13-1232-cv

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,

– v. –

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

Defendants-Appellees.

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

BRIEF FOR DEFENDANTS-APPELLEES

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, the undersigned counsel for Defendants-Appellees Shire LLC and Shire U.S. Inc. (collectively "Shire"), certifies that each entity is an indirect wholly-owned subsidiary of Shire plc and no publicly held corporation other than Shire plc owns 10 percent or more of the stock, or of an interest, in either entity.

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JURISDICTIONAL STATEMENT

Shire is satisfied with the Jurisdictional Statement set forth at page 1 of the Corrected Brief of Plaintiffs-Appellants ("Pltfs' Br.").

STATEMENT OF THE ISSUE PRESENTED FOR REVIEW

Did the district court err in deciding that the Plaintiff drug wholesalers failed to state a claim upon which relief can be granted in claiming that Shire's alleged breach of agreements for the supply of an unbranded version of its patented pharmaceutical product, Adderall XR, to Shire's generic competitors by delivering up to 60 percent of all branded and unbranded Adderall XR Shire had made, but less than all of the unbranded Adderall XR the generic competitors had ordered, constituted monopolization in violation of Section 2 of the Sherman Act?[1]

STATEMENT OF THE STANDARD OF REVIEW

This Court applies a *de novo* standard of review to the grant of a Federal Rule of Civil Procedure 12(b)(6) motion to dismiss, accepting a complaint's factual allegations as true and drawing all reasonable inferences in the plaintiff's favor. *Fink v. Time Warner Cable*, 714 F.3d 739, 740-41 (2d Cir. 2013). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v.*

[1] Section 2 of the Sherman Act, 15 U.S.C. § 2, provides in relevant part: "Every person who shall monopolize . . . any part of the trade or commerce among the several States . . . shall be deemed guilty of a felony."

Iqbal, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

STATEMENT OF THE CASE

This appeal involves two purported class actions, consolidated *sub nom. In re Adderall XR Antitrust Litigation*, Lead Case No. 1:12-cv-3711 (VM), brought by Louisiana Wholesale Drug Company, Inc. ("Louisiana Wholesale"), and Value Drug Company ("Value Drug").[2] Each Complaint contains one count asserting that Shire has violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing a relevant United States product market referred to as "AXR Product," which includes branded Adderall XR and its generic equivalents, including unbranded Adderall XR produced by Shire. The active pharmaceutical ingredient in AXR Product is amphetamine that is subject to control by the Drug Enforcement Administration ("DEA"). Shire holds valid patents covering AXR Product. It started manufacturing branded AXR Product in 2001 and generic AXR Product in 2009. Under agreements with Teva Pharmaceuticals USA Inc.

[2] The *Value Drug* Complaint, Civil Action No. 12 Civ. 5001 (VM), filed June 26, 2012, is virtually identical to the earlier filed *Louisiana Wholesale* Complaint, Civil Action No. 12 Civ. 3711 (VM), filed May 9, 2012. The district court accepted *Value Drug* as a related case to *Louisiana Wholesale* and consolidated the two actions for all purposes. JA-6 at ECF No. 22. The district court stayed proceedings in *Value Drug* pending a decision on Shire's motion to dismiss the *Louisiana Wholesale* Complaint. *Id.* Accordingly, Shire will follow the convention of Pltfs' Br. and refer to Louisiana Wholesale and Value Drug as "Plaintiffs," but cite only to the *Louisiana Wholesale* Complaint.

("Teva")[3] and Impax Laboratories Inc. ("Impax"), Shire began supplying Teva in April 2009 and Impax in October 2009 with an unbranded version of Adderall XR for each to resell as generic AXR Product. Despite having licenses to Shire's patents covering Adderall XR, Teva and Impax, at that time, could not sell their own generic AXR Products because the Food and Drug Administration ("FDA") had not approved those generic products. Thus, competition between branded and generic Adderall XR occurred only because of Shire's supply of unbranded Adderall XR to Teva and Impax. As Plaintiffs recognize, Shire's supply of generic AXR Product to Teva and Impax has represented up to 60 percent of all AXR Product DEA has allowed Shire to make.

