

Recent Pharmaceutical Industry Cases Raising Intellectual Property-Antitrust Issues

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Antitrust Enforcement: Cutting Edge Lessons from the Pharmaceutical Industry

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**RECENT PHARMACEUTICAL INDUSTRY CASES
RAISING INTELLECTUAL PROPERTY-ANTITRUST ISSUES**

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SUMMARY OUTLINE OF RECENT PHARMACEUTICAL INDUSTRY CASES RAISING INTELLECTUAL PROPERTY-ANTITRUST ISSUES¹

I. Cases Arising From Settlement Agreements

A. *Cardizem CD (Diltiazem Hydrochloride)*

1. Cardizem CD (diltiazem hydrochloride) is a prescription drug manufactured by Hoechst-Marion Roussel, Inc. ("HMRI") that is used to treat angina and hypertension. The Cardizem litigation arises primarily out of an interim "settlement" of patent infringement litigation brought by HMRI against Andrx Pharmaceuticals, Inc., the first ANDA filer for Cardizem CD. In September 1997, the FDA tentatively approved Andrx's generic Cardizem product. Thus, Andrx would have been expected to be able to enter the market upon the expiration of the 30-month stay in July 1998. However, in settling the patent infringement litigation, HMRI and Andrx allegedly agreed that, beginning upon final FDA approval of Andrx's generic product, HMRI would pay Andrx \$10 million per quarter not to enter the market with its generic product until the conclusion of the patent litigation.

2. The FTC issued a complaint against HMRI and Andrx. (See <http://www.ftc.gov/os/2000/03/hoechstandrxcplmt.htm>). The FTC alleged that the interim settlement agreement constituted an unreasonable restraint of trade in violation of Section 5 of the FTC Act, that HMRI had the specific intent to preserve its monopoly in the alleged market for Cardizem CD, that HMRI's actions created a dangerous probability that it would accomplish its unlawful monopolistic objectives, that both parties acted with the specific intent that HMRI monopolize the relevant markets and engaged in overt acts in furtherance of a conspiracy to monopolize the alleged relevant markets, and that all of these acts and practices constituted unfair methods of competition in violation of Section 5 of the FTC Act. The FTC complaint was settled by consent order. (See <http://www.ftc.gov/os/2001/04/hoechstagr.pdf>; see also <http://www.ftc.gov/os/2001/04/andrxcagr.pdf>).

3. Multiple antitrust claims were filed against HMRI and Andrx, including claims by a generic competitor (Biovail Corporation) and by putative classes of purchasers. The Judicial Panel on Multidistrict Litigation consolidated the class action cases and transferred them to the Eastern District of Michigan. In July 2002, Andrx and Aventis Pharmaceuticals, Inc. (which acquired HMRI) announced a settlement with the direct purchasers for \$110 million (as well as with Biovail), and, in January 2003, they

¹ Contributors to this article include George G. Gordon, Thomas L. Kenyon, Julie H. Ketover and Elissa J. Taub.

announced that they would pay \$80 million to settle with the indirect purchaser class and the state attorneys general.

4. Noteworthy decisions include Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft, 48 F. Supp. 2d 37 (D.D.C. 1999), holding, *inter alia*, that individual plaintiffs' claims would be aggregated for purposes of determining whether the amount-in-controversy requirement was satisfied; Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft, 54 F. Supp. 2d 1042 (D. Kan. 1999), holding, on purchasers' motion to remand, that the court had neither diversity nor federal question jurisdiction; Aetna U.S. Healthcare, Inc. v. Hoechst Aktiengesellschaft, 67 F. Supp. 2d 1242 (D. Kan. 1999), holding, *inter alia*, that the court lacked jurisdiction to reconsider an order remanding a removed action to state court and that the motion for reconsideration would not be referred to the court in which the MDL was pending; In re Cardizem CD Antitrust Litig., 90 F. Supp. 2d 819 (E.D. Mich. 1999), holding that restitution claims and claims for injunctive relief could be aggregated for purposes of determining whether the jurisdictional amount for diversity jurisdiction was satisfied, and neither the complete preemption doctrine nor the artful pleading doctrine supplied federal question jurisdiction for those suits that did not satisfy requirements for diversity jurisdiction; Andrx Pharm, Inc. v. Biovail Corp Int'l., 256 F. 3d 799 (D.C. Cir. 2001), holding that Biovail's antitrust claims against Andrx should not have been dismissed by the district court; In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 618 (E.D. Mich. 2000), holding, *inter alia*, that the plaintiffs stated a claim that defendants were engaged in a sham transaction rendering the *Noerr-Pennington* doctrine inapplicable, adequately alleged antitrust injury, and stated a claim of unjust enrichment under the laws of various states; In re Cardizem CD Antitrust Litig., 105 F. Supp. 2d 682 (E.D. Mich. 2000), holding, *inter alia*, that the agreement between HMRI and Andrx constituted a *per se* violation of the Sherman Act, that the agreement was not ancillary to any pro-competitive purpose, and that the agreement was not protected from antitrust liability under the *Noerr-Pennington* doctrine (this decision is currently on appeal with no decision yet); In re Cardizem CD Antitrust Litig., 200 F.R.D 297 (E.D. Mich. 2001), certifying a class of direct purchasers of Cardizem CD for claims under the Sherman Act; and In re Cardizem CD Antitrust Litig., 200 F.R.D 326 (E.D. Mich. 2001), certifying a class of indirect purchasers of Cardizem CD for claims under Michigan's antitrust laws.

