13-1232-cv

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

In re ADDERALL XR ANTITRUST LITIGATION

LOUISIANA WHOLESALE DRUG COMPANY, INC., on behalf of itself and all others similarly situated, VALUE DRUG COMPANY, on behalf of itself and all others similarly situated,

Plaintiffs-Appellants,

—against—

SHIRE LLC, SHIRE U.S., INC.,

Defendants-Appellees.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

CORRECTED BRIEF OF PLAINTIFFS-APPELLANTS

BRUCE E. GERSTEIN, ESQ.
ELENA K. CHAN, ESQ.
KIMBERLY HENNINGS, ESQ.
GARWIN GERSTEIN & FISHER LLP
1501 Broadway, Room 1416
New York, New York 10036
(212) 398-0055

Attorneys for Plaintiffs-Appellants

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 16.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for appellants Louisiana Wholesale Drug Company, Inc. ("LWD") and Value Drug Company ("VD") (collectively "Plaintiffs") certify that neither entity has a parent corporation nor does any publicly held corporation own 10 percent or more of the stock of either entity.

JURISDICTIONAL STATEMENT

Jurisdiction is proper in this court under 28 U.S.C. § 1291 because this is an appeal from a final judgment of the United States District Court for the Southern District of New York that disposed of all claims in an antitrust case in which jurisdiction was proper under 28 U.S.C. §§ 1331 and 1337(a) and 15 U.S.C. § 15. The judgment was entered on March 7, 2013 and the notice of appeal was filed on April 2, 2013. JA-7, JA-144.

STATEMENT OF THE ISSUE PRESENTED

Whether a complaint alleging a monopolist's breach of Hatch-Waxman[1] patent litigation settlements, in which the brand name drug manufacturer agrees to

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[1] Hatch-Waxman refers to the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1518, as amended, which sets forth the regulatory framework of the drug approval process. Among its purposes was to "speed the introduction of low-cost generic drugs to market." *Caraco Pharm. Labs, Ltd. v. Novo Nordisk A/S*, ___ U.S. ___, 2012 U.S. LEXIS 3106, *12 (Apr. 17, 2012)

license its generic competitors and supply them with all of their product requirements, states an antitrust duty to deal claim under *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) ("*Aspen Skiing*"). The district court, relying on *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) ("*Tamoxifen*"), dismissed Plaintiffs' complaint on the grounds that an antitrust duty to deal claim could not arise from Hatch-Waxman settlements which did not exceed the "scope of the patent" because any competitive harm resulting from the agreements' breach would be no greater than if the monopolist had paid its competitors to stay off the market until patent expiration. In light of the Supreme Court's decision in *Federal Trade Commission v. Actavis, Inc.*, ___ U.S. ___, 2013 U.S. Lexis 4545 (June 17, 2013) ("*Actavis*"), which rejected the "scope of the patent" test, the district court's decision was erroneous.

STATEMENT OF THE CASE

This appeal arises out of Plaintiffs' consolidated actions alleging that Defendants Shire LLC and Shire U.S., Inc. ("Shire" or "Defendants") violated Section 2 of the Sherman Act by unlawfully impeding competition in connection with Shire's prescription pharmaceutical product Adderall XR. Specifically, Plaintiffs allege that in 2006, Shire settled Hatch-Waxman patent infringement litigation that threatened to end its Adderall XR monopoly by licensing its competitors and agreeing to provide them with all of their AXR Product[2] requirements in return for their agreement to stay off the market for three years. JA-12-13. In 2009, however, after reaping the benefit of three more years of monopoly profits, Shire refused to deal with its competitors and supply them with AXR Product. JA-14 at ¶ 8. Plaintiffs allege that Shire's refusal to comply with its duty to deal was an unlawful act of monopolization. JA-15 at ¶ 9.

In June 2012, Shire moved to dismiss Plaintiffs' complaints. JA-39-71. Shire argued (among other things[3]) that its alleged breach of its supply agreements could not form the basis for a monopolization claim because Shire's patents granted it the power to lawfully exclude generic competition within the temporal scope of its patents. JA-53-59. In support of its argument, Shire relied extensively on this Circuit's decision in *Tamoxifen*. JA-53-59.

