No.

IN THE
Supreme Court of the United States

UPSHER-SMITH LABORATORIES INC.,

Petitioner,

v.

LOUISIANA WHOLESALE DRUG CO., INC. ET AL.,

Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITION FOR WRIT OF CERTIORARI

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August 29, 2012

QUESTION PRESENTED

Whether the Third Circuit erred by holding, contrary to the Second, Eleventh, and Federal Circuits, that an agreement settling patent litigation that does not restrict competition outside the scope of the exclusionary right granted by the patent itself may presumptively violate the antitrust laws.

PARTIES TO THE PROCEEDING AND RULE 29.6 DISCLOSURE STATEMENT

Petitioner Upsher-Smith Laboratories, Inc. has no parent corporation and no publicly held company owns 10% or more of its stock.

Respondents are Louisiana Wholesale Drug Company, Inc.; CVS Pharmacy, Inc.; Rite Aid Corporation; Albertson's, Inc.; Eckerd Corporation; Hy-Vee, Inc.; The Kroger Company; Maxi Drug, Inc.; Safeway, Inc.; Walgreen Company; and Merck & Co., Inc.

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INTRODUCTION

This case presents a clear and acknowledged circuit split warranting this Court's intervention. At least five times in the past eight years, this Court has been asked to address the standard for assessing antitrust liability in cases where patent holders and alleged infringers have settled their disputes on terms that restrict no more competition than the patent itself would preclude. In each instance this Court has declined, presumably because an unbroken line of court of appeals decisions uniformly applied the "scope of the patent" test—a test derived from this Court's precedent, which recognizes that a patent, by definition, confers a lawful monopoly to practice the invention and that agreements that do nothing more than limit competition within the scope of the patent cannot violate the antitrust laws.

That uniformity has now come to an end. In the decision below, the Third Circuit specifically and emphatically rejected the scope of the patent test. Instead, the court adopted an entirely different legal framework in which patent settlements, like the one at issue here, are *presumptively unlawful*. That decision, which guts the exclusionary right conferred by the patent laws, is inconsistent with decisions from the Second, Eleventh, and Federal Circuits, each of which has applied the scope of the patent test. *See FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010); *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008); *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006); *Schering-Plough Corp. v. FTC*, 402

F.3d 1056, 1066 (11th Cir. 2005); *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003).

Rarely is this Court confronted with such a clear and acknowledged circuit conflict on an issue of undoubted national significance. And the conflict is particularly acute (and undeniable) because the Eleventh Circuit in *Schering-Plough* applied the scope of the patent test to reject an antitrust challenge to the *very same settlement agreement* at issue here. It cannot be that a single settlement agreement may violate federal antitrust law in Philadelphia but not in Atlanta. The Framers established a unitary Supreme Court precisely to avoid such conflicts on matters of federal law. If ever there were a clear-cut case where this Court's review is warranted, it is this one.

OPINIONS BELOW

The Third Circuit's opinion is reported at 686 F.3d 197, and is reprinted in the Appendix to the Petition ("App.") at 1a. The district court's unreported order adopting the Special Master's Report and Recommendation is available at 2010 WL 1172995, and reprinted at App. 54a. The Special Master's unreported Amended Report and Recommendation and Order is available at 2009 WL 508869, and reprinted at App. 56a.

JURISDICTION

The Third Circuit entered judgment on July 16, 2012. App. 1a-2a. Petitioners invoke this Court's jurisdiction under 28 U.S.C. § 1254(1).

PERTINENT STATUTORY PROVISIONS

Section 1 of the Sherman Act provides in pertinent part:

> Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.

15 U.S.C. § 1.

The full text of 35 U.S.C. § 271 ("Infringement of patent") is reproduced in the Appendix. App. 128a.

The text of 21 U.S.C. § 355(j) is reproduced in the Appendix. App. 136a.

STATEMENT OF THE CASE

This case turns on the simple and straightforward question whether a patent holder and an alleged infringer violate the antitrust laws by settling their dispute where, as here, the settlement does not restrict competition beyond the exclusionary scope of the patent itself. The answer to that question is no. The law has long recognized the benefits—to the parties, the courts, and the public—of settlement, and has encouraged settlement, including in patent cases.

The decision below, however, would presumptively impose antitrust liability for settlement of patent cases where consideration flows to the alleged infringer, even though consideration is exchanged in every patent settlement. Such a rule would discourage settlements, increase litigation costs, and place greater burdens on the courts. In the context of litigation involving the Hatch-Waxman

Act and generic pharmaceuticals, such a rule would result in diminished competition because generic companies would face greater hurdles to bringing so-called "Paragraph IV" patent challenges and thus would likely challenge fewer drug patents.

A. The Hatch-Waxman Act

The Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act") established a new procedure for obtaining FDA approval to market generic drugs. *See* 21 U.S.C. § 355. The Act balances two primary interests: (1) encouraging the development of generic drugs, and (2) protecting the patent rights of brand-name drug manufacturers to reward their research and development efforts.

The Hatch-Waxman Act made it easier for generic drug companies to introduce competing versions of a brand-name drug by allowing the generic company to rely on the FDA's determination that the brand-name drug is safe and effective. To gain approval, the generic company must file what is known as an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. § 355(j). In the ANDA, the applicant must demonstrate that its generic version of the drug is "bioequivalent" to the branded drug, meaning that it works in the same way and provides the same benefits. *See id.* § 355(j)(2)(A)(iv). To protect the patent rights of the branded manufacturer, however, the Hatch-Waxman Act requires the generic company to file one of four certifications concerning any patent that claims the branded product. *See id.* § 355(j)(2)(A)(vii); *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 677-78 (1990). The certification relevant here is a Paragraph IV certification—a

certification either that the generic drug does not infringe the patent, or that the patent is invalid or unenforceable. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The patents for which certification is required are listed in an FDA publication known as "the Orange Book." *Caraco Pharm. Labs. Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1676 (2012).

Because a Paragraph IV certification amounts to an assertion by the generic company that the patent on a brand-name drug should not be enforced against it, filing a Paragraph IV certification is a technical act of patent infringement, *see* 35 U.S.C. § 271(e), which entitles the branded manufacturer to sue immediately rather than requiring it to wait until the generic company makes potentially infringing sales in the market. Through the resulting litigation, a generic company can obtain a judicial determination of whether the patent is valid or infringed before going to market and before causing economic injury to the branded company. So long as the generic company waits for the judicial determination before going to market, it does not risk paying substantial damages that it might otherwise incur if it were to lose the patent case, because it will not have made any infringing sales.

Nonetheless, such patent litigation is, by its nature, very costly to generic companies operating on thin margins, and forces generic companies to be selective in choosing which patents to challenge. This factor is heightened because the generic company is generating no revenue on sales of the generic product to fund litigation, while the branded company may have hundreds of millions of dollars of revenue at stake in the litigation. If the ability to

settle is restrained, a generic challenger filing a Paragraph IV certification must be prepared *ab initio* to litigate its patent case to the bitter end against the deep-pocketed branded company. While the generic company has no risk of damages, the branded company stands to lose its patent protection if the generic company's challenge is sustained, and it will accordingly spare no cost in litigation. *See generally Tamoxifen*, 466 F.3d at 206-07; *Schering-Plough*, 402 F.3d at 1074.

B. Factual Background

1. The K-Dur Drug and Underlying Patent Litigations

This case involves the drug K-Dur 20 ("K-Dur"), a sustained-release potassium chloride supplement manufactured by Schering-Plough Corp. ("Schering"). On September 5, 1989, Schering obtained U.S. Patent No. 4,863,743 (the "'743 Patent"), which claimed the controlled-release coating applied to the potassium chloride crystals in K-Dur, and listed the patent in the Orange Book as claiming K-Dur. App. 13a, 67a. The patent did not expire until September 5, 2006. App. 8a, 67a.

In August 1995, Petitioner Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), a generic drug manufacturer, sought FDA approval to introduce a competing generic version of K-Dur pursuant to the Hatch-Waxman Act, 21 U.S.C. § 355, and filed an ANDA with a Paragraph IV certification claiming that its generic version of K-Dur did not infringe the '743 Patent. App. 13a, 70a. In response, Schering brought a patent infringement action seeking to enjoin Upsher-Smith from marketing its generic

drug until the '743 Patent expired in September 2006. *See* App. 13a.

Schering's patent case against Upsher-Smith was hotly contested and proceeded through exhaustive fact and expert discovery and summary judgment briefing. App. 72a. In June 1997, on the eve of trial, the parties settled the case, as litigants routinely do. App. 14a, 73a; *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1060 (11th Cir. 2005). Under the terms of the settlement, Upsher-Smith received a license from Schering to market two competing generic K-Dur products beginning in September 2001, a full *five years earlier* than would otherwise have been permitted under the '743 Patent—nearly half of the remaining time on the patent. App. 14a; *Schering-Plough Corp.*, 402 F.3d at 1059. In addition to this patent-shortening settlement, Schering and Upsher-Smith further entered into a license agreement whereby Upsher-Smith agreed to license its "Niacor-SR" product (and five other products) to Schering in exchange for monetary consideration. App. 14a; *Schering-Plough Corp.*, 402 F.3d at 1059-60.

In December 1995, a second generic drug company, ESI Lederle ("ESI"), also sought FDA approval to market a generic version of K-Dur, claiming its product did not infringe the '743 Patent. App. 15a-16a, 75a; *Schering-Plough Corp.*, 402 F.3d at 1060. In response, Schering sued ESI. In late 1996, the parties entered into court-supervised mediation suggested by the presiding Judge. App. 16a; *Schering-Plough Corp.*, 402 F.3d at 1060. After fifteen months of mediation, the parties reached a settlement. *Schering-Plough Corp.*, 402 F.3d at 1060-61. Under the terms of that agreement,

Schering granted ESI a license to market its generic product at the end of 2003, over two and a half years before the '743 Patent expired. App. 16a; *Schering-Plough Corp.*, 402 F.3d at 1060. At the urging of the Magistrate Judge supervising the mediation, the agreement also provided for a payment from Schering to ESI of $5 million, which the Magistrate Judge characterized as "nothing more than legal fees," and the possibility of additional consideration based on when ESI's ANDA was ultimately approved. App. 78a; *see also Schering-Plough Corp.*, 402 F.3d at 1061.

2. The FTC's Antitrust Challenge To The Upsher-Smith And ESI Settlement Agreements

In March 2001, nearly four years after these settlements were entered, the FTC filed an administrative complaint against Schering, Upsher-Smith, and ESI, alleging, *inter alia*, that the settlements constituted illegal agreements in restraint of trade in violation of Section 1 of the Sherman Act and Section 5 of the FTC Act. App. 16a-17a; *Schering-Plough Corp.*, 402 F.3d at 1061. Specifically, the FTC alleged that both agreements contained substantial "reverse payments" from Schering to Upsher-Smith and ESI to keep them off the market, and therefore violated the antitrust laws. App. 17a; *Schering-Plough Corp.*, 402 F.3d at 1061.

The complaint was tried before an Administrative Law Judge ("ALJ"). App. 17a; *Schering-Plough Corp.*, 402 F.3d at 1061. Following a two-month trial that "covered 8,629 pages of transcript, involved forty-one witnesses, and included thousands of

exhibits," *Schering-Plough Corp.*, 402 F.3d at 1068, the ALJ dismissed the FTC's complaint, App. 17a. The ALJ first found that the Upsher-Smith settlement *did not contain a reverse payment*; rather, "[t]he fact testimony at trial was unrebutted and credible in establishing that the licensing agreement was a bona fide arms-length transaction." *In re Schering-Plough Corp.*, No. 9297, 2002 WL 1488085, at *93 (F.T.C. June 27, 2002); *see also* App. 17a; *Schering-Plough Corp.*, 402 F.3d at 1061.

And, the ALJ rejected *per se* antitrust condemnation of either agreement; instead, he found them both lawful, explaining that "[a]pplication of antitrust law to markets affected by exclusionary statutes such as the Patent Act cannot ignore the rights of the patent holder." App. 82a; *In re Schering-Plough Corp.*, 2002 WL 1488085, at *90.

The full Commission reversed. "Although the FTC ostensibly used a truncated rule of reason analysis, it essentially indicated that any settlement involving reverse payments over $2 million ... would be *quid pro quo* for market delay and, thus, illegal." App. 83a; *see also In re Schering-Plough Corp.*, 136 F.T.C. 956, 1062 (2003). The Commission then, after substituting its own factual findings for those of the ALJ, found that Schering's payment to Upsher-Smith was a *quid pro quo* to keep Upsher-Smith off the market (as it found Schering's payment to ESI to be), and thus held the agreements unlawful. *See Schering-Plough Corp.*, 136 F.T.C. at 1052.

Schering and Upsher-Smith sought review in the Eleventh Circuit, which reversed the Commission. That court held the Upsher-Smith and ESI settlements did not to violate the antitrust laws

because neither settlement exceeded "the scope of the exclusionary potential of the ['743] patent." *Schering-Plough Corp.*, 402 F.3d at 1066. Moreover, with regard to the Upsher-Smith settlement, the Court held that the FTC's finding that Schering's payment to Upsher-Smith was not a fair price for the licenses obtained and was instead a *quid pro quo* for delayed market entry was "not supported by law or logic" or substantial evidence. *Id.* at 1070. On these bases, the court continued, "the substantial and overwhelming evidence undercuts the Commission's conclusion that Schering's agreement with Upsher was illegal." *Id.* at 1071.

3. This Case

Shortly after the FTC filed its administrative complaint, Respondents—private plaintiffs—filed this lawsuit challenging the very same settlement agreements, but in the District of New Jersey. They alleged, as had the FTC, that Schering's settlement agreements with Upsher-Smith and ESI violated Section 1 of the Sherman Act, and argued, as had the FTC, that because the agreements contained so-called "reverse payments," they should be held *per se* unlawful. Summary judgment proceedings were held before former District Judge Stephen Orlofsky, acting as Special Master. At the close of discovery, Petitioners moved for summary judgment.

The Special Master issued a lengthy opinion recommending that summary judgment be granted for Petitioners. App. 56a-127a. In so holding, he "appl[ied] an analysis consistent with the approach that has been adopted by the Second, Eleventh and Federal Circuits." App. 116a. "Under that framework, as long as the Upsher and ESI

settlements restrained competition only within the scope of Schering's patent, and the underlying patent lawsuits were not objectively baseless, Defendants are entitled to summary judgment on [ ] Plaintiff's antitrust claims." *Id.* The Special Master then found that neither the Upsher-Smith nor ESI settlement exceeded the scope of the '743 Patent. App. 116a-119a. Indeed, he specifically observed that, with regard to the Upsher-Smith settlement, the Eleventh Circuit had already concluded as much, and that with respect to the ESI settlement, plaintiffs "have not even argued that its terms exceed the exclusionary scope of the patent." App. 118a.

The District Court reviewed the Special Master's Report and Recommendation de novo and adopted it as the opinion of the court. App 54a-55a. Plaintiffs appealed to the Third Circuit.

The Third Circuit reversed. The court acknowledged that other Circuits apply the "scope of the patent test" under which "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent," but nonetheless "[took] issue with" that test and rejected it. App. 28a, 31a-33a, 39a. Instead, and in sharp contrast to every other circuit court to consider the issue, the Third Circuit held that "the finder of fact must treat any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade." App. 40a-41a.

This petition follows.

REASONS FOR GRANTING THE WRIT

The Court should grant this petition because the Third Circuit has held—in direct and acknowledged conflict with the Second, Eleventh, and Federal Circuits—that a party to a settlement of patent litigation that restricts competition only within the exclusionary potential of the patent may nonetheless be subject to liability under the antitrust laws. In the context of this case, it subjects Petitioner to different standards for assessing antitrust liability over the same settlement agreement—one that fully exonerates it, the other that renders its agreement presumptively unlawful. That division over the very same settlement agreement warrants this Court's review. Applying the proper test, as the Eleventh Circuit (and the district court in this case) did, Petitioner is entitled to judgment in its favor as a matter of law. Regardless, allowing uncertainty and confusion to linger over the proper test will serve only to deter generic companies from making patent challenges in the first place, thereby resulting in less competition for pharmaceuticals.

The Court should further grant review because the Third Circuit's novel holding is manifestly incorrect and runs counter to this Court's settled antitrust and patent-law precedents, which undergird the until-now unanimously accepted and applied scope of the patent test.

A. The Decision Below Conflicts With The Decisions Of Every Other Court Of Appeals To Review The Antitrust Implications Of Hatch-Waxman Patent Settlements.

As the Third Circuit recognized, prior to its decision, every court of appeals to have evaluated whether an agreement settling Hatch-Waxman patent litigation had reached the same conclusion: such settlements cannot, as a matter of law, sustain antitrust liability as long as they do not restrain competition beyond the scope of the exclusionary potential of the patent. *See* App. 28a, 31a-32a. This conclusion stems from the uniform application of the "scope of the patent" test by the Second, Eleventh, and Federal Circuits (as well as several federal district courts). And these Circuits have explained this test in nearly identical language:

- **Second Circuit:** *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187, 213 (2d Cir. 2006) ("[T]he question is whether the 'exclusionary effects of the agreement' exceed the 'scope of the patent's protection.'") (citation omitted), *cert. denied sub nom. Joblove v. Barr Labs., Inc.*, 551 U.S. 1144 (2007); *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105 (2d Cir. 2010) ("[T]his Court [has] held that the right to enter into reverse exclusionary payment agreements falls within the terms of the exclusionary grant conferred by the branded manufacturer's patent.") (citation omitted), *cert. denied sub nom. Louisiana Wholesale Drug Co. v. Bayer AG*, 131 S. Ct. 1606 (2011).

- **Eleventh Circuit:** *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1310 (11th Cir. 2003) ("When the exclusionary power of a patent is implicated ... the antitrust analysis cannot ignore the scope of the patent exclusion."), *cert. denied*, 543 U.S. 939 (2004); *Schering-Plough Corp. v. FTC*, 402 F.3d 1056, 1066 (11th Cir. 2005) ("[T]he proper analysis of antitrust liability requires an examination of ... the extent to which the [settlement] agreements exceed th[e] scope ... of the exclusionary potential of the patent...."), *cert. denied*, 548 U.S. 919 (2006); *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012) ("[A]bsent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.").

- **Federal Circuit:** *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1336 (Fed. Cir. 2008) ("The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent."), *cert denied sub nom. Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 129 S. Ct. 2828 (2009).

Under this test, as the Federal Circuit has explained, "[a] settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled—a monopoly over the manufacture and distribution of the patented invention." *Ciprofloxacin*, 544 F.3d at 1337. After all, "a patent by its very nature is anticompetitive," *id.* at 1333, meaning that "[w]hatever damage is done to

competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly," *Tamoxifen*, 466 F.3d at 212-13. "[T]he outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent." *Ciprofloxacin*, 554 F.3d at 1336. As long as the settlement agreement does no more than confirm a bar on conduct that the patent itself precludes, there is no antitrust violation as a matter of law.

The Third Circuit acknowledged the uniform application of the scope of the patent test by the other courts of appeals. *See* App. 28a, 31a-32a. Nonetheless, the court "[took] issue with" the test and "reject[ed]" it in favor of a rule that whenever Hatch-Waxman patent settlements contain the exchange of monetary consideration, "any payment from a patent holder to a generic patent challenger who agrees to delay entry into the market" constitutes "*prima facie* evidence of an unreasonable restraint of trade." App. 33a, 39a-41a. In other words, the Third Circuit held such settlements presumptively unlawful. It became the first and only court to do so.[1]

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[1] The Third Circuit's claim that two other Circuits, the Sixth and D.C. Circuits, have rejected the scope of the patent test is without merit and—even if meritorious—would only reflect a deeper circuit split. *See* App. 22a-25a (citing *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003), *Andrx Pharm. Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001)

This clear conflict on the seminal—and virtually dispositive—legal question of the standard by which patent litigation settlements are to be judged requires the Court's review. And in particular, the Court should review *this case* to resolve the circuit split over the settlement agreement specifically involved here. The Eleventh Circuit considered—and rejected—a Sherman Act challenge to the very settlement at issue here precisely because it did not restrain competition beyond the scope of the '743 Patent. Yet, different plaintiffs, solely by virtue of filing suit in a different forum, were able to make an end-run around that holding, and the finality it was

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(considering the same settlement agreement as *Cardizem*)). The settlement agreement at issue in both *Cardizem* and *Andrx*—interim agreements that did not finally terminate patent litigation—went *beyond* the scope of the patent monopoly; it "included not only a substantial reverse payment but also an agreement that the generic manufacturer would not market *non*-infringing products." *Tamoxifen*, 466 F.3d at 213-14 (emphasis added). In fact, the Sixth Circuit in *Cardizem* cited the district court's scope of the patent decision in *Ciprofloxacin* with approval. *See Cardizem*, 332 F.3d at 907 n.12. Even FTC, which has repeatedly challenged the scope of the patent test, conceded as much in its briefing to the Third Circuit in this very case. *See* Br. for the FTC as *Amicus Curiae*, *In re K-Dur Antitrust Litig.*, Nos. 10-2077, 10-2078, 10-2079 (3d Cir. May 18, 2011), 2011 WL 2115235, at *16 n.21. The Solicitor General has echoed this point as well. *See, e.g.*, Br. for the U.S. as Amicus Curiae, *Joblove v. Barr Labs., Inc.*, No. 06-830 (U.S. May 23, 2007), 2007 WL 1511527, at *16 n.7 ("*Cardizem* involved payments to exclude competition in drugs that did *not* fall within the scope of the allegedly infringed patent, and thus it is uncertain whether the per se rule employed by the Sixth Circuit extends beyond the unique circumstances of that case.").

supposed to bring, because a different court "[took] issue with" the heretofore universally-applied (and well-grounded) scope of the patent test. Petitioner cannot be forced to live under different standards governing the exact same agreement, and this Court should intervene. To do otherwise perpetuates inconsistency and uncertainty, and invites inevitable forum shopping, in which the generic pharmaceutical industry must (try to) abide by the lowest common denominator.

Faced with uncertainty over liability arising from patent litigation settlements, generic companies will be chilled from bringing patent challenges in the first place. If the ability to settle is restrained or even uncertain, a generic challenger filing a Paragraph IV certification must be prepared to litigate its patent case to the bitter end—an expensive proposition for any generic company, especially when facing a branded company who has incentive to "go to the mat" and to spare no expense in litigating against the generic company. And the chilling effect will be even more pronounced given the substantial number of pharmaceutical companies with headquarters in the Third Circuit.

Simply put, generic companies will not be as willing to file a Paragraph IV challenge if they know they must, in effect, litigate to the end to avoid the inevitable antitrust lawsuits that will follow any settlement. As Judge Posner has observed, "[a] ban on reverse-payment settlements would reduce the incentive to challenge patents by reducing the challenger's settlement options should he be sued for infringement, and so might well be thought anticompetitive." *Asahi Glass Co. Ltd. v. Pentech*

Pharm., Inc., 289 F. Supp. 2d 986, 994 (N.D. Ill. 2003) (Posner, J., sitting by designation); *see also Valley Drug*, 344 F.3d at 1308 ("By restricting settlement options, which would effectively increase the cost of patent enforcement, the proposed rule would impair the incentives for disclosure and innovation."); *Tamoxifen*, 466 F.3d at 203 ("Rules severely restricting patent settlements might also be contrary to the goals of the patent laws because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.").

The upshot is disruption to the generic pharmaceutical industry, resulting in less—not more—competition. The Court should grant certiorari to provide much-needed clarity.

B. The Decision Below Contravenes This Court's Settled Patent And Antitrust Precedent.

This Court should further grant review because the Third Circuit's novel holding is manifestly incorrect and runs counter to this Court's settled precedent that undergirds the until-now unanimously accepted and applied scope of the patent test.

The Constitution itself authorizes Congress "[t]o promote the Progress of Science and useful Arts" by granting inventors "the exclusive Right" to their inventions "for limited Times." U.S. Const. Art. I § 8 cl. 8. Congress has exercised that authority by enacting the federal patent laws, which expressly grant patent holders "the right to exclude others from making, using, offering for sale, or selling the invention" for a limited period of time. 35 U.S.C.

§ 154(a)(1). "[T]he essence of a patent grant," as this Court has explained, "is the right to exclude others from profiting by the patented invention." *Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980); *see also Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964) ("The grant of a patent is the grant of a statutory monopoly."); *E. Bement & Sons v. Nat'l Harrow Co.*, 186 U.S. 70, 91 (1902) ("The very object of [the patent] laws is monopoly."). But the Third Circuit's test transforms a patent's exclusionary right into something less.

Because a patent confers the right to restrain competition within its exclusionary zone, by definition there can be no unlawful restraint of competition within that zone. "It is only when [a patent holder] steps *out* of the scope of his patent rights … that he comes within the operation of the Anti-Trust Act." *United States v. Gen. Elec. Co.*, 272 U.S. 476, 485 (1926) (emphasis added); *see also Schering-Plough*, 402 F.3d at 1067 ("A patent holder does not incur antitrust liability when it chooses to exclude others from producing its patented work."); *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708 (Fed. Cir. 1992); *cf. United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963) ("[A] valid patent … does not give the patentee any exemption from the provisions of the Sherman Act *beyond* the limits of the patent monopoly.") (emphasis added).

This is why, unsurprisingly, the Second, Eleventh, and Federal Circuits (as well as other courts) have recognized that an agreement to settle patent litigation cannot be characterized as an unlawful restraint on competition as long as that settlement does not restrict competition beyond the

exclusionary potential of the patent itself—at least where, as here, the underlying patent litigation was not an objectively baseless sham and the patent was not fraudulently procured. *See, e.g.*, *Watson*, 677 F.3d at 1312; *Arkansas Carpenters*, 604 F.3d at 105; *Ciprofloxacin*, 544 F.3d at 1336; *Tamoxifen*, 466 F.3d at 213; *Schering-Plough*, 402 F.3d at 1066; *Valley Drug*, 344 F.3d at 1310; *Asahi Glass*, 289 F. Supp. 2d at 992-93. That approach fully and properly reconciles the federal patent laws with the federal antitrust laws. To attach antitrust liability to a settlement entirely within a patent's exclusionary zone would be to negate the lawful monopoly that lies at the heart of the patent laws.

Simply put, the scope of the patent test ensures harmony between the federal patent and antitrust laws. That approach is hardly novel: To the contrary, it is derived from the long-standing rule, set forth by this Court, that the relevant question in an antitrust challenge concerning a patent is whether the conduct at issue *exceeds* the exclusionary scope of the patent. *See, e.g.*, *Sears, Roebuck & Co.*, 376 U.S. at 230 ("[A patent] cannot be used to secure any monopoly beyond that contained in the patent." (citation omitted)); *Singer Mfg. Co.*, 374 U.S. at 197 ("[T]he possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act beyond the limits of the patent monopoly."*)*; *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) ("A patent affords no immunity for a monopoly not fairly or plainly within the grant."); *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 519 (1917) (similar). Under that settled law, antitrust liability may only lie where a defendant's

conduct exceeds the exclusionary rights granted by the patent. *See, e.g.*, *Singer*, 374 U.S. at 194; *Masonite*, 316 U.S. at 277-78; *Motion Picture Patents*, 243 U.S. at 518-19.

The Third Circuit's decision ignores all of this, treating patents as providing less than exclusionary property rights. First, the court of appeals opined that the scope of the patent test impermissibly creates an "almost unrebuttable presumption of patent validity," whereas the general presumption of patent validity "is intended merely as a procedural device." App. 33a. The court's assertion, however, proceeds from a false premise: courts adopting and applying the scope of the patent test have never suggested that the statutory presumption of patent validity is conclusive or unrebuttable. But regardless, as the Second Circuit has explained, the statutory presumption of patent validity is *not* the cornerstone of the analysis, and "irrespective of whether there was a presumption," a patent holder is "entitled to protect its … patent monopoly through settlement." *Tamoxifen*, 466 F.3d at 209 n.22.