B. ***Cipro (Ciprofloxacin Hydrochloride)***

1. Cipro (ciprofloxacin hydrochloride) is an antibiotic patented by Bayer Corporation ("Bayer"). The Cipro litigation involves antitrust claims arising from an alleged settlement agreement between Bayer, Barr Laboratories ("Barr"), the Rugby Group ("Rugby"), and Hoechst-Marion Roussel, Inc. ("HMRI") to settle patent litigation related to Bayer's patent covering ciprofloxacin hydrochloride (the "444 patent").

2. The settlement at issue allegedly required Barr to recognize the validity and enforceability of the '444 patent and not to manufacture or market ciprofloxacin until the patent expires. In exchange, (1) Bayer allegedly agreed to pay Barr and Rugby each an initial lump sum amount of \$24.5 million, and (2) Bayer agreed, at its option, either to make an annual payment to Barr, HMRI, and/or Rugby (of approximately \$24 million) based on its sales from March 1998 to December 2003 (the date of patent expiry), or to supply Barr, HMRI, and/or Rugby with ciprofloxacin to market and distribute under a generic label. At the time of the agreement, Bayer and Barr entered into a consent judgment extinguishing all claims raised in the patent litigation.

3. Approximately 30 lawsuits have been filed around the country on behalf of putative classes of direct and indirect purchasers (including consumers) of Cipro. These plaintiffs essentially allege that the defendants, by executing the agreement and judgment, unlawfully restrained trade in the alleged market for ciprofloxacin, and eliminated the possibility of generic competition, in violation of state antitrust and consumer protection laws. The Judicial Panel on Multidistrict Litigation has transferred the federal claims to the Eastern District of New York.

4. Noteworthy decisions include Altman v. Bayer Corp., 125 F. Supp. 2d 666 (S.D.N.Y. 2000), granting plaintiffs' motion to remand case based on state antitrust claims, holding that that resolution of state-law claims did not necessarily depend on questions of federal patent law; Meyers v. Bayer AG, 143 F. Supp. 2d 1044 (E.D. Wis. 2001), holding that the case based on state-law claims did not meet the amount-in-controversy requirement for diversity jurisdiction, but staying consideration of existence of federal question jurisdiction pending resolution of MDL proceedings, which might result in transfer of the case to another district for pretrial purposes; and In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740 (E.D.N.Y. 2001), remanding removed cases to state court on the grounds that the state-law claims did not necessarily require the resolution of substantial questions of patent law.

C. *Hytrin (Terazosin Hydrochloride)*

1. Hytrin (terazosin hydrochloride) is a drug manufactured by Abbott Laboratories ("Abbott") for the treatment of high blood pressure and enlarged prostate. The Hytrin litigation involves agreements between Abbott and Geneva Pharmaceuticals, Inc. ("Geneva") and between Abbott and Zenith Goldline Pharmaceuticals, Inc. ("Zenith") to settle patent infringement litigation relating to Hytrin.

2. The agreement between Abbott and Geneva was an "interim" settlement agreement that did not finally resolve the patent issues. Geneva allegedly agreed to accept \$4.5 million per month from Abbott to refrain from marketing any generic Hytrin product (including Geneva's approved capsule, which was not at issue in the infringement lawsuit), until another drug maker sold a generic version of Hytrin in the United States or Geneva received a final, unappealable judgment that its proposed

generic tablet did not infringe Abbott's patents. As part of this agreement, Geneva and Abbott allegedly agreed to continue the patent infringement litigation on Geneva's generic tablet.

3. Abbott and Zenith allegedly agreed that Abbott would pay Zenith \$3 million in return for joining Abbott in dismissing the patent litigation and that Abbott would pay Zenith an additional \$6 million per quarter not to sell or distribute any generic Hytrin product until: (1) another drug maker did so in the United States; (2) Abbott allowed Zenith to enter; or (3) Abbott's patents expired.

4. In May 2000, the FTC issued a complaint against Abbott and Geneva, alleging that their alleged agreement constituted an unreasonable restraint of trade, that they acted with the specific intent to monopolize the alleged market for terazosin hydrochloride, that Abbott actually monopolized the alleged market, and all of these activities constituted "unfair methods of competition" in violation of Section 5 of the FTC Act. (See <http://www.ftc.gov/os/2000/03/abbottcmp.htm>). This complaint was settled by consent order. (See <http://www.ftc.gov/os/2000/03/abbottagreement.htm>; <http://www.ftc.gov/os/2000/03/genevaagre.htm>).

5. The agreements between Abbott and Geneva and Abbott and Zenith have given rise to numerous class actions filed on behalf of putative classes of direct and indirect purchasers of terazosin hydrochloride. Noteworthy decisions in the Hytrin litigation include: Abbott Labs. v. Zenith Labs., Inc., 934 F. Supp. 925 (N.D. Ill. 1995), holding, inter alia, that the court had federal question jurisdiction over the patent infringement suit, but that there was no actual controversy that would warrant declaratory judgment; In re Terazosin Hydrochloride Antitrust Litig., 164 F. Supp. 2d 1340 (S.D. Fla. 2000), granting partial summary judgment for the direct purchasers, concluding that the defendants' agreements were per se illegal under the Sherman Act (this decision is currently on appeal with no decision yet); In re Terazosin Hydrochloride Antitrust Litig., 160 F. Supp. 2d 1365 (S.D. Fla. 2001), holding, inter alia, that indirect purchasers lacked standing to sue for damages under the Sherman Act, that failure to designate named plaintiffs that were injured within various states precluded claims under the antitrust statutes of those states, and that the plaintiffs stated antitrust claims under various states' antitrust laws but failed to state antitrust claims under other states' antitrust laws; and In re Terazosin Hydrochloride Antitrust Litig., 203 F.R.D. 551 (S.D. Fla. 2001), certifying a class of direct purchasers.