On March 6, 2013, Judge Victor Marrero of the Southern District of New York granted Shire's motion. JA-120-143. Despite acknowledging that Plaintiffs did not challenge Shire's agreements with its competitors in themselves, but rather, Shire's refusal to deal as required by those agreements, the district court concluded

[2] "AXR Product" refers generally to branded Adderall XR and/or its generic equivalents.

[3] The district court did not address Shire's other arguments in its motion to dismiss that Plaintiffs had failed to allege a relevant market or that Plaintiffs lacked standing to sue for damages.

that the only relevant inquiry was whether, pursuant to *Tamoxifen*, the agreements fell within the temporal scope of Shire's patents. JA-142. According to the district court, because the agreements did not exceed the temporal scope of Shire's patent, Plaintiffs' claim necessarily failed. *Id.*

On March 7, 2013, judgment was entered. JA-7.

On April 2, 2013, Plaintiffs timely noticed this appeal. JA-144-146.

Statement of the Standard of Review

This Court applies a *de novo* standard of review to the grant of a motion to dismiss, accepting as true all facts as alleged in the complaint and drawing all inferences in the plaintiff's favor. *Curtis v. Citibank, N.A.*, 204 Fed. Appx. 929, 932 (2d Cir. 2006). *See also IUE AFL-CIO Pension Fund v. Herrmann*, 9 F. 3d 1049, 1052 (2d Cir. 1993) (appellate court should review complaint "liberally" drawing all inferences in favor of the pleader).

Statement of Relevant Facts

Shire manufactures and sells Adderall XR for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). JA-11 at ¶ 2, JA-21 at ¶ 36. From October 2001 through September 2011, Shire realized net sales for Adderall XR of over $6.5 billion. JA-11 at ¶ 2, JA-21 at ¶ 37. At its height, in 2008, Adderall XR had sales of $1.1 billion, accounting for 47% of Shire's overall revenues that year. JA-21 at ¶ 37. Shire contends that Adderall XR is protected by various patents.

JA-12 at ¶ 4, JA-46.

In November 2002 (one year after Adderall XR entered the market), Barr Pharmaceuticals (subsequently acquired by Teva Pharmaceuticals USA, Inc. in 2008) ("Teva") filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to manufacture and sell a less-expensive generic version of Adderall XR. JA-11 at ¶ 3, JA-22 at ¶ 39. A year later, in November 2003, Impax Laboratories, Inc. ("Impax") also filed an ANDA. In so doing, both Teva and Impax contended that Shire's patents for Adderall XR were invalid, unenforceable and/or not infringed. JA-12 at ¶ 4.

Shire sued Teva and Impax for patent infringement in 2002 and 2003, respectively. Under the Hatch-Waxman regulatory regime, the mere filing of the lawsuits automatically stayed FDA approval of Teva and Impax's ANDAs for up to 30 months. After the respective 30 month stays expired, however, either or both generics could enter "at risk" (*e.g.,* they could be liable for damages if their products were ultimately found to be infringing) once the FDA granted final approval. Further, subject to FDA approval, generics could enter the market if Shire's patents were held invalid, unenforceable and/or not infringed. JA-12 at ¶ 4, JA-13 at ¶¶ 39-40. Generic entry under either circumstance would open the floodgates for generic competition, which Shire knew would likely take 90% of Shire's Adderall XR sales. JA-12 at ¶ 4.

