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THE FTC'S ENFORCEMENT INITIATIVE AGAINST IMPROPER "ORANGE BOOK" LISTINGS IN THE PHARMACEUTICAL INDUSTRY

By Joel Grosberg and Stephen Sullivan¹

The Federal Trade Commission ("FTC") is aggressively investigating and acting against drug manufacturer's improper "Orange Book" listings as part of the FTC's efforts to strengthen competition in the pharmaceutical industry and to limit the scope of *Noerr* immunity to the antitrust laws. Within the last year, the FTC has entered into two consent decrees with pharmaceutical manufacturers regarding an improper "Orange Book" listing and has filed two *amicus* briefs concerning the scope of *Noerr* immunity as applied to "Orange Book" listings and whether a de-listing remedy is appropriate for improper Orange Book listings. The FTC has also announced that it has several pending public and non-public investigations concerning the potential anticompetitive effects of improper patent listings in the Orange Book.

Similarly, the FTC's published study on generic drug entry in the pharmaceutical industry has identified improper "Orange Book" listings as a significant barrier to generic drug entry. Policing the use of "Orange Book" listings carry out two FTC priorities. First, the strengthening of competition in the pharmaceutical industry by decreasing the barriers to generic drug entry is a clear FTC priority.² Second, actions involving "Orange Book" listings invariably raise the issue of

the proper scope of *Noerr* immunity. Recently, Timothy T. Muris, Chairman of the FTC, has indicated that FTC will continue to look for cases to bring involving improper Orange Book listings as part of its efforts to limit the scope of *Noerr* immunity and to support generic drug entry.

I. The FDA Generic Drug Approval Process

The 1984 Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, establishes the two-tier structure for the approval of new and generic drugs.³ A New Drug Application (“NDA”) must be filed to obtain FDA approval to market a new drug. The NDA includes information on the various patents covering the subject drug. The FDA lists the patent information in its publication, the “Approved Drug Products with Therapeutic Equivalence,” commonly known as the “Orange Book.”⁴

Under Hatch-Waxman, the marketing of a generic drug only requires the filing of an Abbreviated New Drug Application (“ANDA”). The ANDA requires the generic manufacturer to demonstrate that that generic drug is the same and bioequivalent to the brand-name drug. The ANDA also requires the filing of a certification concerning each patent listed in the relevant NDA. There are four possible certifications. The fourth certification, referred to as a “Paragraph IV certification,” certifies that the patents covering the brand-name pharmaceutical are either invalid or are not infringed. The ANDA applicant filing a Paragraph IV certification must notify the patent holders of the NDA drug. The patent holders then have 45 days to initiate an infringement action against the generic applicant.⁵

If the NDA patent holder brings a patent infringement suit, FDA approval of the drug is automatically stayed for 30 months unless the sued-upon patent expires and/or there is a final judicial determination of non-infringement from which no appeal can be taken prior to the 30-

month period.⁶ In contrast, for patents not listed in the Orange Book, a patent holder must sue a generic company for patent infringement in the district courts based on ordinary federal litigation procedures, without the benefit of a 30-month stay. Under non-Hatch-Waxman litigation, the branded firm must obtain a preliminary injunction to prevent the sale of the generic product before the conclusion of the suit. The operation of this 30-month stay under the Hatch-Waxman Amendments is the FTC's primary concern with regard to "Orange Book" listings.⁷ The FTC believes the process is subject to abuses that extend the patent monopoly substantially beyond the terms of the original patent. The FTC's generic drug study examined these issues in detail and provided much of the empirical data supporting the FTC's enforcement policy against improper Orange Book listings.