D. ***K-Dur 20 (Potassium Chloride)***

1. K-Dur 20 (potassium chloride) is a supplement manufactured by Schering-Plough Corporation that is used to treat or prevent low potassium levels in the blood. Upsher-Smith Laboratories and ESI Lederle, Inc. filed ANDAs to manufacture and sell generic K-Dur 20, and Schering-Plough filed patent infringement litigation. The antitrust litigation relates to the settlement of this litigation.

2. In the first agreement, Schering-Plough agreed to pay Upsher-Smith \$60 million to license certain intellectual property from Upsher-Smith. Schering-Plough also granted Upsher-Smith a license to launch a proposed generic version of K-Dur 20 in September 2001. In the second agreement, Schering-Plough agreed to pay ESI up to \$15 million and agreed that ESI could enter the market on January 1, 2004. Schering-Plough also paid ESI \$15 million for the rights to market two additional products.

3. In March 2001, the FTC filed a complaint against Schering-Plough, Upsher-Smith, and American Home Products (an affiliate of ESI) ("AHP"), in which it alleged that the agreements constituted unlawful agreements to delay entry of a generic alternative to K-Dur 20 in violation of Section 5 of the FTC Act. (See <http://www.ftc.gov/os/2001/04/scheringpart3cmp.pdf>). In October 2001, the FTC and AHP entered into a consent agreement. (See <http://www.ftc.gov/os/2002/02/ahpagree.pdf>).

4. On June 27, 2002, after an administrative trial, the ALJ dismissed the FTC's complaint. (See <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp1.pdf>; <http://www.ftc.gov/os/2002/07/scheringinitialdecisionp2.pdf>). The decision explains that complaint counsel did not "prove or properly define" the relevant product market and that Schering did not have monopoly power in the relevant market (oral potassium supplements). In addition, the ALJ found no evidence that the payments under the agreement were intended as consideration for staying off the market, as opposed to consideration for settling the infringement cases and for drugs licensed to Schering-Plough, or that the agreements served to delay the entry of generic competition. Significantly, the ALJ found that complaint counsel failed to carry its burden of showing that, absent the settlement, the alleged infringers would have prevailed in the patent litigation or otherwise entered the market earlier than provided for under the agreement. Complaint counsel filed an appeal, and oral argument before the FTC was held in January 2003.

5. A number of antitrust class actions have been filed in federal courts across the country on behalf of putative classes of direct and indirect purchasers. Those cases have been consolidated and transferred to the District of New Jersey by the Judicial Panel on Multidistrict Litigation. Class action cases have also been filed in various state courts.

6. Noteworthy decisions include McGrew v. Schering-Plough Corp. et al., No. CIV.A. 01-2311-GTV, 2001 WL 950790 (D. Kan. Aug. 6, 2001), in which the Court remanded the removed case back to state court on the ground that the Court lacked subject matter jurisdiction.

E. ***Naprelan (Naproxen Sodium)***

1. Naprelan (naproxen sodium) is a non-steroidal anti-inflammatory drug manufactured and sold by Elan Corporation plc (“Elan”). Three putative class action lawsuits have been filed and consolidated in the Eastern District of Pennsylvania alleging antitrust violations by Elan and Skyepharma Inc. (“Skyepharma”) relating to Naprelan.

2. The plaintiffs allege that Skyepharma, the first ANDA filer, and Elan violated Section 1 by settling patent infringement litigation brought by Elan to enforce its ‘320 patent. The plaintiffs allege that the settlement agreement prevented Skyepharma and later ANDA filers from bringing generic versions of Naprelan to market. The plaintiffs further allege that Elan violated Section 2 by bringing allegedly sham patent infringement litigation on the ‘320 patent against Andrx Pharmaceuticals, Inc.

3. There have been no noteworthy antitrust decisions to date.

F. ***Novaldex (Tamoxifen Citrate)***

1. Novaldex (tamoxifen citrate) is a drug sold by AstraZeneca that is used to treat breast cancer. The tamoxifen litigation involves an agreement between Imperial Chemical Industries, PLC (an affiliate of AstraZeneca) and Barr Laboratories to settle patent infringement litigation relating to Imperial’s patent for tamoxifen (the “‘516 patent”).

