



**A SUMMARY OF RECENT PHARMACEUTICAL CASES
RAISING INTELLECTUAL PROPERTY-ANTITRUST ISSUES**

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SUMMARY OF RECENT PHARMACEUTICAL INDUSTRY CASES RAISING INTELLECTUAL PROPERTY-ANTITRUST ISSUES

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

4. Noteworthy decisions related to these cases 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 has been affirmed -- see paragraph 5 below); 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, leave to appeal denied, No. 01-0107 (6th Cir. June 18, 2001); and In re Cardizem CD Antitrust Litig., 200 F.R.D. 326 (E.D. Mich. 2001), certifying a class of exemplar indirect purchasers of Cardizem CD for claims under Michigan's antitrust laws, leave to appeal denied, No. 01-0109 (6th Cir. June 18, 2001).

5. In June 2003, the Sixth Circuit affirmed the district court's holding that the settlement agreement was *per se* unlawful. In re Cardizem Antitrust Litig., 332 F.3d 896 (6th Cir. 2003). The court held, among other things, that the agreement was "a naked, horizontal restraint of trade that is *per se* illegal because it is presumed to have the effect of reducing competition in the market for Cardizem CD and its generic equivalents to the detriment of consumers." Id. at 911. The Eleventh Circuit has explicitly disagreed with the Sixth Circuit's holding on this point. See Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294, 1310 (11th Cir. 2003) (discussed below in the section on the Hytrin antitrust litigation). HMRI and Andrx appealed the Sixth Circuit's decision to the U.S. Supreme Court, which denied certiorari on October 12, 2004. See Andrx Pharmaceuticals, Inc. v. Kroger Co., 125 S. Ct. 307 (2004).

6. On November 26, 2002, the court granted final approval to a \$110 million class action settlement with direct purchasers. On October 1, 2003, the court granted final approval to an \$80 million settlement for the benefit of third-party payors and consumers. See In re Cardizem CD Antitrust Litig., 218 F.R.D. 508 (E.D. Mich. 2003), aff'd, 391 F.3d 812 (6th Cir. 2004); see also <http://www.cardizemsettlement.com>.

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 among 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 38 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. See In re Ciprofloxacin Hydrochloride Antitrust Litig., No. 1383, 2001 WL 253240 (J.P.M.L. Jan. 10, 2001).

4. The court denied plaintiffs' motion for summary judgment that the challenged settlement agreement was *per se* unlawful, holding that the agreement should be analyzed instead under the antitrust rule of reason. In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003). The court explained that *per se* analysis was not appropriate because, among other things, the antitrust claims arose out of settlement of a patent dispute and the application of still-developing law on the Hatch-Waxman amendments. The court specifically distinguished the cases involving Hytrin and Cardizem, in which the courts had applied *per se* analysis to the settlement agreements at issue because those agreements did

not finally dispose of the litigation and potentially blocked competition from non-infringing products.

5. In the same decision, the court also granted in part and denied in part the defendants' motions to dismiss. The court rejected the plaintiffs' allegation that they suffered injury-in-fact because, but for the settlement agreement, Barr would have prevailed in the litigation and launched a generic version of Cipro. The court stated that, without a finding that the patent was invalid, this theory was "unduly speculative." Given the substantial risk faced by an alleged infringer that enters while the patent litigation is pending, the court also rejected the plaintiffs' theory that, but for the alleged settlement, Barr would have entered during the patent litigation. The court accepted, however, the plaintiffs' theory that, but for the challenged settlement agreement, Bayer may have negotiated a license agreement with the alleged infringers, allowing them to enter the market. The court also quickly brushed aside the defendants' *Noerr-Pennington* argument, which was based on the fact that the judge had signed a consent judgment. According to the court, the *Noerr-Pennington* doctrine could not cover what was essentially a private agreement in which the judge played no role other than signing the consent judgment.

6. On July 21, 2004, the California Court of Appeal upheld in part the trial court's certification of a class of "hundreds of thousands" of consumers who claim they paid inflated prices for Cipro due to an alleged conspiracy to keep less expensive generic versions of the drug off the market. See In re CIPRO Cases I and II, 17 Cal. Rptr. 3d 1, No. D043543, 2004 WL 1627983 (Cal. Ct. App. 2004); see also <http://www.california-cipro litigation.com>. The appeals court did, however, exclude from the class individuals who paid a flat co-pay for their prescription drugs.

7. Other related 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 ground 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 has been reversed on appeal -- see paragraph 6 below); 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. The Eleventh Circuit vacated the certification of the class of direct purchasers on the grounds that there may be conflicts between members of the putative class, some of whom may not have been injured by the alleged delay in generic entry. See Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 350 F.3d 1181 (11th Cir. 2003). On remand, the district court denied the direct purchasers' motion for class certification, holding that the proposed representatives failed to produce evidence that the class was free from intra-class conflicts. See In re Terazosin Hydrochloride Antitrust Litig., 223 F.R.D. 666, 680 (S.D. Fla. 2004). However, on April 8, 2004, the district court certified a multistate indirect purchaser class. See In re Terazosin Hydrochloride Antitrust Litig., 220 F.R.D. 672 (S.D. Fla. 2004). This decision is currently the subject of an interlocutory appeal in the Eleventh Circuit.