Second, the court of appeals grounded its holding in an amorphous notion of "the public interest [which] supports judicial testing and elimination of weak patents." App. 35a-36a. But the federal patent laws do not require that a patent be "tested" before granting exclusionary rights. The "line of Supreme Court cases" on which the Third Circuit relied to support its contrary premise is wholly inapposite. For example, *Cardinal Chem. Co. v. Morton Int'l Inc.*, 508 U.S. 83, 85 (1993), merely held that reviewing a decision of patent invalidity was not mooted by deciding non-infringement, because a decision on the

former sweeps more broadly than the latter. *See id.* at 85. Similarly, the issue in *Edward Katzinger Co. v. Chi. Metallic Mfg. Co.*, 329 U.S. 394 (1947), *Lear, Inc. v. Adkins*, 395 U.S. 653 (1969), *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173 (1942), and *Pope Mfg. Co. v. Gormully*, 144 U.S. 224 (1892), was whether a patent licensee was estopped from challenging the patent's validity. This Court held in each case that there was no such estoppel, *see* 329 U.S. at 399-401, 395 U.S. at 669-70, 317 U.S. at 176-77, 144 U.S. at 236, but did not remotely suggest that a licensee (or anyone else) is either compelled to launch such a challenge or precluded from settling it on terms the parties see fit. Indeed, in *Sola*, the Court specifically observed that it is only price-fixing agreements "not within the protection of a patent" that are unlawful. 317 U.S. at 176. In sum, this Court's precedent provides no support for the Third Circuit's decision.

At bottom, the court of appeals' decision seems driven by the notion that there must necessarily be something wrong with settlements in which consideration flows from the patent holder to the alleged infringer. That impulse, however, ignores that fact that *all* settlements involve an *exchange of consideration*, and the form of that consideration should have no bearing on the lawfulness of the settlement. *See, e.g.*, *Schering-Plough*, 402 F.3d at 1074 ("[E]ven in the pre-Hatch-Waxman context, implicit consideration flows from the patent holder to the alleged infringer.") (quotation marks omitted); *Tamoxifen*, 466 F.3d at 207 n.20 ("[E]ven the typical settlement of the ordinary patent infringement suit appears to involve what may be characterized as a reverse payment."); *Asahi Glass*, 289 F. Supp. 2d at

994 ("*[A]ny* settlement agreement can be characterized as involving 'compensation' to the defendant, who would not settle unless he had something to show for the settlement.") (emphasis in original). And there is nothing anomalous about the fact that the net flow of monetary consideration may run to the generic challenger in the Hatch-Waxman context for the simple reason that the generic company has yet to begin making infringing sales. As the Second Circuit has explained, if anything, "reverse payments are particularly to be expected in the drug-patent context because the Hatch-Waxman Act created an environment that encourages them." *Tamoxifen*, 466 F.3d at 206.

Unlike in a typical patent infringement case in which the alleged infringer faces potentially crippling damages for selling the patented product, the Hatch-Waxman Act permits a generic company to challenge a patent without entering the market first, which means it is unlikely to face infringement damages. *See id.* at 206-07, 209. For this reason, monetary consideration in a Hatch-Waxman settlement will logically flow from the patent holder to the patent challenger. The "inflexible compromise-without-payment theory" now adopted by the Third Circuit "neglects to understand that 'reverse payments are a natural by-product of the Hatch-Waxman process.'" *Schering-Plough*, 402 F.3d at 1074 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003)).

By holding so-called "reverse payments" to be "*prima facie* evidence of an unreasonable restraint of trade," App. 41a—and thereby holding settlement

agreements with such payments to be presumptively unlawful—the Third Circuit seeks to accomplish, by judicial fiat, exactly what Congress has refused to do. Numerous bills have been introduced in recent years that would have altered the law governing patent settlements and outlawed Hatch-Waxman patent settlements that include monetary consideration. *See*, *e.g.*, H.R. 3995, 112th Cong. (2012); S. 27, 112th Cong. (2011); S. 3677 (amend.), 111th Cong. (2010); S. 369, 111th Cong. (2009); H.R. 3962, 111th Cong. (2009); H.R. 1706, 111th Cong. (2009); S. 316, 110th Cong. (2007); H.R. 1432, 110th Cong. (2007); S. 3582, 109th Cong. (2005). None of these bills, however, has passed.

In the end, basic patent and antitrust law principles do not support the rejection of the scope of the patent test in favor of a presumption of illegality simply because a settlement involves an exchange of consideration. The Third Circuit's contrary conclusion has broad ramifications for the ability of parties to resolve patent disputes in the pharmaceutical sector and beyond. Because the court of appeals' decision is inconsistent with the holdings of every other circuit to reach the issue, as well as this Court's guiding precedents addressing the intersection of patent and antitrust law, this Court should grant review.

CONCLUSION

For the foregoing reasons, the Court should grant this petition for writ of certiorari.

August 29, 2012

Respectfully submitted,

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APPENDIX

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PRECEDENTIAL

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 10-2077

In Re: K-DUR ANTITRUST LITIGATION

Louisiana Wholesale Drug Co., Inc.,
on behalf of itself and all others similarly situated,
Appellants

No. 10-2078

In Re: K-DUR ANTITRUST LITIGATION

CVS Pharmacy, Inc.; Rite Aid Corporation,
Appellants

No. 10-2079

In Re: K-DUR ANTITRUST LITIGATION

Walgreen Co., Eckerd Corporation, The Kroger Co.,
Safeway Inc., Albertson's Inc., Hy-Vee, Inc., and
Maxi Drug, Inc.,
Appellants

No. 10-4571

In Re: K-DUR ANTITRUST LITIGATION

Merck & Co., Inc.;
Upsher-Smith Laboratories, Inc.,
Appellants

On Appeal from the United States District Court for the District of New Jersey
(D.C. No. 2-01-cv-01652)
District Judge: Honorable Garrett E. Brown, Jr.

Argued December 12, 2011

Before: SLOVITER, VANASKIE, *Circuit Judges* and STENGEL*, *District Judge*

(Filed: July 16, 2012)

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OPINION OF THE COURT

SLOVITER, *Circuit Judge*.

In this appeal, we consider the antitrust implications of an agreement by a manufacturer of a generic drug that, in return for a payment by the patent holder, agrees to drop its challenge to the patent and refrain from entering the market for a specified period of time.

A secondary issue concerns the certification by the District Court of a class of antitrust plaintiffs. Specifically, we must determine whether the antitrust injury allegedly suffered by class members can be shown through common proof, i.e. proof applicable to all plaintiffs, and whether there are insurmountable conflicts preventing named plaintiffs from adequately representing the members of the class.

These appeals arise out of the settlement of two patent cases involving the drug K-Dur 20 ("K-Dur"), which is manufactured by Schering-Plough Corporation ("Schering"). Plaintiffs are Louisiana Wholesale Drug Company, Inc., on behalf of a class of wholesalers and retailers who purchased K-Dur directly from Schering and nine individual plaintiffs,

including CVS Pharmacy, Inc., Rite Aid Corporation, and other pharmacies. Defendants are Schering and Upsher-Smith Laboratories ("Upsher Smith").[1]

I. STATUTORY AND REGULATORY FRAMEWORK

K-Dur is Schering's brand-name sustained-release potassium chloride supplement.[2] Sustained-release potassium chloride is used to treat potassium deficiencies, including those that arise as a side effect of the use of diuretic products to treat high blood pressure.

Schering did not hold a patent for the potassium chloride salt itself, as that compound is commonly known and not patentable. Instead, Schering held a formulation patent on the controlled release coating it applied to the potassium chloride crystals. Schering identified patent number 4,863,743 ("the '743 patent") as the patent that would be infringed by the production of a generic version of K-Dur. Schering assigned the '743 patent to its subsidiary Key Pharmaceuticals, Inc. The '743 patent was set to expire on September 5, 2006.

By statute, a pharmaceutical company must obtain from the Food and Drug Administration

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[1] In appeals numbered 10-2077, 10-2078, and 10-2079, Appellants challenge the District Court's grant of summary judgment on behalf of defendants, relying on their patents. In No. 10-4571, defendants challenge the District Court's certification of a class of plaintiffs.

[2] After the facts at issue in this case, Merck & Co. acquired Schering, the named defendant in these actions. However, in keeping with the practice of the parties and amici, the court will refer to Schering.

("FDA") approval before it may market a prescription drug. 21 U.S.C. § 355(a). For a new drug, the approval process requires submission of a New Drug Application ("NDA"), which includes exhaustive information about the drug, including safety and efficacy studies, the method of producing the drug, and any patents issued on the drug's composition or methods of use. *Id.* § 355(b)(1). The FDA publishes the patent information submitted in NDAs in the "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." *See* FDA Electronic Orange Book, http://www.fda.gov/cder/ob/.

In 1984, attempting to jumpstart generic competition with name brand pharmaceuticals, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act. Pub. L. No. 98-417, 98 Stat. 1585 (1984). The Hatch-Waxman Act amended the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399, to permit a potential manufacturer of a generic version of a patented drug to file an abbreviated application for approval with the FDA. *See* 21 U.S.C. § 355(j). This short form application, known as an Abbreviated New Drug Application ("ANDA"), may rely on the FDA's prior determinations of safety and efficacy made in considering the application of the patented drug. *Id.* § 355(j)(2)(A).

When a generic manufacturer files an ANDA, it is also required to file a certification that, "in the opinion of the applicant and to the best of his knowledge," the proposed generic drug does not infringe any patent listed with the FDA as covering

the patented drug. *Id.* § 355(j)(2)(A)(vii). The generic manufacturer can satisfy this requirement by certifying one of the following four options with respect to the patent for the listed drug: "(I) that such patent information has not been filed, (II) that such patent has expired, (III) [by certifying] the date on which such patent will expire, or (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." *Id.* § 355(j)(2)(A)(vii). The generic manufacturers at issue here, Upsher and ESI, used the fourth of these certification options, the so-called "paragraph IV certification." *Id.* § 355(j)(2)(A)(vii)(IV). When a would-be generic manufacturer submits a paragraph IV certification, it must consult the Orange Book and provide written notice to each listed patent owner impacted by the ANDA. *Id.* § 355(j)(2)(B)(iii)(I). By statute, a paragraph IV certification constitutes a technical act of patent infringement. 35 U.S.C. § 271(e)(2)(A).

Upon receiving notice of a paragraph IV certification with respect to one of its pharmaceutical patents, the patent holder may initiate an infringement suit based on the filing of the paragraph IV certification alone within forty-five days after the generic applicant files its ANDA and paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iii). Filing suit by the patent holder within that window effects an automatic stay that prevents the FDA from approving the generic drug until the earlier of (1) thirty months have run or (2) the court hearing the patent challenge finds that the patent is either invalid or not infringed. *Id.* § 355(j)(5)(B)(iii)(I).

Congress explained that the purpose of the Hatch-Waxman Act is "to make available more low cost generic drugs." H.R. Rep. No. 98-857(I), at 14-15, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48. In order to encourage generic entry and challenges to drug patents, the Hatch-Waxman Act rewards the first generic manufacturer who submits an ANDA and a paragraph IV certification by providing it with a 180-day period during which the FDA will not approve subsequent ANDA applications. 21 U.S.C. § 355(j)(5)(B)(iv). The 180-day exclusivity period is triggered on the date on which the first ANDA applicant begins commercial marketing of its drug. *Id.* Notably, the 180-day exclusivity window is only available to the first filer of an ANDA with a paragraph IV certification, meaning that even if the first filer never becomes eligible to use its 180-day exclusivity period because it settles, loses, or withdraws the litigation, that potential benefit will not pass to subsequent filers. 21 U.S.C. § 355(j)(5)(D)(iii). It has been suggested that the first filer is usually the most motivated challenger to the patent holder's claimed intellectual property. *See* C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. Rev. 1553, 1583 (2006) (noting "a sharp difference in incentives ... between [the first paragraph IV] filer and all other generic firms").

As explained further below, in the years after the passage of Hatch-Waxman, some of the patent infringement suits occurring under the Hatch-Waxman framework were resolved through settlement agreements in which the patent holder paid the would-be generic manufacturer to drop its patent challenge and refrain from producing a

generic drug for a specified period. These agreements are known as "reverse payment agreements" or "exclusion agreements." Concerned about the possible anticompetitive effects of reverse payment agreements, *see* S. Rep. No. 107-167, at 4 (2002), Congress amended Hatch-Waxman as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Those amendments require branded and generic pharmaceutical companies who enter into patent litigation settlements to file those settlement agreements with the Federal Trade Commission ("FTC") and the Department of Justice ("DOJ") for antitrust review. Pub. L. No. 108-173, §§ 1111-1118, 117 Stat. 2066, 2461-64 (codified as amended at 21 U.S.C. § 355(j)).

II. FACTUAL AND PROCEDURAL BACKGROUND

A. Approval of the '743 Patent

The patented invention claims a controlled-release dispersible potassium chloride tablet. The '743 patent was developed using a technique called "microencapsulation," a process in which small particles of a drug are coated to make them disperse over time. The research supporting the '743 patent built on work that Schering had done for an earlier patent for a controlled-release aspirin tablet, Patent No. 4,555,399 ("the '399 patent"). The application for what became the '743 patent was initially rejected by the Patent and Trademark Office ("PTO") as obvious in light of the '399 patent and other prior art. In order to circumvent the prior art, Schering amended its application for what became the '743 patent to clarify that the controlled release coating in the invention contained ethylcellulose with a viscosity of

greater than 40 cp,[3] whereas the '399 patent called for the use of ethylcellulose with a viscosity of 9-11 cp. Schering argued that a coating containing ethylcellulose of greater than 40 cp was not obvious under the prior art. After this amendment, the PTO granted the '743 patent on September 5, 1989.

B. The Schering-Upsher Litigation and Settlement

In August 1995, Upsher filed the first ANDA seeking approval to produce a generic version of K-Dur to be called Klor-Con M20. Upsher provided a paragraph IV certification to Schering in November 1995, certifying that its generic would not infringe Schering's '743 patent. On December 15, 1995, within the forty-five-day window provided by Hatch-Waxman, Schering sued Upsher in the District of New Jersey for patent infringement, triggering the 30-month automatic stay in FDA approval of Upsher's generic.

Upsher's defense against Schering's patent infringement suit was based on differences between the chemical composition of the controlled release coating in its generic product and that of the invention claimed in the '743 patent. Throughout the litigation, Upsher vigorously defended against Schering's infringement claims, at one point telling the court that Schering's claims of infringement "are baseless and could not have been made in good faith." App. at 3610.

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[3] Centipoise, abbreviated "cp", is a measure of viscosity. McGraw-Hill Dictionary of Scientific and Technical Terms 354 (6th ed. 2003).

The parties began trying to settle the infringement case at least as early as May 1997. During settlement negotiations, Upsher requested both a cash payment and an early entry date for its generic product. However, Schering expressed concern about possible antitrust problems that might arise if it made a reverse payment.

In the early morning of June 18, 1997, just hours before the District Court was to rule on the pending cross motions for summary judgment and begin, if necessary, a patent trial, Upsher and Schering agreed to settle the case. The settlement was memorialized in an eleven-page short-form agreement dated June 17, 1997 ("the Schering-Upsher agreement"). That agreement provided that, while Upsher did not concede the validity, infringement, or enforceability of the '743 patent, it would refrain from marketing its generic potassium chloride supplement or any similar product until September 1, 2001, at which point it would receive a non-royalty non-exclusive license under the '743 patent to make and sell a generic form of Klor-Con. Additionally, Upsher granted Schering licenses to make and sell several pharmaceutical products Upsher had developed, including Niacor-SR, a sustained-release niacin product used to treat high cholesterol. In return, Schering promised to pay Upsher sixty million dollars ($60,000,000) over three years, plus additional smaller sums depending upon its sales of Niacor-SR in defined markets. While the parties to this litigation dispute whether the payment was solely for the licensing of Upsher products or instead formed part of the consideration for dropping the patent action, the agreement lists Upsher's promises to dismiss the patent

infringement action and not to market any sustained-release microencapsulated potassium chloride tablet until September 1, 2001, as part of the consideration for the payment.

The settlement agreement and the acquisition of licenses from Upsher were ratified by Schering's board of directors on June 24, 1997. Subsequent to the settlement, Upsher and Schering abandoned plans to make and market Niacor-SR.

In this action, the parties dispute the facts related to the Niacor-SR license. Plaintiffs contend that the license was a sham and that the $60 million paid as royalties for Niacor-SR was actually compensation for Upsher's agreement to delay the entry of its generic extended-release potassium tablet. On the other hand, defendants contend that Schering's board valued the license deal separately and that $60 million was its good faith valuation of the licenses at the time.

C. The Schering-ESI Litigation and Settlement

In December 1995, ESI Lederle[4] ("ESI") filed an ANDA seeking FDA approval to make and sell a generic version of K-Dur along with a paragraph IV certification stating that its proposed generic did not infringe the '743 patent. Within the forty-five-day

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[4] ESI is the generic division of American Home Products, Inc., which changed its name to Wyeth in 2002. Melody Peterson, *American Home Is Changing Name to Wyeth*, New York Times, Mar. 11, 2002. Wyeth was subsequently acquired by Pfizer, Inc. in 2009. Pfizer, "Wyeth Transaction," http://www.pfizer.com/investors/shareholder_services/wyeth_transaction.jsp (last visited May 8, 2012). Plaintiffs settled their claims against ESI's corporate parent Wyeth in January 2005.

period provided by the Hatch-Waxman Act, Schering sued ESI for patent infringement in the Eastern District of Pennsylvania. ESI defended on the ground that, unlike K-Dur, its generic equivalent did not employ a "coating material with two different ingredients" as specified by the '743 patent, but rather was made by a "different technology which produces a multi-layered coating with each layer comprised of a separate material having only a single ingredient." App. at 1696-97.

In the fall of 1996, Schering and ESI agreed to participate in court-supervised mediation before a magistrate judge. The settlement agreement the parties eventually reached ("the Schering-ESI agreement") called for Schering to grant ESI a royalty-free license under the '743 patent beginning on January 1, 2004. In exchange, Schering would pay ESI $5 million up front and a varying sum depending on when ESI's ANDA was approved by the FDA. Specifically, Schering agreed to pay ESI an amount ranging from a maximum of $10 million if ESI's ANDA was approved before July 1999 down to a minimum of $625,000 if the ANDA was not approved until 2002. As part of the settlement, ESI also represented that it was not developing and had no plans to develop any other potassium chloride product.

The FDA approved ESI's generic K-Dur product in May 1999, and Schering paid ESI the additional $10 million as required under the settlement agreement.

D. The FTC Action

In March 2001, the FTC filed a complaint against Schering, Upsher, and ESI alleging that Schering's

settlements with Upsher and ESI unreasonably restrained commerce in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Specifically, the FTC alleged that the settlement payments from Schering to Upsher and ESI constituted reverse payments intended to delay generic entry and improperly preserve Schering's monopoly.

In June 2002, after a lengthy trial, the Administrative Law Judge ("ALJ") issued an initial decision dismissing the FTC's complaint and finding that neither agreement violated Section 5 of the FTC Act. *In re Schering-Plough Corp.*, Initial Decision, 136 F.T.C. 1092, 1263 (2002). The ALJ found that there was no reverse payment in the Schering-Upsher agreement because the licensing deal included in that agreement was separately valued and was not a payment to Upsher to delay generic entry. *Id.* at 1243. The ALJ also found that the Schering-ESI agreement was not an attempt to unlawfully preserve Schering's monopoly power in the market. *Id.* at 1236, 1262-63.

In December 2003, the FTC unanimously reversed the ALJ's ruling, finding that there was a "direct nexus between Schering's payment and Upsher's agreement to delay its competitive entry" and that this agreement "unreasonably restrain[ed] commerce." *In re Schering-Plough Corp.*, Final Order, 136 F.T.C. 956, 1052 (2003). The FTC likewise found that the ESI settlement violated antitrust law, noting that Schering had not attempted to rebut the natural presumption that the payment to ESI was for delay in generic entry, except to argue unpersuasively that the parties felt

judicial pressure to settle. *Id.* at 1056-57. In making these determinations, the FTC found that it was "neither necessary nor helpful to delve into the merits of the [underlying patent disputes]." *Id.* at 1055. Rather, the FTC determined that, where a name brand pharmaceutical maker pays a generic manufacturer as part of a settlement, "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *Id.* at 988. In applying the rule of reason, the FTC concluded that the possible existence of a reverse payment raises a red flag and can give rise to a prima facie case that an agreement is anticompetitive. *Id.* at 991, 1000-01. The FTC concluded that the reverse payment at issue was illegal because the settling parties could show neither (1) that the payment was for something other than delay of generic entry nor (2) that the payment had pro-competitive effects. *Id.* at 988-89, 1061.

Schering appealed the FTC's ruling to the Eleventh Circuit, which reversed in *Schering-Plough Corp. v. FTC*, 402 F.3d 1056 (11th Cir. 2005). The Eleventh Circuit's ruling in *Schering-Plough* is discussed in Section III(C) *infra*.

E. The Instant Litigation

Separate from the FTC's challenge, various private parties filed antitrust suits attacking the settlements. Those suits, the matters giving rise to this appeal, were consolidated in the District of New Jersey by the Judicial Panel on Multidistrict Litigation. In 2006, by consent of the parties, the District Court appointed Stephen Orlofsky as Special

Master with responsibility to handle all motions, including motions for class certification and summary judgment.[5]

On April 14, 2008, the Special Master certified a class of plaintiffs consisting of forty-four wholesalers and retailers who purchased K-Dur directly from Schering. The District Court adopted that decision on December 30, 2008.[6]

In February 2009, the Special Master issued a Report and Recommendation granting defendants' motions for summary judgment and denying plaintiffs' motions for partial summary judgment. In his Report and Recommendation, the Special Master applied a presumption that Schering's '743 patent was valid and that it gave Schering the right to exclude infringing products until the end of its term, including through reverse payment settlements. Under this analysis, the settlements in this case would only be subject to antitrust scrutiny if (1) they exceeded the scope of the '743 patent or (2) the underlying patent infringement suits were objectively baseless. The Special Master determined that neither of these exceptions applied. The District

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[5] Because there was no objection to the appointment of a Special Master, we have no occasion to address the use of Special Master to prepare Reports and Recommendations on summary judgment motions. *See In re Bituminous Coal Operators' Ass'n, Inc.*, 949 F.2d 1165, 1168 (D.C. Cir. 1991) ("Rule 53 of the Federal Rules of Civil Procedure authorizes the appointment of special masters to *assist*, not to replace, the adjudicator, whether judge or jury, constitutionally indicated for federal court litigation.") (emphasis in original) (*citing La Buy v. Howes Leather Co., Inc.*, 352 U.S. 249, 256 (1957)).

[6] The class certification decision is discussed in Section IV *infra*.

Court subsequently adopted the Report and Recommendation in its entirety.

F. Economic Background and the History of Reverse Payment Settlements

Reverse payment settlements appear to be unique to the Hatch-Waxman context, and the FTC has made them a top enforcement priority in recent years. A 2010 analysis by the FTC found that reverse payment settlements cost consumers $3.5 billion annually. FTC, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* 2 (2010), *available at* http://www.ftc.gov/os/2010/01/100112 payfordelayrpt.pdf. The FTC estimates that about one year after market entry an average generic pharmaceutical product takes over ninety percent of the patent holder's unit sales and sells for fifteen percent of the price of the name brand product. *Id.* at 8. This price differential means that consumers, rather than generic producers, are typically the biggest beneficiaries of generic entry.

III. THE ANTITRUST ISSUE (Appeals Nos. 10-2077, 10-2078, 10-2079)

A. Jurisdiction and Standard of Review

The District Court had jurisdiction pursuant to 15 U.S.C. § 15(a) and 28 U.S.C. §§ 1331 and 1337. This court has jurisdiction over the antitrust appeals pursuant to 28 U.S.C. § 1291.

This court exercises plenary review of the District Court's grant of summary judgment, applying the same summary judgment standard that guides the District Court. *Eichenlaub v. Twp. of Indiana*, 385 F.3d 274, 279 (3d Cir. 2004).

B. General Antitrust Standard

The Sherman Act provides, in part, that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." 15 U.S.C. § 1. Under a literal reading, this provision would make illegal every agreement in restraint of trade. *See Arizona v. Maricopa Cnty. Med. Soc'y*, 457 U.S. 332, 342 (1982). However, it has not been so interpreted. Rather the Supreme Court has long construed it to prohibit only unreasonable restraints. *See State Oil Co. v. Khan*, 522 U.S. 3, 10 (1997). Whether a restraint qualifies as unreasonable and therefore conflicts with the statute is normally evaluated under the "rule of reason." *Id.* Applying this approach, "the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect." *Id.* This inquiry has been divided into three parts. First, the plaintiff must show that the challenged conduct has produced anti-competitive effects within the market. *United States v. Brown Univ.*, 5 F.3d 658, 668 (3d Cir. 1993). If the plaintiff meets the initial burden, "the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently pro-competitive objective." *Id.* at 669. Finally, the plaintiff can rebut the defendant's purported pro-competitive justification by showing that the restraint is not reasonably necessary to achieve the pro-competitive objective. *Id.*

Courts have recognized, however, that "[s]ome types of restraints ... have such predictable and pernicious anticompetitive effect, and such limited potential for pro-competitive benefit, that they [should be] deemed unlawful *per se*." *State Oil Co.*, 522 U.S. at 10. Examples of agreements that have been held unlawful pursuant to the *per se* rule include horizontal price fixing, output limitations, market allocation, and group boycotts. *See Copperweld Corp. v. Independence Tube Corp.*, 467 U.S. 752, 768 (1984); *N. Pac. Ry. v. United States*, 356 U.S. 1, 5 (1958). The *per se* rule is applied where a "practice facially appears to be one that would always or almost always tend to restrict competition or decrease output." *Broad. Music, Inc. v. CBS, Inc.*, 441 U.S. 1, 19-20 (1979).

In some situations, courts apply an antitrust analysis that falls between the full rule of reason inquiry on the one hand and the rigid *per se* approach on the other. This so-called "quick look" or "truncated rule of reason" analysis applies where the plaintiff has shown that the defendant has engaged in practices similar to those subject to *per se* treatment. *See Brown Univ.*, 5 F.3d at 669. Having so shown, plaintiff is not required to make a full showing of anti-competitive effects within the market; rather defendant has the burden of demonstrating pro-competitive justifications. *Id.*

C. Precedent from Other Circuits

Neither this court nor the Supreme Court has yet weighed in on the legality of reverse payment settlements. However, five other circuits have addressed the question. Two of those courts – the first two to consider the question – concluded that

such agreements should be subject to strict antitrust scrutiny, at least where the settling parties attempted to manipulate the 180-day exclusivity period to block all potential generic competition. The three courts to address the question of reverse payments more recently have reached a contrary result, ruling that such agreements are permissible so long as they do not exceed the potential exclusionary scope of the patent.

1. D.C. Circuit – *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001)

The D.C. Circuit considered a reverse payment in *Andrx Pharmaceuticals, Inc. v. Biovail Corp. International*, 256 F.3d 799 (D.C. Cir. 2001), *cert. denied*, 535 U.S. 931 (2002). Unlike the instant case, that case did not involve a settlement resolving patent litigation. Rather, while allowing the patent litigation to continue, the name brand manufacturer agreed to compensate the would-be generic producer to delay marketing a generic product.

In September 1995, Andrx Pharmaceuticals ("Andrx") filed an ANDA seeking to manufacture and sell a generic form of Cardizem CD, a heart drug for which Hoechst Marion Russell, Inc. ("HMRI") held the patent. *Id.* at 803. Andrx filed a paragraph IV certification and was timely sued for patent infringement by HMRI. *Id.* The filing of the patent infringement suit triggered the thirty-month waiting period during which the FDA could not give final approval to Andrx or any subsequent ANDA applicants seeking to make a generic version of Cardizem CD. *Id.* (citing 21 U.S.C. § 355(j)(5)(B)(iii)). In June 1997, a second generic

manufacturer, Biovail Corp. International ("Biovail"), filed an ANDA and a paragraph IV certification to produce generic Cardizem CD. Shortly thereafter, the FDA issued a tentative approval of Andrx's ANDA. *Id.*

Soon after the tentative approval was issued, HMRI and Andrx entered into an agreement pursuant to which HMRI would pay Andrx $40 million per year beginning on the date that Andrx received final approval from the FDA and ending on the date that Andrx either began selling generic Cardizem CD or was adjudged liable for patent infringement in the pending suit. *Id.* The apparent purpose of this agreement was to create a bottleneck by delaying the triggering of Andrx's 180-day period of exclusivity, and thereby delaying generic entry not only by Andrx but also by any other potential generic manufacturer. *Id.* at 804.