2. Imperial sued Barr for infringement of the ‘516 patent, and the patent was found unenforceable after trial. Imperial Chem. Indus., PLC v. Barr Lab., Inc., 795 F. Supp. 619 (S.D.N.Y. 1992). Imperial appealed this judgment, but Barr and Imperial reached a settlement agreement during the appeal and moved jointly to vacate the judgment of the district court. Imperial Chem. Indus., PLC v. Heumann Pharma GMBH & Co., 991 F.2d 811, 1993 WL 118931 (Fed. Cir. March 19, 1993). Under the alleged agreement, Imperial licensed Barr to sell Novaldex, and Barr (which was the first ANDA filer) agreed not to pursue final approval of its ANDA prior to the expiration of the ‘516 patent. In 1996, another generic company, Pharmachemie, filed an ANDA for tamoxifen. Zeneca Limited (now AstraZeneca), which had obtained the patent rights of the ‘516 patent from Imperial, sued Pharmachemie for infringement. Later, Barr filed a petition with the FDA seeking enforcement of its 180-day exclusivity period as the first ANDA filer. The FDA then imposed a stay on approval of all other ANDAs for tamoxifen (Mylan and Novopharm had also filed ANDAs) until 180 days after the date of Barr’s first commercial marketing of the drug or the date of a final decision of a court holding the ‘516 patent invalid or not infringed. Pharmachemie sought injunctive and declaratory relief, challenging the FDA’s decision and disputing Barr’s entitlement to the exclusivity period. The district court granted summary judgment to Pharmachemie. While Barr’s appeal was pending, Zeneca won its patent suit against Pharmachemie, and the court

of appeals held that this ruling mooted Barr's appeal of the lower court's judgment in favor of Pharmachemie.

3. In August 2001, the Judicial Panel on Multidistrict Litigation consolidated several pending actions against Barr and Zeneca in the Eastern District of New York. The plaintiffs in these actions assert that the defendants' settlement of the patent litigation restrained trade by allocating the alleged market for and raising the price of tamoxifen citrate.

4. Noteworthy decisions include Mylan Pharm., Inc. v. Henney, 94 F. Supp. 2d 36 (D.D.C. 2000), granting Mylan's and Pharmachemies' claims for declaratory relief based on their dispute with the FDA regarding Barr's entitlement to the 180-day period of market exclusivity; Pharmachemie B.V. v. Barr Labs, Inc., 276 F.3d 627 (D.C. Cir. 2002), vacating the district court's judgment in the foregoing case because that judgment was mooted by Zeneca's intervening victory in the patent infringement litigation against Pharmachemie; and Barr Labs., Inc. v. Thompson, No. CIV. A. 02-1867(EGS), 2002 WL 31840634 (D.D.C. Dec. 18, 2002), holding that Barr could not market generic tamoxifen until after the expiration of AstraZeneca's additional six-months' pediatric exclusivity period, notwithstanding the fact that the FDA's 1987 "final approval" letter for Barr's ANDA stated an earlier "effective date."

G. ***Procardia XL (Nifedipine)***

1. Procardia XL (nifedipine) is a prescription drug manufactured and sold by Pfizer, Inc. ("Pfizer") to treat angina and hypertension. The antitrust claims in this litigation involve an alleged agreement between Pfizer Inc. and Mylan Pharmaceuticals, Inc. ("Mylan") to settle patent infringement litigation.

2. Multiple generic competitors filed ANDAs with the FDA for approval to sell generic versions of Procardia. Pfizer sued Mylan (the first ANDA filer) for patent infringement, and Mylan amended its answer to include antitrust counterclaims. On March 2, 2000, Mylan announced that it had entered into a settlement agreement with Pfizer pursuant to which the patent infringement litigation was terminated, and Mylan obtained a license to market a generic sustained release nifedipine product manufactured by Pfizer (rather than the generic product for which Mylan had earlier received FDA approval).

3. In August 2000, one of the other ANDA filers, Teva Pharmaceuticals USA ("Teva"), filed a Citizen Petition with the FDA to determine whether Mylan was entitled to the 180-day exclusivity period as the first ANDA filer and, if so, when that period would expire. In February 2001, the FDA ruled that Mylan was not eligible for the 180-day exclusivity period and, alternatively, that any such exclusivity had already expired. (See <http://www.fda.gov/ohrms/dockets/dailys/01/Mar01/030501/pav0001.pdf>). The FDA approved Biovail's generic product for marketing on the same day.

4. The agreement between Pfizer and Mylan has been challenged in antitrust litigation by Biovail, on the grounds that the agreement unfairly extended Mylan's 180-day exclusivity period, and by at least five health plans seeking class action relief.

5. Noteworthy decisions include Pfizer, Inv. v. Shalala, 182 F. 3d 975 (D.C. Cir. 1999), in which the D.C. Circuit held that neither Pfizer's challenge to the FDA's acceptance of Mylan's ANDA for processing nor its challenge to the FDA's denial of its citizen petition seeking recognition that its dosage form was unique was ripe for review.

II. Cases Relating to Orange Book Listings

A. ***BuSpar (Buspirone Hydrochloride)***

1. BuSpar (buspirone hydrochloride) is an antidepressant manufactured by Bristol-Myers Squibb Co. ("BMS"). The antitrust litigation arises out of BMS's listing in the Orange Book of a patent (the '365 patent) covering the oral administration of a metabolite of buspirone hydrochloride and an earlier settlement of patent litigation with Danbury Pharmaceutical, Inc. and its affiliate Schein Pharmaceuticals, Inc. ("Schein"). Four patent disputes and twenty-two antitrust cases filed by generic competitors, direct purchasers, indirect purchasers, and thirty state attorneys general were consolidated by the Judicial Panel on Multidistrict Litigation in August 2001 and transferred to the United States District Court for the Southern District of New York. Twelve "tag-along" cases were also transferred to the Southern District of New York.

