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]

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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.

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 ("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

[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.

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.

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

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.

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

[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

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 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

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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.

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]

[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)).

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 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.

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

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

[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.

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 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 violation in that agreement. *Id.* With respect to the ESI settlement, the court acknowledged the

[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.

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.

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

[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).

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 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.

[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).

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 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

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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.*

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/2011/05/1105 mmagreements.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 DC 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]

[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.

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 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 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

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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.

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 493; *Bogosian*, 561 F.2d at 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

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

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.