Accordingly, in 2006, Shire faced a choice: (a) risk losing its patents' exclusionary power in the near future if the litigation continued; or (b) settle the lawsuits and eliminate the challenges to its monopoly for a specified period of time by giving its competitors patent licenses effective at a later date. Shire chose the latter, more certain option. Under the settlements negotiated, Shire: (a) provided Teva and Impax with patent licenses effective in April 2009 and October 2009, respectively that guaranteed Shire three more years of monopoly profits; and (b) agreed to provide all of Teva and Impax's requirements for finished AXR Product, so that even if these generics did not have FDA final approval for their own proposed products by 2009, they could still enter the market and compete by selling finished pills that Shire supplied. JA-12 at ¶¶ 5-6, JA-23 at ¶¶ 41-42. The settlements' supply provisions were the equivalent of "requirements contracts" that gave Teva and Impax the right to purchase all of their AXR Product requirements from Shire and required Shire to fill all of Teva and Impax's AXR Product requirements. JA-12 at ¶ 6, JA-24 at ¶ 43, JA-25 at ¶¶ 46, 48. In sum, by settling the Hatch-Waxman patent litigation, Shire effectively agreed to relinquish its monopoly power over AXR Product by giving its competitors patent licenses and agreeing to supply all of their product requirements starting in April 2009. JA-12 at ¶ 6, JA-24 at ¶ 44. Shire received a valuable benefit in exchange for its agreement to voluntarily relinquish its monopoly on a date certain in the future and its agreement to supply Teva and Impax's requirements – certainty that its monopoly would not be forcibly relinquished earlier. In exchange, Teva and Impax received certainty that they would able to compete with Shire (and among themselves) even if regulatory approval for their respective generic products was not obtained.

Shire received the benefit of the settlements and continued to receive monopoly profits on its sales of Adderall XR for three more years in the absence of any competition from the generics. In 2009, when the licenses became effective, however, neither Teva nor Impax had obtained FDA approval to manufacture their own AXR Product, so pursuant to the agreements both companies opted to purchase their requirements for finished product from Shire.[4] Shire, however, unilaterally and intentionally breached its contractual supply obligations to Teva and Impax and refused to comply. JA-14 at ¶ 8, JA-27-28 at ¶¶ 53-59. Rather than providing Teva and Impax with all the finished AXR Product that they requested (which would have allowed these companies to capture 90% or more of Shire's sales of AXR Product), beginning in October 2009, Shire improperly restricted and/or refused to supply AXR Product in order to limit Teva and Impax's ability to compete. Instead, Shire kept substantial product for itself, limiting the ability of the generics to penetrate the market and gain market share and permitting Shire to

[4] The active pharmaceutical ingredient used to manufacture AXR Product is a controlled substance that is strictly regulated by the DEA. JA-30 at ¶ 63 n. 3.

continue to charge higher prices for the sales of product that it did not supply to Teva and Impax. JA-14 at ¶ 8.

Without the full supply needed to fill orders, Teva and Impax had neither the ability nor incentive to actively price compete against Shire (or each other) as they otherwise would have done. *Id.* The supply shortfall of less-expensive, generic AXR Product that Shire created forced purchasers to buy more of Shire's higher priced branded Adderall XR than they would have otherwise, enabling Shire to improperly retain for itself 40-50% of the AXR Product market, even though it charged substantially more for a product that was identical to the generic products that Teva and Impax sold for far less. JA-14 at ¶ 8, JA-29 at ¶ 62.

Shire's refusal to sell AXR Product to Teva and Impax was motivated by anticompetitive intent so that Shire could limit generic penetration and continue to charge: (a) a monopoly price that it could not have charged absent the supply shortage it created; and (b) even higher prices once its plan was fully in effect. JA-29 at ¶ 61.[5] Indeed, in October 2009, a Shire employee, Jeff Cooperrider, admitted to a Teva employee that Shire was not going to deliver the product it was obligated to supply because Shire had decided that it wanted to keep the product to sell for

[5] In fact, once Shire reduced Teva and Impax's ability to gain market share and/or price compete, Shire raised the price for Adderall XR so that it could charge even greater monopoly prices. JA-29 at ¶ 62.

itself. JA-27 at ¶ 56.

There was no legitimate business justification for Shire's conduct, and the justification that Shire offered in defense of a subsequent breach of contract suit brought by Impax was a mere pretext. JA-29 at ¶ 63.[6] As a result of Shire's conduct, Plaintiffs and other direct purchasers of Adderall XR from Shire have been overcharged and deprived of the full benefits of competition from less-expensive, generic versions of AXR Product. JA-15 at ¶ 9, JA-34 at ¶¶ 79-82. Shire's conduct also limited the generics' ability and incentive to price compete with each other, thereby causing prices for Teva and Impax's generic products to be artificially inflated, and causing Plaintiffs and other class members to pay more for the generic AXR Products they bought.