Plaintiffs are drug wholesalers who have purchased branded AXR Product directly from Shire and generic AXR Product presumably from Teva and Impax.[4] Plaintiffs base their monopolization claim upon breach-of-contract allegations separately asserted against Shire by Teva in 2009 and Impax in 2010 that Shire had failed to provide each at different times with all of the generic AXR Product each claimed it was entitled to receive under its respective supply agreement. Plaintiffs

[3] The supply agreement with Teva was originally with Barr Pharmaceuticals, Inc. ("Barr"), which became affiliated with Teva in December 2008. For ease of reference, the Complaints collectively refer to these entities as "Teva," *see* JA-11 n.1, and Shire will do likewise in this brief.

[4] Plaintiffs nowhere allege in the Complaints from whom they bought generic AXR Product. Based upon a reading of the Complaints as a whole, Shire assumes that Plaintiffs were purchasers of generic AXR Product from Teva or Impax during the relevant period.

assert that Shire's alleged partial deliveries to the generic companies interfered with Teva's and Impax's efforts to sell generic AXR Product in competition with Shire's branded AXR Product, which in turn caused Plaintiffs to pay higher prices for their AXR Product purchases. Plaintiffs principally rely upon the Supreme Court's recent decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013), to support their argument that the district court erred in dismissing the Complaints, and *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985), to sustain the viability of their monopolization claim.

On March 6, 2013, the district court dismissed the *Louisiana Wholesale* Complaint pursuant to Rule 12(b)(6). *See Louisiana Wholesale Drug Co. v. Shire LLC*, 12 Civ. 3711 (VM), 2013 U.S. Dist. LEXIS 34251 (S.D.N.Y. Mar 6, 2013); JA-120-43. The district court found Shire's challenged partial refusal to supply generic AXR Product to Teva and Impax to be conduct within the scope of Shire's patents covering AXR Product and, therefore, protected from liability under the antitrust laws. *Id.* at *22; JA-138-39. The district court also rejected Plaintiff's *Aspen Skiing*-type monopolization claim, recognizing *Aspen Skiing*'s limitations and the distinguishing features of Shire's challenged conduct from the exclusionary conduct found in *Aspen Skiing*. *Id.* at *22-24; JA-139-41.

While the district court relied, in part, upon this Court's decision in *In re Tamoxifen Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006), and the *Actavis* decision

abrogates the *Tamoxifen* holding as to so-called "reverse payment agreements," *Actavis* does not impugn the principle underlying the district court's decision, namely that a patentee's conduct occurring within the scope of its patents and specifically permitted by the patent laws (here partially refusing to deal in the patented product) is protected from antitrust liability. That principle and the district court's ruling are fully consistent with this Court's decision in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981).

The *Actavis* decision does not undercut the vitality of *SCM* or the decision below because: (i) *Actavis*, like *Tamoxifen*, dealt with an entirely different issue arising at the intersection of the patent and antitrust laws—the extent to which the antitrust laws should apply to settlements of patent litigation (an issue Plaintiffs expressly state is not raised here, *see* Pltfs' Br. 14, n.7)—and not the application of the antitrust laws to a patentee's unilateral refusal to deal in its patented product; and (ii) the holdings in *SCM* and by the district court reflect the balancing of the policies of the patent and antitrust laws undertaken by the *Actavis* majority in reaching the decision in that case.

Finally, as the district court correctly found, the *Aspen Skiing* decision offers no support for Plaintiffs' monopolization claim; simply stated, Shire's challenged conduct does not fit into whatever is left of the *Aspen Skiing* paradigm.

STATEMENT OF RELEVANT FACTS

The relevant allegations of the Complaint, JA-10-38, are as follows.

1. On October 11, 2001, FDA approved New Drug Application No. 21-303 submitted by Shire (the "Shire NDA") for the manufacture and sale of branded Adderall XR for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD"). JA-11 ¶ 2, JA-21 ¶ 36.