6. The Eleventh Circuit reversed the district court's grant of summary judgment that the settlement agreements at issue were *per se* unlawful. Valley Drug Co. v. Geneva Pharmaceuticals, Inc., 344 F.3d 1294 (11th Cir. 2003), cert. denied, 125 S. Ct. 308 (2004). The Court of Appeals held that the settlement agreements were not *per se* unlawful and must be analyzed under the antitrust rule of reason. The court expressly disagreed with the Sixth Circuit's decision in In re Cardizem Antitrust Litigation (see above), explaining that "we do not think that a payment from the patentee to the alleged infringer should be automatically condemned under the antitrust laws" and that "the presence of an exit payment as part of the settlement does not alone demonstrate that the Agreements had obvious anticompetitive tendencies above and beyond ... the exclusionary rights under the ... patent." Valley Drug Co., 344 F.3d at 1311.

7. On August 31, 2004, the court dismissed the antitrust claims of the individual direct purchasers, indirect purchaser class plaintiffs, and state plaintiffs against Abbott, holding that Abbott's seventeen patent-enforcement lawsuits did not fall under the "sham litigation" exception to *Noerr-Pennington* immunity since the suits were not objectively baseless and were not brought in bad faith. See In re Terazosin Hydrochloride Antitrust Litig., 335 F. Supp. 2d 1336, 1363-67 (S.D. Fla. 2004) (granting summary judgment to Abbott). The court relied heavily on Abbott's successes in the litigation, including settlements it reached with infringement defendants. In addition, the court found that plaintiffs' failed to present evidence that Abbott's actions caused their alleged harm. Id. at 1367-69. Finally, the court determined that the record lacked evidence that Abbott procured the relevant patents by fraud on the Patent and Trademark Office. Id. at 1369-70.

8. Recently, on remand from the Eleventh Circuit, the district court, found the Abbott-Geneva settlement *per se* unlawful under Section 1 of the Sherman Act. See In re Terazosin Hydrochloride Antitrust Litig., --- F.Supp.2d ---, 2005 WL 147395, 2005 US Dist. LEXIS 108 (S.D. Fla. Jan. 5, 2005) (granting summary judgment in favor of class plaintiffs and a third-party health plan). Specifically, the Court held that

such “reverse” payments to settle patent infringement litigation were *per se* illegal after examining three factors: (1) whether the parties had a bona fide dispute; (2) whether the settlement was reasonable; and (3) whether the effects of the settlement were less anticompetitive than the “likely outcome of the litigation”. 2005 WL 147395, at *9.

D. K-Dur 20 (Potassium Chloride)

1. K-Dur 20 (potassium chloride) is a supplement manufactured by Schering-Plough Corporation (“Schering-Plough”) that is used to treat or prevent low potassium levels in the blood. Upsher-Smith Laboratories (“Upsher-Smith”) and ESI Lederle, Inc. (“ESI”) filed ANDAs to manufacturer 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. On December 18, 2003, the FTC reversed the ALJ. See In the Matter of Schering-Plough Corp., No. 9297, 2003 WL 22989651 (FTC Dec. 8, 2003). The Commissioners held that complaint counsel had satisfied their burden of proving that the agreement had an anticompetitive effect, and that the respondents had not met their burden of proving sufficient countervailing pro-competitive benefits. (See <http://www.ftc.gov/os/adjpro/d9297/index.htm>). The Commissioners held that complaint counsel need not present evidence regarding the potential outcome of the underlying patent litigation. In summary, under the facts, the Commissioners found proof that the parties would have chosen an earlier entry date in the settlement agreement if not for the payments sufficient to show that the payments delayed generic entry (this proof came largely from the parties' negotiating history). With respect to the competitive effect of the delay, the Commissioners explained that no formal definition of the market was necessary because there was sufficient direct evidence that delay of generic entry would have an anticompetitive effect (i.e., the available evidence showed that generic entry had the effect of lowering prices for the molecule). The Commissioners also found unpersuasive the respondents' evidence that the payments by Schering-Plough were for the license rights and not for delay. In particular, the Commissioners pointed to evidence -- including Schering-Plough's previous valuation of a similar opportunity -- that the payments overstated the value of the license rights that Schering-Plough obtained. Schering-Plough is pursuing an appeal in the Eleventh Circuit.

6. 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. See In re K-Dur Antitrust Litig., 176 F. Supp. 2d 1377 (J.P.M.L. 2001). Class action cases have also been filed in various state courts, including New York, Louisiana, Massachusetts and Maine.