[6] Shire claimed: (a) that the DEA failed to set a high enough quota to make enough pills to meet demand; and (b) because of the purportedly DEA-created shortage, Shire was allowed under the supply agreements to "fairly" and "reasonably" allocate supply based on its view of the sales that Teva, Impax, and Shire would have obtained in an unconstrained market. JA-29 at ¶ 63. As an initial matter, the DEA has rejected Shire's assertion that the DEA quota created a supply shortage. DEA officials have repeatedly stated that any shortage of pills to sell to generic competitors was not due to the DEA quota but Shire's decision to allocate more pills to itself so it could sell more higher-priced pills. JA-30 at ¶ 64. Moreover: (a) even if the DEA quota did create a supply shortage (which is not the case), the supply agreements did not allow Shire to choose how to allocate the pill supply; and (b) even if Shire had been contractually allowed to allocate the pill supply (which is not the case), Shire did not act fairly and reasonably in allocating the supply. JA-30 at ¶ 65-66.

SUMMARY OF THE ARGUMENT

In their complaints, Plaintiffs allege that Shire violated its antitrust duty to deal - a cause of action recognized by the Supreme Court in *Aspen Skiing* - by refusing to supply its generic competitors (Teva and Impax) with AXR Product that Shire had agreed to provide them as part of Hatch-Waxman patent litigation settlements. Pursuant to the settlement agreements executed in 2006, Teva and Impax agreed to drop their claims that Shire's Adderall XR patents were invalid and/or not infringed, and agreed to stay off the market until 2009, in return for patent licenses and Shire's commitment to supply them with all of their AXR Product requirements (if needed). The agreements resulted in each party receiving specific bargained-for consideration. Shire, the patent owner, was guaranteed three additional years of monopoly profits from its sales of Adderall XR. Teva and Impax received patent licenses effective in April and October 2009, respectively, and Shire's promise to supply them with all their AXR Product requirements, as needed. As the district court noted, Plaintiffs alleged that as a result of these agreements, "Shire effectively abandoned its right to a monopoly…" JA-129.

Shire took full advantage of the benefits of its bargain, exploiting its monopoly and charging supracompetitive prices for the three additional years. As soon as it came time to relinquish its monopoly control over AXR Product, however, Shire breached its contractual obligations to Teva and Impax and refused to supply them with all of their AXR product needs. The anticompetitive effect of Shire's conduct was to constrain competition in the market for AXR Product, whereby Shire was permitted to continue to charge supracompetitive prices and reduce price competition between Teva and Impax.

In granting Shire's motion to dismiss Plaintiffs' complaint, the district court applied this Court's holding in *Tamoxifen – i.e.,* that Hatch-Waxman patent litigation settlement agreements that do not exceed the so-called "scope of the patent" are not subject to antitrust scrutiny – to bar Plaintiffs' claims brought under *Aspen Skiing*, even though Plaintiffs had not alleged the settlement agreements were in themselves anticompetitive. Nonetheless, the district court extended the *Tamoxifen* analysis to conclude that because the anticompetitive harm Plaintiffs alleged was no greater than if Shire had paid the generics to stay off the market until expiration of the AXR patents - conduct which the district court deemed permissible under *Tamoxifen* - Plaintiffs could not state an antitrust claim under *Aspen Skiing*. As the district court phrased it:

> The dispute on this issue between the parties, then, boils down to this: Does Shire's decision to license its patent and then allegedly breach its agreements with Teva and Impax – conduct that LWD alleges was done with anticompetitive intent – sufficiently distinguish *Tamoxifen* and other Second Circuit case law generally upholding the validity of patent settlement agreements and instead place this case squarely in the duty to deal established by *Aspen Skiing* and its progeny?

JA-132.

The district concluded that it did not:

> The Court is not convinced that where, as here, a patent holder granting multiple licenses that by their terms do not extend the scope of the patents in question, would nevertheless be subject to antitrust claims based on its conduct under those otherwise unchallenged licenses where the same patent holder would not face such liability if it refused outright to issue a license in the first instance. Even if Shire completely failed to supply Teva and Impax with Adderall XR under the terms of the license, LWD and the rest of the market would be no worse off than had Shire decided against licensing in the first place.

JA-138-39.