II. FTC Study On Generic Drug Entry

In July of 2002, the FTC published its study "Generic Drug Entry Prior to Patent Expiration: A FTC Study" (July 2002) reporting the results of its investigations motivating its current enforcement initiatives. The FTC study identified several issues concerning the operation of the Hatch Waxman Amendments and the use of Orange Book listings by brand-name drug manufacturers. First, the FTC study found that brand-name pharmaceutical companies initiated patent infringement suits against the first generic applicant for 72 percent of the pharmaceuticals examined. In 70 percent of these cases, there was either a court decision or the parties agreed to a final settlement without a decision on the merits of the patent infringement suit. In the remaining 30 percent of the cases, a district court had not yet ruled as of June 1, 2002. Importantly, the generic manufacturer prevailed 73 percent of the time in all of the patent infringement cases in which there is a ruling.⁸

Second, the study reviewed the potential for abuse of the 30-month stay process. The FTC Study found that since 1998, there has been an increasing number of patents listed in the Orange Book for “blockbuster” drug products, and the listing of new patents after an ANDA has been filed. The study also determined that these two factors increased the number of 30-month stays to effectively extend the exclusive rights to market the branded formulation of the drug. A key concern addressed by the Study is whether multiple 30-month stays prevented FDA approval of the generic applicants’ ANDAs. The Study found that the additional Orange Book Filings delayed generic entry for 4 to 40 months *beyond* the initial 30-month period.⁹ The FTC found that delayed generic entry has a significant impact on prices for pharmaceutical products. For example, the FTC indicated that the Congressional Budget Office study found that in 1994, the availability of generic drugs saved consumers between \$8 to \$10 billion on prescription drugs at retail pharmacies.

The FTC concluded that the best way to prevent abuse was for the legislature to permit only one 30-month stay per drug product per ANDA.¹⁰ The FTC also discussed other reform alternatives, which the FTC concluded were unlikely to be as effective.¹¹ For example, the Study proposed (1) the establishing of an administrative procedure for generic applicants to obtain substantive FDA review of listability and (2) permitting a generic applicant to raise listability issues as a counterclaim in the context of patent infringement litigation already initiated by the brand-name company in response to a Paragraph IV notice from the generic applicant.¹² The FTC observed that the FDA does not review the propriety of patents listed in the Orange Book and generic applicants do not have private right of action to challenge those listings. As a result, there is no mechanism to delist an improperly listed patent from the Orange Book.¹³

Both the FDA and the Senate and House of Representatives have recently adopted many of the FTC's recommendations. In June 2003, the FDA approved a new rule limiting only one

automatic 30-day stay per drug product.¹⁴ In addition, the rule also tightens the Orange Book patent listing requirements by prohibiting brand-name companies from listing certain types of patents in the Orange Book and by requiring brand-name companies to perform additional studies before listing other types of patents the FTC identified as being particularly problematic.¹⁵ In addition, both the Senate and House of Representatives recently passed bills that include the FTC study's major legislative recommendations.¹⁶

III. The *Noerr* Doctrine and Wrongful Orange Book Listings

In seeking to police improper Orange Book Listings, the FTC will also have to overcome defenses based on *Noerr* immunity to the antitrust laws. The limitation of the scope of *Noerr* immunity to the antitrust laws has been a major priority of the FTC under Chairman Muris who created a *Noerr* Task Force at the FTC shortly after taking office.¹⁷ Any antitrust actions based upon wrongful Orange Book listings invariably face the defense of *Noerr* immunity; consequently, the Orange Book cases present an ideal opportunity for the FTC to continue its challenge to limit the scope of the *Noerr* doctrine.

Under the *Noerr* doctrine, certain conduct of private parties seeking government actions that have anticompetitive consequences are immune from antitrust liability.¹⁸ In short, when a party is "petitioning" the government, its actions are immune from antitrust liability in order to protect the right for individuals and groups to communicate with the government.¹⁹ In the view of the FTC, some courts have interpreted this protection too broadly.²⁰ The improper "Orange Book" listings were one of the first targets of the *Noerr* Task Force because the listings are not, in the FTC's view, petitioning activity since the FDA does not review the patents presented to it for listing in the "Orange Book." The FTC argues that the FDA takes the claims of the NDA filer at face value and is required to publish the listing.