7. Noteworthy decisions include McGrew v. Schering-Plough Corp., 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; and In re K-Dur Antitrust Litig., 338 F. Supp. 2d 517 (D.N.J. 2004) rejecting defendants' argument that plaintiffs' federal antitrust claims were barred under the applicable statute of limitations since the suit was not filed until more than four years after the settlement agreements and holding plaintiffs stated a claim for restraint of trade under Section 1 of the Sherman Act, conspiracy, unjust enrichment and fraud.

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. ("Andrx").

3. There have been no noteworthy antitrust decisions in the class actions to date, as the case remains on the Civil Suspense Docket pending the Federal Circuit review of the March 14, 2003 decision holding the Naprelan patent invalid. See Action Alliance of Senior Citizens of Greater Philadelphia v. Elan Corp., PLC, Civ. No. 02-CV-2095, 2003 WL 22358451 (E.D. Pa. Sept. 05, 2003). However, the court dismissed a separate antitrust action filed by Andrx based on the Elan-Skyepharma settlement. See Andrx Pharmaceuticals, Inc. v. Elan Corp., PLC, Case No. 00-3481-CIV-Jordan (S.D. Fla. April 24, 2003). The court held that Andrx's allegations showed nothing more than a cross-licensing agreement between Elan and Skyepharma, which was not unlawful. The court emphasized that Andrx had not alleged that Elan paid Skyepharma not to trigger the 180-day exclusivity period but merely alleged that Skyepharma had no intention of doing so.

F. *Nolvadex (Tamoxifen Citrate)*

1. Nolvadex (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 ("Imperial") (an affiliate of AstraZeneca) and Barr Laboratories ("Barr") 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 (Fed. Cir. 1993). Under the alleged agreement, Imperial licensed Barr to sell Nolvadex, 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 antitrust and consumer fraud actions against Barr and Zeneca in the Eastern District of New York. See In Re Tamoxifen Citrate Antitrust Litig., 196 F. Supp. 2d 1371 (J.P.M.L. 2001). The plaintiffs in these actions asserted that the defendants' settlement of the patent litigation restrained trade by allocating the alleged market for and raising the price of tamoxifen citrate. The court granted defendants' motions to dismiss pursuant to Rule 12(b)(6). In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121 (E.D.N.Y. 2003). The court distinguished the challenged settlement agreement from other "branded-generic" agreements held to be *per se* unlawful because it settled the patent litigation in its entirety. The court also held, among other things, that the plaintiffs had not suffered a cognizable antitrust injury because no competing manufacturer of tamoxifen had obtained approval to market a generic product as each subsequent effort to challenge the patent had failed. This decision is currently being appealed.

4. Other noteworthy decisions related to this case 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, 238 F. Supp. 2d 236 (D.D.C. 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 and Mylan Pharmaceuticals, Inc. ("Mylan") to settle patent infringement litigation in 2000.

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, a later ANDA filer, 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 Corporation’s (“Biovail”) 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 ground that the agreement unfairly extended Mylan’s 180-day exclusivity period. See Biovail Corp. v. Mylan Laboratories, Inc., No. 1:01-CV-00066 (N.D. W.Va. May 01, 2001). In addition, at least five health plans and multiple consumers have filed suits alleging violations of Section 1 of the Sherman Act and seeking class action relief. The cases were transferred to the U.S. District Court for the District of District of Columbia, In re Nifedipine Antitrust Litig., 266 F. Supp. 2d 1382 (J.P.M.L. 2003), where the court recently granted defendants’ motions to dismiss federal and state law claims seeking injunctive relief for lack of subject matter jurisdiction. See In re Nifedipine Antitrust Litig., 335 F.Supp.2d 6 (D.D.C. 2004) (dismissing end-payor plaintiffs’ case in its entirety).

5. Noteworthy decisions include: Pfizer, Inc. 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; and Mylan Pharmaceuticals, Inc. v. Thompson, 207 F. Supp.2d 476 (N.D. W.Va. 2001), denying Mylan’s request for a preliminary injunction against the FDA to vacate the approval of Biovail’s ANDA.

H. 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. As discussed in the next section, 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. In addition, Asahi Glass Co. Ltd. (“Asahi”), a supplier of bulk paroxetine, also filed suit against GSK challenging a settlement agreement between GSK and Pentech Pharmaceuticals (“Pentech”) resolving one of the underlying patent infringement cases. The settlement agreement provided that GSK would supply Pentech with free paroxetine hydrochloride and granted Pentech a license to market a paroxetine hydrochloride subject to certain geographic and other restrictions. The court (Judge Richard Posner, sitting by designation) granted GSK’s motion to dismiss the federal patent and antitrust claims, finding that Asahi did not have standing and that, even if it did, the settlement agreement was not unlawful. See Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., Civ. No. 03 C 3646, 2003 WL 22462405 (N.D. Ill. Oct. 29, 2003). Among other things, the court held that “[t]he general policy of the law is to favor the settlement of litigation, and the policy extends to the settlement of patent infringement suits.” The court explained -- absent a situation in which the patentee “knows” the patent “is almost certainly invalid” or there is something “suspicious about the circumstances of a settlement” -- that “a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation.” The case was ultimately dismissed by agreement on appeal in June 2004. See Asahi Glass Co., Ltd. v. Pentech Pharmaceuticals, Inc., No. 04-1195, 2004 WL 1588195 (Fed. Cir. Jun 30, 2004).