2. The active pharmaceutical ingredient used to manufacture AXR Product is amphetamine, a controlled substance that is subject to abuse. To prevent diversion of AXR Product for illegal use, DEA controls the amount of amphetamine Shire can purchase and, consequently, the volume of AXR Product Shire can manufacture. DEA limits the manufacture of the AXR Product in line with DEA's estimates of patient demand for the Product by granting quotas setting the amount of amphetamine Shire can purchase. JA-29-30 ¶ 63.

3. Shire has been manufacturing and selling branded Adderall XR since October 2001. JA-11 ¶ 2, JA-16 ¶¶ 13-15. Shire began manufacturing an unbranded version of Adderall XR under the Shire NDA in 2009, JA-20 ¶ 32, which it, in turn, has sold to Teva and Impax. *See infra* p. 7-8 ¶ 9.

4. Plaintiffs are wholesale purchasers of branded AXR Product from Shire, JA-15-16 ¶ 12, and generic AXR Product presumably from Teva or Impax. *See supra* note 4.

5. Shire owns U.S. Patent No. 6,322,819, U.S. Patent No. 6,605,300 and U.S. Patent No. 6,913,768 (the "Adderall XR Patents") that cover or relate to Adderall XR. JA-18 ¶ 26, JA-21 ¶ 36.

6. In November 2002, Teva filed an Abbreviated New Drug Application ("ANDA") seeking FDA approval to manufacture and sell a generic equivalent to Adderall XR. In November 2003, Impax filed an ANDA also seeking FDA approval for its own generic equivalent to Adderall XR. JA-11-12 ¶ 3, JA-22 ¶ 39.

7. In response, Shire separately sued Teva and Impax for patent infringement under the Hatch-Waxman Act. JA-22 ¶ 39. Such litigation is typical and is expressly contemplated by the Hatch-Waxman Act. JA-13 ¶ 7.[5]

8. In 2006, Shire settled its patent suits against Teva and Impax. As part of the settlements, Shire granted each a patent license to sell a generic equivalent of Adderall XR pursuant to its ANDA starting on April 1, 2009, and October 1, 2009, respectively. Shire also agreed that if either Teva or Impax had not received FDA approval of its ANDA by its respective license effective date, Shire would supply them with unbranded Adderall XR for them to sell as generic AXR Product. JA-23-24 ¶¶ 41-42.

9. Because FDA had not approved either of the Teva or Impax ANDAs by their license effective dates, Shire began supplying unbranded AXR Product to

[5] A succinct description of the NDA, ANDA, and Hatch-Waxman Act processes can be found in *Actavis*, 133 S. Ct. at 2228-29.

Teva in April 2009 and Impax in October 2009.[6] Shire also continued to supply itself with branded AXR Product. Since that time, Shire has supplied 50 to 60 percent of all AXR Product DEA has allowed Shire to make to Teva and Impax for them to resell as generic AXR Product. JA-14 ¶ 8, JA-27 ¶ 53, JA-28 ¶ 58.

10. After the commencement of the supply agreements, separate disputes arose between Shire and Teva in 2009 and then between Shire and Impax in 2010, concerning the amounts of generic AXR Product each was entitled to receive under the supply agreements in light of the DEA quota system, among other things. JA-27 ¶¶ 54-55, JA-28 ¶¶ 58-59, JA-29 ¶ 63.[7]

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[6] When Plaintiffs filed their Complaints, FDA still had not approved the Teva and Impax ANDAs, and Shire remained the only company FDA had approved to manufacture the AXR Product at issue. JA-22 ¶ 39, JA-23-24 ¶¶ 42-43, JA-24-26 ¶¶ 45-49, 51. The Court may take judicial notice that on June 22, 2012, FDA approved the first Adderall XR ANDA owned by Actavis Elizabeth LLC ("Actavis"). FDA subsequently approved Teva's ANDAs (including one filed by its Barr affiliate) on February 12, and April 29, 2013. FDA still has not approved Impax's ANDA. ANDA approvals can be accessed through FDA's website at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails by inserting the appropriate ANDA number (Actavis ANDA No. 077302, Barr ANDA No. 076536, Impax ANDA No. 076852, and Teva ANDA No. 077488).