While Plaintiffs argued below that *Tamoxifen* was not relevant to their *Aspen Skiing* antitrust claims (because, as noted herein, Plaintiffs do not challenge the propriety of the settlement agreements, but rather Shire's refusal to deal as contractually required thereunder), the district court's legal analysis has, in any event, been undone by the Supreme Court's recent decision in *Actavis*. In *Actavis*, the Supreme Court rejected the Eleventh Circuit's formulation of the "scope of the patent" test as set forth in *FTC v. Watson Pharmaceuticals, Inc.*, 677 F.3d 1298 (11^{th} Cir. 2012) - which is analytically identical to the test in *Tamoxifen* - concluding that "reverse payment settlements such as the agreement alleged in the complaint before us can sometimes violate the antitrust laws. We consequently hold that the Eleventh Circuit should have allowed the FTC's lawsuit to proceed." *Actavis,* ___ U.S. ___, 2013 U.S. LEXIS 4545 at *8-9. The Court instructed that inquiring "simply to what the holder of a valid patent could do does not by itself answer the antitrust question," (*id.* at *18), and that "[w]hether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion* that flows from that analysis and not…its starting point." *Id.* at *21 (emphasis in original).

Accordingly, the district court's *Tamoxifen*-based rationale that because Shire could "simply [] write each entity a check in consideration for their agreement to delay or drop their respective generic applications," Shire's decision to allow multiple licenses could not subject it to antitrust liability (JA-134, JA-136-137) has been rejected. As *Actavis* makes clear, Shire's patents do not permit it to simply pay its competitors to stay off the market nor does the fact that Shire entered into patent licensing agreements insulate it from antitrust liability that may arise from those licenses. To the contrary, Shire's decision to grant patent licenses to Teva and Impax and to contractually promise to supply those entities with all of their AXR Product requirements established an antitrust duty to deal, and Shire's unilateral decision to breach that duty for the anticompetitive purpose of impeding competition for AXR Product, as Plaintiffs allege in their complaint, states an antitrust claim as set forth in *Aspen Skiing*.

Because the "scope of the patent" test relied on by the district court in dismissing Plaintiffs' antitrust claim has been rejected by the Supreme Court in *Actavis,* the decision below must be reversed.

ARGUMENT

I. The District Court Erred in Dismissing Plaintiffs' Monopolization Claim

A. The District Court Applied the Wrong Antitrust Standard in Evaluating Defendants' Motion to Dismiss

The district court applied the "scope of the patent" test as set forth in this Court's opinion in *Tamoxifen* to dismiss Plaintiffs' antitrust claim that Shire violated its antitrust duty to deal by refusing to supply its generic competitors with AXR Product. The district court held that, as a matter of law, Plaintiffs could not allege an antitrust claim based on *Aspen Skiing* unless they claimed that the settlement agreements exceeded the scope of Shire's patents:

> LWD does not allege that the scope of the licenses (or the settlement agreements as a whole, for that matter) improperly extend the scope of Shire's patents – and that is the critical inquiry in this case, regardless of Shire's alleged conduct. *See Tamoxifen, 466 F.3d at 212-13.*

JA-137.[7]

As the district court reasoned, because (in its view) under *Tamoxifen's* "scope of the patent" test, Shire could "simply [] write each entity a check in

[7] As the district court noted, *Tamoxifen* held that "[u]nless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is 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.* (quotation omitted). Plaintiffs have not alleged that the settlement agreements delayed competition beyond the expiration dates of the patents at issue in the underlying infringement suits.

consideration for their agreement to delay or drop their respective generic applications," Shire's decision to allow multiple licenses could not subject it to antitrust liability under any circumstances. JA-134, JA-136-137. *See also* JA-139 ("Even if Shire completely failed to supply Teva and Impax with Adderall XR under the terms of the license, [Plaintiffs] and the rest of the market would be no worse off than had Shire decided against licensing in the first place"). In comparing the actual agreements to the hypothetical scope of the patent, the district court ignored the competitive reality that the settlements occurred because Shire concluded that if it did not settle, its patent could be held to be invalid or not infringed before the patent term expired, and therefore, Adderall XR would have no patent protection at all.