IV. FTC "Orange Book" Enforcement Initiatives

The FTC has been involved in four actions challenging improper Orange Book listings, *In re Busiprone*, *Biovail*, *SmithKline Beecham v. Apotex Corp* ("*SmithKline*"), and *Bristol-Myers Squibb Company* (Bristol-Myers).²¹ In the first, the FTC wrote an *amicus* brief regarding the *Noerr* doctrine as a defense to antitrust liability based on Orange Book listing. In *Biovail* and *Bristol-Myers*, the FTC brought enforcement actions against brand-name companies for conduct including the making of an improper Orange Book listing. In *SmithKline*, the FTC wrote another *amicus* brief arguing that a de-listing remedy is appropriate where parties have improperly listed patents in the Orange Book.

A. *In re Busiprone* (February 2002)

The FTC filed an *amicus* brief arguing that an Orange Book listing was not "petitioning" for purposes of *Noerr* immunity. The FTC also argued that even if the listing was petitioning, antitrust immunity would not be appropriate because of the *Walker Process* and "sham" exceptions to *Noerr* immunity.²²

The plaintiffs in the *Busiprone* case alleged an attempted monopolization claim against Bristol-Myers for improperly listing a patent on its drug BuSpar in the Orange Book for the purpose of delaying generic entry. These actions were consolidated in the Southern District of New York and Bristol-Meyers moved to dismiss the attempted monopolization claims based on *Noerr* immunity because the claims were based on the listing of patent information in the Orange Book.²³

The court in *Busiprone* denied the defendant's motion to dismiss and held that the listing of patent information in the Orange Book was not "petitioning" activity under the *Noerr* doctrine.²⁴ *In re Busiprone*, represented a victory for the FTC in its twin goal of limiting the scope of the

Noerr doctrine and policing the use of improper Orange Book listings for anticompetitive purposes.²⁵

The essence of the FTC's argument, which the Court adopted, was that petitioning is "an effort to convince the government to *do* something."²⁶ Bristol-Meyers Squibb did not seek to convince the government to do something because the FDA's actions are purely ministerial in relation to the Orange Book without the involvement of any governmental discretionary activity.²⁷ The FTC relied on prior decisions finding that the filing of tariffs with the Federal Communications ("FCC") Commission was not petitioning activity because the FCC's actions in relation to a tariff were ministerial and did not involve discretionary government activity.²⁸ The Court adopted the FTC's position on petitioning and even Bristol-Meyers Squibb seemed to acquiesce to the analogy between tariffs and Orange Book listings. Instead, Bristol-Meyers Squibb in its brief unsuccessfully tried to treat the Orange Book listing as a step in the patent infringement litigation, which is clearly *Noerr* protected conduct.²⁹

The FTC also prevailed in its alternative arguments that even if listing patent information in the Orange Book was "petitioning" for *Noerr* purposes, the *Walker Process* and "sham" litigation exceptions would apply. Under *Walker Process*, a patent holder may face antitrust liability for trying to enforce a patent that was procured by fraud on the Patent and Trademark Office ("PTO").³⁰ The *Busiprone* court, as argued by the FTC, concluded that the Orange Book listing and patent prosecution processes were sufficiently analogous to warrant extension of the *Walker Process* exception to *Noerr* beyond merely fraud on the PTO.

The FTC pushed for the *Busiprone* court to adopt a general misrepresentation exception to *Noerr*, broader than the *Walker Process* exception, but the *Busiprone* court did not adopt this position. The *Busiprone* court appeared to find more support in the analogy between fraud on the patent office and the listing of patent information in the Orange Book despite the fact that it may

be difficult to see how the FDA's ministerial listing of information in the Orange Book was induced reliance when there is no such hearing process as in the patent context.

The *Busiprone* court also agreed with the FTC that the "sham litigation" exception to *Noerr* did not apply to Bristol-Myers Squibb. The "sham" exception to the *Noerr* doctrine applies when the petitioning activity is "objectively baseless." The court in *Busiprone* again agreed with the FTC that the Orange Book listing by Bristol-Myers Squibb was "objectively baseless," because "the language of the claim, its specification and the prosecution history all demonstrate beyond all reasonable dispute that the '365 Patent does not cover the use of buspirone."