[7] Plaintiffs refer in their Complaints to a December 2011 article in *The New York Times* in which a DEA agent attributed reported shortages of ADHD drugs to "decisions made by manufacturers," including Shire. JA-30 ¶ 64. The Court may take judicial notice that this article also reported that "*Officials at the Food and Drug Administration* say the shortages are a result of overly strict quotas set by the Drug Enforcement Administration," and "[t]he situation has made for a rare open disagreement between two federal agencies." Gardiner Harris, *F.D.A. Finds Short Supply of Attention Deficit Drugs*, N.Y. Times, Dec. 31, 2011,

11. Based upon the supply disputes between Shire and Teva and Impax, Plaintiffs claim that Shire has violated Section 2 of the Sherman Act. JA-36-37 ¶¶ 83-87.

SUMMARY OF THE ARGUMENT

The district court properly dismissed pursuant to Rule 12(b)(6) Plaintiffs' claim that Shire monopolized a purported antitrust market for AXR Product in violation of Section 2 of the Sherman Act by supplying Teva and Impax with up to 60 percent of all AXR Product DEA has allowed Shire to make, instead of 90 percent of that Product which Plaintiffs claim Shire should have sold to Teva and Impax. Plaintiffs' monopolization claim is a transparent attempt to turn ordinary business disputes involving alleged breaches of contract between Shire and its two customers of generic AXR Product, and those customers' demands for more generic AXR Product in the face of supply constraints imposed by DEA, into a treble damages lawsuit under the antitrust laws. Plaintiffs' attempt fails, however, because as recognized by the district court, breaches of contract, even those with an adverse impact upon a competitor, do not *ipse dixit* form the basis of an antitrust claim. *See Louisiana Wholesale Drug Co.*, 2013 U.S. Dist. LEXIS 34251, at *16; JA-133; *see also Brooke Group v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 225 (1993).

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http://www.nytimes.com/2012/01/01/health/policy/fda-is-finding-attention-drugs-in-short-supply.html?pagewanted=all&_r=0 (emphasis added).

By its supply of unbranded Adderall XR to Teva and Impax, Shire established these two generic companies as competitors with a combined share of up to 60 percent of Adderall XR sales. It is undisputed that Shire did not refuse to deal with Teva and Impax, extinguishing their competition, but only declined to supply them with additional AXR Product to which they believed they were entitled to receive under the supply agreements. Shire disagreed with their belief and interpretation of the supply agreements, which was the crux of their breach of contract claims against Shire. Those lawsuits have since settled, and the supply relationship between Shire and each of Teva and Impax continues. *See infra* note 8.

Shire's conduct provides no basis for Plaintiffs' far-fetched monopolization claims, and the district court's dismissal of Plaintiffs' Complaints should be affirmed.

1. Shire's challenged conduct is beyond the purview of the antitrust laws. Shire holds valid and enforceable patents covering AXR Product, and the Patent Act specifically permits a patentee to refuse to deal in its patented good, even if the refusal to deal adversely affects competition. *See* 35 U.S.C. §§ 154(a)(1) and 271(d)(4). At its core, Shire's alleged conduct was a refusal to deal, albeit a partial refusal to deal, within the scope of the Adderall XR Patents. Plaintiffs make no allegation that Shire unlawfully acquired the Adderall XR Patents, that it engaged in any conduct relating to its patented AXR Product that was impermissible under

the patent laws, or that it sought improperly to expand its patent monopoly rights beyond the four corners of the Adderall XR Patents. In the absence of any such allegation, Shire's challenged conduct is protected from antitrust liability. This is the principle underlying the district court's decision and is fully consistent with *SCM*, in which this Court expressly held that "where a patent has been lawfully acquired, subsequent conduct permissible under the patent laws cannot trigger any liability under the antitrust laws. This holding, we believe, strikes an adequate balance between the patent and antitrust laws." 645 F.2d at 1206.

