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

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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 2136dNkS. Patenrkers of Am. v. Perl* .317

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

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

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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>.

counterparts.[3]

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]

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[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 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)

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]

<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>.

[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

Accordingly, the Court held that the Sherman Act did not extend to a 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*

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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*, 404 U.S. 508 (1972).

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 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.*,

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

[9] *Accord In re Wheat Rail Freight Rate Antitrust Litig*

that is the subject of the NDA, together with a supporting 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

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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*").

[15] *Cf. Woods Exploration & Producing Co. v. Aluminum Co. of America*, 438 F.2d 1286, 1295

[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 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.*, Jan. 7, 200(2;r033 093069.5 0 TD /F3 12 Tf -19436 T

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 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);

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 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:

Noerr-protected. In *Primetime 24 Joint Venture v. National Broadcasting Co.*,

[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)).

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 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 litr-b /F33rs wi7

[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.

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 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 sensedinary sensedinary senser (e)(2),

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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

[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;

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.

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.

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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.

[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 patent monopoly may not be used in disregard of the antitrust laws." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964).

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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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:

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