The D.C. Circuit reversed the district court's dismissal with prejudice of Biovail's antitrust claims, holding that the agreement between HMRI and Andrx could "reasonably be viewed as an attempt to allocate market share and preserve monopolistic conditions." *Id.* at 811. The D.C. Circuit treated the payment from HMRI to Andrx as *prima facie* evidence of an illegal agreement not to compete, noting that "Andrx's argument that any rational actor would wait for resolution of the patent infringement suit [before triggering the 180-day exclusivity period] is belied by the *quid* of HRMI's *quo*." *Id.* at 813.

2. Sixth Circuit – *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003)

The Sixth Circuit's decision of *In re Cardizem CD Antitrust Litigation* concerned the same agreement considered by the D.C. Circuit in *Andrx*. 332 F.3d 896 (6th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004). The Sixth Circuit case was brought by direct and indirect purchasers of Cardizem CD who alleged that they suffered antitrust harm as a result of Andrx's agreement with HRMI to delay market entry. *Id.* at 903-04. The Sixth Circuit held that the Andrx-HRMI agreement was "a horizontal agreement to eliminate competition in the market for Cardizem CD throughout the entire United States, a classic example of a *per se* illegal restraint of trade." *Id.* at 908.

While both *Cardizem* and *Andrx* concerned an agreement that caused a bottleneck by preventing other generic manufactures from entering the market by delaying the triggering of the first filer's 180-day exclusivity period, much of the Sixth Circuit's reasoning in *Cardizem* is equally applicable to cases, like the instant one, that do not involve bottlenecking. Specifically, the Sixth Circuit emphasized its concern that, even setting aside the bar to subsequent generic applicants, HMRI had paid Andrx not to enter the market itself, stating, "it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market." *Id.* at 908.

3. Eleventh Circuit – *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294 (11th Cir. 2003) and *Schering-*

Plough Corp. v. FTC, 402 F.3d 1056 (11th Cir. 2005)

The Eleventh Circuit has also considered the question of reverse payments settlements in three significant cases. The first of these, *Valley Drug Co. v. Geneva Pharmaceuticals, Inc.*, 344 F.3d 1294 (11th Cir. 2003), *cert. denied*, 543 U.S. 939 (2004), concerned two agreements arising out of cases where a name brand drug manufacturer sued generic manufacturers for patent infringement and the generic manufacturers defended on the ground of patent invalidity.[7] *Id.* at 1299-301. In the two agreements at issue, the name brand manufacturer agreed to pay the generic manufacturer substantial sums to refrain from entering the market until the end of the name brand manufacturer's patent term. *Id.* at 1300. The patent at issue was subsequently declared invalid in another case. *Id.* at 1306-07. The district court granted summary judgment to antitrust plaintiffs, holding that the settlements were *per se* violations of the Sherman Act. *Id.* at 1301. The Eleventh Circuit reversed on the ground that the name brand manufacturer held a patent that gave it the right to exclude competitors. *Id.* at 1306. In so ruling, the court emphasized the fact that the name brand manufacturer might have prevailed in the underlying patent litigation, *id.* at 1309, and highlighted policy considerations favoring the settlement of patent litigation, *id.* at 1308 n.20. The court applied neither a *per se* nor rule of reason

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[7] One of these agreements was a final settlement of certain claims, the other was structured, like the agreements in *Andrx* and *Cardizem*, to take effect even as the litigation continued. *See Valley Drug*, 344 F.3d at 1300.

analysis to the agreements as a whole; rather, it directed the district court to first determine whether any part of the agreement went beyond the protections afforded by the name brand manufacturer's patent and, if so, to apply traditional antitrust scrutiny only to those portions of the agreement. *Id.* at 1311-1312.

A subsequent Eleventh Circuit case, *Schering-Plough Corp. v. FTC*, arose out of the same settlement agreement as the instant appeal.[8] 402 F.3d 1056 (11th Cir. 2005), *cert. denied*, 548 U.S. 919 (2006). After the FTC found that both agreements violated antitrust laws, the defendants appealed to the Eleventh Circuit. Applying the test articulated in *Valley Drug*, the Eleventh Circuit set aside the ruling of the FTC. *Id.* at 1065-66, 1076. The court rejected the FTC's conclusion that Schering's $60 million payment to Upsher was for something other than the licenses it obtained, finding by "overwhelming evidence" that the payment was only for the licenses. *Id.* 1069-71. As such, the court found that there was no reverse payment from Schering to Upsher and thus necessarily no antitrust

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[8] Defendants argue in passing that this court should begin its analysis in this case with a strong presumption in favor of following the Eleventh Circuit's decision in *Schering-Plough*. However, none of the cases cited by defendants employs such a presumption; rather, they stand for the unsurprising proposition that this court will follow the decisions of its sister courts where it finds them persuasive. *See, e.g.*, *Ramadan v. Chase Manhattan Corp.*, 229 F.3d 194, 197-203 (3d Cir. 2000) (following the rulings of other courts of appeal on similar facts but conducting an independent analysis). As explained below, we do not find the Eleventh Circuit's decision in *Schering-Plough* persuasive, and thus decline to follow it.

violation in that agreement. *Id.* With respect to the ESI settlement, the court acknowledged the presence of a reverse payment but concluded that the payment was acceptable in light of judicial policy favoring settlements and the court's finding that the settlement terms "'reflect[ed] a reasonable implementation' of the protections afforded by patent law." *Id.* at 1072 (quoting *Valley Drug*, 344 F.3d at 1312).[9]

Plaintiffs construe *Valley Drug* and *Schering-Plough* as requiring courts to conduct an *ex post* evaluation of the strength of the underlying patent before determining whether the patent shields an agreement from antitrust scrutiny. However, following oral argument in this case, the Eleventh Circuit explicitly rejected that interpretation of its prior holdings. In *FTC v. Watson Pharmaceuticals, Inc.*, the Eleventh Circuit clarified that its prior opinions did not call for an evaluation of the strength of the patent but rather only a determination whether, absent sham litigation or fraud in obtaining the patent, the settlement agreement exceeded the scope of the patent. *FTC v. Watson Pharms, Inc.*, No. 10-12729, 2012 WL 1427789, at *11 n.8, *12 (11th Cir. Apr. 25, 2012). Thus the standard applied by the Eleventh Circuit is identical to the scope of the patent test applied by the Second Circuit to which we now turn.

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[9] The Eleventh Circuit subsequently applied, without further significant explication, the scope of the patent test announced in *Valley Drug* and *Schering-Plough* in another case, *Andrx Pharmaceuticals, Inc. v. Elan Corporation, PLC*, 421 F.3d 1227 (11th Cir. 2005).

4. Second Circuit – *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006)

The Second Circuit's decision of *In re Tamoxifen Citrate Antitrust Litigation* arose out of an agreement settling a patent infringement suit over the drug tamoxifen, then the most widely prescribed drug for the treatment of breast cancer. 466 F.3d 187, 190 (2d Cir. 2006), *cert. denied*, 551 U.S. 1144 (2007). That settlement was reached while the patent case was on appeal after the district court had ruled the patent invalid. *Id.* The settlement called for the name brand manufacturer to grant the generic manufacturer a license to sell an unbranded version of tamoxifen and make a reverse payment of $21 million to the generic manufacturer. The settlement was contingent on obtaining a vacatur of the district court's judgment holding the patent to be invalid, which was subsequently obtained. *Id.*

Affirming the district court's dismissal of antitrust plaintiffs' claims, the Second Circuit applied a presumption of patent validity and held that "there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent." *Id.* at 213 (internal citations and quotation marks omitted). The only exceptions to this rule, the court held, occur where there is evidence that the patent was procured by fraud or that the enforcement suit was objectively baseless. *Id.* This test is commonly referred to as the "scope of the patent test" or the "*Tamoxifen* test." The Second Circuit conceded that there was a potentially troubling result of such a rule in that "[t]he less sound the patent or the less clear

the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent." *Id.* at 211. The court determined, however, that this risk was counterbalanced by the judicial preference for settlement. *Id.*

In reaching this conclusion, the Second Circuit concluded that "the Hatch-Waxman Act created an environment that encourages [reverse payments]" because, unlike traditional infringement suits where the patent holder can negotiate by agreeing to forego the infringement damages it expects to recover, there usually are no infringement damages in Hatch-Waxman suits. *Id.* at 206. The Second Circuit thus reasoned that the "reverse payments" common in Hatch-Waxman suits are less troubling because they take the place of infringement damages that the patent holder might have otherwise waived in order to reach a settlement. *Id.*

Judge Pooler dissented from the decision in *Tamoxifen*, contending that the scope of the patent rule applied by the majority "is not soundly grounded in Supreme Court precedent and is insufficiently protective of the consumer interests safeguarded by the Hatch-Waxman Act and the antitrust laws." *Id.* at 224 (Pooler, J., dissenting). Judge Pooler argued, *inter alia*, that judicial reevaluation of patent validity is a public good that reverse payment settlements undercut, *id.* at 225-26, and suggested that the proper antitrust standard is one of reasonableness considering all the circumstances affecting a restrictive agreement including (1) the strength of the patent as it appeared at the time of

settlement, (2) the amount of the reverse payment, (3) the amount the generic manufacturer would have made during its 180-day exclusivity period, and (4) any ancillary anti-competitive effects of the agreement. *Id.* at 228.

In a subsequent reverse payment case, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, the Second Circuit applied the *Tamoxifen* standard and rejected an antitrust challenge to a Hatch-Waxman settlement involving a reverse payment. 604 F.3d 98 (2d Cir. 2010), *cert. denied*, 131 S. Ct. 1606 (2011). However, the judges on the *Arkansas Carpenters* panel made clear that they thought that *Tamoxifen* was wrongly decided and invited appellants to petition for rehearing en banc. *Id.* at 108-10. Among other things, the *Arkansas Carpenters* court noted its concern about evidence suggesting that the number of reverse payment settlements had increased dramatically in the wake of the *Tamoxifen* decision. *Id.* at 109. Rehearing en banc was subsequently denied over a dissent from Judge Pooler. *Ark. Carpenters Health & Welfare Fund v. Bayer AG*, 625 F.3d 779 (2d Cir. 2010).

5. Federal Circuit – *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323 (Fed. Cir. 2008)

In *In re Ciprofloxacin Hydrochloride Antitrust Litigation* the Federal Circuit considered a case related to those confronted by the Second Circuit in *Arkansas Carpenters*. 544 F.3d 1323 (Fed. Cir. 2008), *cert. denied*, 129 S. Ct. 2828 (2009).[10] The

[10] That case was severed by the Second Circuit and transferred to the Federal Circuit because it involved a claim arising out of patent law. *See* Order, No. 05-2863 (2d Cir. Nov. 7, 2007).

Federal Circuit applied the scope of the patent test explicated in *Tamoxifen* and other cases, stating, "[t]he essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent." *Id.* at 1336. The court further "agree[d] with the Second and Eleventh Circuits ... that, in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.*

D. Analysis

While the first two courts of appeal to address the issue of reverse payments subjected those agreements to antitrust scrutiny, later courts have gravitated toward the scope of the patent test under which reverse payments are permitted so long as (1) the exclusion does not exceed the patent's scope, (2) the patent holder's claim of infringement was not objectively baseless, and (3) the patent was not procured by fraud on the PTO. The scope of the patent test was applied by the Special Master in this case and has been applied by at least one other district court in this circuit. *See King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514, 528-29, 533 (E.D. Pa. 2010) (applying scope of the patent test but denying defendants' motion to dismiss where plaintiffs pleaded facts supporting their claim that the underlying patent suit was objectively baseless). As a practical matter, the scope of the patent test does not subject reverse payment agreements to any antitrust scrutiny. As the antitrust defendants concede, no court applying

the scope of the patent test has ever permitted a reverse payment antitrust case to go to trial.

After consideration of the arguments of counsel, the conflicting decisions in the other circuits, the Report of the Special Master, and our own reading, we cannot agree with those courts that apply the scope of the patent test. In our view, that test improperly restricts the application of antitrust law and is contrary to the policies underlying the Hatch-Waxman Act and a long line of Supreme Court precedent on patent litigation and competition.

First, we take issue with the scope of the patent test's almost unrebuttable presumption of patent validity. This presumption assumes away the question being litigated in the underlying patent suit, enforcing a presumption that the patent holder would have prevailed. We can identify no significant support for such a policy. While persons challenging the validity of a patent in litigation bear the burden of defeating a presumption of validity, this presumption is intended merely as a procedural device and is not a substantive right of the patent holder. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534 (Fed. Cir. 1983) ("The presumption, like all legal presumptions, is a procedural device, not substantive law."). Moreover, the effectively conclusive presumption that a patent holder is entitled to exclude competitors is particularly misguided with respect to agreements – like those here – where the underlying suit concerned patent infringement rather than patent validity: In infringement cases it is the patent holder who bears the burden of showing infringement. *See Egyptian*

Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 679 (Fed. Cir. 2008).

Rather than adopt an unrebuttable presumption of patent validity, we believe courts must be mindful of the fact that "[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office." *Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). Many patents issued by the PTO are later found to be invalid or not infringed, and a 2002 study conducted by the FTC concluded that, in Hatch-Waxman challenges made under paragraph IV, the generic challenger prevailed seventy-three percent of the time. *See* FTC, *Generic Drug Entry Prior to Patent Expiration* 16 (2002), *available at* http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf; Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peek Inside the Black Box*, 99 Mich. L. Rev. 365, 385 (2000) (noting that between 1983 and 1999 the alleged infringer prevailed in forty-two percent of patent cases that reached trial).[11] These figures add force to the likelihood – conceded by the *Tamoxifen* majority – that reverse payments enable the holder of a patent that the holder knows is weak

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[11] The Pharmaceutical Research and Manufacturers of America points to a more recent study concluding that, in the years from 2000 to 2009, generics prevailed in slightly less than half of their challenges. RBC Capital Mkts., *Pharmaceuticals: Analyzing Litigation Success Rates* 4 (2010), *available at* http://www.amlawdaily.typepad.com/pharmareport.pdf. Even if the industry's own figures are accepted, they show that a substantial fraction of Hatch-Waxman patent challenges succeed on the merits. Moreover, the study cited by the industry further states that "when you take into account patent settlements and cases that were dropped, the success rate for generics jumps to 76%, substantially in favor of challenging patents." *Id.*

to buy its way out of both competition with the challenging competitor and possible invalidation of the patent. 466 F.3d at 211 ("The less sound the patent or the less clear the infringement, and therefore the less justified the monopoly enjoyed by the patent holder, the more a rule permitting settlement is likely to benefit the patent holder by allowing it to retain the patent.").

Moreover, we question the assumption underlying the view of the Second Circuit and other courts that subsequent challenges by other generic manufacturers will suffice to eliminate weak patents preserved through a reverse payment to the initial challenger. *Cf., e.g.*, *id.* at 211-12. We note that the initial generic challenger is necessarily the most motivated because, unlike all subsequent challengers, it stands to benefit from the 180-day exclusivity period of 21 U.S.C. § 355(j)(5)(B)(iv). Additionally, as the experience of at least one court in this Circuit confirms, the high profit margins of a monopolist drug manufacturer may enable it to pay off a whole series of challengers rather than suffer the possible loss of its patent through litigation. *See King Drug Co. of Florence, Inc.*, 702 F. Supp. 2d at 521-22 (drug manufacturer settled infringement suits by four generic firms, which agreed to delay market entry "in exchange for significant payments ... for various licensing agreements, supply agreements and research and development deals").

This practical analysis is supported by a long line of Supreme Court cases recognizing that valid patents are a limited exception to a general rule of the free exploitation of ideas. It follows that the public interest supports judicial testing and

elimination of weak patents. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 100-01 (1993) (explaining the "importance to the public at large of resolving questions of patent validity" and noting the danger of "grant[ing] monopoly privileges to the holders of invalid patents"); *Bonito Boats, Inc. v. Thundercraft Boats, Inc.*, 489 U.S. 141, 146 (1989) (noting that the patent laws embody "a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy"); *United States v. Masonite Corp.*, 316 U.S. 265, 277 (1942) (a patent "affords no immunity for a monopoly not fairly or plainly within the grant"); *id.* at 280 (patents are to be "strictly construed" because they are "privileges restrictive of a free economy"); *Pope Mfg. Co. v. Gormully*, 144 U.S. 224, 234 (1892) ("It is as important to the public that competition should not be repressed by worthless patents, as that the patentee of a really valuable invention should be protected in his monopoly.").

That reasoning underlies the decision of the Supreme Court in *Edward Katzinger Co. v Chicago Metallic Manufacturing Co.*, where the Court considered whether a patent licensor could be contractually estopped from challenging the validity of the patent under a licensing agreement that also contained a price fixing term. 329 U.S. 394 (1947). The Court reasoned that if the patent was invalid, the price fixing provision would violate federal antitrust law and that, as such, the licensor could not be estopped from challenging the patent. *Id.* at 399, 401-02. In reaching this conclusion the Court emphasized "the broad public interest in freeing our

competitive economy from the trade restraints which might be imposed by price-fixing agreements stemming from narrow or invalid patents." *Id.* at 400 (citing *Sola Elec. Co. v. Jefferson Elec. Co.*, 317 U.S. 173, 177 (1942)). The Court additionally stated: "It is the public interest which is dominant in the patent system and ... the right to challenge [a patent] is not only a private right to the individual, but it is founded on public policy which is promoted by his making the defence, and contravened by his refusal to make it." *Id.* at 401 (internal citations and quotation marks omitted).

This logic is persuasive with respect to the situation at bar because reverse payments permit the sharing of monopoly rents between would-be competitors without any assurance that the underlying patent is valid. *See also United States v. Studiengesellschaft Kohle, m.b.H.*, 670 F.2d 1122, 1136 (D.C. Cir. 1981) (suggesting an agreement might be anticompetitive if it "give[s] potential competitors incentives to remain in cartels rather than turning to another product, inventing around the patent, or challenging its validity"). It appears that these aspects of the Supreme Court's general patent jurisprudence had been overlooked by the Special Master and others adopting the scope of the patent test.

We caution that our decision today is limited to reverse payments between patent holders and would be generic competitors in the pharmaceutical industry. As the Supreme Court has made clear, "antitrust analysis must sensitively recognize and reflect the distinctive economic and legal setting of the regulated industry to which it applies." *Verizon*

Commc'ns. Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 411-12 (2004); *see also* IA Phillip E. Areeda & Herbert Hovenkamp Antitrust Law, ¶ 240d, 289 (3d ed. 2006) ("[T]he presence of regulation in some instances limits the antitrust role and in some instances simply changes it or even enlarges it."). The Supreme Court's admonition is particularly relevant in an industry, like the pharmaceutical industry, that is subject to extensive regulation in which Congress has balanced the protection of intellectual property and the need for competition. Specifically, in passing the Hatch-Waxman Act, Congress drew a careful line between patent protection and the need to provide incentives for competition in the pharmaceutical industry. *See* 130 Cong. Rec. 24425 (Sept. 6, 1984) (statement of Rep. Waxman underscoring the "fundamental balance of the bill"); H.R. Rep. No. 98-857, pt. 2, at 30 (1984) (emphasizing that the bill achieves "what the Congress has traditionally done in the area of intellectual property law[:] balance the need to stimulate innovation against the goal of furthering the public interest"), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2715. The line that Congress drew between these competing objectives strongly supports the application of rule of reason scrutiny of reverse payment settlements in the pharmaceutical industry.

The goal of the Hatch-Waxman Act is to increase the availability of low cost generic drugs. H.R. Rep. No. 98-857, pt. 1, at 14, *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647. One method Congress employed was to encourage litigated challenges by generic manufacturers against the holders of weak or narrow patents. *See* 21 U.S.C. § 355(j)(5)(B)(iv) (establishing 180-day exclusivity period as reward

for successfully challenging a patent); S. Rep. No. 107-167, at 4 (2002) ("Under Hatch-Waxman, manufacturers of generic drugs are encouraged to challenge weak or invalid patents on brand name drugs so consumers can enjoy lower drug prices."). That goal is undermined by application of the scope of the patent test which entitles the patent holder to pay its potential generic competitors not to compete. As one commentator has noted, this approach nominally protects intellectual property, not on the strength of a patent holder's legal rights, but on the strength of its wallet. *See* Hemphill, *Paying for Delay*, *supra* at 1614 ("In the Hatch-Waxman Act ... the promotion and delay of litigation are central preoccupations of the regulatory regime. An open-ended permission for innovators to set innovation policy by self-help [through reverse payments] is less plausible, as Congress has taken explicit steps to fill those gaps.") As the Second Circuit acknowledged in its *Tamoxifen* decision, the principal beneficiaries of such an approach will be name brand manufacturers with weak or narrow patents that are unlikely to prevail in court. *See* 466 F.3d at 211. Thus while such a rule might be good policy from the perspective of name brand and generic pharmaceutical producers, it is bad policy from the perspective of the consumer, precisely the constituency Congress was seeking to protect.

In rejecting the scope of the patent test, we are cognizant that such a test encourages settlement, an objective our decisions generally support. *See, e.g.*, *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 595 (3d Cir. 2010) ("Settlement agreements are to be encouraged because they promote the amicable resolution of disputes and lighten the increasing load

of litigation faced by the federal courts."). However, the judicial preference for settlement, while generally laudable, should not displace countervailing public policy objectives or, in this case, Congress's determination – which is evident from the structure of the Hatch-Waxman Act and the statements in the legislative record – that litigated patent challenges are necessary to protect consumers from unjustified monopolies by name brand drug manufacturers. We also emphasize that nothing in the rule of reason test that we adopt here limits the ability of the parties to reach settlements based on a negotiated entry date for marketing of the generic drug: the only settlements subject to antitrust scrutiny are those involving a reverse payment from the name brand manufacturer to the generic challenger. Data analyzed by the FTC suggest that this will leave the vast majority of pharmaceutical patent settlements unaffected. *See* FTC, Bureau of Competition, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2010*, 2 (2011) (showing that nearly seventy-five percent of Hatch-Waxman Act infringement suits that settled in 2010 did so without reverse payments), *available at* http://www.ftc.gov/os/2011/05/1105mmagreements.pdf.

For all of these reasons we reject the scope of the patent test. In its place we will direct the District Court to apply a quick look rule of reason analysis based on the economic realities of the reverse payment settlement rather than the labels applied by the settling parties. Specifically, the finder of fact must treat any payment from a patent holder to a

generic patent challenger who agrees to delay entry into the market as *prima facie* evidence of an unreasonable restraint of trade, which could be rebutted by showing that the payment (1) was for a purpose other than delayed entry or (2) offers some pro-competitive benefit.

In holding that a reverse payment is *prima facie* evidence of an unreasonable restraint of trade, we follow the approach suggested by the D.C. Circuit in *Andrx* and embrace that court's common sense conclusion that "[a] payment flowing from the innovator to the challenging generic firm may suggest strongly the anticompetitive intent of the parties entering the agreement . ..." 256 F.3d at 809 (internal quotation marks and citation omitted).

We agree, moreover, with the FTC that there is no need to consider the merits of the underlying patent suit because "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise." *In re Schering-Plough Corp.*, Final Order, 136 F.T.C. at 988. Of course, a patent holder may attempt to rebut plaintiff's *prima facie* case of an unreasonable restraint of trade by arguing that there is in fact no reverse payment because any money that changed hands was for something other than a delay in market entry. Alternatively, the patent holder may attempt to rebut the *prima facie* case by demonstrating that the reverse payment offers a competitive benefit that could not have been achieved in the absence of a reverse payment. This second possible defense attempts to account for the –

probably rare – situations where a reverse payment increases competition. For example, a modest cash payment that enables a cash-starved generic manufacturer to avoid bankruptcy and begin marketing a generic drug might have an overall effect of increasing the amount of competition in the market. For the reasons set forth, we will reverse the judgment of the District Court and remand for further proceedings in accordance with the foregoing.

IV. THE CLASS CERTIFICATION ISSUE (Appeal No. 10-4571)

A. Procedural Background

The other issue before us on this appeal concerns plaintiffs' effort to certify a class of persons who purchased K-Dur directly from Schering between November 20, 1998 and September 1, 2001 and subsequently purchased a generic version of K-Dur. As identified by the parties' experts, the class consists of forty-four wholesalers and retailers. The Special Master recommended granting plaintiffs' motion to certify the class. The District Court adopted the Special Master's Report and Recommendation and formally certified the class.

Defendants sought interlocutory review of the District Court's order under Federal Rule of Civil Procedure 23(f). While that petition was pending, the District Court ruled on the cross motions for summary judgment and entered final judgment in defendants' favor. Plaintiffs filed a notice of appeal, and defendants filed a cross appeal, which this court dismissed as untimely. *See* Order, *In re K-Dur Antitrust Litig.*, No. 10-2727 (3d Cir. Nov. 24, 2010). However, this court accepted defendants' Rule 23(f) petition, *see* Order, *In re K-Dur Antitrust Litig.*, No.

09-8006 (3d Cir. Nov. 16, 2010), and we therefore have jurisdiction pursuant to 28 U.S.C. § 1292(e).[12]

B. Standard of Review

This court reviews class certification orders "for abuse of discretion, which occurs if the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 312 (3d Cir. 2008) (internal quotation marks and citation omitted).

C. Defendants' Arguments

In order to certify a class under Rule 23(b)(3), a plaintiff must satisfy both the general class action prerequisites – numerosity, commonality, typicality, and adequacy of representation – and the additional requirements of predominance and superiority. Fed. R. Civ. P. 23(a), (b)(3). The Special Master, in a report adopted in full by the District Court, discussed the class requirements in detail; defendants challenge only a few of those findings. Defendants assert that (1) plaintiffs cannot use common evidence to prove that the class members suffered an actual injury from defendants' conduct

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[12] Plaintiffs argue that because defendants' cross appeal was dismissed as untimely defendants' 23(f) petition should have been dismissed also. An appeals court has discretion to consider an interlocutory appeal even after the entry of final judgment. *Cf. In re Coordinated Pretrial Proceedings in Petroleum Prods. Antitrust Litig.*, 788 F.2d 1571, 1573-74 (Temp. Emer. Ct. App. 1986). Moreover, in granting defendants' 23(f) petition, this court has already considered the issue of the appropriateness of review, and we see no reason to reconsider the decision to hear this appeal.

because showing actual injury means demonstrating lost profits damages, which defendants argue necessarily requires individualized assessments, (2) even assuming that overcharges are an acceptable form of injury, the District Court erred in its conclusion that there was common evidence of injury to all class members, and (3) the class should not have been certified because of inherent conflicts between members. Defendants' first two arguments challenge the District Court's finding with respect to the predominance requirement, while the third goes to the adequacy requirement. We address these arguments in order.

1. Predominance Issues

In order for the predominance requirement to be satisfied "[i]ssues common to the class must predominate over individual issues." *In re Hydrogen Peroxide*, 552 F.3d at 311 (internal citations and quotation marks omitted). Class certification calls for the district court to conduct a "rigorous assessment of the available evidence," *id.* at 312, and is only appropriate in antitrust cases where plaintiffs can show, by a preponderance of the evidence, that proof of the essential elements of the cause of action, including antitrust injury, do not require individual treatment. *Id.* at 307, 311.

It is plaintiffs' thesis that they will prove that class members paid more for K-Dur because of Schering's antitrust violations, and that this constitutes the required antitrust impact. The Special Master accepted this based on Third Circuit law, stating:

> The Third Circuit has held that "when an antitrust violation impacts upon a

> class of persons who do have standing, there is no reason in doctrine why proof of impact cannot be made on a common basis, so long as the common proof adequately demonstrates some damage to each individual."

App. at 7980 (quoting *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 454 (3d Cir. 1977)). Because all of the class members purchased some of the generic versions of K-Dur, plaintiffs have satisfactorily explained their theory of impact.