The Supreme Court's recent decision in *Actavis* does not alter the result. First, the *Actavis* holding is inapposite because the case involved a challenge to a reverse payment agreement settling Hatch-Waxman patent litigation; the Plaintiffs here expressly are not challenging Shire's settlements of the patent cases filed against Teva and Impax. *See* Pltfs' Br. 14, n.7. Indeed, Plaintiffs' claim depends upon the validity and operation of those settlements, including the settlements' product supply component, because without the settlements and Shire's supply of generic AXR Product to Teva and Impax there would have been no generic competition due to there being no FDA approval of Adderall XR generic equivalents. Thus, the antitrust issue in *Actavis*—that a patentee may be illegally maintaining a patent monopoly by improperly broadening the scope, or maintaining the facial validity, of its patent through a substantial payment to an

alleged infringer to settle a lawsuit and agree to delay competition—is simply not present here.

Second, the district court's decision and this Court's holding in *SCM* are entirely consistent with a balancing of the policies of the patent and antitrust laws that the *Actavis* majority undertook to reach its holding. That balancing weighs a patentee's right under the patent laws to restrain competition, including whether the patent laws specifically permit the challenged conduct, against the extent of the restraint on competition, including whether the restraint impeded competition beyond other restraints previously approved to be reasonable. *See Actavis*, 133 S. Ct. at 2231. Balancing patent and antitrust law policies here decidedly tilts in favor of no application of the antitrust laws because Shire's conduct is specifically permitted by the patent laws and any restraint on competition resulting from Shire's unilateral partial refusal to deal falls far short of monopolization—Shire surrendered up to 60 percent of the alleged relevant market to its generic competitors—that courts have condemned in refusal to deal cases.

2. Shire's alleged partial refusal to deal also presents an insufficient basis for a monopolization claim under *Aspen Skiing*, which is "at or near the outer boundary of Section 2 liability." *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004); *Louisiana Wholesale Drug Co.*, 2013 U.S. Dist. LEXIS 34251, at *22-23; JA-140. Shire's conduct created competition

where none existed, and competition has continued despite the breach-of-contract allegations. This contrasts starkly with the challenged conduct in *Aspen Skiing* where the defendant's actions brought then-existing competition to an abrupt halt for the purpose of giving the defendant a monopoly. In short, Shire's conduct does not fit whatever is left of the *Aspen Skiing* paradigm.

ARGUMENT

I. THE DISTRICT COURT PROPERLY DISMISSED PLAINTIFFS' COMPLAINTS PURSUANT TO RULE 12(B)(6)

Plaintiffs allege that Shire has monopolized a purported market for AXR Product in violation of Section 2 of the Sherman Act by supplying Teva and Impax with up to 60 percent of all AXR Product DEA has allowed Shire to make, rather than the entire amount they demanded (improperly according to Shire, *see* JA-29-30 ¶ 63) under supply agreements with Shire. JA-14 ¶ 8, JA-27 ¶ 53, JA-28 ¶ 58.[8]

[8] While Plaintiffs characterize Shire's reasons for refusing to supply all of the generic AXR Product demanded under the supply agreements as "mere pretext," *see* JA-29-30 ¶ 63, the Court is not required to accept this characterization on a motion to dismiss. *See Anderson News, L.L.C. v. Am. Media, Inc.*, 680 F.3d 162, 185 (2d Cir. 2012); *see also Smith v. Local 819 I.B.T. Pension Plan*, 291 F.3d 236, 240 (2d Cir. 2002) ("[C]onclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." (internal quotation marks and citations omitted)). Absent this characterization, the allegations simply show that there were contract interpretation disputes between Shire and Teva and Impax which have since been resolved. *See Teva Pharm. USA, Inc. v. Shire LLC*, Case No. 1:09-cv-8860 (S.D.N.Y. Nov. 20, 2009) (ECF No. 17); *Impax Labs., Inc. v. Shire LLC*, Case No. 1:10-cv-8386 (S.D.N.Y. Feb. 14, 2013) (ECF No. 211).