I. *Children’s Liquid Motrin (Liquid Ibuprofen)*

1. In August 2004, the FTC filed a complaint for injunctive and equitable relief against generic drug manufacturers Perrigo Co. (“Perrigo”) and Alpharma, Inc. (“Alpharma”) alleging the competitors drove up the price of store-brand children’s liquid ibuprofen for wholesale customers in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a). See F.T.C. v. Perrigo Co., File No. 021 0197 (D.C.C. 2004), available at <http://www.ftc.gov/opa/2004/08/perrigoalpharma.htm>. Private lawsuits have followed, including a complaint filed by fifty state attorneys general in the U.S. District Court of the District of Columbia.

2. According to the FTC’s complaint, in 1996 Perrigo and Alpharma each filed applications with the FDA for approval to sell a generic -- or “store brand” -- version of the over-the-counter drug children’s liquid Motrin, used to relieve pain and reduce inflammation. Both companies expected to receive final approval for their products in June 1998. An April 1998 change in the FDA’s regulations, however, gave Alpharma the 180-day period of market exclusivity. The FTC alleged that in June 1998 the companies negotiated an agreement under which Perrigo could sell its product during the exclusivity period and Alpharma would not enter the market for seven years. In return, Alpharma was to receive an up-front payment of \$3.5 million and a royalty on Perrigo’s sales of the drug.

3. Shortly after the FTC complaint was filed, each company entered into a separate consent orders calling for Perrigo to pay \$3.75 million and Alpharma to

pay \$2.5 million in illegal profits, for a total disgorgement of \$6.25 million. The settlements also forbid the companies from entering into agreements not to compete where one party is the first filer of an ANDA. In addition, the companies agreed to pay the state attorneys general an additional \$1.5 million lieu of civil fines or forfeitures to resolve their claim challenging the agreement.

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. See *In re Buspirone Patent Litigation*, 176 F. Supp. 2d 1374 (J.P.M.L. 2001). 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 August 19, 2002, the court granted the direct purchasers’ motion for class certification. See *In re Buspirone Patent Litig.*, 210 F.R.D. 43 (S.D.N.Y. 2002). On January 7, 2003, BMS announced that it had reached an agreement in principle to settle “substantially all” BuSpar antitrust litigation for \$535 million, including claims by state’s attorney general (\$100 million); consumers, consumer organizations, and third-party payors (\$90 million); and direct purchasers (\$220 million). These settlements have received final court approval. See <http://www.busparsettlement.com>.

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

2. On October 18, 2004, the court granted preliminary approval to a \$65 million settlement for indirect purchasers. See Nichols v. SmithKline Beecham Corp., Master File 00-CV-6222 (E.D. Pa. Oct. 18, 2004) (order certifying settlement class and preliminarily approving settlement); see also <http://www.paxilclaims.com>. A final approval hearing will be held on March 9, 2005. On November 2, 2004, the court granted preliminary approval to a \$150 million settlement for direct purchasers. See The Stop & Shop Supermarket Co. v. SmithKline Beecham Corp., Civ. Act. No. 03-4578 (E.D. Pa. Nov. 2, 2004) (order preliminarily certifying settlement class and preliminarily approving settlement); see also <http://www.paxilsettlement.com>. A fairness hearing on the direct purchaser settlement was conducted on January 27, 2005.

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. See SmithKline Beecham Corp. v. Geneva Pharm., Inc., C.A. No. 99-CV-2926, 2002 U.S. Dist. LEXIS 25275 (E.D. Pa. Dec. 20, 2002). 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.

4. On September 29, 2004, a federal judge in Philadelphia dismissed certain of Apotex’s antitrust claims against GSK to the extent that they were based on GSK’s agreement with another generic manufacturer to allow that manufacturer to market its own “authorized generic” version of Paxil during Apotex’s 180-day exclusivity period. See SmithKline Beecham Corp. v. Apotex Corp., Nos. 99-CV-2926, 99-CV-4304, 00-CV-1393, 00-CV-2888, 00-CV-5953, 00-CV-6464, 01-CV-0159, 01-CV-1027, 01-CV-2169, 01-CV-2602, 01-CV-2981, 01-CV-3364, 02-CV-1484, 02-CV-8493, 03-CV-3365, 03-CV-6117, 2004 WL 2222388, at *12 (E.D. Pa. Sep. 29, 2004). Among other

things, the court found that the so-called “authorized generic” agreement was not anti-competitive because it allowed for an increase in competition.