Plaintiffs proposed to prove antitrust injury through common proof consisting largely of the declarations and report of their expert, Dr. Leitzinger. Dr. Leitzinger offered statistical and economic analyses of the overall brand-name and generic drug market and of the specific entry of generic potassium chloride in the market to show that, but for the challenged reverse payment agreements, "all (or virtually all) members of the proposed class" would have purchased at least some less expensive generic potassium chloride earlier, and therefore suffered an antitrust injury as a result of the delay in generic entry. The Special Master considered Dr. Leitzinger's proposed methodology and the criticisms of it made by defendants' expert, Dr. Rubinfeld, in detail. After slightly narrowing the class definition to accommodate a criticism made by defendants' expert,[13] the Special Master found that plaintiffs had satisfied their burden of showing that

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[13] Specifically, the Special Master excluded from the class direct purchasers who did not purchase a generic version of K-Dur after generic entry.

antitrust impact may be proven by evidence common to all class members.

In December 2008, several months after the Special Master's Report and Recommendation, this court issued its decision in *In re Hydrogen Peroxide Antitrust Litigation*, which clarified the standard to be applied when certifying a class of plaintiffs in an antitrust action. 552 F.3d 305. In that case, we held that the preponderance requirement demands more than a mere threshold showing by a party seeking to certify a class and that, in considering a motion for class certification, a district court is required to resolve any factual or legal disputes necessary to determine whether a plaintiff will be able to show antitrust injury for all plaintiffs with common evidence. *Id.* at 316-18.

a. Whether Lost Profits Are the Relevant Antitrust Injury

Defendants argue first that the predominance requirement of Rule 23(b)(3) is not satisfied because, in order to prove actual injury from delayed generic entry, plaintiffs must produce evidence of lost profits, which necessarily requires an individual assessment for each class member. Defendants contend specifically that some of the wholesalers lost substantial sales volumes after generic entry, and that, for such wholesalers, generic entry caused a decrease in profits.

Defendants' lost profits argument is unavailing because it is simply a version of the so-called "passing-on defense" that was rejected by the Supreme Court in *Hanover Shoe, Inc. v. United Shoe Machinery Corporation*. 392 U.S. 481 (1968). In that case, the Supreme Court held that demonstrating

antitrust injury does not require a showing of lost profits. *Id.* at 494. Rather, the Supreme Court ruled that a plaintiff suffers an antitrust injury where it is overcharged for a product, regardless of whether it can show lost profits. *Id.* at 492-95. In reaching this conclusion, the Court noted that requiring plaintiffs to show lost profits was too burdensome on both courts and litigants and would undercut the effectiveness of private antitrust suits as an enforcement mechanism. *Id.* at 492-94; *see also Bogosian*, 561 F.2d at 456 (noting that a lost-profits inquiry would be "enormously complicated, posing a tremendous burden on the presentation of plaintiffs' case" and that "it is precisely for this reason that the Supreme Court eliminated the 'passing-on defense' in *Hanover Shoe*").

Defendants argue that the *Hanover Shoe* rule should not apply here because that case involved an overcharge for an identical product whereas this one involves two different products, a name brand drug with a higher price and a lower priced generic drug. However, defendants cite no authority distinguishing *Hanover Shoe* on that basis, and their own expert conceded that the generic supplement that Schering began manufacturing after Upsher entered the market was made in the same plant as K-Dur and chemically identical to K-Dur. Moreover, in *In re Warfarin Sodium Antitrust Litigation*, this court affirmed class certification where plaintiffs sought overcharges – not lost profits – stemming from anti-competitive behavior that hindered their access to generic pharmaceuticals. 391 F.3d 516, 532 (3d Cir. 2004).

In sum, defendants' contention that plaintiffs are required to show lost profits in order to demonstrate antitrust injury is without support in law or the facts of this case. As such, we reject it.

b. Whether There Was Common Evidence of Injury to All Class Members

Defendants argue that because of discrepancies in the pricing of K-Dur and variations in purchaser behavior, plaintiffs cannot prove injury to all class members by common evidence, even if lost profits are not required to show antitrust injury. They contend further that the District Court applied the wrong standard in evaluating plaintiffs' evidence that antitrust injury could be proven by common evidence.

In support of their argument that antitrust injury requires an individualized assessment for each class member, defendants point to two places where purportedly conflicting evidence demonstrates the need for individualized assessment of antitrust harm. Defendants point out that they did not sell K-Dur to all customers at a single list price; rather, the price paid varied considerably among class members. Additionally, defendants argue that, for certain customers at certain times, Schering offered rebates which caused further price variation among customers. Defendants contend that these pricing variations caused several class members to have zero or negative damages under the formula applied by plaintiffs' expert. Finally, defendants point out that not all class members purchased generic potassium chloride as soon as it became available and argue that, in light of this variation in purchase timing,

plaintiffs need to make an individualized showing that each plaintiff would have purchased a generic product earlier if one had been available.

We do not read *Hydrogen Peroxide* as precluding a class because of variations in purchasing by a very small percentage of those who purchased K-Dur. As the Special Master recognized, defendants conceded "that 45 of the proposed Class members purchased some amount of generic K-Dur." App. at 7984 (emphasis in original). He noted that defendants' arguments "relate to the quantum of damages, rather than the fact of injury." *Id.* Indeed, in *Hydrogen Peroxide* itself, we focused on what was really at issue – that for certification plaintiff need not prove antitrust injury actually occurred.

> Plaintiffs' burden at the class certification stage is not to prove the element of antitrust impact, although in order to prevail on the merits each class member must do so. Instead, the task for plaintiffs at class certification is to demonstrate that the element of antitrust impact is capable of proof at trial through evidence that is common to the class rather than individual to its members.

552 F.3d at 311-12. To the extent that there were minor variations, they can be handled at trial in the context of damages.

With regard to both the price-variation and purchase-timing issues, the Special Master conducted an exceedingly thorough review of plaintiffs' proposal for demonstrating antitrust impact through common evidence and determined

that defendants' objections were without support. Critically, the Special Master recognized his obligation to "probe beyond the pleadings" and to conduct a "rigorous analysis" of the available evidence. App. at 7960 (internal citations and quotation marks omitted).

Our review confirms that the Special Master applied the appropriate standard. In contrast to *Hydrogen Peroxide*, where the court found that there was "no tendency for prices ... to move together," 552 F.3d at 314 (internal quotation marks omitted), plaintiffs in this case presented evidence, credited by the Special Master, of significant, industry-wide price drops after generic entry. Such evidence of an industry-wide price drop after generic entry supports the Special Master's rejection of defendants' arguments about limited price variations and purchase-timing variations between plaintiffs.

First, concerning the price-variation argument, the Special Master carefully considered the conflicting opinions of plaintiffs' and defendants' experts and credited the theories of plaintiffs' expert over that of defendants. The Special Master concluded that "Plaintiffs have satisfied their burden of adducing sufficient evidence and a plausible theory to convince me that impact may be proven by evidence common to all class members." App. at 7988 (internal citations and quotation marks omitted). Our review of the record confirms that plaintiffs presented a comprehensive and detailed means of proving impact through common means, notwithstanding some very limited pricing variation, and that the Special Master conducted an appropriately searching evaluation of this evidence.

With regard to defendants' argument about variations in the timing of the purchase of generic K-Dur, the Special Master explicitly rejected that argument and concluded that "[e]vidence that all (or virtually all) class members substituted a lower priced generic for some of their K-Dur 20 purchases gives rise to the inference that they would have similarly done in the but-for world." App. at 7984. This, combined with plaintiffs' theory of damages, means that impact could be proven on a class-wide basis via common evidence. Here again, the Special Master conducted a thorough evaluation of the available evidence and resolved all significant disputes between conflicting evidence as required under the standard set forth in *Hydrogen Peroxide*.

2. Adequacy Issue – Whether the Class Faces Inherent Conflicts

Defendants next contend that the District Court erred in certifying a class because the class faces inherent conflicts that preclude adequacy of representation. "The inquiry that a court should make regarding the adequacy of representation requisite of Rule 23(a)(4) is to determine that the putative named plaintiff has the ability and the incentive to represent the claims of the class vigorously, ... and that there is no conflict between the individual's claims and those asserted on behalf of the class." *In re Cmty. Bank of N. Va.*, 622 F.3d 275, 291 (3d Cir. 2010) (quoting *Hassine v. Jeffes*, 846 F.2d 169, 179 (3d Cir. 1988)). Only a fundamental conflict will defeat adequacy of representation. *See, e.g.*, *id.* at 303 (adequacy defeated by "obvious and fundamental intra-class

conflict of interest"); *Ward v. Dixie Nat. Life Ins. Co.*, 595 F.3d 164, 180 (4th Cir. 2010).

Defendants contend that three members of the class, all national wholesalers, were net beneficiaries of the absence of generic competition in the potassium chloride supplement market because once generics came on the market those class members saw decreased sales volumes and lower per-pill profits. Defendants argue that, because these three class members have financial incentives to delay generic entry, there is an inherent conflict between them and the rest of the class.

The case law on defendants' argument reveals a split in authority. A large number of district courts, including some in this Circuit, have rejected defendants' argument. *See, e.g.*, *Teva Pharms USA, Inc. v. Abbott Labs.*, 252 F.R.D. 213, 226-27 (D. Del. 2008) (Robinson, J.); *Meijer, Inc. v. Abbott Labs.*, 251 F.R.D. 431, 435 (N.D. Cal. 2008); *but see Valley Drug Co. v. Geneva Pharms., Inc.*, 350 F.3d 1181, 1190 (11th Cir. 2003).[14]

We reject the *Valley Drug* decision for two reasons. First, requiring plaintiffs to show that no class member benefitted from the challenged conduct in the form of greater profits is contrary to the Supreme Court's decision in *Hanover Shoe*. In *Hanover Shoe*, the Supreme Court permitted antitrust plaintiffs to seek overcharge damages rather than lost profits damages precisely because proving lost profits was too complicated and burdensome. 392 U.S. at 93; *Bogosian*, 561 F.2d at

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[14] This is a different appeal than *Valley Drug*, 344 F.3d 1294 (11th Cir. 2003), discussed *supra*.

456. The same logic applies equally, if not more strongly, in the class certification setting because under defendants' proposed approach, plaintiffs would not only have to assess their own lost profits but also those of potential class members. Moreover, because *Hanover Shoe* sets the amount of the overcharge as plaintiffs' damages, all of the class members have the same financial incentive for purposes of the litigation – *i.e.* proving that they were overcharged and recovering damages based on that overcharge. *See* 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice and Procedure* § 1768 (3d ed. 2005) ("[A] potential conflict between the representatives and some class members should not preclude the use of the class-action device if the parties appear united in interest against an outsider at the beginning of the case."). Defendants have not pointed to any plausible scenario in which the class members might seek conflicting forms of relief. For these reasons, we conclude that defendants' conflict argument fails.

D. Conclusion – Class Certification Issues

In sum, with respect to the class certification issues, we reject defendants' arguments and will affirm the District Court's determination approving maintenance of the class action.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION
This Document Relates to:
All Direct Purchaser Actions
Civil Action No. 01-1652 (JAG)
(Consolidated Cases)
MDL Docket No. 1419

ORDER

GREENAWAY, JR., U.S.C.J.[15]

On February 6, 2009, Special Master Stephen M. Orlofsky submitted a report and recommendation ("R&R") (Docket No. 733), pursuant to this Court's appointment order (Docket No. 316) and Federal Rule of Civil Procedure 53. In the R&R, Special Master Orlofsky concluded that: (1) the Motion for Summary Judgment as to All Claims Brought by Direct Purchaser Plaintiffs ("DP Plaintiffs") Related to the Upsher Settlement, filed by defendants Schering Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher") (collectively, "Defendants"), should be granted; (2) Defendants' Motion for Summary Judgment as to All Claims Brought by DP Plaintiffs Related to the ESI Settlement should be granted; (3) DP Plaintiffs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments should be denied; and (4) DP Plaintiffs' Motion for Partial Summary Judgment as to the

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[15] Sitting by designation on the District Court.

Exclusionary Scope of the '743 Patent should be denied.

Pursuant to Federal Rule of Civil Procedure 53(f), DP Plaintiffs filed objections to the R&R. (Docket No. 739.) As required by Rule 53(f), this Court has reviewed *de novo* the R&R and the submissions of all parties. Based on that review,

IT IS, on this 24th day of March, 2010,

ORDERED that Special Master Orlofsky's R&R (Docket No. 733) is adopted as the Opinion of this Court; and it is further

ORDERED that a copy of this Order be served on all parties within seven (7) days of the date of entry of this Order.

S/Joseph A. Greenaway, Jr.
JOSEPH A. GREEN AWAY, JR., U.S.C.J.
(Sitting by designation on the District Court)

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION
This Document Relates to:

All Direct Purchaser Actions

Civil Action No. 01-1652 (JAG)
(Consolidated Cases)

MDL Docket No. 1419

SPECIAL MASTER'S AMENDED REPORT AND RECOMMENDATION ON DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT AS TO THE UPSHER AND ESI SETTLEMENTS AND DIRECT PURCHASER PLAINTIFFS' PARTIAL MOTIONS FOR SUMMARY JUDGMENT AS TO THE APPLICABLE FRAMEWORK FOR ANALYSIS OF EXCLUSION PAYMENTS AND THE EXCLUSIONARY SCOPE OF THE '743 PATENT

ORLOFSKY, SPECIAL MASTER

I. INTRODUCTION

This consolidated antitrust action has been transferred to the District of New Jersey by the Judicial Panel on Multidistrict Litigation pursuant

to 28 U.S.C. § 1407. Pursuant to Rule 53 of the Federal Rules of Civil Procedure[1] and by consent of all parties in the above-captioned action, I have been appointed by order of this Court, dated April 12, 2006, to preside as a Special Master to review and decide all currently pending and future motions directed to Judge Joseph A. Greenaway, Jr. and Magistrate Judge Madeline Cox Arleo including, but not limited to discovery disputes, class certification and summary judgment (the "Appointment Order") (Doc. No. 316).

The Appointment Order provides that the decision of the Special Master on any matter before the Special Master will conclusively resolve that matter unless an appropriate objection is filed pursuant to Fed. R. Civ. P. 53(g).

This Report and Recommendation addresses the following Motions: (1) Motion of Defendants Schering-Plough Corporation ("Schering") and Upsher-Smith Laboratories, Inc. ("Upsher") (collectively, "Defendants") for Summary Judgment as to All Claims Brought By Direct Purchaser Plaintiffs ("DP Plaintiffs" or "DPPs") Related to the

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[1] **(a) Appointment.**

(1) Unless a statute provides otherwise, a court may appoint a master only to:

(A) perform duties consented to by the parties;

*** * ***

(C) address pretrial and post-trial matters that cannot be addressed effectively and timely by an available district judge or magistrate judge of the district.

Fed. R. Civ. P. 53(a).

Upsher Settlement ("Upsher Motion.");[2] (2) Defendants' Motion for Summary Judgment as to All Claims Brought By DPPs Related to the ESI Settlement ("ESI Motion");[3] (3) DPPs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments ("Framework Motion");[4] and (4) DPPs' Motion for

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[2] In support of the Upsher Motion, Defendants' submitted an opening Memorandum of Law (accompanied by 125 exhibits attached to the 7/25/08 O'Shaughnessy Decl.) ("Upsher Mem."), a Statement of Undisputed Facts ("Def. Upsher Facts"), a Reply Memorandum of Law in support of the Upsher and ESI Motions (accompanied by 40 exhibits attached to the 10/3/08 O'Shaughnessy Decl.) ("Upsher/ESI Reply"), a Reply to DPPs' Statement of Disputed Facts in Opposition to the Upsher Settlement ("Def. Upsher Reply Facts"), and a 10/21/2008 letter brief regarding a recent Federal Circuit Court of Appeals decision. In response, DPPs submitted a consolidated Memorandum of Law in opposition to the Upsher Motion and the ESI Motion (accompanied by 158 exhibits attached to the 9/5/2008 Refsin Decl.) ("Upsher/ESI Opp."), a Statement of Disputed Facts in Opposition to the Upsher Motion ("DPP Upsher Facts"), and a 10/31/2008 letter brief.

[3] In support of the ESI Motion, Defendants submitted an opening Memorandum of Law (accompanied by 46 exhibits attached to the 7/3/08 O'Shaughnessy Decl.) ("ESI Mem."), a Statement of Undisputed Facts ("Def. ESI Facts"), the Upsher/ESI Reply, a Reply to DPPs' Statement of Disputed Facts in Opposition to the ESI Motion ("Def. ESI Reply Facts") and the above-referenced 10/21/2008 letter brief. In response, DPPs submitted the Upsher/ESI Opp., a Statement of Disputed Facts in Opposition to the ESI Motion ("DPP ESI Facts"), and the above-referenced 10/31/2008 letter brief.

[4] In support of the Framework Motion, DPPs submitted an opening Memorandum of Law (accompanied by four exhibits) ("Framework Mem."), a Statement of Undisputed Facts ("DPP Framework Facts"), and a Reply Brief (accompanied by two appendices with a total of two exhibits) ("Framework Reply").

Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent ('743 Motion").[5]

After consideration of the parties' voluminous submissions in support of and in opposition to the above-referenced Motions,[6] as well as the oral argument of counsel presented on December 10, 2008, I conclude, based on the following analysis, that: (1) Defendants' Motion for Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the Upsher Settlement is granted; (2) Defendants' Motion for Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the ESI Settlement is granted; (3) DP Plaintiffs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments is denied; and (4) DP Plaintiffs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent is denied.

In response, Defendants submitted a Brief in Opposition to the Framework Motion (accompanied by 14 exhibits attached to the 9/5/08 O'Shaughnessy Decl.) ("Framework Opp.") and a Counterstatement of Material Facts ("Def. Framework Facts").

[5] In support of the '743 Motion, DPPs submitted an opening Memorandum of Law (accompanied by 15 exhibits ("'743 Mem."), a Statement of Undisputed Facts ("DPP '743 Facts"), and a Reply Brief (accompanied by two exhibits) ("'743 Reply"). In response, Defendants' submitted a Brief in Opposition to the '743 Motion accompanied by seven exhibits ("'743 Opp."), and a Counterstatement of Material Facts a ("Def. '743 Facts").

[6] The parties' summary judgment submissions include more than 400 pages of briefs and factual statements and a total of more than 400 exhibits.

II. BACKGROUND

This action involves the drug K-Dur 20, a potassium chloride supplement manufactured by Schering. Schering entered into separate agreements with Upsher and ESI Lederle ("ESI") settling patent litigation that Schering had initiated after Upsher and ESI sought approval from the Food and Drug Administration ("FDA") for their generic versions of K-Dur. The gravamen of DP Plaintiffs' Complaint is that Schering's settlements with Upsher and ESI were collusive, anticompetitive agreements that had the effect and purpose of preventing and delaying the entry of generic substitutes for K-Dur and allowing Schering to maintain a monopoly in the extended release potassium chloride supplement market. (DPP Am. Compl., ¶ 1). *See also In re K-Dur Antitrust Litigation,* 338 F. Supp. 2d 517, 522, 526 (D.N.J. 2004). Plaintiffs allege that but for payments made by Schering to Upsher and ESI under the agreements, Upsher and ESI would have settled on different terms and their generic products would have entered the market earlier than was permitted under the settlements. (DPP Am. Compl. at ¶ 1, 109). *See also In re K- Dur,* 338 F. Supp. 2d at 526.

As is evident from the discussion to follow, this case involves complex legal and factual issues at the intersection of patent and antitrust law. Accordingly, before analyzing the parties' motions, it is necessary to outline the regulatory, factual and procedural contexts in which the issues presented arise.

A. Statutory and Regulatory Framework

A pharmaceutical company must obtain FDA approval to market a prescription drug. 21 U.S.C. § 355(a). In order to obtain approval for a pioneer drug, a company must submit a New Drug Application ("NDA"), which details all safety and efficacy studies, the components in the drug, the methods used in "the manufacture, process and packaging" of the drug, and any patents issued on the composition or methods of using the drug. *Id.* at § 355(b)(1). The FDA publishes the patent information in the "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." *See* FDA Electronic Orange Book, http://www.fda.gov/cder/ob/.

Prior to 1984, a generic drug company also had to undertake its own costly studies regarding the efficacy and safety of a drug, even if the drug was a bioequivalent of a brand name drug already on the market. *See Schering-Plough Corp. v. Fed. Trade Comm'n,* 402 F.3d 1056, 1058-59 n.2 (11th Cir. 2005), *cert. denied,* 126 S.Ct. 2929 (2006) *("Schering")* (explaining the NDA process and indicating its potential cost). The generic was then required to file its own NDA for its version of the drug. The generic company could not begin testing the drug until after the patent life on the brand-name drug expired, since before that time the pioneer company could sue the generic for patent infringement. *See* 35 U.S.C. § 271 (2000) (stating that making or using a patented compound is an act of infringement).

In 1984, Congress enacted the Drug Price Competition & Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified at various

sections of titles 21 and 35 of the United States Code). Among its key provisions, the Hatch-Waxman Act: (1) created the Abbreviated New Drug Application ("ANDA"), which allows a generic drug applicant to piggyback on safety and efficacy studies conducted for the pioneer drug, *see generally* 21 U.S.C. § 355(j); (2) modified the definition of infringement, so that the conduct of safety and efficacy studies for FDA approval is no longer infringing activity, *see generally* 35 U.S.C. § 271(e); and (3) allowed the extension of patent terms to compensate for the period when a patented drug could not be marketed because it was undergoing the FDA approval process. *See generally* 35 U.S.C. § 156.

Under the Hatch-Waxman Act, the pioneer drug maker still files a NDA with full-scale safety and efficacy studies and lists the patents that generics might infringe in the future. 21 U.S.C. § 355(b)(l) (enumerating NDA provisions). However, a generic company may file an ANDA, which requires the generic to prove that the new drug is the bioequivalent of a brand- name drug on the market, but does not require the time-consuming studies required for a NDA. *Id.* at § 355(j)(2)(A) (listing the ANDA provisions). *See also Schering,* 402 F.3d at 1058-59 n.2 (generics can use a "truncated" process, "so long as the generic manufacturer proves that its drug is a bio-equivalent to the already-approved brand name/pioneer drug"); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes ("Hovenkamp"),* 87 Minn. L. Rev. 1719, 1753 (2003) (listing ANDA provisions and noting that generic must be bioequivalent of pioneer

drug). Further, the generic may begin testing before the pioneer's patent expires. 35 U.S.C. § 271(e)(l).

Under the Hatch-Waxman Act, an ANDA filer must make one of the following certifications: (1) that the "patent information has not been filed" on the generic's brand-name equivalent (a paragraph I certification); (2) that a "patent [on the branded drug] has expired" (a paragraph II certification); (3) that a brand-name patent exists, "the date on which such patent will expire," with a promise not to market until that date (a paragraph III certification); or (4) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." (a paragraph IV certification). 21 U.S.C. § 355(j)(2)(A)(vii) (emphasis added).

If the ANDA filer makes a paragraph IV certification, it must consult the Orange Book and provide notification to each NDA or patent owner impacted by the ANDA certification "not later than [twenty] days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed." *Id.* at § 355(j)(2)(B)(ii)(I). The filing of an ANDA with a paragraph IV certification allows the patent holders to sue, as it is considered a technical act of infringement, even though the generic has not yet begun marketing its version of the drug. *See* Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs,* 30 J. Corp. L. 309, 317 (2005) (noting that paragraph IV certification is a technical act of infringement because the generic intends to market and infringe the patent). The

patent owners then have 45 days to bring an infringement suit against the generic. If the affected patent owners do not file suit, the FDA can approve the ANDA without delay. 21 U.S.C. § 355(j)(5)(B)(iii). However, if an affected patent owner brings an infringement suit, approval of the application is automatically stayed for thirty months, or until a district court issues a final decision concluding that the patent has not been infringed or is otherwise invalid. *Id.*

In order to give generic drug makers an incentive to incur the expense and risk of a potential infringement suit by the patent holder, the ANDA procedures give the first ANDA filer a 180-day exclusivity period. *Id.* at 355(j)(5)(B)(iv). During this exclusivity period, the FDA cannot approve any other generic manufacturer's ANDA until 180 days after the earlier of (1) the date of the first ANDA filer's commercial marketing of its generic drug; or (2) the date of a "court [decision ruling] that the patent is invalid or not infringed."[7] *Id.* at 355(j)(5)(B)(iii)(I).

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[7] Prior to 2000, this was calculated from a "final judgment from which no appeal can be or has been taken." 21 C.F.R. § 314.107(e)(l) (1999). Now, a district court decision is sufficient. *Mylan Pharms., Inc. v. Shalala,* 81 F. Supp. 2d. 30 (D.D.C. 2000). Also, prior to 1998, FDA regulations had required that ANDA filers would not get the 180-day exclusivity unless they had successfully defended the patent infringement suit. *See* 59 Fed. Reg. 50,338,367 (Oct. 3, 1994). The "successful defense" requirement was subsequently found to be unreasonable, *Mova Pharms. Corp. v. Shalala,* 140 F.3d 1060, 1069-70 (D.D.C. 1998), and the FDA dropped the requirement in 1998. *See* 63 Fed. Reg. 59,710,711 (Nov. 5, 1998).

B. Factual and Procedural Background[8]

1. The Parties

The DP Plaintiff Class, represented by lead Plaintiff Louisiana Wholesale Drug, is essentially comprised of all persons or entities who purchased K-Dur 20 directly from Schering during the period November 20, 1998, through September 1, 2001.[9] The Class includes wholesalers, hospitals, health maintenance organizations and retail drug store chains.

Schering is a New Jersey corporation engaged in the discovery, development and marketing of, *inter*

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[8] The facts pertinent to the current motions are drawn primarily from the parties' pleadings and their respective statements filed pursuant to Local Rule 56.1. Unless otherwise indicated, the facts set forth below are not in dispute.

[9] On April 14, 2008, I issued a Report and Recommendation (the "April 14 R&R") recommending that DP Plaintiffs' Motion for Class Certification be granted and the following Class certified:

> All persons or entities who have purchased K-Dur 20 directly from Schering at any time during the period November 20, 1998, through September 1, 2001.
>
> Excluded from the proposed class shall be:
>
> Defendants and their officers, directors, management and employees, subsidiaries and affiliates, as well as federal government entities. Also excluded are persons or entities who have not purchased generic versions of K-Dur 20 after the introduction of generic versions of K-Dur 20.

(April 14 R&R, Doc. No. 636). On December 30, 2008, Judge Greenaway overruled the objections of Defendants and DP Plaintiffs to the April 14 R&R and adopted the R&R as the opinion of the Court. (Dec. 30, 2008 Order, Doc. No. 731).

alia, brand name and generic drugs. Upsher is a Minnesota corporation engaged in the discovery, development and marketing of brand name and generic drugs. Former Defendant Wyeth Laboratories ("Wyeth"), formerly known as American Home Products, Inc. ("AHP"), is a Delaware corporation engaged in the development, manufacturing and marketing of, *inter alia,* brand name and generic drugs. Former Defendant ESI is a business unit of Wyeth that engages in the research, manufacture and sale of generic drugs.[10]

2. K-Dur and the '743 Patent

During the time period relevant to the DP Plaintiffs' claims, Schering marketed a potassium chloride supplement under the brand name K-Dur. (DPP Upsher Facts, ¶ 1).[11] K-Dur is used to treat potassium deficiencies such as those that often arise from the treatment of high blood pressure with diuretic products. (DPP '743 Facts, ¶ l; Def. '743 Facts, ¶ 1). Although the active ingredient in K-

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[10] On January 24, 2005, Judge Greenaway granted final approval of a settlement between DP Plaintiffs and Wyeth. (Jan. 24, 2005 Order, Doc. No. 226). As part of the settlement, DP Plaintiffs agreed to the release and dismissal with prejudice of all claims against Wyeth and its related entities, including ESI. (DPP/Wyeth Settlement Agreement, Doc. 170-3).

[11] In the interest of brevity, the record citations herein regarding the factual background refer to the parties' statements filed pursuant to Local Rule 56.1 and, unless necessary, do not separately identify each exhibit cited by the parties in their statements of fact. In addition, because the DPP Upsher Facts and the DPP ESI Facts restate each paragraph of Defendants' Upsher Facts and ESI Facts, it is not necessary to cite separately to Defendants' Upsher Facts and ESI Facts.