2. Noteworthy decisions include: Watson Pharm, Inc. v. Henney, 194 F. Supp. 2d 442 (D. Md. 2001), rejecting Watson's request for an injunction ordering the FDA to de-list the '365 patent on the ground that the action was, in effect, an attempt to obtain judicial review of a purely ministerial administrative determination by the FDA; Mylan Pharm., Inc. v. Thompson, 268 F. 3d 1323, 1329-33 (Fed. Cir. 2001), reversing the district court's order requiring the de-listing of the '365 patent on the ground that neither the patent laws nor the Hatch-Waxman Act provided for a private cause of action to de-list a patent from the Orange Book; In re Buspirone Patent Litig., 185 F. Supp. 2d 363 (S.D.N.Y. 2002), holding, inter alia, that BMS's listing of the '365 patent was not entitled to *Noerr-Pennington* immunity and that the antitrust claims arising out of BMS's settlement with Schein were time-barred; and In re Buspirone Patent Litig., 185 F. Supp. 2d 340 (S.D.N.Y. 2002), granting summary judgment to Mylan and Watson in the patent litigation.

3. On January 7, 2003, BMS announced that it had reached an agreement in principle to settle the BuSpar antitrust litigation for \$535 million and the Taxol antitrust litigation (see below) for \$135 million.

B. Paxil (Paroxetine Hydrochloride)

1. Paxil (paroxetine hydrochloride) is a prescription drug manufactured and sold by GlaxoSmithKline (“GSK”) for the treatment of, among other things, depression and anxiety. Several putative class actions have been filed alleging violations of federal and state antitrust laws and state tort laws based on GSK’s listing and enforcing various patents claiming paroxetine hydrochloride. The plaintiffs in these actions allege that several of GSK’s patents are improperly listed in the Orange Book and that GSK’s patent-infringement litigation against various ANDA filers is “sham” litigation.

2. There have been no noteworthy, published antitrust decisions in this litigation to date.

3. In December 2002, in one of the underlying patent infringement cases (against Apotex Corp., Apotex, Inc., and Torpharm, Inc. (collectively “Apotex”)), the court held (recognizing a split in Federal Circuit authority on the issue) that certain “product-by-process” claims in three GSK patents were invalid. Apotex filed a motion asking the district court to order the de-listing of the patents at issue. The FTC, which has been conducting an investigation relating to Paxil, filed an amicus brief in connection with Apotex’s motion. The FTC’s brief sets forth its concerns regarding the potential anticompetitive effect of improper listings but expresses no opinion regarding whether the particular patents at issue should be de-listed. (See <http://www.ftc.gov/ogc/briefs/smithklineamicus.pdf>). There has been no decision on the motion to date.

C. Taxol (Paclitaxel)

1. Taxol (paclitaxel) is an anti-cancer drug manufactured by Bristol-Myers Squibb Co. (“BMS”). The Taxol litigation relates, *inter alia*, to BMS’s listing of another party’s (American Bioscience Inc.’s) patent (the ‘331 patent) in the Orange Book under BMS’s NDA for Taxol. The listing of the ‘331 patent affected ANDAs that had been filed previously, including ANDAs filed by Ivax Corporation (Baker Norton Pharmaceutical) and Zenith Goldline Pharmaceuticals, Inc.

2. BMS was sued by numerous states and in multiple class actions. On January 7, 2003, BMS announced that it had reached an agreement in principle to settle the Taxol antitrust litigation for \$135 million.

3. Noteworthy decisions include Bristol-Myers Squibb Co. v. Ivax Corp., 77 F. Supp. 2d 606 (D. N.J. 2000), granting, *inter alia*, BMS’s motion to dismiss certain of Ivax’s antitrust and unfair competition claims on *Noerr-Pennington* grounds; Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 522 (D. N.J. 2000); and Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540 (D. N.J. 2000), denying BMS’s motions for summary judgment, holding that Ivax had produced evidence that could support a finding that BMS committed fraud and/or inequitable

conduct in the prosecution of its patents; American Bioscience, Inc. v. Thompson, 243 F.3d 579, 582 (D.C. Cir. 2001), vacating the district court's decision denying ABI's motion for a preliminary injunction to prevent the FDA from approving Baker Norton Pharmaceutical's ANDA because there was no indication of how the FDA interpreted the late listing regulation; American Bioscience, Inc. v. Shalala, 141 F. Supp. 2d 88 (D. D.C. 2001), denying ABI's renewed motion for injunctive relief; and American Bioscience, Inc. v. Thompson, 269 F. 3d 1077 (D.C. Cir. 2001), vacating and remanding the district court's denial of ABI's motion for a preliminary injunction.

D. *Tiazac (Diltiazem Hydrochloride)*

1. Tiazac (diltiazem hydrochloride) is a drug manufactured by Biovail Corporation ("Biovail") for the treatment of hypertension. Andrx Pharmaceuticals, Inc. ("Andrx") filed the first ANDA to manufacture generic Tiazac. The antitrust litigation arises from Biovail's allegedly improper listing of a patent for extended release diltiazem (the '463 patent). Biovail obtained an exclusive license to the '463 patent from a third party and listed the patent in the Orange Book in January 2001, just weeks before the FDA was expected to grant final approval to Andrx's ANDA.