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) (“Ivax”) and Zenith Goldline Pharmaceuticals, Inc. (“Zenith”).

2. BMS was sued by numerous states and in multiple class actions. On January 7, 2003, BMS announced that it had reached an agreement to settle the Taxol antitrust litigation for \$135 million. A final order approving the \$65 million direct purchaser class settlement was entered on August 15, 2003. A final order approving the \$15.2 million third-party payor class settlement was entered on October 22, 2003. See VistaHealth Plan, Inc. v. Bristol-Myers Squibb Co., 287 F. Supp. 2d 65 (D.D.C. 2003). On November 19, 2003, the court granted final approval to a \$50 million indirect purchaser class settlement for the benefit of consumers and state agencies.

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; 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; and Xechem, Inc. v. Bristol-Meyers Squibb Co., 274 F. Supp. 2d 937 (N.D. Ill. 2003) upheld in 2003 WL 22844402 (N.D. Ill. Nov. 26, 2003), holding that lack of ANDA by potential generic did not mean that it could not show preparedness to enter the market for standing purposes but dismissing the plaintiff’s claim as untimely under the applicable four-year statute of limitations. On February 6, 2004, an appellate court lifted an injunction issued on Dec. 30, 2003, that prevented Mylan Laboratories Inc. from marketing paclitaxel.

4. BMS also entered into a consent decree with the FTC regarding its conduct in connection with the Taxol patent.

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/biovailelan_agreement.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. These cases were consolidated by the Judicial Panel on Multidistrict Litigation in the District of District of Columbia on May 29, 2003. See In re Nifedipine Antitrust Litig., 266 F.Supp.2d 1382 (J.P.M.L. 2003). Noteworthy decisions include, In re Nifedipine Antitrust Litig., 335 F. Supp. 2d 6 (D.D.C. 2004), which dismissed with prejudice the claims of end-payors who sought declaratory and injunctive relief under the Clayton Act and monetary damages under various state antitrust and consumer protection statutes. Id. at 16-19.

B. *Ceclor (Cefaclor)*

1. Eli Lilly & Co. ("Lilly") 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. *Ativan & Tranxene (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. See In re Lorazepam & Clorazepate Antitrust Litig., 205 F.R.D. 369 (D.D.C. 2002). The court also approved settlements of approximately \$35 million for third-party payors. See id. On June 16, 2003, the court approved a \$35 million settlement for the direct purchaser class. See In re Lorazepam & Clorazepate Antitrust Litig., No. MDL 1290, 99MS276, Civ. 99-0790, 2003 WL 22037741, 2003-1 Trade Cas. (CCH) 74,134 (D.D.C. June 16, 2003); see also <http://www.mylansettlement.com>.

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 an 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; and 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.

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 ("Warner-Lambert") (which was acquired by Pfizer, Inc. "Pfizer") for the treatment of epilepsy. 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 designed to block generic competition. In August 2002, seventeen class action antitrust cases were consolidated in the District of New Jersey for coordinated pretrial proceedings. See In re Neurontin Antitrust Litig., 217 F. Supp. 2d 1380 (J.P.M.L. 2002). There have been no noteworthy antitrust decisions in this litigation to date, as proceedings were suspended until summary judgment motions in the underlying patent litigation were decided.

F. Prilosec (Omeprazole)

1. Prilosec (omeprazole) is a drug manufactured by AstraZeneca that is used to treat heartburn, ulcers, and reflux. AstraZeneca sued multiple defendants, including Andrx, Cheminor and Genpharm Inc., for infringement of three patents relating to Prilosec.

2. 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. In Twin City Bakery Works and Welfare Fund v. Astra Aktiebolag, 207 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.

3. 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. See Astra Aktiebolag v. Andrx Pharms., Inc., 222 F. Supp. 2d 423 (S.D.N.Y. 2002). This decision

was affirmed by the Federal Circuit in December 2003. See In re Omeprazole Patent Litig., 84 Fed. Appx. 76 (Fed. Cir. 2003).

4. In a separate phase of the trial, the federal district court held defendant Andrx literally infringed on Astra's '281 patent, which addresses the method for making the dosage form of proron pump inhibitors. See In re Omeprazole Patent Litig., NO. M-21-81BSJ, 2004 WL 1171254 (S.D.N.Y. May 25, 2004). However, the court determined that the '281 patent was invalid due to prior art and obviousness. 2004 WL 1171254, at *8-13.

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.