Subsequent to the *Busiprone* court's decision, on January 8, 2003, the parties entered into a settlement, in which Bristol-Myers agreed to pay the plaintiffs \$670 million, without any admission of guilt. Under the settlement agreement, Bristol-Myers will pay \$535 million to resolve claims over BuSpar and \$135 million to settle Taxol-related claims. As a result of this settlement, the court did not need to address the issue of whether Bristol-Myers improper Orange Book listing constituted an antitrust violation. The *Busiprone* decision establishes that Orange Book filings are not automatically immune from antitrust scrutiny. However, an antitrust plaintiff must still prove an underlying antitrust claim.

B. *Biovail (April 2002) and Bristol-Myers Squibb Company (April 2003)*

On April 23, 2002, the Federal Trade Commission ("FTC") announced its first complaint and consent order with a pharmaceutical manufacturer, Biovail Corporation, for allegedly wrongfully listing a patent in the Orange Book in order to prevent entry of a generic drug.³¹ The FTC alleged that Biovail illegally acquired an exclusive patent license and then improperly listed the patent in the Orange Book in order to block the entry of generic competition to its brand-name drug Tiazac.

Prior to the FTC action, Biovail had made use of the 30-month stay provided for by the Hatch-Waxman Amendments to bring and lose a patent infringement lawsuit against Andrx, a company that was seeking approval of its generic version of Biovail's Tiazac drug. In an attempt to further delay the entry of Andrx's generic drug and to maintain its monopoly over the drug Tiazac, Biovail obtained a license from a third-party for another patent that it listed in the FDA Orange Book as covering Biovail's drug Tiazac. The FTC Complaint stated that Biovail knew that the new patent did not claim the form of Tiazac it had been marketing and Biovail did not need the new patent to market Tiazac as it had done in the past. In fact, the new patent covered a new version of Tiazac that was not FDA approved and it would be de-listed if it did not claim the prior and approved product. Biovail made this certification to the FDA. The FTC's Complaint claims that Biovail's patent acquisition, wrongful Orange Book listing, and misleading conduct before the FDA constituted unlawful maintenance of its Tiazac monopoly in violation of Section 5 of the FTC Act.

To remedy these alleged anti-competitive activities, the FTC proposed consent order requires Biovail to divest the acquired patent to its previous owner, to dismiss the infringement case against Andrx, and to refrain from any actions that would trigger another 30-month stay of generic Tiazac entry under the Hatch-Waxman amendments. Moreover, Biovail is required to give the FTC prior notice of any acquisitions of patents that it intends to list in the FDA's Orange Book.

The Biovail consent decree is significant because it is the first time that the FTC found that wrongful Orange Book listing can constitute a violation of the antitrust laws, specifically Section 5 of the FTC Act. Nevertheless, the consent decree did not address the validity of possible defenses that patent holders, such as Biovail, raise in litigation, and did not seek a disgorgement remedy, which Muris has advocated in other matters.

More recently, the FTC brought an enforcement action against Bristol-Myers for improper orange book listings. The FTC alleged that Bristol-Myers obstructed generic entry for three of its products: two anti-cancer drugs, Taxol and Platinol, and the anti-anxiety agent BuSpar. The FTC alleged that Bristol-Myers misled the U.S. Patent and Trademark Office to obtain unwarranted patent protection, filed baseless patent infringement lawsuits to deter entry by generics, and abused FDA regulations to block generic entry.

The FTC and Bristol-Myers entered into a consent order which contains extremely strong restrictions on Bristol-Myers future behavior.³² The consent order contains a provision that prohibits Bristol-Myers from triggering a 30-month stay based on any patent Bristol-Myers lists in the Orange Book after the filing of an application to market a generic drug, and limits Bristol-Myers' ability to provide information about a patent to the FDA that is inconsistent with information it provided to the Patent and Trademark Office.