2. Andrx and classes of consumers filed antitrust actions against Biovail, alleging that Biovail unlawfully prevented generic competition and monopolized the alleged market for diltiazem hydrochloride by improperly listing the '463 patent in the Orange Book (thereby delaying approval of Andrx's ANDA). According to the plaintiffs, the '463 patent was not properly listed in the Orange Book because the patent did not claim Biovail's drug product as approved and marketed. The plaintiffs (and the FTC) allege that Biovail modified its marketed drug product to bring it within the claims of the '463 patent.

3. In February 2002, Andrx and Biovail entered into a settlement agreement pursuant to which Biovail gave Andrx a non-exclusive license to its patents and Andrx agreed to pay Biovail royalties on Andrx's generic Tiazac product.

4. On April 23, 2002, Biovail and the FTC entered into a Consent Agreement, which resulted in a Consent Order dated October 2, 2002. (See <http://www.ftc.gov/os/2002/04/biovaildecision.htm>). The order requires Biovail to divest part of its exclusive rights to Tiazac and prohibits action by Biovail that would cause a statutory stay on the entry of a generic Tiazac product. The order also prohibits Biovail from wrongfully listing patents in the Orange Book in the future and requires Biovail to notify the FTC prior to acquiring patents that will be listed in the Orange Book.

5. Noteworthy decisions include Andrx Pharm., Inc. v. Biovail Corp., 276 F.3d 1368 (Fed. Cir. 2002), holding, inter alia, that the district court had exceeded its authority in shortening the 30-month stay based on Biovail's alleged conduct in listing the '463 patent.

III. Other Cases

A. ***Adalat (Nifedipine)***

1. Adalat (nifedipine) is a prescription drug used to treat hypertension that is marketed by Bayer AG (“Bayer”). Elan Corporation, plc (“Elan”) was the first ANDA filer for a 30 mg generic product and the second for a 60 mg generic product. Biovail Corporation was the first ANDA filer for the 60 mg generic product and the second for the 30 mg generic product.

2. The FTC prepared a Complaint alleging that Elan and Biovail entered into an agreement in October 1999 pursuant to which Elan appointed Biovail to be the exclusive distributor of Elan’s 30 and 60 mg generic Adalat products. (See <http://www.ftc.gov/os/2002/06/biovailelancmp.pdf>). The FDA approved Elan’s 30 mg generic Adalat product in March 2000 and its 60 mg product in October 2001. It approved Biovail’s 30 mg and 60 mg products in December 2000. As a result of the alleged agreement between Biovail and Elan, Biovail began selling Elan’s 30 mg product immediately after receiving final FDA approval and likewise began selling its own 60 mg product after final FDA approval. According to the FTC, the alleged agreement effectively prevented the launching of Elan’s 60 mg product and Biovail’s 30 mg product. The agreement, according to the FTC, gave Biovail substantial incentives not to launch its own 30 mg product and gave Elan substantial incentives not to launch its 60 mg product. Therefore, the FTC contended that it constituted an agreement not to compete between the only two producers of the two generic Adalat products, in violation of Section 5 of the FTC Act. The parties entered into an Agreement and Consent Order in June of 2002, requiring the immediate termination of the agreement between Biovail and Elan and best efforts to launch competing generic Adalat products. (See <http://www.ftc.gov/os/2002/06/biovailelanagreement.pdf>).

3. Biovail and Elan have been sued by consumers in class action litigations alleging that the agreement between Biovail and Elan violated state and federal antitrust laws.

B. ***Cefaclor***

1. Eli Lilly & Co. sued Zenith Goldline Pharmaceuticals, Inc. (“Zenith”), American Cyanamid Co., Biocraft Laboratories, Inc., and Biochemica Opos, S.p.A. (“Opos”) for infringement of certain of Lilly’s patents for the making of cefaclor, an antibiotic marketed as Ceclor. Zenith filed antitrust counterclaims, alleging that Lilly violated Section 1 of the Sherman Act by entering into an illegal horizontal agreement with ACS Dobfar, S.p.A. (“Dobfar”), an Italian company, and Ranbaxy Laboratories, Ltd. (“Ranbaxy”) (other potential makers of bulk cefaclor for dosage manufacturers) to restrict the supply of bulk cefaclor for the United States market.

2. Noteworthy decisions include Eli Lilly & Co. v. American Cyanamid Co., 896 F. Supp. 851 (S.D. Ind. 1995), aff'd 82 F.3d 1568 (Fed. Cir. 1996), denying Lilly's motion for a preliminary injunction; holding, inter alia, that Lilly had failed to establish a likelihood of irreparable harm; Eli Lilly & Co. v. American Cyanamid Co., 66 F. Supp. 2d 924 (S.D. Ind. 1999), holding that Opos's manufacturing method did not infringe Lilly's patents; Eli Lilly & Co. v. American Cyanamid Co., No. IP95-0536-C-B/S, 2001 WL 30191 (S.D. Ind. Jan. 8, 2001), denying Lilly's motion to dismiss Zenith's antitrust counterclaims; Eli Lilly & Co. v. Zenith Laboratories, Inc., 134 F. Supp. 2d 981 (S.D. Ind. 2001), denying Zenith's motion for summary judgment on the ground that Zenith's acts fell outside of the safe harbor from liability for importing infringing products; and Eli Lilly & Co. v. Zenith Goldline Pharm., Inc., 172 F. Supp. 2d 1060 (S.D. Ind. 2001), holding, inter alia, that Zenith's offers of direct evidence did not suffice to establish a conspiracy in restraint of trade, that genuine issues of material fact regarding whether there was an agreement or agreements in restraint of trade prevented summary judgment for both parties, and that there were fact issues with respect to whether the per se rule or rule of reason should apply to the analysis of the alleged restraint of trade and whether the allegedly illegal agreement or agreements caused injury to Zenith.