3. Following that decision, antitrust lawsuits were filed by individual generic manufacturers and individual direct purchasers, and class actions were filed by direct and indirect purchasers alleging that GSK violated Section 2 of the Sherman Act by prosecuting sham patent infringement litigation. On October 29, 2003, the court granted a motion to certify a direct purchaser class. See In re Relafen Antitrust Litig., 218 F.R.D. 337 (D. Mass. 2003). After rejecting a motion to certify a nationwide class of end-payors, see In re Relafen Antitrust Litig., 225 F.R.D. 14 (D. Mass. 2004), an exemplar end-payor class, consisting of consumers and third party payors, was certified in November 2003. See In re Relafen Antitrust Litig., 221 F.R.D. 260 (D. Mass. 2004). GSK agreed to settle the class-action lawsuits brought on behalf of wholesalers and indirect purchasers as well as the lawsuits filed by the individual purchasers and generic manufacturers. On April 2, 2004, the court approved a \$175 million class action settlement for direct purchasers. On November 24, 2004, the court granted preliminary approval to a \$75 million class action settlement for the consumers and third-party payors. See In re Relafen Antitrust Litig., --- F.Supp.2d ----, 2005 WL 418086, at *23 (D. Mass. Feb 22, 2005); see also <http://www.relafenclassaction.com>. A final approval hearing is scheduled for May 4, 2005.

4. Noteworthy decisions include: In re Relafen Antitrust Litig., 346 F.Supp.2d 349, 358-70 (D. Mass. 2004), an opinion elaborating on the court's previous order granting in part and denying in part defendants' motions for summary judgment, holding that plaintiffs' sham litigation and Walker Process fraud claims turn on the state of GSK's knowledge at the time the '639 patent application was filed and since the case presented numerous factual disputes surrounding that question, the case inappropriate for summary judgment on these claims, rejecting GSK's argument that the court could decide the *Noerr-Pennington* issues as a matter of law.

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. GSK filed a motion to dismiss arguing that the plaintiffs could not show a causal connection between the alleged sham patent litigation and the failure of a generic drug to enter the market. The generic drug manufacturers had been unable to obtain FDA approval and GSK argued that this failure had nothing to do with the patent litigation. The district court rejected this argument, holding that the allegedly frivolous lawsuits could have delayed FDA approval: "In the face of these patent lawsuits, it is reasonable to infer that [generic drug manufacturers] directed resources away from FDA approval and toward the defense of the infringement actions and, furthermore, that this reallocation of funds resulted in a delay of FDA approval. In re Wellbutrin SR/Zyban Antitrust Litigation, 281 F.Supp.2d 751, 757 (E.D. Pa. 2003). The case was later voluntarily dismissed without prejudice.

I. *OxyContin* (oxycodone hydrochloride)

1. *OxyContin* is a narcotic painkiller produced by Purdue Pharma L.P. ("Purdue"). In 2000, Endo Pharmaceuticals Inc. ("Endo") filed an ANDA seeking FDA approval for various strengths of oxycodone hydrochloride extended-release tablets. Purdue filed several patent infringement suits against potential generic competitors, including Endo. In an earlier suit, Purdue was granted a preliminary injunction barring generic manufacture Roxane Laboratories, Inc. from selling its controlled release oxycodone product. See Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 98 F.Supp.2d 362 (S.D.N.Y. 2000), aff'd 237 F.3d 1359 (Fed. Cir. 2001). On July 31, 2002, the FDA granted Endo tentative approval of its 10 mg, 20 mg, 40 mg and 80 mg doses. See <http://www.fda.gov/cder/approval/index.htm>.

2. On January 5, 2004, following a bench trial, the U.S. District Court for the Southern District of New York held several of Purdue's *OxyContin* patents invalid because Purdue had engaged in inequitable conduct during its prosecution of those patents before the Patent and Trademark Office, including intentionally misrepresenting material facts and deliberating misleading officials about the effectiveness of *OxyContin* at low doses. See Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., Civ. No. 00 CIV. 8029, 01 CIV. 2109, 01 CIV. 8177, 2004 WL 26523 (S.D.N.Y. Jan. 05, 2004). Although Purdue had proven by a preponderance of the evidence that Endo infringed the patents at issue, the infringement claims were dismissed due to Purdue's inequitable conduct and Purdue was enjoined from enforcing its patents. On February 17, 2004, the Court denied Purdue's motion to suspend the injunction while it appealed the decision to the Federal Circuit. See Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., Civ. No. 00 CIV. 8029, 01 CIV. 2109, 01 CIV. 8177, 2004 WL 306591 (S.D.N.Y. Feb 17, 2004),

appeal dismissed in part by, 2004 WL 1530980, at *1 (Fed. Cir. Jun 18, 2004). The remainder of Purdue's appeal is still pending. In addition, Endo's antitrust counterclaims, which were bifurcated from the patent issues, are still before the District Court.