The FTC also utilized the Bristol-Myers consent order to discuss a significant *Noerr* issue. In the Analysis to Aid Public Comment for the Bristol-Myers consent order, the FTC argues that the pattern exception to *Noerr* should not be limited to repetitive lawsuits, but also should be applicable to any predatory, repetitive use of government process.³³ The Supreme Court had previously held in *California Motor Transport v Trucking Unlimited*³⁴, that companies engaging in a pattern of baseless lawsuits could not acquire immunity under *Noerr*. The FTC states that "[j]ust as the repeated filing of lawsuits brought without regard to the merits...warrants rejection of *Noerr* immunity," so too does the repeated filings of knowing and material misrepresentations with the PTO and FDA."³⁵

C. *SmithKline Beecham v. Apotex Corporation* (January, 2003)

As part of its continuing efforts to police Orange Book abuses, the FTC filed an *amicus* brief in the U.S. District Court for the Eastern District of Pennsylvania regarding the pending

patent litigation between SmithKline Beecham and Apotex for SmithKline's antidepressant drug Paxil.³⁶ On December 20, 2002, the Court in that case issued an order holding that certain SmithKline patent claims relating to Paxil were invalid for lack of novelty. The plaintiff's filed a motion to amend the order to require SmithKline to delist the patents from the Orange Book. The FTC's purpose for filing the brief was to discuss "the potential for improperly-maintained Orange Book listings to serve as barriers to competition, and to advise the Court of the substantial pro-consumer benefits of an appropriate de-listing remedy."³⁷

The FTC has been independently investigating SmithKline's listing of certain patents regarding Paxil at the same time that this private litigation was proceeding. In fact, the FTC's Generic Drug Study identified Paxil as one of only eight drugs (out of the 104 drugs studied) for which the brand-name company listed patents in the Orange Book after a generic drug manufacturer filed its ANDA. The facts surrounding the Paxil litigation clearly demonstrate the potential abuses that can result from improper Orange Book listings and the potential for harmful impact on competition.

In this case, SmithKline obtained multiple 30-month stays for key patents listed in the Orange Book after Apotex filed its ANDA in March 1998. SmithKline filed a patent infringement suit on the only patent listed in the Orange Book at the time Apotex filed its ANDA. The 30-month stay generated by this lawsuit expired on November 2000. Nevertheless, since Apotex's initial ANDA filing, SmithKline listed additional patents for Paxil and obtained four additional overlapping 30-month stays. These stays blocked generic competition for a total of 65 months, and as a result, these stays have continued to prevent the FDA from approving generic applicants' ANDAs for Paxil.³⁸

The FTC argued in its brief that a de-listing remedy is critical in invalid Orange Book listing cases because a branded drug manufacturer, even after a judgment of invalidity in Hatch-

Waxman litigation, can continue to enjoy the 30-month stay on the FDA approval of generic versions of the drug product. The FDA does not de-list a patent unless the brand-name company requests that it de-lists the patent. In contrast, in patent litigation outside the Hatch-Waxman context, a district court's judgment that a patent claim is invalid terminates a patentee's ability to enforce the claim and enables the competitor to begin immediately selling its product. Therefore, the FTC stated in its brief that "it is within the court's authority to require the patentee to de-list the patent to enforce its judgment...and is wholly consistent with a judgment of patent invalidity, which itself has broad preclusive effect."³⁹

V. What's Next?

Chairman Muris, in a speech, entitled "Looking Forward: The FTC and the Future Developments of Competition Policy", indicated that the limitation of the *Noerr* doctrine, specifically as applied to Orange Book listings, will continue to be a major enforcement priority for the FTC. Muris reiterated that he believed that over the years, the *Noerr* immunity has been "expanded in a manner that potentially harms consumers." In particular, Muris stated that courts have granted *Noerr* immunity to conduct, that did not involve petitioning and was intended to delay a competitor's entry or to raise a competitor's costs.