Shire's alleged monopolization occurred in circumstances where it is undisputed that Shire holds a lawful patent monopoly for AXR Product, and Shire could have simply refused to deal with Teva and Impax entirely. Plaintiffs' monopolization claim is simply not "plausible on its face," *Twombly*, 550 U.S. at 570, and provides no basis "that allows the court to draw the reasonable inference that [Shire] is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The district court, accordingly, properly dismissed Plaintiffs' Complaints pursuant to Rule 12(b)(6).[9]

A. SHIRE'S RIGHTS UNDER FEDERAL PATENT LAW PREVENT THE ALLEGED BREACHES OF SUPPLY AGREEMENTS FROM BEING A VALID BASIS FOR PLAINTIFFS' MONOPOLIZATION CLAIM

The mere possession of monopoly power does not violate the Sherman Act. *See, e.g.*, *Pacific Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 447-48 (2009); *Trinko*, 540 U.S. at 407. To prevail on their monopolization claim, Plaintiffs would need to prove that Shire possesses monopoly power in a properly defined relevant market and Shire willfully acquired or maintained that power "as distinguished from growth or development as a consequence of a superior product,

[9] In granting Shire's motion to dismiss, the district court relied upon several decisions, including this Court's decision in *Tamoxifen*, that at the time were good law but have been subsequently abrogated, at least in part, by the decision in *Actavis*. As discussed in Section I.A, *infra*, the district court's decision continues to be supported by a well-recognized line of Supreme Court and Second, Sixth, and Federal Circuit decisions, among other authorities, upholding the right of a patent holder to refuse to deal in the patented product without violating Section 2 of the Sherman Act. And, as discussed in Section I.B, *infra*, nothing in *Actavis* alters the vitality of this line of authorities.

business acumen, or historic accident." *United States v. Grinnell Corp*., 384 U.S. 563, 570-71 (1966). Notably, Plaintiffs do not allege that Shire unlawfully acquired its patent monopoly for AXR Product, only that it declined to consider the supply agreements to be suicide pacts and cede 90 percent of AXR Product sales to its competitors in the face of what Shire considered to be improper demands by Teva and Impax under those agreements. Furthermore, Plaintiffs must allege facts showing an injury to competition and that any injury they may have suffered was attributable to something the antitrust laws were designed to prevent. *See Nat'l Collegiate Athletic Ass'n v. Bd. of Regents*, 468 U.S. 85, 97 (1984); *H.L. Hayden v. Siemens Med. Sys., Inc*., 879 F.2d 1005, 1020 (2d Cir. 1989). Plaintiffs' allegations fail to satisfy these standards.[10]

Plaintiffs allege that each of Shire's settlements with Teva and Impax has two relevant parts. First, Shire granted patent licenses to Teva and Impax to sell generic equivalents to Adderall XR pursuant to their own ANDAs starting on April 1, 2009, and October 1, 2009, respectively. Plaintiffs make no allegation that Shire failed in any way to satisfy its patent licensing obligations under the settlements.

[10] In its motion to dismiss, Shire argued that Plaintiffs failed to allege a proper relevant market and Plaintiffs cannot sue for damages under Section 4 of the Clayton Act, 15 U.S.C. § 15, insofar as they were indirect purchasers of generic AXR Product from Teva and Impax. The District Court declined to address these issues. *See Louisiana Wholesale Drug Co.*, 2013 U.S. Dist. LEXIS 34251, at *22; JA-143.

For the second part of the settlements, Shire agreed that in the event Teva or Impax did not receive FDA approval of their ANDAs as of the date their respective patent licenses became effective, Shire would supply Teva and Impax with generic AXR Product for them to resell. In essence, Shire entered into contracts ensuring that Teva and Impax would have generic Adderall XR products to sell if a regulatory impediment—lack of FDA approval—prevented the generics from entering the market. Shire's commitment and subsequent supply to Teva and Impax are notably inconsistent with the behavior of an alleged monopolist.

Plaintiffs do not allege that Shire simply refused to perform the supply component of the settlements or deal with Teva and Impax. Indeed, Plaintiffs affirmatively allege that Shire has supplied Teva and Impax with 50 to 60 percent of all the AXR Product DEA has permitted Shire to manufacture. The alleged breaches of contract were based upon claims that Shire failed to supply additional AXR Product that Teva and Impax felt they were entitled to buy, to which entitlement Shire disagreed. Even assuming for sake of argument that there were breaches of the contracts, Shire's conduct would not provide a proper basis for a claimed violation of Section 2 of the Sherman Act. At most, Shire *partially* refused to deal with Teva and Impax for AXR Product.