Dur—potassium chloride—is not patented, K-Dur is covered by a formulation patent, No. 4,863,743 (the "'743 Patent"), owned by Key Pharmaceuticals, Inc. ("Key"), a division of Schering. (Schering Ans. to DPP Am. Compl., ¶ 23-24). The '743 Patent, which claims a controlled-release dispersible potassium chloride tablet, was issued on September 5, 1989 and expired on September 5, 2006. (Schering Ans. to DPP Am. Compl. at ¶ 24; DPP Upsher Facts, ¶ 9).

The '743 Patent has 12 claims, all of which depend on or incorporate Claim 1. (DPP Upsher Facts, ¶ 49; DPP '743 Facts, ¶ 12; Def. '743 Facts, ¶ 12). Claim 1 of the '743 Patent states:

> A pharmaceutical dosage unit in tablet form for oral administration of potassium chloride, comprising;
>
> a plurality of coated potassium chloride crystals, the amount of potassium chloride being in the range of about 64% to about 86.5% by weight based on the total weight of the dosage unit;
>
> a coating material for the individual potassium chloride crystals, the coating material comprising ethylcellulose in the amount in the range of about 9% to about 15% by weight based on the total weight of the coated crystals and at least one member selected from hydroxypropylcellulose and polyethylene glycol in an amount in the range of about 0.5% to about 3% by weight based on the total weight of the coated crystals and said ethylcellulose has a viscosity greater than 40 cp.

('743 Mem., Ex. 1 ('743 Patent) at Col. 8, line 18-Col. 10, line 21). With regard to tablets, the '743 Patent specification states, *inter alia,* "[t]he useful ethylcellulose designations are 7 and higher, corresponding to a viscosity of at least 6 cp, preferably more than 40 cp (designations 45 or higher) for crystals to be compressed into tablets." *(Id.* at Col. 4, lines 63-66).

3. <u>Development and Prosecution of the '743 Patent</u>

The sustained release potassium chloride tablet claimed in the '743 Patent was developed at Key by Charles Hsiao and Chi-Tze Chou using a technique called "microencapsulation."

(DPP Upsher Facts, ¶ 4). Microencapsulation is a process in which small particles of a drug are coated to give them sustained release properties. (DPP Upsher Facts, ¶ 5). Tableting exposes the coated microcapsules to compression forces as the individual crystals are compressed into a tablet. *(Id.).* Dr. Hsiao and Ms. Chou used a coating consisting of insoluble ethylcellulose ("EC") with a viscosity of greater than 40 centipoise ("cp") and either hydroxypropylcellulose ("HPC") or polyethylene glycol ("PEG"). (DPP Upsher Facts, ¶ 8). Viscosity is a property of fluid that refers to its resistance to flow. (DPP '743 Facts, ¶ 14; Def. '743 Facts, ¶ 14). The addition of HPC or PEG permits the potassium chloride to leach out through the EC coating. *(Id.).*

The '743 Patent issued from patent application No. 830,981 (the "'981 application"), filed February 19, 1986. (Schering Ans. to DPP Am. Complaint, ¶ 29). The '981 application was a continuation-in-

part of application No. 702,714 (the "'714 application"), filed February 19, 1985. (DPP '743 Facts, ¶ 19; Def. '743 Facts, ¶ 19). As originally filed, Claim 1 of the '981 application did not contain any limitation on the viscosity grade of the ethylcellulose used in the coating material. (DPP Upsher Facts, ¶ 50). In addition, as originally filed, Claim 1 described a "dosage unit" for oral administration of potassium chloride, and was not limited to a tablet dosage form. *(Id.)*.

On August 31, 1988, the Patent and Trademark Office ("PTO") rejected the then-pending claims of the '981 application based on Patent No. 4,555,399 (the "'399 Patent") and other prior art. (DPP '743 Facts, ¶ 28; Def. '743 Facts, ¶ 28). The '399 Patent had previously been granted to Dr. Hsaio for a controlled release tablet aspirin tablet in which aspirin crystals are coated with EC and HPC and compressed into tablet form. (DPP Upsher Facts, ¶ 51; DPP '743 Facts, ¶ 23; Def. '743 Facts, ¶ 23). Example 1 of the '399 Patent describes the use of Ethocel N-10 (Dow), an EC with a viscosity of 9-11 cp. (Upsher/ESI Opp., Ex. 167 ('399 Patent) at Col. 3, line 8; '743 Mem., Ex. 2 (Feb. 27, 1989 Amendment) at 5). However, DP Plaintiffs dispute that the '399 Patent limited the claimed invention in any way to 9-11 cp ethylcellulose. (DPP Upsher Facts, ¶ 51).

After the PTO's August 31, 1988 rejection, Key filed a response that included an amendment to Claim 1 and arguments in support of patentability. (DPP Upsher Facts, ¶ 52). Key amended Claim 1 by specifying that the invention was a "tablet" and by adding the phrase "said ethylcellulose has a viscosity

greater than 40 cp" at the end of Claim 1. (DPP Upsher Facts, ¶ 52-53; '743 Mem., Ex. 2 (Feb. 27, 1989 Amendment) at 1-2). In its remarks accompanying the amendment, Key stated, *inter alia,* that "the claims have been amended to more precisely define the claimed invention," and argued that a review of the prior art '399 Patent would not lead one skilled in the art to use EC with a viscosity of greater than 40 cp to make a sustained release potassium chloride tablet as claimed in the '981 application. (DPP Upsher Facts, ¶ 54). Key further stated that the prior art '399 Patent disclosed only EC with a viscosity of 9-11 cp. (*Id.*). On March 31, 1989, the Patent Examiner granted Key the '743 Patent. (DPP Upsher Facts, ¶ 55).

4. <u>The Upsher Patent Litigation</u>

On August 8, 1995, Upsher filed an ANDA with the FDA seeking permission to sell a generic version of K-Dur. (DPP Upsher Facts, ¶ 12). Upsher's generic product, Klor-Con© M20, was a microencapsulated, controlled release 20mEq potassium chloride tablet. *(Id.* at 13). Upsher certified to the FDA that its product was bioequivalent to K-Dur and stated that its product was "the same as the reference drug, K-DUR." *(Id.* at 15-16). In its November 3, 1995 paragraph IV Certification Notice to Schering, Upsher claimed that its generic drug would not infringe the '743 Patent. (DPP Upsher Facts, ¶ 17). Specifically, Upsher asserted that its product did not infringe Key's product because: (1) "the viscosity of ethyl cellulose employed in KLOR-CON© M is outside the range limited by claim 1 of the '743 patent;" and (2) "[t]he KLOR-CON© M product does not contain

hydroxypropylcellulose." (Upsher Mem., Ex. 17 (Nov. 13, 1995 Patent Certification Notice) at 8-9).[12] Upsher's product used sorbitan monooleate ("SMO"). (DPP Upsher Facts, ¶ 18). Upsher disputes "any implication that it used SMO in place of HPC or PEG," and disputes that the SMO used in Upsher's product was present in an amount corresponding to the claimed amount of HPC or PEG required by the claims of the '743 Patent. *(Id.)*. In its Patent Certification Notice, Upsher also asserted that because, in its amendment of Claim 1, Key inserted a limitation of viscosity for EC of greater than 40 cp, prosecution history estoppel precluded Key from "assert[ing] the doctrine of equivalents in alleging that the KLOR-CON© M product infringes its claims." (Upsher Mem., Ex. 17 (Nov. 13, 1995 Patent Certification Notice) at 9-13).

On December 15, 1995, Key filed an action in the United States District Court for the District of New Jersey against Upsher alleging "willful and deliberate" infringement of the '743 Patent. (DPP Upsher Facts, ¶ 19). The case was assigned to Judge Walls. *(Id.* at ¶ 23). Key's action was timely commenced within the 45-day period specified in the Hatch-Waxman Act. *(Id.* at ¶ 19). Upsher answered Key's complaint, denying infringement and alleging declaratory judgment counterclaims for patent invalidity, non-infringement and unenforceability. *(Id.* at ¶ 23).

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[12] Upsher's Patent Certification Notice also stated that "the KLOR-CON° M product does not contain magnesium stearate of polyvinylpyrolidone." *(Id.* at 9).

Discovery in the case included the exchange of tens of thousands of pages of documents and depositions of the inventors and patent attorneys from Key and Schering, as well as of the Upsher technical people and consultants who developed the Upsher formulation. *(Id.* at ¶ 24). Schering retained as an expert, Dr. Gilbert S. Banker, dean of the University of Iowa College of Pharmacy. *(Id.* at ¶ 25). Key retained as its technical expert, Dr. Christopher Rhodes, a co-editor with Dr. Banker of the textbook, *Modern Pharmaceutics.* *(Id.* at ¶ 27). Drs. Banker and Rhodes each submitted expert reports, and both were deposed for multiple days. *(Id.* at ¶ 28, 30). Dr. Banker opined that the '743 Patent was valid and infringed by Upsher's product; Dr. Rhodes opined that the '743 Patent was invalid and that the Upsher formulation was not equivalent to the claims of the '743 Patent. *(Id.* at ¶ 29).

On February 6, 1997, Upsher moved for summary judgment on the issue of non- infringement. *(Id.* at ¶ 31). Upsher argued that Key was barred by prosecution history estoppel from claiming that the Upsher product was equivalent to the '743 Patent, and that no factual equivalency existed between its generic product and the claims of the '743 Patent. *(Id.* at ¶ 31). In opposition to the Motion, Key argued that it was not barred by prosecution history estoppel from asserting equivalency, and that factual disputes existed regarding whether Upsher's formulation was equivalent to the '743 Patent. *(Id.* at ¶ 32). Key separately moved for summary judgment on Upsher's affirmative defenses that the '743 Patent was unenforceable based on inequitable conduct before the PTO. *(Id.* at ¶ 34). Upsher opposed Key's motion on the ground that fact

disputes concerning the alleged inequitable conduct precluded summary judgment. *(Id.* at ¶ 35).

On June 17, 1997, Judge Walls held a hearing on certain motions, including Upsher's motion for summary judgment. ("743 Mem., Ex. 9). Trial in the *Key v. Upsher* matter was scheduled to being on June 18, 1997.

5. <u>The Upsher Settlement</u>

Upsher initiated contact with Schering to discuss settlement of the patent litigation. (DPP Upsher Facts, 68). The first settlement meeting took place on May 21, 1997, with subsequent discussions between the parties occurring on May 28, June 3, and June 12, and June 16, 1997. (DPP Upsher Facts, ¶¶ 197, 199, 205; Def. Upsher Reply Facts, ¶¶ 197, 199, 205). In the early morning hours of June 18, 1997, the parties signed and finalized an agreement, dated June 17, 1997 (the "June 17 Agreement"), "as to the terms under which [Upsher and Schering, on behalf of itself and Key] will settle the *[Key v. Upsher]* action and will enter into a transaction licensing rights to certain Upsher-Smith products to an affiliate of Schering." (DPP Upsher Facts, ¶ 208; Def. Upsher Reply Facts, ¶ 208; Upsher Mem., Ex. 61 (June 17, 1997 letter from Raman Kapur to Ian Troup) at p. 1).

The terms of the June 17 Agreement pertinent to the instant Motions provided that: (1) Upsher would not market its Klor-Con© M20 product, or any other sustained release microencapsulated potassium chloride tablet, prior to September 1, 2001; (2) effective September 1, 2001, Schering would grant Upsher a non-royalty bearing non-exclusive license to market its Klor-Con©M20 and Klor-Con©M10

product in the United States; (3) Upsher would grant Schering licenses to Upsher's Niacor-SR© and five other Upsher products;[13] and (4) "[i]n consideration for the licenses, rights and obligations described in paragraphs 1 through 10" of the agreement, Schering would pay to Upsher a total of $60 million, comprised of $28 million payable upon approval of the agreement by Schering's Board of Directors, $20 million on the first anniversary of the approval date, and $12 million on the second anniversary of the approval date.[14] (Upsher Mem., Ex. 61 (June 17 Agreement) at ¶¶ 3, 7-11).

The parties dispute the facts regarding the *bona fides* of the Niacor-SR© license deal and the reasons it was included in the June 17 Agreement. DP Plaintiffs contend that the deal was effectively a sham and that all or part of the $60 million paid to Upsher by Schering under the Agreement was really for Upsher's agreement to delay the entry of its generic K-Dur. (Upsher Opp., pp. 37-66; DPP Upsher Facts, ¶¶ 72-106, 192-277). Schering contends that the Niacor-SR© license was a separately valued deal, that the $60 million was a good faith payment for rights Schering believed — in

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[13] The five other Upsher products were KLOR CON© 8, KLOR CON© 10, KLOR CON© M20, PREVALITE©, and Pentoxifylline. (Upsher Mem., Ex. 61 (June 17 Agreement) at ¶¶ 7-10).

[14] The Agreement also provided for milestone and royalty payments contingent upon Schering's sales of Niacor-SR©. Subsequent to the June 17 Agreement, Schering decided not to pursue the Niacor-SR© opportunity, and Schering never marketed the drug. However, the facts regarding the reasons for Schering's decision are disputed. (DPP Am. Compl., ¶ 74; Schering Ans. to Am. Compl., ¶ 74).

its business judgment at the time — were worth $60 million, and that the deal was included in the June 17 Agreement only after Schering was satisfied that the deal stood on its own merit. (Upsher Mem., pp. 41-66; Upsher/ESI Reply, pp. 18-27; DPP Upsher Fact, ¶¶ 72-106; 192-277).

6. The ESI Patent Litigation and Settlement

On December 29, 1995, ESI sought FDA approval to market a generic version of K-Dur. (DPP ESI Facts, p 3; Schering Ans. to DPP Am. Complaint, ¶ 78). ESI's product was a sustained release tablet for oral administration of potassium chloride. It used the ingredients potassium chloride, EC and HPC in amounts within the ranges specified by Claim 1 of the '743 Patent. (DPP ESI Facts, ¶ 4). ESI submitted a Paragraph IV Certification and notified Schering of its Paragraph IV Certification and ANDA filing. (Schering Ans. to DPP Am. Complaint, ¶ 78).

On February 16, 1996, Schering (through Key) sued ESI in the United States District Court for the Eastern District of Pennsylvania, alleging that ESI's generic product infringed the '743 Patent. (DPP ESI Facts, ¶ 5; Schering Ans. to DPP Am. Compl., ¶ 80). ESI argued that its product did not literally infringe the "743 Patent because ESI's product did not have a "coating material with different ingredients" as required by the '743 Patent. (ESI Opp., Ex. 145 (ESI Reply Mem. in Support of Defendant's Mot. for a Markman Ruling on Patent Claim Construction and/or for Partial Summary Judgment of No Literal Infringement and Response to Plaintiffs Cross Motion) at p. 2). ESI stated that its "tablets are

made by a completely different technology which produces a multi-layered coating with each layer comprised of a separate material having only a single ingredient." *(Id.* at p. 13).

In the Fall of 1996, Schering and ESI agreed to engage in court-supervised mediation. (DPP ESI Facts, ¶ 7). The mediation session was suggested by the presiding District Judge, the Hon. Jan DuBois, to whom the case was assigned. *(Id.).* U.S. Magistrate Judge Thomas Rueter was appointed mediator. *(Id.).* During the mediation sessions, Magistrate Judge Rueter met with the parties both jointly and separately and urged them to settle. *(Id.* at ¶ 8).

In December 1997, Schering obtained information from ESI concerning problems ESI had encountered in demonstrating the bioequivalence of its generic product to K-Dur, as required for approval of ESI's ANDA. (DPP Upsher Facts, ¶ 9; Def. ESI Reply Facts, ¶ 9; ESI Mem., Ex. 13 (Dec. 15, 1997 letter, AHP 05 00175)). The information showed that the FDA had twice rejected ESI's bioequivalence studies and that ESI's most recent effort to conduct a trial showing bioequivalence had begun on December 8, 1997. *(Id.).* Also in mid-December 1997, the parties discussed a proposed settlement whereby Schering would grant ESI a royalty free license to market its generic Micro-K® 20 product on December 31, 2003, and ESI would grant Schering licenses for certain ESI products in exchange for a $5 million up-front royalty fee plus additional royalty fees based on sales of the products. (DPP ESI Facts, ¶¶ 10-11; Def. ESI Reply Facts, ¶¶ 10-11).

Judge DuBois held a Markman hearing on January 21 and 22, 1998. (DPP ESI Facts, ¶ 13). At

the close of the January 22, 1998 session of the hearing, Judge DuBois told the parties:

> I want you to take this business decision, and it is a business decision and decide it without any more help than you're getting from Judge Rueter. I don't want you to use the adjudicatory powers of the Court.
>
> We're talking about the conciliatory services that the Court offers, and that's what I want you to use to resolve the case. I don't want to have to adjudicate either this case or the two-week long or longer trial of this case. I want you to try to do it.
>
> I think that's the best way to resolve a dispute of this kind, particularly since I think you can craft a settlement among yourselves.

(ESI Mem., Ex. 17 (Jan. 22, 1998 Tr.) at 139). At the end of the hearing, after summoning the parties to his chambers, Judge DuBois directed the parties to Magistrate Judge Rueter to try to settle the case. (DPP ESI Facts, ¶ 13; ESI Mem., Ex. 18 (Herman 10/30/01 Dep.) at 129-130).[15]

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[15] In their Statement of Disputed Facts, DP Plaintiffs have asserted that certain of the statements cited in Defendants' Statement of Facts regarding the ESI Settlement are inadmissible hearsay. In this regard, I note that hearsay statements may be considered on summary judgment if the statements are capable of being admissible at trial. *Shelton v. Univ. of Med. & Dentistry,* 223 F.3d 220, 223 n.2 (3d Cir. 2000). Moreover, to the extent that the statements are offered not to show the truth of the matter asserted, but to demonstrate their effect on the listener, they may be admissible. *See Marks v. Marina,* 213 Fed. Appx. 147,213 Fed. Appx. 147, 2007 U.S. App.

The parties had another mediation session with Magistrate Judge Rueter on Friday, January 23, 1998, which began around 5:30 p.m. and continued until 11:30 p.m. (DPP ESI Facts, ¶ 14). Participating in all or part of the session were three of Schering's counsel and one Schering executive, Martin Driscoll, who participated by phone in parts of the session while attending a New Jersey Nets basketball game with his children. *(Id).* By the time of the January 23, 1998 mediation session, the parties had agreed to a $15 million license from ESI to Schering for ESI's two generic products, and ESI had indicated that it required money to settle the case. (DPP ESI Facts, ¶ 15).

Magistrate Judge Rueter encouraged Schering to pay ESI $5 million, which he characterized as "nothing more than legal fees." (DPP ESI Facts, ¶ 16-17). During the January 23, 1998 mediation session, Magistrate Judge Rueter called Mr. Driscoll three times at the basketball game. In those calls, Magistrate Judge Rueter told Mr. Driscoll that he had been instructed by the court to reach a settlement that night and that if the parties did not reach a settlement that night, the judge wanted the parties in court at 8 a.m. the next day. (DPP ESI Fact, ¶ 16-18; ESI Mem., Ex. 12 (FTC Trial Tr.) at 2707-11; ESI Mem., Ex. 19 (Driscoll Dep.) at 295; ESI Mem., Ex. 20 (Driscoll I.H. Tr.) at 105-7). Magistrate Judge Rueter also called John Hoffman,

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LEXIS 479, at *10-11 (3d Cir. Jan. 10, 2007) (court properly admitted evidence offered not for its truth, but to show the effect on the listener); *Faulkner v. Super Valu Stores, Inc.,* 3 F.3d 1419, 1434 (10th Cir. 1993) ("statements offered for the effect on the listener ... are generally not hearsay.").

Schering's then in-house antitrust counsel, at home and asked Schering to pay ESI $5 million. (DPP ESI Facts, ¶ 17; ESI Mem., Ex. 10 (Hoffman Dep.) at 328, 330; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2618-20). Prior to and during the mediation, ESI requested more than $5 million to settle the case. (DPP ESI Facts, ¶ 18).

During the January 23 session, Magistrate Judge Rueter urged Mr. Driscoll to settle and emphasized that he thought the parties could reach a middle ground. (DPP ESI Facts, ¶ 18; ESI Mem., Ex. 12 (FTC Trial Tr.) at 2707-11). Mr. Driscoll expressed his belief that ESI might have difficulty getting its product approved and discussed with Magistrate Judge Rueter a proposal under which Schering would pay ESI a certain amount if ESI's ANDA was approved by a certain date, and a lesser amount if ESI received approval at a later date. (DPP ESI Facts, ¶ 19; ESI Mem., Ex. 19 (Driscoll Dep.) at 295-96; ESI Mem., Ex. 12 (FTC Trial Tr.) at 2711-12). Magistrate Judge Rueter discussed the proposal with Mr. Hoffman, and characterized it as a "bet." (DPP ESI Facts, ¶ 21; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2620). Regarding Schering's doubt that ESI would receive FDA approval, Magistrate Judge Rueter told Mr. Hoffman that he should "put [his] money where [his] mouth is," and stated that if Schering's concern was correct, the proposal wouldn't cost Schering anything. (DPP ESI Facts, ¶ 22; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2621).

The January 23, 1998 mediation session concluded with the parties' agreement that Schering would pay ESI $10 million if its ANDA was approved by July 1999, with Schering's payment incrementally

decreasing to $625,000 if ESI's ANDA was approved in 2002. (ESI Mem., Ex. 16 (C+B-2 002196-97) at ¶ II). The parties further agreed that Key would grant ESI a "royalty free, non-exclusive license under US Patent '743 beginning 1/1/04." *(Id.* at ¶ VI). Once the terms had been agreed to by Schering and ESI, Magistrate Judge Rueter called the participants into chambers and asked them to put the terms in writing and initial or sign them. (DPP ESI Facts, 24; ESI Mem., Ex. 11 (FTC Trial Tr.) at 2621). Counsel for ESI prepared a handwritten document summarizing the settlement principles. (ESI Mem., Ex. 16 (C+B-2 002196-97); ESI Mem., Ex. 8 (FTC Trial Tr.) at 2488-89; 2537). The document was prepared, and was signed by representatives of Key and ESI, in the presence of Magistrate Judge Rueter. *(Id.).*

Schering and ESI signed a formal settlement agreement in June of 1998. (DPP ESI Facts, ¶ 26). Among its terms, the Agreement provided that: (1) Key would grant to ESI a non-exclusive, royalty-free license, effective January 1, 2004, to market a "Referencing Product"[16] (ESI Mem., Ex. 24 (Settlement Agreement) at ¶ 3.1(a)(i)); (2) except with respect to a Referencing Product for which ESI was permitted to seek FDA approval pursuant to the Agreement, ESI would not, prior to the expiration of

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[16] The Agreement defined a "Referencing Product" as an ESI KCI Product, a potassium chloride product that is the subject of an ANDA or NDA that references a Key NDA, or a potassium chloride product marketed by ESI as equivalent to, or otherwise substitutable on a generic basis for, K-Dur. (ESI Mem., Ex. 24 (Settlement Agreement) at ¶ 1.2). An ESI KCI Product was defined as the 20 Meq extended release potassium chloride tablet described in Key's ANDA. (*Id.*).

the '743 Patent: (i) apply for, sponsor or support an application for AB rating for any potassium chloride product with respect to K-Dur, or (ii) conduct, sponsor, file or support a substitutability or equivalence study of a potassium chloride product with respect to K-Dur *(id.* at ¶ 2.9); and (3) Key would pay to ESI $5 million plus an additional sum ranging from $10 million, if ESI's ANDA received FDA approval by June 30, 1999, to $625,000, if ESI received approval in 2002 *(id.* at ¶ 4.1). In the Agreement, ESI represented that it was not "developing, or currently intends or plans to develop, a potassium chloride product, other than an ESI KCI Product or other potassium chloride products" that it already made. *(Id.* at ¶ 2.8).

ESI received FDA approval for its generic K-Dur product in May 1999, and Schering paid ESI the $10 million required under Paragraph 4.1(b) of the Settlement Agreement. (DPP ESI Facts, ¶ 21). In July 2001, ESI announced that it was exiting the oral generic business altogether, and in 2002, ESI left the oral generics market. (DPP ESI Facts, ¶ 28).

7. <u>The FTC Action</u>

On March 30, 2001, the Federal Trade Commission ("FTC") filed a complaint against Schering, Upsher and AHP (the "FTC Action"). (DPP ESI Facts, ¶ 29). The complaint alleged, *inter alia,* that Schering's settlements with Upsher and ESI unreasonably restrained commerce and constituted unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act (the "FTC Act"). (ESI Mem., Ex. 29 (FTC Complaint) at ¶¶ 68-69). The complaint further alleged that Schering monopolized and conspired with Upsher and ESI to

monopolize the potassium supplement market. *(Id.* at ¶ 70-71).

Between January and March 2002, the FTC Action was tried before an Administrative Law Judge ("ALJ"). *In re Schering-Plough,* 2002 LEXIS 40, *6 (June 27, 2002) (*"Schering-ALJ").* The trial before the ALJ included the testimony of 41 witnesses, thousands of exhibits, and resulted in 8,629 pages of transcript. *Id.* On June 27, 2002, the ALJ issued a lengthy decision – including 431 findings of fact – ruling that the Upsher and ESI Agreements were lawful settlements of legitimate patent disputes and dismissing the FTC complaint. *Id.* at *8-9. *See also Schering,* 402 F.3d at 1061. The ALJ ruled that the theories advanced by the FTC required a presumption that the '743 Patent was not valid or that Upsher's and ESI's products did not infringe the patent. *Id.* at *8-9. *See also Schering,* 402 F.3d at 1061. The ALJ concluded that there was "no basis in law or fact to make that presumption." *Schering-ALJ,* 2002 LEXIS 40, at *9. The ALJ further concluded that a *per se* antitrust analysis of the agreements was not appropriate. *Id* at *219-33. Rather, applying a rule of reason analysis, the ALJ emphasized the need to consider the exclusionary power of the patent at issue. *Id.* at *235-43 ("Application of antitrust law to markets affected by exclusionary statutes such as the Patent Act cannot ignore the rights of the patent holder.") Considering the exclusionary power of the '743 Patent and the inability to predict the outcome of the patent litigation, the ALJ rejected the FTC's argument that, absent Schering's payments to Upsher and ESI, the generics could have entered the market earlier. *Id.* at *242-43.

The FTC's complaint counsel appealed to the full Commission, which reversed the ALJ. *In re Schering-Plough Corp.,* 2003 FTC LEXIS 187 (Dec. 8, 2003) *("Schering-FTC")*. Although the Commission refrained from holding that Schering's payments to Upsher and ESI made the settlements *per se* illegal, it also declined to apply the full rule of reason analysis employed by the ALJ. *Id.* at *13, 22-27. Instead, under the analysis adopted by the Commission, once the FTC demonstrates the agreements' anticompetitive effects, the "respondents must demonstrate that the challenged provisions are justified by procompetitive benefits that are both cognizable and plausible." *Id.* at *14. The Commission ruled that the FTC had demonstrated the anticompetitive effect of the agreements, and reasoned that "[a]bsent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[17] *Id.* at *16, 52. Although the FTC ostensibly used a truncated rule of reason analysis, it essentially indicated that any settlement involving reverse payments over $2 million (an estimated cost of legal fees) would be *quid pro quo* for market delay and, thus, illegal. *Id.* at* 175-76. The FTC further rejected the ALJ's conclusion that the licenses granted to Schering under the agreements were

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[17] Although the FTC found both the Upsher and ESI Agreements unlawful, it noted the limited evidence presented regarding the ESI settlement and stated that "[a]s a matter of prosecutorial discretion, we might not have brought a stand-alone case based on such relatively limited evidence." *Schering-FTC,* 2003 FTC LEXIS 187, at*166.

adequate consideration for the payments made by Schering, ruling instead that the payments were for delay. *Id* at *15-16.