Muris stated that the *Noerr* Task Force was looking to bring cases to establish three principles:

- 1) "Adopt an appropriately narrow view of conduct that constitutes immunized "petitioning" currently used in cases involving tariff filings and private settlements;
- 2) Make clear that the *Walker Process* exception to *Noerr* immunity extends beyond the Patent and Trademark Office context to analogous non-legislative proceedings; and

3) Recognize fully an independent misrepresentation exception-separate and distinct from the "sham" exception set forth in *Professional Real Estate Investors, Inc. v. Columbia Pictures Industries*. In short, material misrepresentation should not be protected."

As described above, the *Busiprone* decision clearly supported the FTC's goal of narrowing what constitutes petitioning and also clearly accomplished the second goal of applying *Walker Process* outside the PTO context. However, neither the *Busiprone* decision, nor the Biovail and Bristol-Myers consent decrees, articulate the third principle of establishing an independent misrepresentation exception to the *Noerr* doctrine. Therefore, it is likely that the FTC, under Chairman Muris, will be looking for cases to establish an independent misrepresentation exception to the *Noerr* doctrine, particularly as related to Orange Book listings. Moreover, it is important to note that the *Busiprone* decision involved a 12(b)(6) motion to dismiss and as a result of this private litigation settling, the parties did not fully litigate the *Noerr* issue and the Court did not rule that Bristol Myers' improper Orange Book listing constituted an antitrust violation. The FTC will likely want to bring an enforcement action to delineate and fully litigate that an improper Orange Book listing clearly violate the antitrust laws. Even if the court in the Paxil litigation does order a de-listing remedy, the FTC will likely still pursue a case against SmithKline to establish the principle that the listing of improper patents in the Orange Book constitutes an antitrust violation. Moreover, the FTC, under Chairman Muris, may also attempt to seek a disgorgement remedy, from the branded manufacturer for improper Orange Book listings.

Conclusion

Based on the FTC generic study, recent enforcement actions and speeches, it is expected that the FTC will aggressively continue to monitor and enforce competition in the pharmaceutical industry. In particular, improper Orange Book listings and its intersection with the *Noerr*

immunity will be a key enforcement priority for the FTC under Chairman Muris. The FTC has publicly announced that it has several pending public and non-public investigations concerning the potential anti-competitive effects of improper patent listings in the Orange Book, including the SmithKline/Paxil investigation. As a result of these ongoing investigations, the FTC is likely to bring an action against a pharmaceutical manufacturer in an attempt to establish that improper patent listings can constitute an antitrust violation and to limit the potential defenses that pharmaceutical companies have utilized in the past.

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² See, e.g., Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study (July 2002); (“FTC Generic Drug Entry Study”); Prepared Statement of the Federal Trade Commission Before the Committee on Commerce, Science, and Transportation, United States Senate, April 23, 2002 (<http://www.ftc.gov/05/2002/04/pharmtestimony.htm>); Timothy J. Muris, Chairman of the Federal Trade Commission, Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy, December 10, 2002 (<http://www.ftc.gov/speeches/muris/handler.htm>); Comments of the United States Federal Trade Commission Before the Department of Health and Human Services, Food and Drug Administration, In the Matter of Applications for FDA Approval to Market a New Drug; Patent Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying that a Patent Claiming a Drug is Invalid or Will Not be Infringed, Docket No. 02N-0417, December 23, 2002 (<http://www.ftc.gov/be/V030002.pdf>).

³ Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. § 355 (1994)).

⁴ See *Id.* at § 355.

⁵ See *Id.* at § 355(j)(5)(B)(ii)-(iii).

⁶ See *Id.* at § 355(j)(5)(B).

⁷ See *Id.* at § 355(j)(2)(B); FTC Generic Drug Entry Study (describing FTC concerns about Orange Book listings and the delay of generic entry).

⁸ FTC Generic Drug Entry Study at 13-23.