Shire holds valid and enforceable patents covering Adderall XR and thus has a lawful monopoly over AXR Product. Plaintiffs, in fact, affirmatively plead that

Shire is the owner of the Adderall XR Patents and was, as of the date of the filing of the litigations, the sole source for AXR Product. *See supra* pp. 6-8. There are no allegations suggesting that Shire used the Adderall XR Patents in violation of the patent laws or sought in any way to expand the scope of the four corners of the lawfully granted patent monopoly accorded by those Patents. Absent such allegations, Shire cannot be deemed to be unlawfully monopolizing a market where it holds a lawful patent monopoly. As this Court held in *SCM Corp. v. Xerox Corp.*, "Simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws." 645 F.2d at1204.

United States patent law contains no requirement that a patentee sell or license its invention to any one and creates no sanction for a patentee's unilateral refusal to sell or license the invention. Indeed, the essence of a patentee's right is "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States" for a limited term of years. 35 U.S.C. § 145(a)(1)-(2); *see also Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 215 (1980) ("[T]he essence of a patent grant is the right to exclude others from profiting by the patented invention."). When operating within the scope of its lawful patent, the patentee is afforded protection from the Sherman Act within "the limits of the patent monopoly." *United States v. Singer Mfg. Co.*, 374 U.S. 174, 196-97 (1963).

Under 35 U.S.C. § 271(d)(4), a patentee is not "deemed guilty of misuse or illegal extension of the patent right by reason of . . . refus[ing] to license" any of its patent rights, and correspondingly, it has long been held that a unilateral refusal to use or license a patent cannot form the basis for an antitrust claim. *See, e.g.*, *Standard Oil Co. v. United States*, 283 U.S. 163, 179 (1931); *SCM Corp.*, 645 F.2d at 1209; *In Re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000) ("Intellectual property rights do not confer a privilege to violate the antitrust laws . . . . But it is also correct that the antitrust laws do not negate the patentee's right to exclude others from patent property.") (citation and quotation marks omitted). Whether a patentee has violated Section 2 of the Sherman Act "is governed by the rules of application of the antitrust laws to market participants, with due consideration to the exclusivity that inheres in the patent grant." *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d at 1325 (citation and quotation marks omitted).

Thus, in the first instance, Shire could have simply refused to deal with Teva and Impax and totally excluded them from selling AXR Product without violating Section 2 of the Sherman Act. *Id.* at 1327. By definition, then, a patentee's partial refusal to sell its patented product, as alleged here, is conduct outside the coverage of the antitrust laws. As the district court pointed out:

> 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 that same patent holder would not face such liability if it refused outright to issue a license in the first instance.

Louisiana Wholesale Drug Co., 2013 U.S. Dist. LEXIS 34251, at *22; JA-138-39. The district court then went on to state: "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." *Id.*; JA-139 (emphasis in original). Conversely, the district court recognized that: "It would be a strange result indeed if Shire's decision to allow multiple licenses—thereby increasing competition—would take the patents 'out of the picture,' to use [Louisiana Wholesale's] terminology . . . , and thus increase its exposure to antitrust liability." *Id.* at *20; JA-136-37.

A patentee may be susceptible to breach-of-contract allegations with respect to a license it may have granted under its patent, but such a claim does not remove the protections from antitrust liability that carry with a patent. As the district court observed, "not every sharp-elbowed business practice—though potentially wrongful as a breach of contract or even fraud—necessarily amounts to an antitrust violation, as indeed, Shire's actions in this case do not." *Id.* at *16; JA-133; *see also Brooke Group*, 509 U.S. at 225 ("Even an act of pure malice by one business competitor against another does not, without more, state a claim under the federal

antitrust laws."); *Agency Dev., Inc. v. Med Am. Ins. Co.*, 310 F. Supp. 2d 538, 544 (W.D.N.Y. 2004).