In *Actavis*, however, the Supreme Court squarely rejected the "scope of the patent" test and with it, the "view that the only pertinent question is whether '[a settlement agreement] fall[s] within the legitimate 'scope' of the patent's 'exclusionary potential.'" *Actavis*, ___ U.S. ___, 2013 U.S. LEXIS 4545 at *19. The Court noted that even accepting as fact that the agreements' anticompetitive effects fall within the scope of the exclusionary potential of the patent, that fact or characterization did not immunize the agreement from antitrust attack. *Id.* at *18. As the Court observed, "[w]hether a particular restraint lies 'beyond the limits of the patent monopoly' is a *conclusion*… and not…[a] starting point," (*id.* at *21) (emphasis in original), and to refer "simply to what the holder of a valid patent could do does not answer the antitrust question." *Id.* at *18. Consequently, the district court's entire legal premise upon which its decision to dismiss is based, *i.e.*, that Shire had the right to settle the infringement suits by paying the generics to delay launch until the expiration date of Shire's Adderall XR patents, has been overruled. Accordingly, the district court's decision dismissing the complaint must be reversed.

B. Plaintiffs' Allegations State a Valid Refusal to Deal Claim

Plaintiffs have alleged an antitrust violation based on a monopolist's refusal to deal with its rivals as set forth in *Aspen Skiing*. *Aspen Skiing* is generally considered "the leading case for § 2 liability based on refusal to cooperate with a rival." *Verizon Communications, Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 408 (2004). While as a general matter a firm is free to deal with whomever it chooses, this right is not unqualified, and "[u]nder certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2." *Id.* (quoting *Aspen Skiing)*. The Supreme Court has repeatedly reaffirmed the validity of this cause of action. *See e.g., Eastman Kodak,* 504 U.S. 451 (1992) at 483 n. 12 ("It is true that as a general matter a firm can refuse to deal with its competitors. But such a right is not absolute; it exists only if there are legitimate competitive reasons for the refusal") (citing *Aspen Skiing*); *Pac. Bell Tel. v.*

Linkline Communications, Inc., 555 U.S. 428, (2009) (citing *Aspen Skiing* for the proposition that "[t]here are also limited circumstances in which a firm's unilateral refusal to deal with its rivals can give rise to antitrust liability").[8]

[8] Courts within this Circuit have also recognized the viability of refusal to deal claims. *See Eatoni Ergonomics, Inc. v. Research in Motion Corp.,* 2012 U.S. App. LEXIS 12641 (2d Cir. June 21, 2012) (termination of a prior, voluntary course of dealing can give rise to a Section 2 violation); *In re Elevator Antitrust Litig.,* 502 F.3d 47, 52-53 (2d Cir. 2007) (same); *Miniframe Ltd. v. Microsoft Corp.,* 2013 U.S. Dist. LEXIS 49813 (S.D.N.Y. March 28, 2013) (same); *New York Jets LLC v. Cablevision*, 2005 U.S. Dist. LEXIS 23763, *27-28 (S.D.N.Y. Oct. 18, 2005): (allowing Jets' claim that Cablevision refused to air Jets' advertisements as an exclusionary act to prevent competition in the market for certain types of entertainment facilities because "while Cablevision is generally free to engage in business or refuse to engage in business with whomever it chooses, it may not do so when the purpose of such refusal is to maintain a monopoly"); *Creative Copier v. Xerox Corp.*, 344 F. Supp. 2d 858 (D. Conn. 2004) (Xerox terminated a prior course of dealing without legitimate business justification).

Courts in other jurisdictions have held similarly. *See, e.g., MetroNet Svcs. Corp. v. Qwest Corp.,* 383 F.3d 1124, 1131- 1134 (9th Cir. 2004) (a refusal to deal can be illegal under the antitrust laws pursuant to *Aspen Skiing* and *Trinko*); *American Central Eastern Texas Gas Co. v. Union Pacific Resources Group,* 93 Fed. Appx. 1 (5th Cir. 2004) (unpublished opinion affirming confirmation of arbitration award for a refusal-to-deal claim pursuant to *Trinko* where there was a prior course of dealing and considerable evidence that the defendant refused to deal for anticompetitive reasons.); *MCI Comms. v. AT&T*, 708 F.2d 1081, 1132-33 (7th Cir. 1983) (affirming a jury's liability findings on refusal to deal/essential facilities); *Evergreen Helicopters, Inc. v. Erickson Air-Crane,* 2011 U.S. Dist. LEXIS 8081, *15 (D. Or. Jan. 26, 2011) (denying summary judgment motion on a refusal to deal claim where there was evidence that the defendant ended a prior course of dealing for exclusionary purposes); *Safeway Inc. v. Abbott Labs.*, 2010 U.S. LEXIS 2145 (N.D. Ca. Jan. 12, 2010) (denying motion to dismiss on refusal to deal claim) and *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874, 894 (N.D. Ca. 2011) (denying motion for summary judgment and holding that liability under Section 2 could