C. ***Lorazepam & Clorazepate***

1. Lorazepam and clorazepate dipotassium are used to treat anxiety, seizures, and alcohol withdrawal. The antitrust claims arise from an agreement between Mylan Laboratories, Inc. ("Mylan"), Profarmaco S.r.l. ("Profarmaco"), Cambrex Corporation ("Cambrex"), and Gyma Laboratories of America, Inc. ("Gyma") for exclusive licenses for the Drug Master Files of lorazepam and clorazepate Active Pharmaceutical Ingredients ("APIs").

2. Mylan entered into contracts with Profarmaco and Gyma under which these companies granted Mylan exclusive licenses for the APIs for ten years, providing Mylan with control over Profarmaco's supply of lorazepam and clorazepate entering the United States. In return for the licenses, Mylan offered to pay Cambrex, Profarmaco, and Gyma a percentage of gross profits on sales of lorazepam and clorazepate tablets. Mylan also attempted to execute an exclusive licensing arrangement with SST Corporation, another United States distributor of the APIs, for control of its lorazepam supply. In January 1998, Mylan raised its price of clorazepate tablets by amounts ranging from 1,900% to 3,200%, and, in March of that year, Mylan raised its price of lorazepam tablets by amounts ranging from 1,500% to 2,600%.

3. The FTC brought an action against Mylan, Cambrex, Profarmaco, and Gyma seeking permanent injunctive relief and equitable disgorgement of profits resulting from the unlawful agreements in restraint of trade of both lorazepam and clorazepate. (See <http://www.ftc.gov/os/1999/9902/mylanamencmp.htm>). The FTC also charged defendants with conspiring to monopolize, attempting to monopolize, and

actually monopolizing the alleged markets for generic lorazepam and clorazepate tablets in violation of Section 5 of the FTC Act. In addition, no fewer than 33 states filed actions under Sections 1 and 2 of the Sherman Act and their respective state statutes against the defendants and SST Corporation. In February 2002, the district court approved settlements with the FTC, state attorneys general, and certain consumers for, among other things, a payment of \$100 million. The court also approved settlements of approximately \$35 million for third-party payors. Numerous private actions have been filed on behalf of direct purchasers.

4. Noteworthy decisions include FTC v. Mylan Labs, Inc., 62 F. Supp. 2d 25 (D.D.C. 1999), holding, *inter alia*, that the FTC could sue for monetary relief in addition to injunctive relief, that the states could not recover for excess payments for drugs made to competitors of named parties under an “umbrella” damages theory, that restitution and disgorgement of profits were available under state statutes only when expressly provided for, that plaintiffs stated claims of monopoly, price fixing and unreasonable restraints of trade, and that SST could be included in the suit, even though it was not a signatory to the licensing agreements; FTC v. Mylan Labs, Inc., 99 F. Supp. 2d 1 (D. D.C. 1999), holding, on reconsideration of order dismissing several state law claims, that the states could obtain restitution and disgorgement, even if the relevant state statutes did not explicitly provide for these remedies to the extent the state laws referenced or were modeled after the FTC Act or otherwise permitted equitable remedies; In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12 (D.D.C. 2001), certifying direct purchaser class and rejecting the defendants’ argument that the plaintiffs lack standing because the FTC had already obtained a disgorgement remedy; and In re Lorazepam & Clorazepate Antitrust Litig., 205 F.R.D. 369 (D. D.C. 2002), approving settlement agreements.

D. ***Monodox (Doxycycline Monohydrate)***

1. Monodox (doxycycline monohydrate) is an antibiotic manufactured by Watson Pharmaceuticals, Inc. (“Watson”). This litigation arises out of an agreement between Watson and Halsey Drug Co. (“Halsey”), in which Watson acquired Halsey’s ANDA for generic Monodox.

2. Watson has an NDA for Monodox (though Monodox does not have patent protection). Halsey received FDA approval for a generic version of Monodox. However, in exchange for \$30 million, Halsey assigned its rights under the ANDA to Watson, and Watson did not market a generic Monodox product. Eon Labs Manufacturing, Inc. (“Eon”) later received approval for an ANDA for generic Monodox, and, at that time, Watson began marketing its generic Monodox. Eon sued Watson, alleging that Watson rushed its product to market to maintain monopoly power over the supply of doxycycline, that Watson’s conduct artificially inflated the prices for generic doxycycline, and that Watson’s conduct deprived Eon of profits it would have made if it had been first to market.

3. Noteworthy decisions include Eon Labs Manufacturing, Inc. v. Watson Pharm, Inc., 164 F. Supp. 2d 350 (S.D.N.Y. 2001), dismissing Eon's complaint; holding, inter alia, that Eon's failure to show antitrust damages precluded its claim that Watson entered into a contract in restraint of trade when it acquired Halsey's rights and its claim that Watson violated the Sherman Act by selling doxycycline under a generic label.

E. ***Neurontin (Gabapentin)***

1. Neurontin (gabapentin) is an anticonvulsant manufactured by Warner-Lambert Company (which was acquired by Pfizer, Inc.). Warner-Lambert sued a number of generic drug companies, including Apotex Corp., TorPharm, Inc., and Purepac following notice of their ANDAs for generic versions of Neurontin.