The Defendants chose to appeal the FTC's decision to the Eleventh Circuit, which reversed the Commission. *Schering,* 402 F.3d 1068. The Eleventh Circuit's decision in *Schering,* and its previous decision in *Valley Drug Co. v. Geneva Pharm., Inc.,* 344 F.3d 1294 (11th Cir. 2003), *cert. denied,* 125 S.Ct. 308 (2004), are discussed, *infra.*

III. DISCUSSION

A. The Parties' Motions

1. Defendants' Upsher and ESI Motions

In their Motions, Defendants contend that unless DP Plaintiffs can show either: (1) that Schering's underlying patent litigation was "objectively baseless"; (2) that the '743 Patent was procured by fraud; or (3) that terms of the settlements extended the patent's coverage beyond the patent's potential exclusionary scope, the Upsher and ESI Settlements were lawful, even if they did include "reverse payments" to Upsher and ESI Defendants argue that under the foregoing standard, DP Plaintiffs cannot establish that Schering's patent infringement suits were baseless. According to Defendants, the patent litigation with Upsher and ESI involved disputed issues of fact and law such that Schering's claim of infringement could not possibly be deemed objectively baseless. Therefore, Defendants argue, summary judgment must be granted in their favor.

With respect to the Upsher Settlement, Defendants further argue that DP Plaintiffs cannot

show that there was a "reverse payment" to Upsher and, thus, their antitrust claim must fail. In short, Defendants contend that because the $60 million Schering paid Upsher was fair value for the Niacor license – and not a net payment for delay of Upsher's generic K-Dur – there can be no antitrust violation.

In their opposition to Defendants' Upsher and ESI Motions, and in their separate Framework Motion, DP Plaintiffs contend that the legal standard proposed by Defendants is incorrect. DP Plaintiffs argue that the correct framework is either a *per se* analysis, or what they term the "FTC/Hovenkamp approach." Under the framework proposed by DP Plaintiffs, settlement agreements involving reverse payments would be subject to a rebuttable presumption of illegality, which could be overcome by proof of a pro-competitive justification for the payment. With respect to whether the payments to Niacor were, in fact, "reverse payments," DPPs argue that the question of whether Schering paid more than fair value for the Niacor license is a "quintessential factual issue" which cannot properly be decided on summary judgment.

In addition to Defendants' two primary summary judgment arguments summarized above, Defendants contend that DP Plaintiffs have failed to present sufficient evidence of an actual anticompetitive effect on the relevant product market resulting from the settlement. According to Defendants, all generic potassium chloride supplements are interchangeable with K-Dur and, thus, must be included in the relevant market. Defendants argue that because DP Plaintiffs have failed to prove the relevant market,

they cannot prove that the Upsher Settlement caused any anticompetitive effects in that market.

In response to Defendants' arguments regarding the relevant market, DP Plaintiffs contend that the anticompetitive effects of delayed generic are indisputable, have been admitted by Schering, and can be proved by direct evidence that eliminates a need for the "relevant market" analysis urged by Defendants. DP Plaintiffs further argue that if a market definition is required, the relevant market cannot simply include all potassium chloride supplements that may be therapeutic substitutes for K-Dur. Rather, they argue, the market consists of K-Dur and its AB-rated equivalents.

Finally, Defendants contend that they are entitled to summary judgment on DP Plaintiffs' damages claims on two grounds. First, Defendants argue that this is not a price-fixing case and DP Plaintiffs cannot claim "overcharge" damages because, as distributors, they were not overcharged for K-Dur but, rather, were allegedly prevented from buying additional products, *i.e.,* generic versions of K-Dur. Defendants argue that the proper measure of damages under these circumstances is lost profits, and that DP Plaintiffs have failed to offer any evidence of such damages. Second, Defendants contend that DPPs have no claim for damages for K-Dur purchases that were subject to generic bypass.

In response, DP Plaintiffs assert that overcharge damages have long been the standard remedy for direct purchasers suing for antitrust violations. With respect to generic bypass, DPPs contend that Defendants' position is inconsistent with the only published decision on the issue, as well as with the

principles underlying the antitrust laws. (Upsher Opp., p. 78 (citing *In re Relafen Antitrust Litig.,* 346 F. Supp. 2d 349, 368-70 (D. Mass. 2004)). DP Plaintiffs further argue that even if an adjustment for bypass were required, it would not affect the amount of overcharges suffered by the Plaintiff Class.

2. DPPs' '743 Motion

DP Plaintiffs also seek partial summary judgment as to the exclusionary scope of Schering's '743 patent. This motion has two principal components. First, DPPs argue that under the doctrine of prosecution history estoppel and the "All Elements Rule," the scope of the '743 patent cannot extend to exclude Upsher's generic product. DPP's second contention is that, by its express terms, the Schering/Upsher Settlement Agreement exceeds the exclusionary scope of the '743 patent. Specifically, DPPs contend that the terms of the agreement prevent Upsher not only from selling the allegedly infringing Klor Con M, but also "any other sustained release microencapsulated potassium chloride tablet," irrespective of whether such products infringed Schering's patent.

B. Summary Judgment Standard

Motions for summary judgment are governed by Federal Rule of Civil Procedure 56. "Summary judgment is appropriate under Fed. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law." *Med Alert Ambulance, Inc. v. Atlantic Health Sys., Inc.,* No. 04-1615 (JAG),

2007 WL 2297335, *2 (D.N.J. Aug. 6, 2007) (citing *Celotex Corp. v. Catrett,* 477 U.S. 317, 322-23 (1986)).

Under Rule 56(c), the moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex,* 477 U.S. at 323 (1986) (quoting Fed. R. Civ. P. 56). "Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists." *MedAlert,* 2007 WL 2297335 at *3 (citing *Jersey Cent. Power & Light Co. v. Lacey Twp.,* 772 F.2d 1103, 1109 (3d Cir. 1985)). The party opposing the motion may not rest upon mere allegations or denials of the pleadings, "but must set forth specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 256 (1986). *See also Ridgewood Bd. of Educ. v. N. E. for M.E.,* 172 F.3d 238, 252 (3d Cir. 1999) ("Speculation and conclusory allegations do not satisfy [the nonmoving party's] duty.").

"'A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial.'" *Med Alert,* 2007 WL 2297335 at *3 (quoting *Gleason v. Norwest Mortg., Inc.,* 243 F.3d 130, 138 (3d Cir. 2001)). *See also Dasrath v. Continental Airlines, Inc.,* 467 F. Supp. 2d 431,443 (D.N.J. 2006) ("A dispute is 'genuine' if 'the evidence is such that a reasonable jury could return a verdict for the non-moving party.'") (quoting *Anderson,* 477 U.S. at 248).

In addition, "[a] fact is 'material' only if it might affect the outcome of the suit under the applicable rule of law." *Id.*

C. Traditional Antitrust Analysis

Section 1 of the Sherman Act declares that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is ... illegal." 15 U.S.C. § 1. It is well-settled, however, that this provision outlaws only unreasonable restraints of trade. *See State Oil v. Kahn,* 522 U.S. 3, 10 (1997). In order to determine whether an "unreasonable restraint" of trade has taken place, courts have traditionally used one of two different analyses: the *per se* rule and the rule of reason. *See State Oil Co.,* 522 U.S. at 10.

The *per se* analysis applies only under circumstances where courts have previously considered the type of conduct and found that its expected effects are overwhelmingly anticompetitive and have little prospect of yielding any pro-competitive benefit. *Id.* For a *per se* analysis to apply, the courts must have adequate judicial experience with the type of conduct at issue and must have found that it yields anticompetitive effects in the vast majority of cases (almost one-hundred percent of the time). *See* Herbert Hovenkamp, *Sensible Antitrust Rules for Pharmaceutical Competition,* 39 U.S.F. L. Rev. 11, 19-20. Under the *per se* approach, a court can condemn the action as a *per se* illegal restraint on trade "without elaborate inquiry into the defendant's market power, the actual anticompetitive effects of the restraint in a particular case, or the rationales

offered for it." *Id.* at 20. The *per se* analysis applies to only a few types of conduct, including "naked" exit payments (those payments made solely to keep a competitor out of the market), market-division agreements, and price fixing. *Id.* at 20-21.

In most cases, where the conduct is not so clearly anticompetitive, courts use the rule of reason analysis. Further, courts have begun to realize that categorization of conduct often is not clear cut, *id.* at 20-21, and that "[t]here is always something of a sliding scale in appraising reasonableness." *Cal. Dental Ass* 'n *v. Fed. Trade Comm'n*, 526 U.S. 756, 780 (1999). In the rule of reason analysis, "'the finder of fact must decide whether the questioned practice imposes an unreasonable restraint on competition, taking into account a variety of factors, including specific information about the relevant business, its condition before and after the restraint was imposed, and the restraint's history, nature, and effect.'" *In re Tamoxifen Citrate Antitrust Litig.,* 466 F.3d 187, 201 n.13 (2d Cir. 2006), *cert. denied sub. nom., Joblove v. Barr Labs, Inc.,* 127 S.Ct. 3001 (2007) *("Tamoxifen II")* (quoting *State Oil Co.,* 522 U.S. at 10).[18]

Courts have divided the rule of reason analysis into three parts, which involve burden-shifting between the two parties. First, the plaintiff must show that the conduct has produced adverse, anti-competitive effects within the relevant market. *U.S.*

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[18] The opinion in *Tamoxifen II* amended and superseded *In re Tamoxifen Citrate Antitrust Litig.,* 429 F.3d 370 (2d Cir. 2005) *("Tamoxifen I"). Tamoxifen II* predominantly made changes and corrections to the citations in the *Tamoxifen I* opinion, but did not modify the court's analysis or holding.

v. Brown Univ., 5 F.3d 658, 668 (3d Cir. 1993). *See also Tamoxifen II,* 466 F.3d at 201 n. 13. If the plaintiff is able to prove this effect, then the burden shifts to the defendant, who must attempt to prove that the conduct "promotes a sufficiently pro-competitive objective." *Id.* at 669. If the defendant meets this standard, the burden then shifts back to the plaintiff to prove that the restraint is not reasonably necessary to achieve the pro-competitive objective. *Id.*

In addition to the *per se* and rule of reason standards, a third type of analysis has evolved: the "quick look" or "truncated rule of reason." *See Fed. Trade Comm'n v. Ind. Fed'n of Dentists,* 476 U.S. 447, 459 (1986). The truncated rule of reason analysis permits the plaintiff to shift the burden to the defendant more quickly, once the plaintiff has shown that the defendant has engaged in conduct similar to those practices falling into the per se category, e.g., restraints on price, output or customers. *Id.* The plaintiff need not establish the relevant market or the defendant's market power, but the defendant has the opportunity to demonstrate pro-competitive justifications and efficiencies. *Id.*

D. **Analyses Applied By Other Courts to "Reverse Payment" Settlements**

To date, only a few courts have considered the issue of what analytical framework should be applied to antitrust claims involving reverse payment settlements of patent litigation by pioneer and generic drug companies. Although one Circuit Court has applied a *per se* analysis, the other courts that have considered this issue have adopted approaches

that focus on the exclusionary scope of the patent at issue. The reasoning of these cases is summarized below.

1. The Sixth Circuit's *Per Se* Analysis

The Sixth Circuit was the first federal appellate court to consider the legality of a settlement involving a reverse payment. *In re Cardizem CD Antitrust Litig.,* 332 F.3d 896 (6th Cir. 2003), *cert. denied,* 543 U.S. 939 (2004). In that case, the brand name drug maker, Hochst Marion Roussel ("HMR"), manufactured and sold the drug Cardizem CD. *Id.* at 901. HMR's original patent for the active ingredient of Cardizem CD expired in late 1992. *Id.* In September 1995, a generic manufacturer, Andrx, Inc., filed an ANDA and submitted a Paragraph IV certification, stating that its drug did not infringe the patents covering Cardizem. *Id.* at 902. As the first ANDA filer, Andrx was eligible for the 180-day exclusivity period. *Id.* In November 1995, HMR received a new patent for Cardizem CD's "dissolution profile." *Id.* In January 1996, HMR sued Andrx for patent infringement, thus triggering the 30-month stay of FDA approval of Andrx's ANDA. *Id.* In September 1997, the FDA tentatively approved Andrx's ANDA, indicating that it would be finally approved upon the expiration of the stay or a court ruling of non-infringement. *Id.*

Shortly after the FDA granted tentative approval, HMR and Andrx entered into the agreement that was at issue in the case. *Id.* Among its terms, the agreement provided that Andrx would not market a generic version of Cardizem CD until the earliest of: (1) a final, unappealable determination in favor of Andrx in the infringement case; (2) HMR and Andrx

entering into a license agreement; or (3) HMR entering into a license agreement with a third party. *Id.* Andrx further agreed not to "relinquish or otherwise compromise" its right to the 180-day exclusivity period. *Id.* In exchange, HMR agreed to make quarterly payments of $10 million to Andrx beginning on the date its ANDA received final FDA approval. *Id.*

On July 9, 1998, the FDA approved Andrx's ANDA, and HMR began making quarterly payments to Andrx. *Id.* at 903. Only in June 1999, after the FDA approved a reformulated generic version submitted by Andrx, did the two companies terminate their agreement and enter into a final settlement of the patent infringement suit. *Id.* At the time of the settlement, HMR made a further payment of $50.7 million to Andrx, bringing the total payments to more than $89 million. *Id.* On June 23, 1999, Andrx began marketing its generic product, triggering its 180-day exclusivity period. *Id.*

The court found that the parties' agreement was "at its core, a horizontal agreement to eliminate competition" and, thus, "a classic example of a *per se* illegal restraint of trade." *Id.* at 908. In finding the agreement *per se* illegal, the Sixth Circuit appeared particularly troubled by the fact that HMR's agreement with Andrx effectively used the 180-day exclusivity period to delay the entry of other generic competitors. In this regard, the court noted:

> By delaying Andrx's entry into the market, the Agreement also delayed the entry of other generic competitors, who could not enter the market until the expiration of Andrx's 180 period of

> exclusivity, *which Andrx had agreed not to relinquish or transfer.*

Id. at 907 (emphasis added).

2. <u>The Eleventh Circuit Approach in *Valier Drug* and *Schering v. FTC*</u>

(a) <u>*Valley Drug*</u>

Three months after the *Cardizem* decision, the Eleventh Circuit reached a different result in the case of *Valley Drug Co. v. Geneva Pharms., Inc.,* 344 F.3d 1294 (11th Cir. 2003). *Valley Drug* involved separate settlement agreements between Abbott Laboratories and two generic competitors, Geneva Pharmaceuticals and Zenith Goldine Pharmaceuticals, which had filed ANDAs challenging Abbot's patents relating to Hytrin, a brand name hypertension drug marketed by Abbott since 1987.[19] *Valley Drug,* 344 F.3d at 1298. Abbott filed suit against Geneva alleging infringement of its '207 Patent. *Id.* at 1299. In the suit, Geneva admitted infringement but asserted that Abbott's patent was invalid. *Id.* Zenith filed its own lawsuit against Abbott seeking delisting of the '207 Patent and another Abbott patent (from the Orange Book), and requesting a declaratory judgment that its generic product did not infringe the two patents. *Id.* Abbott asserted counterclaims for infringement against Zenith. *Id.*

Abbott entered into an agreement with Zenith on March 31, 1998 and with Geneva one day later. The

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[19] Abbott had multiple patents relating to terazosin hydrochloride, the active ingredient in Hytrin. *Id.* The patents covered various forms of the terazosin hydrochloride compound and methods for using it. *Id.*

Zenith Agreement included the following terms: (1) both parties dropped their lawsuit claims; (2) Zenith acknowledged the validity of Abbott's patents and admitted that any generic terazosin product it might market would infringe those patents; (3) Abbott agreed to make quarterly payments of $6 million dollars to Zenith until March 1, 2000 or the termination of the agreement; (4) Zenith agreed not to market any product containing terasozin hydrochloride until Abbott's '207 patent expired on February 17, 2000; and (5) Zenith agreed not to transfer any of its ANDA rights, including the 180-day exclusivity period it earned as the first ANDA filer. *Id.* at 1300.

Similarly, under the terms of the Geneva Agreement: (1) Abbott agreed to pay Geneva $4.5 million per month until another manufacturer brought a terazosin product to market, or Abbott won the '207 patent infringement suit; (2) Geneva agreed not to market any terazosin product until a second patent expired in February 2000 or until it obtained a court judgment of non-infringement or invalidity in the '207 patent infringement suit; (3) Geneva agreed not to transfer its rights under the ANDA, including its 180-day exclusivity period; and (4) Geneva agreed to challenge any subsequent ANDA filer's attempt to enforce the "successful defense" requirement. *Id.* On September 1, 1998, the district court hearing Abbott's infringement suit against Geneva declared the '207 Patent invalid. *Id.* at 1301 (citing *Abbott Labs. v. Geneva Pharms., Inc.,* 1998 WL 566884 (N.D. Ill. Sept. 1, 1998)). That decision was affirmed by the Federal Circuit, and Abbott's petition for certiorari was denied. *Id.* (citing 182 F.3d 1315 (Fed. Cir. 1999) and 528 U.S. 1078 (2000)).

In the subsequent private antitrust action, the Eleventh Circuit reversed the district court's decision granting summary judgment against the defendants.[20] *Valley Drug,* 344 F.3d at 1295. The Eleventh Circuit concluded that the district court misapplied the law when it found the agreements to be *per se* antitrust violations. *Id.* at 1295. The court reasoned that the "exclusionary potential of the ['207] patent" shielded the agreements' effects from *per se* antitrust evaluation. *Id.* at 1311. Thus, because the '207 patent would not expire until 2014, the effect of the agreements on competition was "no broader than the potential exclusionary effect of the '207 patent, and was actually narrower to the extent [they] permitted Zenith [and Geneva] to market [their] drug[s] before the '207 patent expired." *Id.* at 1305.

While the court noted that the agreements resembled a horizontal market allocation, it recognized that the patent rights held by Abbott changed the evaluation. *Id.* at 1304. The court emphasized that the patent grant involves the right to exclude, which can lead to lawful agreements allocating the market geographically or by customer

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[20] On remand, the district court still applied a *per se* analysis and found the agreements at issue in *Valley Drug* to be *per se* illegal. *See In re Terazosin Hydrochloride Antitrust Litig.,* 352 F. Supp. 1 279 (S.D. Fla. 2005). However, in its subsequent decision in *Schering,* the Eleventh Circuit found the agreements in *Valley Drug* to be "wholly different" from the Upsher and ESI Agreements. *Schering,* 402 F.3d at 1066, n. 14. The court noted that the "critical difference" is that the agreements in *Valley Drug* did not involve final settlements of the patent litigation, and did not permit the generic company to market its product before patent expiration. *Id.*

type. *Id.* at 1304. The court concluded that the district court erred when it focused on market allocation without considering the lawful exclusionary rights granted to Abbott under the '207 Patent. *Id.* at 1305.

The court further concluded that it was inappropriate to analyze the agreements under a traditional rule of reason framework because "the anticompetitive effects of exclusion cannot be seriously debated." *Id.* at 1311. Rather, the court reasoned, a threshold analysis of the exclusionary scope of the patent must precede any specific antitrust inquiry. *Id.* at 1312. If the terms of the agreements are found to have effects "beyond the exclusionary effects of Abbott's patent," they "may then be subject to traditional antitrust analysis to assess their probable anticompetitive effects in order to determine whether those provisions violate § 1 of the Sherman Act." *Id.*

The court identified a number of factors influencing its reasoning. First, it emphasized the competing regimes of patent and antitrust law. *Id.* at 1305-06. Second, the fact that the '207 patent subsequently was found to be invalid was not dispositive. *Id.* at 1308. Rather, the court concluded, the "reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into." *Id.* at 1306 (citing *Polk Bros. v. Forest City Enters.,* 776 F.2d 185, 189 (7th Cir. 1985); *SCM Corp. v. Zerox Corp.,* 645 F.2d 1195, 1209 (2d Cir. 1981)). Third, noting the "important role played by settlement in the enforcement of patent rights," the court rejected the notion that the mere existence or substantial size of

a reverse payment was sufficient to trigger *per se* illegality, especially where the lack of any damages reduces the risk for the generic manufacturers in the infringement suit. *Id.* at 1309-10 (citing *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 261 F. Supp. 2d 188,251-52 (E.D.N.Y. 2003) *("Cipro I"*) (discussing the asymmetries of litigation risk create by Hatch-Waxman and rejecting argument that payments from the patentee to the infringer are subject to *per se* antitrust analysis)).

(b) *Schering v. FTC*

In Schering's appeal of the *Schering-FTC* decision, the Eleventh Circuit reversed the FTC and reaffirmed the reasoning first set forth in *Valley Drug. Schering,* 402 F.3d 1056. The court restated its view that "neither the rule of reason nor the *per se* analysis is appropriate in this context." *Id.* at 1065. Recognizing the tension between the antitrust and patent laws, the court observed:

> By their nature, patents create an environment of exclusion, and consequently, cripple competition. The anticompetitive effect is already present. "What is required here is an analysis of the extent to which antitrust liability might undermine the encouragement of innovation and disclosure, or the extent to which the patent laws prevent antitrust liability for such exclusionary effects."

Schering 402 F.3d at 1065-66 (quoting *Valley Drug,* 344 F.3d at 1311, n.27). Clarifying the standard it adopted in *Valley Drug,* the court explained that "the proper analysis of antitrust liability requires an

examination of: (1) the scope of the exclusionary potential of the patent; (2) the extent to which the agreements exceed that scope; and (3) the resulting anticompetitive effects." *Id.* at 1066. Applying the foregoing analysis to the Upsher and ESI agreements, the Eleventh Circuit found them well within the scope of the patent and thus legal patent settlements.[21] *Id.* at 1076. In reaching this conclusion, the court emphasized the fact that the agreements permitted Upsher to enter the market more than five years before the '743 Patent expired, and ESI to enter the market more than two years before the expiration of the patent. *Id.* at 1067-68. The court further noted that "there has been no allegation that the '743 patent itself is invalid or that the resulting infringement suits against Upsher and ESI were 'shams.'" *Id.* at 1068. The court rejected the FTC's contention that, absent the payments to Upsher and ESI, the parties could have "simply compromised" on earlier entry dates. Finding no evidence in the record to support this conclusion – which the court viewed as "somewhat myopic" – the court reasoned:

> It is uncontested that parties settle cases based on their perceived risk of prevailing in and losing the litigation. Pre-Hatch-Waxman, Upsher and ESI normally would have had to enter the market with their products, incurring

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[21] The Eleventh Circuit also rejected the FTC's conclusion that the Niacor license was not worth $60 million, but was a payment to keep Upsher off the market, and stated that the FTC's conclusion was "not supported by law or logic." *Id.* at 1070.

the costs of clinical trials, manufacturing and marketing. This market entry would have driven down Schering's profits, as it took sales away. As a result, Schering would have sued ESI and Upsher, seeking damages for lost profits and willful infringement. ...

By contrast, the Hatch-Waxman Amendments grant generic manufacturers standing to mount a challenge without incurring the cost of entry or risking enormous damages flowing from any possible infringement. *See In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 261 F. Supp. 2d 188, 251 (E.D.N.Y. 2003).

Hatch-Waxman essentially redistributes the relative risk assessments and explains the flow of settlement funds and their magnitude. *Id.* Because of the Hatch-Waxman scheme, ESI and Upsher gained considerable leverage in patent litigation: the exposure to liability amounted to litigation costs, but paled in comparison to the immense volume of generic sales and profits. This statutory scheme could then cost Schering its patent.

By entering into the settlement agreements, Schering realized the full potential of its infringement suit – a determination that the '743 patent was valid and that ESI and Upsher would

> not infringe in the future. Furthermore, although ESI and Upsher obtained less than they what they would have received from successfully defending the lawsuits (the ability to immediately market their generics), they gained more than if they had lost. A conceivable compromise, then, directs the consideration from the patent owner to the challengers. *Id.*

Schering, 402 F.3d at 1074.

Noting the "private and social benefits" of settlements in avoiding the "the inveterate and costly effects of litigation," the court reiterated its view that neither the presence of a reverse payment, nor its size, should "dictate the availability of a settlement remedy." *Id.* at 1075 (citing D. Crane, *Exit Payments in Settlement of Patent Infringement Lawsuits; Antitrust Rules and Economic Implications,* 54 Fla. L. Rev. 747, 760 (2002)). The court further reasoned that "[a]n exception cannot lie, as the [FTC] might think, when the issue turns on validity *(Valley Drug)* as opposed to infringement (the Schering agreements)." *Id.* at 1075-76.

3. The Second Circuit's *Tamoxifen* Decision

In *Tamoxifen II,* the Second Circuit considered a "reverse payment" settlement between the pioneer drug company, Zenica,[22] and generic manufacturer

[22] Zeneca refers collectively to Imperial Chemical Industries, PLC ("ICI") and its former subsidiaries, Zeneca, Inc., AstraZeneca Pharmaceuticals LP, and Astra Zeneca PLC, which succeeded to ICI's rights to the patent at issue. *Tamoxifen II,* 466 F.3d at 190, 193.

Barr Laboratories.[23] *Tamoxifen II,* 466 F.3d at 190. Zeneca held the patent rights to and manufactured tamoxifen citrate, a leading breast cancer drug. *Id.* at 193. Barr filed an ANDA for a generic version of tamoxifen, which it amended in 1987 to include a Paragraph IV certification. *Id.* After Zeneca timely sued Barr and Barr's raw material supplier for patent infringement, the district court declared Zeneca's patent invalid based on its conclusion that Zeneca deliberately withheld information from the PTO. *Id.* Zeneca appealed the invalidity decision, and in 1993, while the appeal was pending, the parties entered into a settlement agreement. *Id.*

Under the agreement's principal terms: (1) Barr agreed not to market its generic version of tamoxifen until Zeneca's patent expired in 2002 and thus amended its ANDA to a Paragraph III certification; (2) Barr received a non-exclusive license to sell tamoxifen tablets manufactured by Zeneca under Barr's own label; (3) Zeneca agreed to pay Barr $21 million plus an additional $45 million over ten years to Barr's raw material supplier; and (4) the parties agreed that if Zeneca's patent were subsequently declared invalid or unenforceable in a final, unappealable judgment, Barr would be allowed to revert to a Paragraph IV certification. *Id.* 193-94. In addition, pursuant to the settlement, the parties jointly moved for *vacatur* of the district court's patent invalidity judgment, which motion was granted by the Federal Circuit. *Id.* at 194.

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[23] The case was before the Second Circuit on plaintiffs' appeal of the district court's dismissal of their antitrust claims pursuant to Fed. R. Civ. P. 12(b)(6). *Id.*

The validity of Zeneca's patent was subsequently challenged by three other ANDA filers, all of whom were unsuccessful in their attempts to rely on the vacated invalidity judgment. *Id.* at 195. In each case, the court upheld the validity of Barr's patent. *Id.* In the meantime, the "successful defense" rule was invalidated, and Barr became eligible for the 180-day exclusivity period, which would only be triggered by Barr marketing its own generic version of tamoxifen. *Id.* at 195-96. In March 1999, the FDA confirmed Barr's entitlement to the exclusivity period. *Id.* at 196.

The private antitrust plaintiffs alleged that the settlement agreement unlawfully: (1) enabled Zeneca and Barr to "resuscitate" a patent that had been held invalid and unenforceable; (2) perpetuated Zeneca's monopolization of the tamoxifen market and allowed Zeneca and Barr to share the monopoly profits; and (3) maintained artificially high prices for tamoxifen and prevented competition from other generic manufacturers. *Id.* at 196-97.

The Second Circuit affirmed the district court's dismissal of the antitrust complaint and upheld the legality of the settlement. *Id.* at 197-99. In reaching its decision, the court noted the tension between the antitrust laws and an innovator's right under patent law to exclude competition. *Id.* at 201. The court further emphasized "our longstanding adherence to the principle that 'courts are bound to encourage' the settlement of litigation." *Id.* at 202 (citing *Gambale v. Deutsche Bank AG,* 377 F.3d 133, 143 (2d Cir. 2004). The court observed:

> It is well settled that '[w]here there are legitimately conflicting [patent] claims

> ..., a settlement by agreement, rather than litigation, is not precluded by the [Sherman] Act," although such a settlement may ultimately have an adverse effect on competition. ...
>
> Rules severely restricting patent settlements might also be contrary to the goals of the patent law because the increased number of continuing lawsuits that would result would heighten the uncertainty surrounding patents and might delay innovation.

Id. (quoting *Standard Oil Co. v. United States,* 283 U.S. 163, 171 (1931) (other citations omitted).