In *Aspen Skiing*, the owner of multiple ski slopes sought to harm a competitor by terminating a voluntary, long-standing business arrangement between the parties consisting of the sale of a joint ticket (the "All-Aspen" ticket) that permitted customers to ski on multiple slopes. *Aspen Skiing*, 472 U.S. at 589-91. After the plaintiff refused to agree to the defendant's demands for an increased share of the profits, which defendant conceded was "an offer that [plaintiff] could not accept," the defendant terminated the sale of the joint ticket in any form. *Id.* at 592-93.[9] The Supreme Court upheld a Section 2 jury verdict for the plaintiff, rejecting the defendant's argument that it had an unqualified right to refuse to deal with whom it pleases, concluding that the evidence was sufficient to show that the defendant's discontinuance of the All-Aspen ticket was a decision by a monopolist to make an important change in the character of the market, for anticompetitive purpose rather than a valid business reason. *Id.* at 604-09 (detailing evidence to

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arise if a defendant unilaterally alters a voluntary course of dealing and "anticompetitive malice" motivates the defendant's conduct"). *Cf. Christy Sports, LLC v. Deer Valley Resort Co.,* 555 F.3d 1188, 1197 (10th Cir. 2009) (affirming dismissal of a refusal to deal claim, but noting that under *Trinko* and *Aspen Skiing* a refusal to cooperate with competitors might constitute a §2 violation where the defendant "terminated a profitable relationship without any economic justification.")

[9] The plaintiff tried to market a variety of ticket offerings in an attempt to re-create the joint ticket, even to the point of effectively purchasing defendant's tickets at retail price for re-sale, but none of these attempts were successful. *Id.* at 593-95.

support conclusion that defendant "elected to forgo [ticket sales] because it was more interested in reducing competition in the Aspen market over the long run by harming its smaller competitor").

Plaintiffs' factual allegations regarding the existence of an antitrust duty to deal are far more compelling than the circumstances that existed in *Aspen Skiing.* In *Aspen Skiing,* there was no contract or formal agreement between the parties that gave rise to the monopolist's duty to deal. Instead, the Court *inferred* the existence of the duty from a prior course of dealing among the parties. Here, the basis for Shire's duty to deal with its rivals could not be more explicit: Shire entered into contractual agreements with Teva and Impax to license its patents and provide them will all the AXR Product they required.[10] Moreover, the agreements at issue here were more than just typical commercial licensing agreements; they arose in the context of Hatch-Waxman litigation and reflected a compromise in which Shire agreed to relinquish its monopoly - by entering into license and

[10] The explicitness of Shire's duty to deal also stands in marked contrast to two recent cases within this Circuit which provide examples of circumstances in which no duty to deal existed. *See Eatoni*, 2012 U.S. App. LEXIS 12641 at *6-7 (parties' agreement purporting to establish duty to deal was merely an agreement to collaborate in good faith on future products); *Miniframe Ltd.*, 2013 U.S. Dist. LEXIS 49813 at *14 (dealing between computer software corporation and product end-users is not equivalent to a monopolist's prior cooperation with a rival).

requirement contracts with its prospective generic competitors - in return for its competitors agreeing to stay off the market for three years.

