker Process* provide alternative legal grounds on which a patentee may be stripped of its immunity from the antitrust laws," and *Walker Process* liability may be imposed "without the additional sham inquiry required under *PRE*."). The Third Circuit, on the other hand, has held that the "misrepresentation" exception is subject to the Supreme Court's "sham" standard in *PRE*. *Cheminor*, 168 F.3d at 123. To *amicus's* knowledge, the Second Circuit has not ruled on the issue: in *PrimeTime*, the Second Circuit agreed with the Ninth Circuit that a different exception to *Noerr* (the "pattern" exception) falls outside the scope of *PRE*, but *PrimeTime* did not address whether the "misrepresentation" exception also is separate from *PRE*'s "sham" test. *See PrimeTime*, 219 F.3d at 101.

In the Orange Book listing context, that is precisely what a competitor may be alleged to have done. By making a false filing in the Orange Book, a branded pharmaceutical company can impose lengthy delay on its competitor's ability to enter the market, wholly without regard to the merits of its litigation claim. Moreover, it is not the case, as BMS contends, that the "issue here really comes down to whether or not BMS's patent infringement suits are sham litigation." Def. Mem. at 13. The listing inquiry is whether the new patent claims the *branded* drug (that is, it falls within the scope of the NDA). An infringement suit, by contrast, inquires whether the patent is infringed by the *generic* drug. A branded company may have a colorable claim that a generic drug infringes a patent, even though it has no basis (and, in fact, knows it to be false) that the patent covers the branded drug. Through its Orange Book filing, the branded drug company obtains an anticompetitive effect unrelated to the judicially determined outcome of litigation; it does so on the basis of an allegedly false assertion to the FDA that the patent is properly listable; and, therefore, that filing may fall within the scope of the "sham" exception to the *Noerr-Pennington* doctrine.

IV. THERE IS NO GENERAL "PATENT ENFORCEMENT IMMUNITY" FROM THE ANTITRUST LAWS

Finally, BMS asserts that "the patent law affords immunity to patent holders' assertions of their rights," and appears to imply that such immunity is independent of, and extends in unspecified ways beyond, *Noerr-Pennington* immunity. Def. Mem. at 11. BMS argues that such immunity is the corollary of the patent holder's right to exclude.[27] *Id.* Although BMS's

[27] BMS neither explains why a patent holder's right to exclude should be treated differently from the right to exclude of all other property owners, nor addresses the well-established precedent holding that abuse of patent rights provides grounds for antitrust liability in the same manner as abuse of other property rights. For example, the Supreme Court has expressly stated that "the

description of this "immunity" sounds broad at first blush, defendant's concession that "[t]here can be no liability unless evidence of bad faith, *e.g.*, fraud, is presented," *id.* – precisely what plaintiffs here have alleged – makes clear that there is little substance to this argument. Rather, the point seems to be that legitimate good-faith litigation to enforce valid patents should not give rise to liability, a true observation irrelevant to the case at hand.

CONCLUSION

The filing of patent information for listing in the Orange Book is not a petition seeking discretionary government action or any legislative, regulatory, or adjudicatory judgment. It is, instead, a mechanical act that leads to ministerial processing by the FDA, akin to tariff filings that have long been considered subject to full antitrust scrutiny. Improper Orange Book filings, such as those alleged in the present case, have harmful effects on generic competition prior to, independent of, and without any regard to the merits of any subsequent patent litigation, and are not analogous to pre-litigation threat letters "incidental" to litigation.

Moreover, even if such filings were deemed petitioning under *Noerr*, plaintiffs appear to have adequately alleged abuse of the petitioning process sufficient to invoke the "misrepresentation" and "sham" exceptions to *Noerr* immunity.

Accordingly, the Court should deny BMS's motion to dismiss the plaintiffs' claims under the antitrust laws.

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patent monopoly may not be used in disregard of the antitrust laws." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964). *See also Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969) ("there are established limits which the patentee must not exceed in employing the leverage of his patent to control or limit the operations of the licensee"); *United States v. Singer Manufacturing Co.*, 374 U.S. 174 (1963) (patent settlement violated Sherman Act); *United States v. New Wrinkle, Inc.*, 342 U.S. 371 (1952); *United States v. Line Materials Co.*, 333 U.S. 287 (1948); *United States v. Masonite Corp.*, 316 U.S. 265 (1942).

Respectfully submitted,

WILLIAM E. KOVACIC [WK-0681]
General Counsel

SUSAN A. CREIGHTON [SC-9427]
Deputy Director, Bureau of Competition

JEFFREY W. BRENNAN [JB-5037]
Assistant Director, Bureau of Competition

_____
R. TED CRUZ [RC-1558]
Director, Office of Policy Planning

DONALD S. CLARK [DC-8829]
JOHN T. DELACOURT [JD-1432]
SIMON A. STEEL [SS-6573]
Attorneys

Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580
phone: (202) 326-3683
fax: (202) 326-3548

January 8, 2002

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that true and correct copies of the foregoing Memorandum of Law of *Amicus Curiae* Federal Trade Commission In Opposition to Defendant's Motion to Dismiss was served this 8th day of January, 2002, via facsimile and first-class mail, on:

Evan R. Chesler, Esq.
Cravath, Swaine & Moore
Worldwide Plaza
825 Eighth Avenue
New York, NY 10019
Fax: 212-474-3700
Counsel for Bristol-Myers Squibb Co.

Steven Lieberman, Esq.
Rothwell, Figg, Ernst & Manbeck
Suite 701 East Tower
555 13th Street, N.W.
Washington, D.C. 20004
Fax: 202-783-6031
Counsel for Mylan Pharmaceuticals, Inc.

Barry S. White, Esq.
Frommer, Lawrence & Haug, L.L.P.
745 Fifth Avenue
New York, NY 10151
Fax: 212-588-0500
Counsel for Watson Pharmaceuticals, Inc.

Jonathan L. Greenblatt, Esq.
Shearman & Sterling
801 Pennsylvania Avenue, N.W.
Suite 900
Washington, D.C. 20004
Fax: 202-508-8100
Counsel for Watson Pharmaceuticals, Inc.

Bruce Gerstein, Esq.
Garwin, Bronzaft, Gerstein & Fisher
1501 Broadway, Suite 1416
New York, NY 10036
Fax: 212-764-6620
Liasion Counsel for Direct Purchasers

Mitchell W. Berger, Esq.
Berger Singerman
350 East Las Olas Boulevard
Suite 1000
Fort Lauderdale, FL 33301
Fax: 954-523-2872
Counsel for Par Pharmaceuticals, Inc.

Michael M. Buchman, Esq.
Milberg, Weiss, Bershad, Hynes & Lerach, LLP
One Pennsylvania Plaza
New York, NY 10119
Fax: 212-868-1229
Counsel for End Payors

Richard L. Schwartz, Esq.
Office of the Attorney General
Antitrust Bureau
120 Broadway
New York, NY 10271
Fax: 212-416-6015
Liasion Counsel for the States

_____
John T. Delacourt