The court also declined to find the settlements unlawful based on plaintiffs' contention that the Federal Circuit would have affirmed the invalidity of Zeneca's patent. *Id.* at 203-05. "We cannot judge this post-trial, pre-appeal settlement on the basis of the likelihood *vel non* of Zeneca's success had it not settled but rather pursued its appeal." *Id.* at 203 (citing, *inter alia, Asahi Glass Co. v. Pentech Pharms., Inc.,* 289 F. Supp. 2d 986, 993 (N.D. Ill. 2003) (Posner, J., sitting by designation) ("No one can be *certain* that he will prevail in a patent suit."); *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 261 F. Supp. 2d 188,200-01 (E.D.N.Y. 2003) (noting that courts should not speculate about the outcome of litigation); *Valley Drug,* 344 F.3d at 1306 ("[T]he reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into.")).

Citing with approval the reasoning of the courts in *Cipro I, Valley Drug, Schering,* and *Asahi Glass,*

the court further held that the mere existence of a reverse payment, especially in the context of the Hatch-Waxman Act, is not enough to trigger *per se* unlawfulness. *Id.* at 205-6 (citing *Valley Drug,* 344 F.3d at 1309; *Asahi Glass,* 289 F. Supp. 2d at 994; *Cipro I,* 261 F. Supp. 2d at 252; *Schering,* 402 F.3d at 1074). While the court acknowledged that reverse payments may seem "suspicious," it reasoned that this "suspicion abates upon reflection." *Id.* at 208. Rather, the court held, *"so long as the patent litigation is neither a sham nor otherwise baseless,* the patent holder is seeking to arrive at a settlement in order to protect that to which it presumably entitled: a lawful monopoly." *Id.* at 208-09 (emphasis added). In this sense, the settlement did not exceed the scope of the patent. *Id.* at 209 n.22.

The court also noted its general agreement with the Eleventh Circuit regarding the importance of analyzing the scope of the patent, and concluded: "Whatever damage is done to competition by settlement is done pursuant to the monopoly extended to the patent holder by patent law unless the terms of the settlement enlarge the scope of that monopoly." *Id.* at 212. The court agreed that"'[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent.'" *Id.* at 213 (quoting *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 363 F. Supp. 2d 514,535 (E.D.N.Y. 2005) *("Cipro II").*

4. *In re Cipro*

On October 15, 2008, the Federal Circuit Court of Appeals affirmed the district court's decision in *Cipro II* granting summary judgment in favor of the defendants. *In re Ciprofloxacin Hydrochloride Antitrust Litig.,* 544 F.3d 1323, (Fed. Cir. 2008) *("Cipro III").* The facts of the *Cipro* case are generally similar to those of the cases discussed above. Bayer held a patent for the active ingredient in the branded drug Cipro, which patent had an expiration date of December 9, 2003. *Id.* at 1327-28. In 1991, Barr Labs, Inc. filed an ANDA with a paragraph IV certification for a generic version of Cipro. *Id.* at 1328. Thereafter, Bayer sued Barr for patent infringement. *Id.*

Shortly before trial, Bayer entered into settlements with Barr and other generic manufacturers. Pursuant to Bayer's settlement with Barr, Barr agreed to convert its paragraph IV ANDA to a paragraph III ANDA, thus certifying that it would not market its generic version of Cipro until after Bayer's patent expired. *Id.* at 1328-29. In exchange, Bayer agreed to make a settlement payment of $49.1 million to Barr. *Id.* at 1329. Under a separate "Cipro Supply Agreement," Bayer agreed to either supply Barr with Cipro for resale or make quarterly payments to Barr until December 31, 2003. *Id.* Barr, in turn, agreed not to manufacture, or have manufactured, a generic version of Cipro in the United States. *Id.* Beginning at least six months before the expiration of Bayer's patent, Bayer agreed to allow Barr to sell a competing ciprofloxacin product. *Id.* Bayer and Barr then entered into a consent judgment under which Barr affirmed the

validity and enforceability of Bayer's patent and admitted infringement. *Id.*

In the subsequent antitrust action brought by indirect and direct purchasers, the district court granted summary judgment in favor of defendants. *Id.* at 1329 (citing *Cipro II*, 363 F. Supp. 2d at 548). Using a rule of reason analysis, the district court first determined that the relevant market was ciprofloxacin and that Bayer had market power within that market. *Id.* at 1330. The court then concluded that "any adverse effects on competition stemming from the Agreements were within the exclusionary zone of [Bayer's patent], and hence could not be redressed by antitrust law." *Id.* Having determined that there was no evidence that the Agreements "created a bottleneck on challenges to [Bayer's patent] or otherwise restrained competition beyond the scope of the patent," the district court concluded that the plaintiffs had failed to show that the Agreements had an anticompetitive effect beyond that authorized by the patent. *Id.*

Affirming the district court, the Federal Circuit distinguished the Sixth Circuit's decision in *Cardizem* and stated:

> We find ... the district court's analysis to be sound. … [T]he district court applied a rule of reason analysis in assessing the lawfulness of the Agreements. In that analysis, it considered whether there was evidence of sham litigation or fraud before the PTO, and whether any anticompetitive effects of the Agreements were outside the exclusionary zone of the patent.

> The application of a rule of reason analysis to a settlement agreement involving an exclusion payment in the Hatch-Waxman context has been embraced by the Second Circuit, and advocated by the FTC and the Solicitor General. And, although the Sixth Circuit found a per se violation of the antitrust laws in *In re Cardizem*, the facts of that case are distinguishable from this case and from the other circuit court decisions. In particular, the settlement in that case included, in addition to a reverse payment, an agreement by the generic manufacturer to not relinquish its 180-day exclusivity period, thereby delaying the entry of other generic manufacturers. *In re Cardizem*, 332 F.3d at 907. Furthermore, the agreement provided that the generic manufacturer would not market non-infringing versions of the generic drug. *Id.* at 908 n. 13. Thus, the agreement clearly had anticompetitive effects outside the exclusion zone of the patent. [citation omitted] To the extent that the Sixth Circuit may have found a per se antitrust violation based solely on the reverse payments, we respectfully disagree.

Id. at 1335.

Citing with approval the approaches adopted by the Eleventh and Second Circuits, the Federal Circuit concluded:

> [I]n cases such as this, wherein all anticompetitive effects of the settlement are within the exclusionary power of the patent, the outcome is the same whether the court begins its analysis under antitrust law by applying a rule of reason approach to evaluate the anti-competitive effects, or under patent law by analyzing the right to exclude afforded by the patent. The essence of the inquiry is whether the agreements restrict competition beyond the exclusionary zone of the patent. This analysis has been adopted by the Second and Eleventh Circuits and by the district court below and we find it to be completely consistent with Supreme Court precedent.

Id. at 1336 (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.,* 382 U.S. 172, 175-77 (1965) (holding that there may be a violation of the Sherman Act when a patent is procured by fraud, but recognizing that a patent is an exception to the general rule against monopolies). The court further noted its agreement with the Second and Eleventh Circuits that "in the absence of evidence of fraud before the PTO or sham litigation, the court need not consider the validity of the patent in the antitrust analysis of a settlement agreement involving a reverse payment." *Id.*

E. Framework Applicable to the Upsher and ESI Settlements

Having considered the analyses of the cases summarized above, I first conclude that the Upsher and ESI settlements were not *per se* unlawful. DP Plaintiffs' arguments that a *per se* approach is consistent with "traditional antitrust principles" and the legislative purpose of the Hatch-Waxman Act ignore the important purpose underlying the exclusionary rights granted by patent law. *See Tamoxifen,* 429 F.3d at 385; *Cipro III,* 544 F.3d at 1333. Moreover, with the sole exception of the *Cardizem* case, all of the courts that have considered so-called "reverse payment" settlements, as well as the FTC, have declined to apply a *per se* analysis. *See Valley Drug,* 344 F.3d at 1304; *Schering,* 402 F.3d at 1065; *Tamoxifen II,* 466 F.3d at 206; *Schering-FTC,* 2003 FTC LEXIS 187, at *13, 22-27. *But see In re Cardizem,* 332 F.3d at 908. To the extent that the *Cardizem* court reached a contrary conclusion, the facts of that case are distinguishable.

Unlike the interim settlement in *Cardizem,* Schering's settlements in this case finally resolved its litigation with Upsher and ESI. Moreover, the settlement agreements in this case permitted the Upsher and ESI generic products to enter the market five years and almost three years, respectively, before the expiration of Schering's '743 Patent. Finally, the agreements in this case did not manipulate the 180-day exclusivity period to create a "bottleneck" precluding the entry of other generic drugs. Upsher's settlement with Schering did not preclude Upsher from transferring or relinquishing the 180-day exclusivity and, because the "successful

defense" requirement was in place at the time of the settlement, Upsher arguably was not entitled to the exclusivity period.

I further decline to adopt the "FTC/Hovenkamp" framework proposed by DP Plaintiffs, and note that Plaintiffs have not cited – nor am I aware of – any case that has applied this legal framework. The standard articulated by the FTC treats settlements involving reverse payments as presumptively anticompetitive, but purports to allow rebuttal of that presumption with a showing of the pro-competitive effect of the settlement. *Schering-FTC*, 2003 FTC LEXIS, at *57-58. However, the order entered by the FTC prohibited settlements in which the generic company "receives anything of value," with an exception for payments, limited to $2 million, linked to litigation costs. *Id.* at *176. Similarly, the framework suggested by Professor Hovenkamp applies a rebuttable presumption of illegality, which the infringement plaintiff can rebut by showing both "(1) that the ex ante likelihood of prevailing in the infringement lawsuit is significant, and (2) that the size of the payment is no more than the expected value of the litigation and collateral costs attending the lawsuit." *See* Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759 (2003) (emphasis added).

Similar to a *per se* analysis, the FTC/Hovenkamp framework effectively discounts the fact that Schering's '743 Patent gave it the right to exclude infringing competitors. Moreover, it essentially requires a presumption that if the patent holder pays money to the generic company, the patent at issue

must be either invalid or not infringed. In my view, the weight of authority counsels against adopting such a presumption. *See, e.g., Schering,* 402 F.3d at 1066 (noting presumption of patent validity); *Tamoxifen,* 466 F.3d at 208-09; *Cipro II,* 363 F. Supp. 2d at 534-35 (declining to infer invalidity based on reverse payment).

I recognize that in this case, the key disputed issues in the patent case involved infringement, rather than validity. In this regard, DP Plaintiffs note that although patents are presumptively valid by statute; *see* 35 U.S.C. § 282, there is no corresponding presumption of infringement. *See* Framework Mem., p. 11. Thus, according the DP Plaintiffs, the probabilistic nature of patents is particularly relevant. *Id.* DP Plaintiffs further contend that Schering's payments to Upsher and ESI are *prima facie* evidence that the parties expected the litigation to result in more competition than was provided for under the settlement agreements. Plaintiffs' arguments are unpersuasive. Although there is no presumption of infringement, neither is there a statutory presumption that Schering's patent was not infringed. *See Schering-FTC,* 2003 FTC LEXIS 187, at * 61 ("We cannot assume that Schering had a right to exclude Upsher's generic competition for the life of the patent <u>any more than we can assume that Upsher had the right to enter earlier</u>.") (emphasis added).

Accordingly, I decline to discount the exclusionary power of Schering's patent based on the *possibility* that it was not infringed by the Upsher and ESI products. *See Cipro II,* 363 F. Supp. 2d at 514 and n. 19 (rejecting argument that exclusionary power of

the patent should be discounted by the probability of an invalidity finding, and noting the applicability of its analysis to cases in which infringement is the dominant issue); *Tamoxifen,* 466 F.3d at 211-12 (citing *Cipro II,* supra); *Asahi Glass,* 289 F. Supp. 2d at 992-93 ("It is not 'bad faith' to assert patent rights that one is not certain will be upheld in a suit for infringement pressed to judgment and to settle the suit to avoid risking the loss of the rights. No one can be *certain* that he will prevail in a patent suit."). In addition, I conclude that it is inappropriate to conduct an *ex post* inquiry into infringement issues that were resolved by the parties' settlement. As the *Cipro II* court observed regarding issues of patent validity, "[s]uch an inquiry would undermine any certainty for patent litigants seeking to settle their disputes." *Cipro II* 363 F. Supp. 2d at 530. *See also Schering,* 402 F.3d at 1072-73 (noting public policy favoring settlement of patent disputes); *Schering-FTC,* 2003 FTC LEXIS 187, at *60 (expressing concern that "a mandated inquiry into [the merits of the patent case], as part of an antitrust review, would ultimately have a chilling effect on the efficient settlement of patent litigation").

Finally, I reject DP Plaintiffs' suggestion that Judge Greenaway previously weighed and rejected the analytical framework that has now been adopted by the Second, Eleventh and Federal Circuits. In his Sept. 29, 2004 opinion, Judge Greenaway denied Defendants' 12(b)(6) motion to dismiss, finding, *inter alia,* that Plaintiffs' had adequately <u>*alleged*</u> anti-competitive conduct. As summarized by Judge Greenaway, Defendants had argued that:

> Plaintiffs fail to allege that Defendants engaged in anti-competitive behavior by entering into the settlement agreements. [Defendants] argue that Plaintiffs have not established anti-competitive behavior because the settlement agreements in question do not have an anti-competitive effect. Rather, the settlement agreements are pro-competitive because they allowed Upsher and ESI to enter the market years before Schering's K-Dur patent expired, and such agreements, as a matter of law, are not antitrust violations. By not alleging that the settlements do not reasonably reflect the objective merits of the patent suits, or that Upsher or ESI would have won the patent suit, Plaintiffs have not stated anti-competitive behavior, and thus have no claim.

In re K-Dur, 338 F. Supp. 2d 517, 530-31. Defendants further argued that the settlements (and the payments by Schering allegedly for delay) could not be anti-competitive because Schering had a valid patent and, thus, was entitled to exclude generic competitors until the patent expired. Thus, according to Defendants, absent an allegation of patent invalidity or non-infringement, the entry dates in the agreement are beyond attack. *Id.* at 531.

Contrary to DP Plaintiffs' suggestion, Judge Greenaway did not decide that the framework DP Plaintiffs' now propose (or any other framework)

would apply beyond the pleading stage, *i.e.,* at dispositive motions or trial. On the contrary, in denying Defendants' Motion to Dismiss, he stated that "[i]n this Court's view Plaintiffs can sustain a claim of anti-competitive conduct simply by *alleging* facts which show that the outcome of the settlement agreements would have been more pro-competitive absent the cash payments from Schering to Upsher and ESI."[24] *Id.* at 532 (emphasis added). Moreover, Judge Greenaway noted the different standards that had been applied by the Sixth Circuit in *Cardizem* (reverse payments *per se* illegal) and the 11th Circuit in *Valley Drug* (rejecting *per se* approach), and expressly stated that he did not need to address whether Defendants' alleged conduct was *per se* illegal. *Id.* at 533. Further, although he noted that the FTC had found the Defendants' conduct unlawful and stated that the FTC's findings were "of some interest," he also stated that the FTC's findings were not binding, and he did not adopt the standard used by the FTC in its analysis.

Finally, Judge Greenaway's decision was issued in 2004, before the 11th Circuit's decision in

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[24] As Judge Greenaway noted, his opinion addressed a Rule 12(b)(6) motion to dismiss and was decided under the framework of that rule, which treats all of Plaintiffs' allegations as true and draws all inferences in Plaintiffs' favor. *Id* at 527 (noting that Plaintiffs' alleged that but for the reverse payments, Upsher and ESI would have settled on different terms and entered the market sooner); 528 (noting the standard for 12(b)(6) and 12(c) motions); 529 (noting that there is no heightened pleading standard in antitrust cases); 533 (stating that Plaintiffs had sufficiently pled anti-competitive conduct and noting that, at pleading stage, court must consider defendants' pro-competitive justifications as unproven).

Schering and before the decisions of the Second and Federal Circuits following the 11th Circuit approach. Thus, the Circuit Court case law regarding the appropriate analytical framework has developed significantly since Judge Greenaway decided Defendants' motion to dismiss in 2004.

In summary, I will not adopt the FTC/Hovenkamp framework, but, rather, will apply an analysis consistent with the approach that has been adopted by the Second, Eleventh and Federal Circuits. Under that framework, as long as the Upsher and ESI settlements restrained competition only within the scope of Schering's patent, and the underlying patent lawsuits were not objectively baseless, Defendants are entitled to summary judgment on DP Plaintiffs' antitrust claims.

1. <u>The Settlements Do Not Exceed the Exclusionary Scope of the '743 Patent</u>

It is undisputed that the Schering's '743 Patent gave it the right to exclude infringing products until September 5, 2006. It is likewise undisputed that the Upsher Settlement permitted Upsher to market its generic product more than five years before the '743 Patent expired; and the ESI Settlement permitted ESI to market its generic product more than two years before the patent's expiration. Thus, with respect to the entry dates the parties agreed upon, the Upsher and ESI Agreements clearly were well within the exclusionary scope of the '743 Patent.

Having reviewed the Agreements and the record in this case, I further conclude that there is no evidence that any other aspects of the settlement

exceeded the exclusionary scope of the '743 Patent.[25] In the Upsher Settlement, Upsher agreed not to market Klor-Con M20© or "any other sustained release microencapsulated potassium chloride tablet," prior to Sept. 1, 2001. DP Plaintiffs' contend that by virtue of the above-quoted language, the agreement precluded Upsher from marketing non-infringing products and exceeded the scope of the patent. I disagree. First, there is no evidence in the record that Upsher had developed or planned to develop and market "any other sustained release microencapsulated potassium chloride tablet." Absent evidence that any other such generic product existed or was contemplated by Upsher, there is simply no basis upon which to conclude that the terms of the Upsher Agreement exceeded the scope of the '743 Patent. Moreover, I note that in *Schering,* the Eleventh Circuit determined, on the record before it,[26] that the Upsher Agreement's restraint covering "sustained release microencapsulated

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[25] Contrary to DP Plaintiffs' argument, Judge Greenaway did not decide that the terms of the Upsher and ESI Settlements exceeded the exclusionary scope of Schering's patent. Rather, he merely concluded that Plaintiffs had *alleged* that the settlement agreements exceeded the scope of the patent. *In re K-Dur,* 338 F. Supp. 2d at 532.

[26] The record in *Schering* included the ALJ's factual finding that the quoted language was included in the settlement so that "Upsher-Smith could continue to market its Klor Con 8 and Klor Con 10 wax matrix tablets without any restrictions," and because "Schering wanted to prevent Upsher-Smith from simply renaming its Klor Con M 20 product to get around the language and intent of the settlement agreement." *Schering-ALJ,* 2002 FTC LEXIS 40, at *62-63 (¶ 158). The ALJ found that "no other restrictions on any of Upsher-Smith's other products were intended by the settlement agreements." *Id.*

potassium chloride tablet[s]" covered the "identical reach of the '743 patent" and was a lawful ancillary restraint. *Schering,* 402 F.3d at 1072 ("Ancillary restraints are generally permitted if they are 'reasonably necessary' toward the contract's objective of utility and efficiency.").

With respect to the ESI Agreement, DP Plaintiffs have not even argued that its terms exceed the exclusionary scope of the patent. Although the terms of the ESI Settlement included ESI's agreement not to conduct, sponsor or support an application for AB rating or equivalence study for a potassium chloride product with respect to K-Dur, ESI also expressly stated in the agreement that neither it nor any of its affiliates were developing, or planned or intended to develop any such product. Accordingly, as with the Upsher Settlement, there is no evidence that the ESI Agreement excluded any non-infringing products.

Finally, I reject DP Plaintiffs' argument in their '743 Motion that under the doctrine of prosecution history estoppel and the "All Elements Rule," the scope of the '743 patent cannot extend to exclude Upsher's generic product. The DPP's '743 Motion would require me not only to conduct a detailed inquiry into the merits of the patent case, but to decide the infringement issues that were resolved when Schering and Upsher settled. For the reasons discussed above regarding the analytical framework applicable to the Upsher and ESI Settlements, I decline to conduct such an inquiry. *See Cipro II,* 363 F. Supp. 2d at 524-30 (reviewing refusals of courts and the FTC to undertake an after-the-fact inquiry into the merits of the patent issues in a settled case). To the extent that I consider the infringement issues

raised by DP Plaintiffs, I do so only to determine whether Schering's patent lawsuits were objectively baseless.

2. Schering's Patent Infringement Lawsuits Against Upsher and ESI Were Not Objectively Baseless

Because I have concluded that the Upsher and ESI settlements did not exceed the exclusionary scope of the '743 Patent, DP Plaintiffs' antitrust claims fail unless they can show that Schering's patent litigation against Upsher and ESI was objectively baseless.[27] As set forth below, I conclude that DP Plaintiffs cannot satisfy the objectively baseless standard with respect to either of the patent lawsuits. In order to establish that Schering's patent lawsuits were objectively baseless, DP Plaintiffs must show that the lawsuits were "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits." *Professional Real Estate Investors, Inc. v. Columbia Pictures, Indus., Inc.,* 508 U.S. 49, 60 (1993) *("PRE").* If an objective litigant could conclude that the suit is reasonably calculated to elicit a favorable outcome, the suit is [not objectively baseless], and an antitrust claim premised on the sham exception must fail." *Id. See also Cheminor Drugs, Ltd. v. Ethyl Corp.,* 993 F. Supp. 271,281 (D.N.J. 1998) (Greenaway, J.) (case must be shown to have "absolutely no objective merit"), *aff'd,* 168 F.3d 119 (3d Cir. 1999). Where there is no dispute over the "predicate facts" of the underlying lawsuit, the question of whether the suit

[27] DP Plaintiffs do not contend that Schering's '743 Patent was procured by fraud on the PTO.

was objectively baseless is a matter of law. *PRE,* 508 U.S. at 63-64. Predicate facts are the facts and circumstances that were available to the party that brought the underlying lawsuit. *PRE,* 508 U.S. at 63 (citing *Nelson v. Miller,* 607 P.2d 438, 444 (Kan. 1980). *See also In re Relafen Antitrust Litig.,* 346 F. Supp. 2d 349, 362 n. 7 (D. Mass. 2004) (recognizing that probable cause is a question of law when the relevant predicate facts involve an unsettled condition of law).

The party seeking to establish that a lawsuit was objectively baseless must do so with clear and convincing evidence. *C.R. Bard, Inc. v. M3 Sys., Inc.,* 157 F.3d 1340, 1369 (Fed. Cir. 1998); *Handgards, Inc. v. Ethicon, Inc.,* 601 F.2d 986,996 (9th Cir. 1979). "The U.S. Supreme Court has defined 'clear and convincing evidence' as evidence that places in the Court, as factfinder, an 'abiding conviction that the truth of its factual contentions are highly probable.'" *Bayer Schering Pharma AG v. Barr Laboratories, Inc.,* No. 05-cv-2308, 2008 U.S. Dist. LEXIS 15917, *50 (quoting *Colorado v. New Mexico,* 467 U.S. 310,316 (1984) (internal quotation marks omitted)). *See also A.K. Stamping Co., Inc. v. Instrument Specialties Co., Inc.,* 106 F. Supp. 2d 627, 639 n. 13 (D.N.J. 2000) (Greenaway, J.) ("'Clear and convincing' falls between the 'reasonable doubt' standard governing criminal cases and the "preponderance of the evidence" standard typical of civil actions.").

(a) *The Upsher Case*

(i) *Prosecution History Estoppel*

DP Plaintiffs have argued that even if the objectively baseless standard applies, they have

developed a record which establishes that it was virtually certain that Upsher would have won the patent case. DP Plaintiffs' principal argument is that Schering's primary infringement argument was legally baseless because, during prosecution of the '743 Patent, Schering amended its claims to require EC with a viscosity of "greater than 40 cp." Specifically, DP Plaintiffs note that during prosecution of the '743 patent -- in response to the examiner's rejection of its claims as obvious in light of the prior art -- Schering amended its claims to require an EC with a viscosity of "greater than 40 cp." Upsher's generic product, however, uses Ethocel 20, with a viscosity of 18-22 cp and, thus, did not literally infringe the '743 patent. Therefore, Schering could only claim infringement under the "doctrine of equivalents." According to DP Plaintiffs, however, having surrendered its claim to a product using EC with a viscosity of less than 40 cp, Schering was barred by the doctrine of prosecution estoppel from claiming that Upsher's product using Ethocel 20 was equivalent to Schering's product claimed in the '743 patent.

Defendants dispute DPPs' contention that Schering's reliance on the doctrine of equivalents was objectively baseless. In the patent lawsuit, Key conceded that it was estopped from claiming equivalency as to EC described in the prior art '399 Patent, which had a viscosity of 9-11 cp. Key contended, however, that under the applicable law, it was not estopped from claiming equivalency as to EC with a range between the 11 cp disclosed in the prior art and the 40 cp literally claimed in the '743 Patent. Upsher moved for summary judgment contending that Key's amendment of the patent to recite a

viscosity of "greater than 40 cp," estopped Key from claiming equivalence as to any product with a viscosity lower than 40 cp.

Defendants note that at the time Schering filed its lawsuit against Upsher, Federal Circuit law imposed a "flexible bar" under which a claim amendment did not necessarily surrender all range of equivalency regarding the subject matter literally given up by the amendment. *See Hughes Aircraft Co. v. United States,* 717 F.2d 1351, (Fed. Cir. 1983). However, shortly before the settlement, the Supreme Court issued a decision in the case of *Warner Jenkinson Co. v. Hilton Davis Chemical Co.,* 520 U.S. 17 (1997), which called into question the applicability and scope of the "flexible bar" rule. Thus, by the time of the settlement, the law regarding Schering's ability to rely on the doctrine of equivalents was unsettled. *See Festa Corp. v. Shoketsu Kinzoku Kogyo Kabushiki,* 234 F.3d 558, 574 (Fed. Cir. 2000) (noting inconsistency in rules as to the scope of prosecution history estoppel), *vacated on other grounds,* 535 U.S. 722 (2002). *See also In re Wellbutrin SR Antitrust Litig.,* 2006 U.S. Dist. LEXIS 9687, at *24 (E.D. Pa. Mar. 9, 2006) (noting that during the 1980s and 1990s, there were two conflicting approaches to prosecution history estoppel, "the more prevalent of which was known as the flexible bar rule, according to which the doctrine of prosecution history estoppel extends only to the subject matter ... relinquished during the prosecution"). In view of the unsettled state of the law regarding prosecution estoppel at the time of the Upsher litigation and settlement, I conclude that Schering's equivalence argument can not be deemed objectively baseless. To be sure, Schering might

have lost the argument had the case proceeded to a decision on summary judgment or at trial. In this regard, I note that at the summary judgment argument, Judge Walls expressed doubt about Schering's infringement claim in light of the claim amendment. However, the test is not whether Schering might have lost the patent suit; it is whether the suit was so objectively baseless "that no reasonable litigant could realistically expect success on the merits." *PRE,* 508 U.S. at 60. I conclude as a matter of law that DP Plaintiffs cannot satisfy that test.

(ii)*Other Equivalence and Inequitable Conduct Issues*

Finally, DP Plaintiffs argue that as a factual matter, Schering's argument in the patent case that the SMO in Upsher's product was equivalent to the HPC and PEG required by the '743 patent was objectively baseless. According to DP Plaintiffs, the facts show that: (1) Schering misrepresented the function of HPC and PEG as plasticizers; (2) Schering misrepresented the function of SMO as a plasticizer; and (3) Schering improperly ignored the principal function of HPC and PEG. DP Plaintiffs further argue that summary judgment should be denied so that a jury can consider the invalidity and unenforceability claims that Schering would have had to overcome to prevail on its infringement claim.

DP Plaintiffs' opposition to the Upsher Motion, and the parties' extensive recitations of the conflicting evidence in the patent case regarding these issues, foreclose any finding that Schering's lawsuit was objectively baseless. In particular, the issue of whether SMO was equivalent to HPC was

hotly disputed in the patent case, with both sides offering expert opinion in support of their positions. In addition, as Defendants note, Upsher argued in the patent case that multiple fact disputes precluded summary judgment in favor of Key on Upsher's inequitable conduct claim. Because it is clear that there were genuine factual and legal disputes regarding Schering's claims in the patent lawsuit, DP Plaintiffs cannot establish that those claims were objectively baseless.