The district court claimed that *Aspen Skiing* was distinguishable because "*Aspen Skiing,* unlike *Tamoxifen* and the instant case, did not involve application of rights and remedies encompassed by patent law." JA-132. But as the Supreme Court observed in *Actavis*, "this Court's precedents make clear that patent-related settlement agreements can sometimes violate the antitrust laws." *Actavis*, ___ U.S. ___, 2013 U.S. LEXIS 4545 at *21. Citing a long line of such cases, the *Actavis* court noted that:

> These cases do not simply ask whether a hypothetical valid patent's holder would be able to charge, *e.g.*, the high prices that the challenged patent-related term allowed. Rather, they seek to accommodate patent and antitrust policies, finding challenged terms and conditions unlawful unless patent law policy offsets the antitrust law policy strongly favoring competition.

Id. at *24.

Similarly, *Actavis*, in discussing the Supreme Court's opinion in *United States v. Line Material Co.*, 333 U.S. 287 (1946), noted that the mere presence of a patent does not override the concerns of antitrust policy:

> In short, rather than measure the length or amount of a restriction solely against the length of the patent's term or its earning potential, as the Court of Appeals apparently did here, this Court answered the antitrust question by considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power and potentially offsetting legal considerations present in the circumstances, such as here those related to patents…Whether a particular restraint lies "beyond the limits of the patent

> monopoly" is a *conclusion* that flows from that analysis and not…its starting point.

Id. at *20-21 (emphasis in original).

The district court, however, started and ended its analysis with the conclusion that there could be no antitrust liability relating to "Shire's alleged conduct under the agreements, because the terms of those settlement agreements with Teva and Impax do not exceed the scope of the patents in question." JA-142. Accordingly, since the district court applied the wrong legal standard to determine whether the allegations in Plaintiffs' complaint stated a claim under the antitrust laws, its dismissal of the complaint must be reversed.[11]

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[11] Because the district court applied the wrong legal standard, its basis for distinguishing *Safeway*, 761 F. Supp. 2d at 881-84, a case in which the alleged duty to deal arose from a patent licensing agreement, was also erroneous. In *Safeway* plaintiffs alleged that the defendant used various licensing deals to induce its competitors to develop AIDS drugs to be used in combination with the defendant's "booster" product, and then, after developing its own combination product, increased the price of its booster by 400% in order to make it prohibitively expensive for patients to use rivals' products. *See Safeway*, 761 F. Supp. 2d at 881-84. In denying the defendant's motions to dismiss and for summary judgment, the district court applied *Aspen Skiing* to reject the argument that the defendant had no duty to deal with its rivals. *Id.* at 894. The district court here, however, in addition to noting that "neither Safeway nor the other refusal-to-deal cases cited by Plaintiff" would alter the Court's conclusions that Plaintiff failed to state a claim because the settlement agreements did not exceed the scope of the patents, noted further that *Safeway* was distinguishable because of the "anticompetitive effect for a different drug." JA-141-142. Such a distinction is without significance and, if anything, emphasizes the anticompetitive effect caused by Shire's refusal to deal here. Plaintiffs here are not complaining about how a price in one market affects competition in a different market. Plaintiffs' complaint is that Shire's refusal to

CONCLUSION

For the foregoing reasons, this Court should reverse the order of the district court dismissing the complaint and remand for further proceedings in the district court.

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Respectfully submitted,

/s/ Bruce E. Gerstein

GARWIN, GERSTEIN & FISHER LLP
Bruce E. Gerstein
Kimberly Hennings
1501 Broadway, Suite 1416
New York, NY 10036
Tel: (212) 398-0055
Fax: (212) 764-6620

SMITH SEGURA & RAPHAEL LLP
David P. Smith
David C. Raphael, Jr.
Brian D. Brooks
3600 Jackson Street, Suite 111
P.O. Box 1632
Alexandria, LA 71309
Tel: (318) 445-4480
Fax: (318) 487-1741

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supply Teva and Impax with AXR Product as it was required to do pursuant to the settlement agreements caused prices for AXR Product to be higher. Stripped of any immunity the "scope of the patent" test may have been believed to confer, Plaintiffs' complaint adequately alleges an antitrust violation.

ODOM & DES ROCHES, LLP
John Gregory Odom
Stuart E. Des Roches
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078

HEIM, PAYNE & CHORUSH, LLP
Russ Chorush
600 Travis, Suite 6710
Houston, Texas 77002
Tel: (713) 221-2000
Fax: (713) 221-2021

COUNSEL FOR DIRECT PURCHASER PLAINTIFFS-APPELLANTS