3. Following the District Court's decision, insurance companies Aetna Inc. and Humana brought an antitrust suit in the Southern District of New York alleging Purdue illegally blocked the sale of generic OxyContin. Several class action suits have been filed on behalf of end users and third party payors by consumer-advocate groups and a union welfare fund. While some of these case have been consolidated in the Southern District of New York, see, e.g., Balloveras v. The Purdue Pharma Co., No. 04-20360-CIV, 2004 WL 1202854, at *2 (S.D. Fla. May 19, 2004); Burse v. Purdue Pharma Co., No. C-04-594, C-04-713, 2004 WL 1125055, at *3 (N.D. Cal. May 3, 2004); Lynn v. Purdue Pharma Co., No. Civ.04-0300, 2004 WL 1242765, at *4 (D.N.M. Jun 07, 2004), Schecher v. Purdue Pharma L.P., 317 F. Supp. 2d 1253, 1263 (D. Kan. 2004); Williams v. The Purdue Pharma Co., No. Civ.A. 04-451, 2004 WL 1219061, at *2 (D.D.C. June 3, 2004), at least one such suit has been remanded to state court due to the absence of a substantive federal question. See Coker v. Purdue Pharma Co., 314 F. Supp. 2d 777, 784 (W.D. Tenn. 2004). These suits remain in their initial stages.

4. In January 2004, the Attorney General of Connecticut, in cooperation with other state's Attorney Generals, began investigating whether Purdue's actions caused states to overpay for OxyContin used by Medicaid recipients. See John Christoffersen, "Connecticut Attorney General Vows OxyContin Investigation," Newsday, Jan. 6, 2004. The Connecticut Attorney General, noted the court's patent "decision provides a very clear road map for [antitrust] claims based on its dramatic findings of anticompetitive and possibly deceptive conduct." Id. In addition, he commented, "[t]here are few investigations that begin with such a powerful and compelling federal court finding about anticompetitive conduct as we seem to have here." Id.

J. *Augmentin (amoxicillin & potassium clavulanate)*

1. On May 23 2002, a federal district court declared three of GlaxoSmithKline's ("GSK") patents for the antibiotic Augmentin invalid. See Geneva Pharms. v. Glaxosmithkline PLC, 189 F. Supp. 2d 377 (E.D. Va. 2002) and Geneva Pharms., Inc. v. Glaxosmithkline PLC, 213 F. Supp. 2d 597 (E.D. Va. 2002). After a bench trial, the Court held that three of GSK's patents set to expire in December 2002 were invalid for double-patenting. Previously, the Court ruled four patent scheduled to expire in 2017 and 2018 were invalid. These decisions were upheld in November 2003. See Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373 (Fed. Cir. 2003).

2. GSK has been named in several putative class action suits by indirect purchasers and third party payors alleging that the company unlawfully suppressed competition from generic alternatives to Augmentin and maintained an

illegal monopoly. In July 2004, GSK agreed to settle the claims of individual consumers and third party payors. See Ryan-House v. Glaxosmithkline PLC, Civ. Action. No. 2:02-CV-442 (E.D. Va. July 28, 2004) (order certifying settlement class and preliminarily approving settlement). Following a fairness hearing on October 28, 2004, the district court approved a \$29 million settlement. See <http://www.augmentinlitigation.com>.

3. Generic manufacturer Geneva Pharmaceuticals, Inc. also filed an antitrust suit against GSK in December 2003. There have been no noteworthy decisions published to date.

K. Remeron (Mirtazapine)

1. Remeron (mirtazapine) is an antidepressant manufactured by Organon, Inc. ("Organon") which stimulates the body's release of norepinephrine and serotonin while also blocking two specific serotonin receptors. In 1996, Organon was granted United States Patent No. 5,977,099 (the "'099 patent") for a method of treating depression using a combination of mirtazapine and a selective serotonin reuptake inhibitor ("SSRI"). Organon, however, did not submit an NDA to gain FDA approval for this combination use of mirtazapine. Organon later listed the '099 patent in the Orange Book. After Organon's original patent (4,062,848) on mirtazapine expired in 2001, several generic drug manufacturers, filed ANDAs seeking approval for their generic version of mirtazapine. Organon, and its patent company Akzo Nobel N.V., subsequently filed inducement of infringement actions against ANDA filers Mylan Pharmaceuticals, Inc. ("Mylan"), Teva Pharmaceuticals USA, Inc. ("Teva"), and Alphapharm Pty Ltd. ("Alphapharm") (collectively "Defendants"), alleging Defendants, by encouraging the substitution of generic mirtazapine for Remeron-SSRI combination therapy, would induce doctors and pharmacists to infringe its '099 patent. The generic manufacturers asserted fraud and antitrust counterclaims under Section 1 of the Sherman Act for by fraudulently obtaining the '099 patent, improperly listing the patent in Orange Book, and asserting the inducement infringement.

2. On the claims inducement of infringement of the '099 patent, summary judgment was granted to Mylan and Teva. See Organon, Inc. v. Teva Pharmaceuticals, Inc., 244 F. Supp. 2d 370 (D.N.J. 2002). The court rejected Organon's argument that its listing of the '099 patent in the Orange Book was a protected activity under the *Noerr-Pennington* doctrine. The court, however, did find that Organon's infringement suits against generic manufacturers were not "sham" litigation that fell outside of *Noerr-Pennington* immunity. The appeal of this decision was dismissed. See Organon Inc. v. Mylan Pharmaceuticals, Inc., No. 03-1216, 03-1217, 03-1218, 2003 WL 460442 (Fed. Cir. Feb. 05, 2003).