2. Individual and putative class action lawsuits have been filed against Pfizer and Warner-Lambert alleging that their patent infringement litigation against the ANDA filers is sham litigation. In August 2002, seventeen class action antitrust cases were consolidated in the District of New Jersey for coordinated pretrial proceedings. In re Neurontin Antitrust Litigation, 217 F. Supp. 2d 1380 (MDL 2002).

3. There have been no noteworthy antitrust decisions in this litigation to date.

F. ***Prilosec (Omeprazole)***

1. Prilosec (omeprazole) is a drug manufactured by AstraZeneca that is used to treat heartburn, ulcers, and reflux.

2. AstraZeneca sued multiple defendants, including Andrx, Cheminor and Genpharm Inc., for infringement of three patents relating to Prilosec.

3. Class action antitrust lawsuits were brought by indirect purchasers of and third party payors for Prilosec. The plaintiffs alleged that AstraZeneca has brought "sham" patent litigation in an attempt to prevent generic competitors from entering the market.

4. In Twin City Bakery Works and Welfare Fund v. Astra Aktiebolag, 307 F. Supp. 2d 221 (S.D.N.Y. 2002), the court dismissed the plaintiffs' antitrust claims, holding that AstraZeneca's assertion of its patents was not objectively baseless as a matter of law because a sufficient number of its infringement claims survived summary judgment and proceeded to trial.

5. After trial, on October 11, 2002, Judge Jones in the Southern District of New York ruled that the patents for the formulation of the drug were literally

infringed by all but one defendant, the formulation patents were neither obvious nor anticipated, and the method of use patent was invalid as anticipated.

G. ***Relafen (Nabumetone)***

1. Relafen (nabumetone) is a non-steroidal anti-inflammatory manufactured and sold by GlaxoSmithKline (“GSK”).

2. In August 2001, the District Court for the District of Massachusetts held that GSK’s patent covering nabumetone (the ’639 patent) was both invalid and unenforceable due to inequitable conduct. Following that decision, antitrust lawsuits were filed by a generic manufacturer, individual generic manufacturers and individual direct purchasers, and class actions were filed by direct and indirect purchasers alleging that GSK violated Section 2 by prosecuting sham patent infringement litigation.

3. There have been no noteworthy antitrust decisions to date.

H. ***Wellbutrin (Bupropion)***

1. Several putative class actions have been filed alleging violations of federal and state antitrust laws and state tort laws based on GlaxoSmithKline’s (“GSK’s”) alleged conduct in listing, and enforcing, various patents related to bupropion, the active ingredient in Wellbutrin.

2. There have been no noteworthy published antitrust decisions in this litigation to date.

IV. **Related Developments**

A. ***The FTC’s Generic Drug Study***

1. On July 30, 2002, the FTC released “Generic Drug Entry Prior to Patent Expiration: An FTC Study” (the “Generic Drug Study”) (see <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>). The report was the culmination of an industry-wide study that began in April 2001 and was based upon subpoenaed responses from 28 brand-name companies and 50 generic drug companies. The Generic Drug Study presents statistical information regarding ANDA filings, Orange Book listings, and related patent infringement litigation. The study makes “two primary recommendations.”

2. First, the Generic Drug Study recommends that the Hatch-Waxman Act be amended to permit only one automatic 30-month stay per ANDA (i.e., eliminate 30-month stays arising from patents listed in the Orange Book after the filing of the ANDA). (Id. at ii.)

3. Second, the Generic Drug Study recommends that legislation be passed to require that the FTC and DOJ be notified and provided with copies of relevant documents “if a brand-name company and a generic applicant enter into an agreement that relates in any way to the 180-day exclusivity [period for first ANDA filers] or which concerns the manufacture, marketing, or sale of either the brand name drug or its generic equivalent.” (*Id.* at viii.) The study makes other “minor” recommendations relating to the 180-day exclusivity period. (*Id.* at ix-xi.)

B. FDA’s Proposed Amendments to the Hatch-Waxman Regulations

1. On October 24, 2002, the FDA issued proposed amendments to its Orange Book listing regulations to “clarify the types of patents that must and must not be listed” in the Orange Book. *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*, 67 Fed. Reg. 65,448, at 65,451-52 (October 24, 2002) (hereafter the “Proposed Rule”). The Proposed Rule was issued, in part, in response to “high profile litigation” regarding patent listings and a Citizen Petition filed by the FTC in which the FTC sought clarification of certain issues relating to the listing of patents in the Orange Book. *Id.* at 65449.

2. The Proposed Rule would amend the listing requirements to clarify that (1) patents claiming packaging, metabolites, and intermediates may not be listed; (2) product-by-process patents meeting the listing requirements must be listed; and (3) patents claiming a drug substance that is the “same” as the active ingredient that is the subject of an approved or pending NDA (e.g., an anhydrate form of a hydrated drug product) must be listed. *Id.* at 65451-65453. The Proposed Rule would also amend the required declaration for patent listings to better reflect the amended listing requirements.

3. The Proposed Rule would also follow the FTC’s recommendation in its Generic Drug Study by permitting only one 30-month stay per ANDA.

4. Comments regarding the Proposed Rule were due by December 23, 2002. For the FTC’s comments, see <http://www.ftc.gov/be/v030002.pdf>.