(b) *The ESI Case*

DP Plaintiffs have not argued, nor identified any evidence, that Schering's patent litigation against ESI was objectively baseless. Moreover, it is undisputed that ESI had problems demonstrating the bioequivalence of its product to K-Dur and that the FDA had twice rejected ESI's bioequivalence studies. Additional undisputed evidence reflects that Schering believed ESI did not have a viable product and that Schering settled under some pressure from the presiding court. *See Schering-FTC,* 2003 FTC LEXIS 187, at *165 (acknowledging that "Schering was subject to intense, and perhaps unseemly, judicial pressure to settle the patent litigation, and [that] Schering may well have been concerned about its future litigation prospects if it resisted."). In sum, there is no evidence that Schering's lawsuit against ESI was objectively baseless, and, thus, Defendants are entitled to summary judgment on DP Plaintiffs' claims relating to the ESI Settlement.

IV. CONCLUSION

For the reasons set forth above, I conclude that Defendants' Motions for Summary Judgment as to DP Plaintiffs' claims relating to the Upsher and ESI

Settlements should be granted. I further conclude that DP Plaintiffs' Motions for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments and as to the Exclusionary Scope of the '743 Patent should be denied.

As provided in the Order entered by Magistrate Judge Arleo in this matter, the Special Master's decision on any motion can be appealed to Judge Greenaway in the manner, and subject to the standards of review set forth in Rule 53 of the Federal Rules of Civil Procedure and applicable Local Rules.

ENTERED this 6th day of February, 2009

s/Stephen M. Orlofsky
STEPHEN M. ORLOFSKY
SPECIAL MASTER

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE K-DUR ANTITRUST LITIGATION
This Document Relates To:

All Direct Purchaser Actions

Civil Action No. 01-1652 (JAG)
(Consolidated Cases)

MDL Docket No. 1419

ORDER

The Special Master having considered: (1) the Motion of Defendants Schering-Plough Corporation and Upsher-Smith Laboratories, Inc. (collectively, "Defendants") for Summary Judgment as to All Claims Brought By Direct Purchaser Plaintiffs ("DPPs") Related to the Upsher Settlement; (2) Defendants' Motion for Summary Judgment as to All Claims Brought By DPPs Related to the ESI Settlement; (3) DPPs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments; and (4) DPPs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent, the briefs submitted by all parties in support of and in opposition to the Motions, and the oral argument of counsel, for the reasons set forth in the foregoing Amended Report and Recommendation;

IT IS HEREBY ORDERED, this 6th day of February, 2009, that:

(1) Defendants' Motion for Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the Upsher Settlement is **GRANTED**;

(2) Defendants' Motion for Summary Judgment as to All Claims Brought By DP Plaintiffs Related to the ESI Settlement is **GRANTED**;

(3) DP Plaintiffs' Motion for Partial Summary Judgment as to the Applicable Framework for Analysis of Exclusion Payments is **DENIED**; and

(4) DP Plaintiffs' Motion for Partial Summary Judgment as to the Exclusionary Scope of the '743 Patent is **DENIED**.

ENTERED this 6th day of February, 2009

s/Stephen M. Orlofsky
STEPHEN M. ORLOFSKY
SPECIAL MASTER

PERTINENT STATUTORY PROVISIONS

35 U.S.C. § 271 provides:

§ 271. Infringement of patent

(a) Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.

(b) Whoever actively induces infringement of a patent shall be liable as an infringer.

(c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

(d) No patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts

which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

(e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

(2) It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent,

(B) an application under section 512 of such Act or under the Act of March 4, 1913 (21 U.S.C. 151-

158) for a drug or veterinary biological product which is not primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques and which is claimed in a patent or the use of which is claimed in a patent, or

(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act, if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug, veterinary biological product, or biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

(3) In any action for patent infringement brought under this section, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under paragraph (1).

(4) For an act of infringement described in paragraph (2)--

(A) the court shall order the effective date of any approval of the drug or veterinary biological product involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed,

(B) injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product,

(C) damages or other monetary relief may be awarded against an infringer only if there has been commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of an approved drug, veterinary biological product, or biological product, and

(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.

The remedies prescribed by subparagraphs (A), (B), (C), and (D) are the only remedies which may be granted by a court for an act of infringement

described in paragraph (2), except that a court may award attorney fees under section 285.

(5) Where a person has filed an application described in paragraph (2) that includes a certification under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), and neither the owner of the patent that is the subject of the certification nor the holder of the approved application under subsection (b) of such section for the drug that is claimed by the patent or a use of which is claimed by the patent brought an action for infringement of such patent before the expiration of 45 days after the date on which the notice given under subsection (b)(3) or (j)(2)(B) of such section was received, the courts of the United States shall, to the extent consistent with the Constitution, have subject matter jurisdiction in any action brought by such person under section 2201 of title 28 for a declaratory judgment that such patent is invalid or not infringed.

(6)(A) Subparagraph (B) Applies, in lieu of paragraph (4), in the case of a patent--

(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

(ii) for which an action for infringement of the patent with respect to the biological product--

(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.

(f)(1) Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(2) Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where

such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer.

(g) Whoever without authority imports into the United States or offers to sell, sells, or uses within the United States a product which is made by a process patented in the United States shall be liable as an infringer, if the importation, offer to sell, sale, or use of the product occurs during the term of such process patent. In an action for infringement of a process patent, no remedy may be granted for infringement on account of the noncommercial use or retail sale of a product unless there is no adequate remedy under this title for infringement on account of the importation or other use, offer to sell, or sale of that product. A product which is made by a patented process will, for purposes of this title, not be considered to be so made after--

(1) it is materially changed by subsequent processes; or

(2) it becomes a trivial and nonessential component of another product.

(h) As used in this section, the term "whoever" includes any State, any instrumentality of a State, and any officer or employee of a State or instrumentality of a State acting in his official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this title in the same manner and to the same extent as any nongovernmental entity.

(i) As used in this section, an "offer for sale" or an "offer to sell" by a person other than the patentee, or any designee of the patentee, is that in which the sale will occur before the expiration of the term of the patent.

21 U.S.C. § 355(j) provides:

(j) Abbreviated new drug applications

(1) Any person may file with the Secretary an abbreviated application for the approval of a new drug.

(2)(A) An abbreviated application for a new drug shall contain--

(i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a "listed drug");

(ii)(I) if the listed drug referred to in clause (i) has only one active ingredient, information to show that the active ingredient of the new drug is the same as that of the listed drug;

(II) if the listed drug referred to in clause (i) has more than one active ingredient, information to show that the active ingredients of the new drug are the same as those of the listed drug, or

(III) if the listed drug referred to in clause (i) has more than one active ingredient and if one of the active ingredients of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug, information to show that the different active ingredient is an active ingredient of a listed drug or of a drug

which does not meet the requirements of section 321(p) of this title, and such other information respecting the different active ingredient with respect to which the petition was filed as the Secretary may require;

(iii) information to show that the route of administration, the dosage form, and the strength of the new drug are the same as those of the listed drug referred to in clause (i) or, if the route of administration, the dosage form, or the strength of the new drug is different and the application is filed pursuant to the approval of a petition filed under subparagraph (C), such information respecting the route of administration, dosage form, or strength with respect to which the petition was filed as the Secretary may require;

(iv) information to show that the new drug is bioequivalent to the listed drug referred to in clause (i), except that if the application is filed pursuant to the approval of a petition filed under subparagraph (C), information to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in clause (i) and the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in clause (i);

(v) information to show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug referred to in clause (i) except for changes required because of differences approved under a petition filed

under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers;

(vi) the items specified in clauses (B) through (F) of subsection (b)(1) of this section;

(vii) a certification, in the opinion of the applicant and to the best of his knowledge, with respect to each patent which claims the listed drug referred to in clause (i) or which claims a use for such listed drug for which the applicant is seeking approval under this subsection and for which information is required to be filed under subsection (b) or (c) of this section--

(I) that such patent information has not been filed,

(II) that such patent has expired,

(III) of the date on which such patent will expire, or

(IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted; and

(viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) of this section for a method of use patent which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.

The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii).

(B) Notice of opinion that patent is invalid or will not be infringed

(i) Agreement to give notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall include in the application a statement that the applicant will give notice as required by this subparagraph.

(ii) Timing of notice

An applicant that makes a certification described in subparagraph (A)(vii)(IV) shall give notice as required under this subparagraph--

(I) if the certification is in the application, not later than 20 days after the date of the postmark on the notice with which the Secretary informs the applicant that the application has been filed; or

(II) if the certification is in an amendment or supplement to the application, at the time at which the applicant submits the amendment or supplement, regardless of whether the applicant has already given notice with respect to another such certification contained in the application or in an amendment or supplement to the application.

(iii) Recipients of notice

An applicant required under this subparagraph to give notice shall give notice to--

(I) each owner of the patent that is the subject of the certification (or a representative of the owner designated to receive such a notice); and

(II) the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent (or a representative of the holder designated to receive such a notice).

(iv) Contents of notice

A notice required under this subparagraph shall--

(I) state that an application that contains data from bioavailability or bioequivalence studies has been submitted under this subsection for the drug with respect to which the certification is made to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent referred to in the certification; and

(II) include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.

(C) If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary seeking permission to file such an application. The Secretary shall approve or disapprove a petition submitted under this subparagraph within ninety days of the date the petition is submitted. The Secretary shall approve such a petition unless the Secretary finds--

(i) that investigations must be conducted to show the safety and effectiveness of the drug or of any

of its active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug; or

(ii) that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

(D)(i) An applicant may not amend or supplement an application to seek approval of a drug referring to a different listed drug from the listed drug identified in the application as submitted to the Secretary.

(ii) With respect to the drug for which an application is submitted, nothing in this subsection prohibits an applicant from amending or supplementing the application to seek approval of a different strength.

(iii) Within 60 days after December 8, 2003, the Secretary shall issue guidance defining the term "listed drug" for purposes of this subparagraph.

(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and

size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except--

(i) with the written agreement of the sponsor or applicant; or

(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office

personnel demonstrate to the reviewing division why such decision should be modified.

(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).

(4) Subject to paragraph (5), the Secretary shall approve an application for a drug unless the Secretary finds--

(A) the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of the drug are inadequate to assure and preserve its identity, strength, quality, and purity;

(B) information submitted with the application is insufficient to show that each of the proposed conditions of use have been previously approved for the listed drug referred to in the application;

(C)(i) if the listed drug has only one active ingredient, information submitted with the application is insufficient to show that the active ingredient is the same as that of the listed drug;

(ii) if the listed drug has more than one active ingredient, information submitted with the application is insufficient to show that the active ingredients are the same as the active ingredients of the listed drug, or

(iii) if the listed drug has more than one active ingredient and if the application is for a drug which has an active ingredient different from the listed drug, information submitted with the application is insufficient to show--

(I) that the other active ingredients are the same as the active ingredients of the listed drug, or

(II) that the different active ingredient is an active ingredient of a listed drug or a drug which does not meet the requirements of section 321(p) of this title, or no petition to file an application for the drug with the different ingredient was approved under paragraph (2)(C);

(D)(i) if the application is for a drug whose route of administration, dosage form, or strength of the drug is the same as the route of administration, dosage form, or strength of the listed drug referred to in the application, information submitted in the application is insufficient to show that the route of administration, dosage form, or strength is the same as that of the listed drug, or

(ii) if the application is for a drug whose route of administration, dosage form, or strength of the drug is different from that of the listed drug referred to in the application, no petition to file an application for the drug with the different route of administration, dosage form, or strength was approved under paragraph (2)(C);

(E) if the application was filed pursuant to the approval of a petition under paragraph (2)(C), the application did not contain the information required

by the Secretary respecting the active ingredient, route of administration, dosage form, or strength which is not the same;

(F) information submitted in the application is insufficient to show that the drug is bioequivalent to the listed drug referred to in the application or, if the application was filed pursuant to a petition approved under paragraph (2)(C), information submitted in the application is insufficient to show that the active ingredients of the new drug are of the same pharmacological or therapeutic class as those of the listed drug referred to in paragraph (2)(A)(i) and that the new drug can be expected to have the same therapeutic effect as the listed drug when administered to patients for a condition of use referred to in such paragraph;

(G) information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug referred to in the application except for changes required because of differences approved under a petition filed under paragraph (2)(C) or because the drug and the listed drug are produced or distributed by different manufacturers;

(H) information submitted in the application or any other information available to the Secretary shows that (i) the inactive ingredients of the drug are unsafe for use under the conditions prescribed, recommended, or suggested in the labeling proposed for the drug, or (ii) the composition of the drug is unsafe under such conditions because of the type or quantity of inactive ingredients included or the manner in which the inactive ingredients are included;

(I) the approval under subsection (c) of this section of the listed drug referred to in the application under this subsection has been withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section, the Secretary has published a notice of opportunity for hearing to withdraw approval of the listed drug under subsection (c) of this section for grounds described in the first sentence of subsection (e) of this section, the approval under this subsection of the listed drug referred to in the application under this subsection has been withdrawn or suspended under paragraph (6), or the Secretary has determined that the listed drug has been withdrawn from sale for safety or effectiveness reasons;

(J) the application does not meet any other requirement of paragraph (2)(A); or

(K) the application contains an untrue statement of material fact.

(5)(A) Within one hundred and eighty days of the initial receipt of an application under paragraph (2) or within such additional period as may be agreed upon by the Secretary and the applicant, the Secretary shall approve or disapprove the application.

(B) The approval of an application submitted under paragraph (2) shall be made effective on the last applicable date determined by applying the following to each certification made under paragraph (2)(A)(vii):

(i) If the applicant only made a certification described in subclause (I) or (II) of paragraph

(2)(A)(vii) or in both such subclauses, the approval may be made effective immediately.

(ii) If the applicant made a certification described in subclause (III) of paragraph (2)(A)(vii), the approval may be made effective on the date certified under subclause (III).

(iii) If the applicant made a certification described in subclause (IV) of paragraph (2)(A)(vii), the approval shall be made effective immediately unless, before the expiration of 45 days after the date on which the notice described in paragraph (2)(B) is received, an action is brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under subsection (b)(1) or (c)(2) of this section before the date on which the application (excluding an amendment or supplement to the application), which the Secretary later determines to be substantially complete, was submitted. If such an action is brought before the expiration of such days, the approval shall be made effective upon the expiration of the thirty-month period beginning on the date of the receipt of the notice provided under paragraph (2)(B)(i) or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action, except that--

(I) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action

for patent infringement or invalidity), the approval shall be made effective on--

(aa) the date on which the court enters judgment reflecting the decision; or

(bb) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed;

(II) if before the expiration of such period the district court decides that the patent has been infringed--

(aa) if the judgment of the district court is appealed, the approval shall be made effective on--

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity); or

(BB) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent that is the subject of the certification is invalid or not infringed; or

(bb) if the judgment of the district court is not appealed or is affirmed, the approval shall be made effective on the date specified by the district court in a court order under section 271(e)(4)(A) of Title 35;

(III) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent is invalid or not infringed, the approval shall be made effective as provided in subclause (I); or

(IV) if before the expiration of such period the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and if the court decides that such patent has been infringed, the approval shall be made effective as provided in subclause (II).

In such an action, each of the parties shall reasonably cooperate in expediting the action.

(iv) 180-day exclusivity period

(I) Effectiveness of application

Subject to subparagraph (D), if the application contains a certification described in paragraph (2)(A)(vii)(IV) and is for a drug for which a first applicant has submitted an application containing such a certification, the application shall be made effective on the date that is 180 days after the date of the first commercial marketing of the drug (including the commercial marketing of the listed drug) by any first applicant.

(II) Definitions

In this paragraph:

(aa) 180-day exclusivity period

The term "180-day exclusivity period" means the 180-day period ending on the day before the date on which an application submitted by an applicant other than a first applicant could become effective under this clause.

(bb) First applicant

As used in this subsection, the term "first applicant" means an applicant that, on the first day on which a substantially complete application containing a certification described in paragraph (2)(A)(vii)(IV) is submitted for approval of a drug, submits a substantially complete application that contains and lawfully maintains a certification described in paragraph (2)(A)(vii)(IV) for the drug.

(cc) Substantially complete application

As used in this subsection, the term "substantially complete application" means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

(dd) Tentative approval

(AA) In general

The term "tentative approval" means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the

requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (F) or section 355a of this title, or there is a 7-year period of exclusivity for the listed drug under section 360cc of this title.

(BB) Limitation

A drug that is granted tentative approval by the Secretary is not an approved drug and shall not have an effective approval until the Secretary issues an approval after any necessary additional review of the application.

(C) Civil action to obtain patent certainty

(i) Declaratory judgment absent infringement action

(I) In general

No action may be brought under section 2201 of Title 28, by an applicant under paragraph (2) for a declaratory judgment with respect to a patent which is the subject of the certification referred to in subparagraph (B)(iii) unless--

(aa) the 45-day period referred to in such subparagraph has expired;

(bb) neither the owner of such patent nor the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brought a civil action against the applicant for infringement of the patent before the expiration of such period; and

(cc) in any case in which the notice provided under paragraph (2)(B) relates to noninfringement, the notice was accompanied by a document described in subclause (III).

(II) Filing of civil action

If the conditions described in items (aa), (bb), and as applicable, (cc) of subclause (I) have been met, the applicant referred to in such subclause may, in accordance with section 2201 of Title 28, bring a civil action under such section against the owner or holder referred to in such subclause (but not against any owner or holder that has brought such a civil action against the applicant, unless that civil action was dismissed without prejudice) for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval, except that such civil action may be brought for a declaratory judgment that the patent will not be infringed only in a case in which the condition described in subclause (I)(cc) is applicable. A civil action referred to in this subclause shall be brought in the judicial district where the defendant has its principal place of business or a regular and established place of business.

(III) Offer of confidential access to application

For purposes of subclause (I)(cc), the document described in this subclause is a document providing an offer of confidential access to the application that is in the

custody of the applicant under paragraph (2) for the purpose of determining whether an action referred to in subparagraph (B)(iii) should be brought. The document providing the offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information. A request for access to an application under an offer of confidential access shall be considered acceptance of the offer of confidential access with the restrictions as to persons entitled to access, and on the use and disposition of any information accessed, contained in the offer of confidential access, and those restrictions and other terms of the offer of confidential access shall be considered terms of an enforceable contract. Any person provided an offer of confidential access shall review the application for the sole and limited purpose of evaluating possible infringement of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV) and for no other purpose, and may not disclose information of no relevance to any issue of patent infringement to any person other than a person provided an offer of confidential access. Further, the application may be redacted by the applicant to remove any information of no relevance to any issue of patent infringement.

(ii) Counterclaim to infringement action

(I) In general

If an owner of the patent or the holder of the approved application under subsection (b) of this section for the drug that is claimed by the patent or a use of which is claimed by the patent brings a patent infringement action against the applicant, the applicant may assert a counterclaim seeking an order requiring the holder to correct or delete the patent information submitted by the holder under subsection (b) or (c) of this section on the ground that the patent does not claim either--

(aa) the drug for which the application was approved; or

(bb) an approved method of using the drug.

(II) No independent cause of action

Subclause (I) does not authorize the assertion of a claim described in subclause (I) in any civil action or proceeding other than a counterclaim described in subclause (I).

(iii) No damages

An applicant shall not be entitled to damages in a civil action under clause (i) or a counterclaim under clause (ii).

(D) Forfeiture of 180-day exclusivity period

(i) Definition of forfeiture event

In this subparagraph, the term "forfeiture event", with respect to an application under this subsection, means the occurrence of any of the following:

(I) Failure to market

The first applicant fails to market the drug by the later of--

(aa) the earlier of the date that is--

(AA) 75 days after the date on which the approval of the application of the first applicant is made effective under subparagraph (B)(iii); or

(BB) 30 months after the date of submission of the application of the first applicant; or

(bb) with respect to the first applicant or any other applicant (which other applicant has received tentative approval), the date that is 75 days after the date as of which, as to each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period under subparagraph (B)(iv), at least 1 of the following has occurred:

(AA) In an infringement action brought against that applicant with respect to the patent or in a declaratory judgment action brought by that applicant with respect to the patent, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent is invalid or not infringed.

(BB) In an infringement action or a declaratory judgment action described in subitem (AA), a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed.

(CC) The patent information submitted under subsection (b) or (c) of this section is withdrawn by the holder of the application approved under subsection (b) of this section.

(II) Withdrawal of application

The first applicant withdraws the application or the Secretary considers the application to have been withdrawn as a result of a determination by the Secretary that the application does not meet the requirements for approval under paragraph (4).

(III) Amendment of certification

The first applicant amends or withdraws the certification for all of the patents with respect to which that applicant submitted a certification qualifying the applicant for the 180-day exclusivity period.

(IV) Failure to obtain tentative approval

The first applicant fails to obtain tentative approval of the application within 30 months after the date on which the application is filed, unless the failure is caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed.

(V) Agreement with another applicant, the listed drug application holder, or a patent owner

The first applicant enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section 45 of Title 15 to the extent that that section applies to unfair methods of competition).

(VI) Expiration of all patents

All of the patents as to which the applicant submitted a certification qualifying it for the 180-day exclusivity period have expired.

(ii) Forfeiture

The 180-day exclusivity period described in subparagraph (B)(iv) shall be forfeited by a first applicant if a forfeiture event occurs with respect to that first applicant.

(iii) Subsequent applicant

If all first applicants forfeit the 180-day exclusivity period under clause (ii)--

(I) approval of any application containing a certification described in paragraph (2)(A)(vii)(IV) shall be made effective in accordance with subparagraph (B)(iii); and

(II) no applicant shall be eligible for a 180-day exclusivity period.

(E) If the Secretary decides to disapprove an application, the Secretary shall give the applicant notice of an opportunity for a hearing before the Secretary on the question of whether such application is approvable. If the applicant elects to accept the opportunity for hearing by written request within thirty days after such notice, such hearing shall commence not more than ninety days after the expiration of such thirty days unless the Secretary and the applicant otherwise agree. Any such hearing shall thereafter be conducted on an expedited basis and the Secretary's order thereon shall be issued within ninety days after the date fixed by the Secretary for filing final briefs.

(F)(i) If an application (other than an abbreviated new drug application) submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which the subsection (b) application was submitted effective before the expiration of ten years from the date of the approval of the application under subsection (b) of this section.

(ii) If an application submitted under subsection (b) of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section, except that such an application may be submitted under this subsection after the expiration of four years from the date of the approval of the subsection (b) application if it contains a certification of patent invalidity or noninfringement described in subclause (IV) of paragraph (2)(A)(vii). The approval of such an application shall be made effective in accordance with subparagraph (B) except that, if an action for patent infringement is commenced during the one-year period beginning forty-eight months after the date of the approval of the subsection (b) application, the thirty-month period referred to in subparagraph (B)(iii) shall be extended by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application.

(iii) If an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application contains reports of

new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under this subsection for the conditions of approval of such drug in the subsection (b) application effective before the expiration of three years from the date of the approval of the application under subsection (b) of this section for such drug.

(iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under this subsection for a change approved in the supplement effective before the expiration of three years from the date of the approval of the supplement under subsection (b) of this section.

(v) If an application (or supplement to an application) submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application under subsection (b) of this section, was approved during the period beginning January 1, 1982, and ending on September 24, 1984, the Secretary may not make the approval of an application submitted under this subsection which refers to the drug for which

the subsection (b) application was submitted or which refers to a change approved in a supplement to the subsection (b) application effective before the expiration of two years from September 24, 1984.

(6) If a drug approved under this subsection refers in its approved application to a drug the approval of which was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under this paragraph or which, as determined by the Secretary, has been withdrawn from sale for safety or effectiveness reasons, the approval of the drug under this subsection shall be withdrawn or suspended--

(A) for the same period as the withdrawal or suspension under subsection (e) of this section or this paragraph, or

(B) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

(7)(A)(i) Within sixty days of September 24, 1984, the Secretary shall publish and make available to the public--

(I) a list in alphabetical order of the official and proprietary name of each drug which has been approved for safety and effectiveness under subsection (c) of this section before September 24, 1984;

(II) the date of approval if the drug is approved after 1981 and the number of the application which was approved; and

(III) whether in vitro or in vivo bioequivalence studies, or both such studies, are required for applications filed under this subsection which will refer to the drug published.

(ii) Every thirty days after the publication of the first list under clause (i) the Secretary shall revise the list to include each drug which has been approved for safety and effectiveness under subsection (c) of this section or approved under this subsection during the thirty-day period.

(iii) When patent information submitted under subsection (b) or (c) of this section respecting a drug included on the list is to be published by the Secretary, the Secretary shall, in revisions made under clause (ii), include such information for such drug.

(B) A drug approved for safety and effectiveness under subsection (c) of this section or approved under this subsection shall, for purposes of this subsection, be considered to have been published under subparagraph (A) on the date of its approval or September 24, 1984, whichever is later.

(C) If the approval of a drug was withdrawn or suspended for grounds described in the first sentence of subsection (e) of this section or was withdrawn or suspended under paragraph (6) or if the Secretary determines that a drug has been withdrawn from sale for safety or effectiveness reasons, it may not be published in the list under subparagraph (A) or, if the withdrawal or suspension occurred after its

publication in such list, it shall be immediately removed from such list--

(i) for the same period as the withdrawal or suspension under subsection (e) of this section or paragraph (6), or

(ii) if the listed drug has been withdrawn from sale, for the period of withdrawal from sale or, if earlier, the period ending on the date the Secretary determines that the withdrawal from sale is not for safety or effectiveness reasons.

A notice of the removal shall be published in the Federal Register.

(8) For purposes of this subsection:

(A)(i) The term "bioavailability" means the rate and extent to which the active ingredient or therapeutic ingredient is absorbed from a drug and becomes available at the site of drug action.

(ii) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may assess bioavailability by scientifically valid measurements intended to reflect the rate and extent to which the active ingredient or therapeutic ingredient becomes available at the site of drug action.

(B) A drug shall be considered to be bioequivalent to a listed drug if--

(i) the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar

experimental conditions in either a single dose or multiple doses; or

(ii) the extent of absorption of the drug does not show a significant difference from the extent of absorption of the listed drug when administered at the same molar dose of the therapeutic ingredient under similar experimental conditions in either a single dose or multiple doses and the difference from the listed drug in the rate of absorption of the drug is intentional, is reflected in its proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug.

(C) For a drug that is not intended to be absorbed into the bloodstream, the Secretary may establish alternative, scientifically valid methods to show bioequivalence if the alternative methods are expected to detect a significant difference between the drug and the listed drug in safety and therapeutic effect.

(9) The Secretary shall, with respect to each application submitted under this subsection, maintain a record of--

(A) the name of the applicant,

(B) the name of the drug covered by the application,

(C) the name of each person to whom the review of the chemistry of the application was assigned and the date of such assignment, and

(D) the name of each person to whom the bioequivalence review for such application was assigned and the date of such assignment. The information the Secretary is required to maintain

under this paragraph with respect to an application submitted under this subsection shall be made available to the public after the approval of such application.

(10)(A) If the proposed labeling of a drug that is the subject of an application under this subsection differs from the listed drug due to a labeling revision described under clause (i), the drug that is the subject of such application shall, notwithstanding any other provision of this chapter, be eligible for approval and shall not be considered misbranded under section 352 of this title if--

(i) the application is otherwise eligible for approval under this subsection but for expiration of patent, an exclusivity period, or of a delay in approval described in paragraph (5)(B)(iii), and a revision to the labeling of the listed drug has been approved by the Secretary within 60 days of such expiration;

(ii) the labeling revision described under clause (i) does not include a change to the "Warnings" section of the labeling;

(iii) the sponsor of the application under this subsection agrees to submit revised labeling of the drug that is the subject of such application not later than 60 days after the notification of any changes to such labeling required by the Secretary; and

(iv) such application otherwise meets the applicable requirements for approval under this subsection.

(B) If, after a labeling revision described in subparagraph (A)(i), the Secretary determines that

the continued presence in interstate commerce of the labeling of the listed drug (as in effect before the revision described in subparagraph (A)(i)) adversely impacts the safe use of the drug, no application under this subsection shall be eligible for approval with such labeling.