3. The court later dismissed the generic manufacturers' federal antitrust counterclaims, except for claim that Organon committed fraud on the Patent and Trademark Office. See Organon Inc. v. Mylan Pharms., Inc., 293 F. Supp. 2d 453 (D.N.J. 2003). In finding Organon entitled to *Noerr-Pennington* immunity and that its

patent enforcement did not constitute “sham” litigation even though summary judgment was granted to generic manufacturers on infringement claim, the court held that at the time it initiated the infringement suit, Organon had “an objective basis to believe it could assert a claim of patent infringement with a reasonable calculation of a favorable outcome.” Id. at 461.

4. Direct and indirect purchasers, including consumers, employees, and union health and welfare funds, brought antitrust class actions alleging Organon unlawfully filed patent applications in order to prevent generic competitors from entering the market. These cases were consolidated in U.S. District Court for the District of New Jersey. States attorney general also brought antitrust claims against Organon. In October 2004, Organon and Akzo Nobel N.V. announced a nationwide settlement for consumers, state and local public entity purchasers.

5. In the direct purchaser case, the court in In re Remeron Antitrust Litigation, 335 F. Supp. 2d 522, 531-32 (D.N.J. 2004) permitted the claims of the direct purchasers relating to the alleged gaming of the FDA approval process to delay the entry of generic competition to go forward as part of an overall allegation that Organon’s actions constituted a scheme to monopolize in violation of section 2 of the Sherman Act. Recently, the court rejected the direct purchaser plaintiffs’ “direct evidence” of price after generic entry to establish defendants had monopoly power over the mirtazapine market prior to generic entry. See In re Remeron Antitrust Litig., Master Docket No. 03-0085, -- F. Supp. 2d --- (D.N.J. Feb. 18, 2005) (denying plaintiffs’ motion for partial summary judgment and granting defendants’ motion for summary judgment).

L. Accupril (Quinapril Hydrochloride)

1. Pfizer Inc. (“Pfizer”), the manufacturer of the hypertension treatment Accupril, initiated patent infringement litigation against Teva Pharmaceuticals USA (“Teva”) over Teva’s proposed generic version of Accupril (quinapril hydrochloride). A federal court ruled in October 2003 that Teva’s proposed generic infringed Pfizer’s 4,743,450 patent which expires in 2007, but held that a trial was necessary on Teva’s claim of inequitable conduct and the validity of certain claims. See Warner-Lambert Co. v. Teva Pharmaceuticals USA, 289 F. Supp. 2d 515 (D.N.J. 2003). After trial, the court rejected Teva’s claims the patent was invalid because Pfizer engaged in inequitable conduct. See Warner-Lambert Co. v. Teva Pharmaceuticals USA Inc. et al., No. 99- 922 (DRD), 2004 WL 1498162 (D.N.J. June 29, 2004). The court also rejected Teva’s motion to amend its answer to add antitrust counterclaims.

2. In March 2004, a union benefit fund, on behalf of Accupril end-payers, filed suit in the U.S. District Court for the District of New Jersey, alleging Warner-Lambert Co. (now Pfizer) fraudulently obtained a patent on its Accupril (quinapril hydrochloride) tablets, illegally maintaining a monopoly on the drug by delaying generic competition. See Painters District Council No. 30 Health and Welfare Fund v. Pfizer Inc., D.N.J., No. C04-1020-DRD-SDW, 3/4/04). Specifically, the lawsuit

alleges that Pfizer improperly obtained a stabilization patent (U.S. Patent No. 4,743,450) from the U.S. Patent and Trademark Office by failing to disclose the existence of Vasotec, an earlier hypertension medication made by Merck & Co., as prior art. The plaintiffs have withdrawn all of these lawsuits without prejudice.

IV. Other 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 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 65, 449.

2. The FDA published the final version of the new regulations on June 12, 2003. See <http://www.fda.gov/oc/initiatives/generics/>.

C. Medicare Prescription Drug Improvement And Modernization Act

1. The Medicare Prescription Drug Improvement Act (the "Act"), passed by Congress in December 2003, requires settlement agreements between brand name pharmaceutical manufactures and generic drug applicants to be filed with the FTC and the Department of Justice. Under the Act, agreements regarding the manufacture, marketing, sale or exclusivity period of the branded or generic drug for which an ANDA has been submitted must be filed within ten business days after the agreement is executed. The filing requirements only apply to agreements made after January 7, 2004. |

2. A copy of the Pharmaceutical Agreement Filing Requirements can be found at: <http://www.ftc.gov/os/2004/01/040106pharmrules.pdf>.