⁹ *Id.* at 39-56.

¹⁰ *Id.* at i-xi.

¹¹ *Id.* at i-xi.

¹² *Id.* at i-xi.

¹³ *Id.* at i-xi.

¹⁴ Application for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not Be Infringed, 68 Fed. Reg. 36675 (2003)

¹⁵ *Id.*

¹⁶ H.R. 1, 108th Cong. §§ 1101-1118 (2003); H.R. 1, incorporating S. 1, 108th Cong. §§ 701-706, 901-911 (2003).

¹⁷ See, Timothy J. Muris, Chairman of the Federal Trade Commission, Looking Forward: The Federal Trade Commission and the Future Development of U.S. Competition Policy, December 10, 2002 (<http://www.ftc.gov/speeches/muris/handler.htm>).

¹⁸ *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).

¹⁹ *Id.*

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- ²⁰ See, Timothy J. Muris, Prepared Statement of the FTC Before the Committee on Commerce, Science, and Transportation, United States Senate, April 23, 2002 (<http://www.ftc.gov/05/2002/04/pharmtestimony.htm>).
- ²¹ *In re Busiprone Patent Litigation/In re Busiprone Antitrust Litigation*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002); *Biovail Corporation*, File No. 011 0094, (<http://www.ftc.gov/os/2002/04/biovailtiazac.htm>) (April 23, 2002).
- ²² Memorandum of Law of *Amicus Curiae* The Federal Trade Commission in Opposition to Defendant's Motion to Dismiss *In re Busiprone Patent Litigation/In re Busiprone Antitrust Litigation* ("*FTC's Amicus Brief*").
- ²³ *Id.* at 369-70.
- ²⁴ *Id.* at 371.
- ²⁵ *In re Busiprone* 185 F. Supp. 2d 363 (S.D.N.Y. 2002).
- ²⁶ *Id.* at 7.
- ²⁷ *Id.*
- ²⁸ *Litton Systems v. American Tel & Tel. Co.*, 700 F. 2d 785, (2d Cir. 1983) *cert. denied*, 464 U.S. 1073 (1984); see also, *Ticor Title Ins. Com. v. FTC*, 998 F.2d 1124, 1138 (3d Cir. 1993), and *City of Kirkwood v. Union Elec. Co.*, 671 F.2d 1173, 1181 (8th Cir. 1982).
- ²⁹ Memorandum in Support of Bristol-Meyers Squibb Company's Motion to Dismiss *In re Busiprone Patent Litigation/In re Busiprone Antitrust Litigation*; Reply Memorandum in Support of Bristol-Meyers Squibb Company's Motion to Dismiss *In re Busiprone Patent Litigation/In re Busiprone Antitrust Litigation*.
- ³⁰ *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965).
- ³¹ *Biovail Corporation*, File No. 011 0094 (<http://www.ftc.gov/opa/2002/04/biovailtiazac.htm>).
- ³² *Bristol-Myers Squibb Company*, Dkt. No. C-4076 (Apr. 14, 2003).
- ³³ *Bristol-Myers* Analysis to Aid Public Comment.
- ³⁴ 404 U.S. 508 (1972)
- ³⁵ *Bristol-Myers* Analysis to Aid Public Comment, *supra* note 44, at 16.
- ³⁶ *SmithKline Beecham v. Apotex Corporation*, Case No. 99-CV-4304, 00-CV-4888; 01-CV-159; 01-CV-2169 (E.D. Pa. 2003).
- ³⁷ *SmithKline Beecham v. Apotex Corporation*, Case No. 99-CV-4304; 00-CV-4888; 01-CV-159; 01-CV-2169, Memorandum of Law of Federal Trade Commission as *Amicus Curiae* Concerning Torpharm's Cross Motion for Entry of an Amended Order ("*FTC's SmithKline Memorandum*") at 1.
- ³⁸ *FTC's SmithKline Memorandum* at 12-13.
- ³⁹ *FTC's SmithKline Memorandum* at 17.