Relying upon *SCM*, the Sixth Circuit so held in *Miller Insituform, Inc. v. Insituform of North America, Inc.*, 830 F.2d 606 (6th Cir. 1987). In that case, defendant had exclusive rights to a patented process, and it granted an exclusive sublicense in a designated territory to plaintiff. *Id.* at 607. Subsequently, defendant allegedly conspired to take back control of plaintiff's exclusive territory and terminated the sublicense agreement. *Id.* Plaintiff sued, claiming a violation of Section 2 of the Sherman Act. *Id.* Affirming the grant of summary judgment against plaintiff and citing *SCM*, the Sixth Circuit held:

> Similarly, we conclude that the holder of a patent retains the power to exclude others from manufacturing, using, and selling his inventions without running afoul of the antitrust laws. Here, by terminating the sublicense agreement with the appellant, appellee merely exercised his power to exclude others from using the Insituform process, as was its right under *35 U.S.C. § 154*. In so doing, it did not violate *Section 2* of the Sherman Act.

Id. at 609 (italics in original). The court also explicitly rejected plaintiff's claim that termination of the agreement constituted patent misuse, rendering defendant liable for antitrust violations: "The mere failure to observe state contractual obligations does not rise to the level of misuse of a patent that will render one liable for violations of *Section 2* of the Sherman Act." *Id.* (italics in original).

Plaintiffs place much emphasis upon the fact that the allegedly-breached supply agreements arose in the context of patent litigation settlements under the Hatch-Waxman Act, whereby Teva and Impax agreed not to launch their Adderall XR generic equivalent products for several years. While that may be true, it makes no difference to the outcome here. Plaintiffs make no claim that the settlements were improper, including the timing of the launch of generic Adderall XR, that Shire failed to provide the necessary patent licenses enabling Teva and Impax to sell their generic versions of Adderall XR, or that the supply component of the settlements were somehow unfair. Once Shire began supplying unbranded Adderall XR to the generics, the settlement context for the settlement agreements fell away. Thus, the breach-of-contract disputes upon which Plaintiffs base their monopolization claim were nothing more than ordinary business disputes, with no implications for Shire's patent settlements. If "there is nothing suspicious about the circumstances of a patent settlement, then to prevent a cloud from being cast over the settlement process a third party should not be permitted to haul the parties to the settlement over the hot coals of antitrust litigation." *Asahi Glass Co., Ltd. v. Pentech Pharm. Inc.*, 289 F. Supp. 2d 986, 992 (N.D. Ill. 2003) (Posner, J., sitting by designation).

B. PLAINTIFFS' RELIANCE UPON THE SUPREME COURT'S RECENT *ACTAVIS* DECISION IS MISPLACED

Plaintiffs rely heavily upon *Actavis* to support their argument that the district court erred in dismissing their Complaints. Plaintiffs' reliance is simply misplaced. *Actavis* is inapposite because it dealt with an entirely different issue arising at the intersection of the patent and antitrust laws—the extent to which the antitrust laws should apply to settlements of patent litigation and not a patentee's unilateral refusal to deal. Nothing in *Actavis*: (i) alters the well-recognized legal standards holding a patentee's refusal to deal in a product covered by its valid patent to be immunized from antitrust liability; or (ii) supports a conclusion that the district court erred.

In *Actavis*, the Supreme Court established the antitrust standard for determining the legality of reverse payment agreements settling Hatch-Waxman Act patent litigation. Under a reverse payment agreement, the patentee—a brand pharmaceutical company—has sued a generic pharmaceutical company for patent infringement, and the parties have settled the litigation under terms that require: (i) the generic to delay marketing its generic product until a later date to preserve a period of marketing exclusivity for the branded drug; and (ii) the brand to pay the generic a substantial sum of money. 133 S. Ct. at 2227. The issue before the Court was whether the Eleventh Circuit used the proper legal standard in dismissing a Federal Trade Commission ("FTC") complaint claiming that such a

settlement violated the antitrust laws. The Eleventh Circuit had applied the so-called "scope-of-the-patent test" and determined that "a reverse payment settlement 'is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent.'" *Id*. at 2230 (quoting *FTC v. Watson Pharm., Inc.*, 677 F.3d 1298, 1312 (11th Cir. 2012)). The Supreme Court reversed, stating that such settlements "can sometimes violate the antitrust laws," *id.* at 2232, and holding that the legality of such settlements should be determined by application of the antitrust rule of reason standard. *Id*. at 2237.[11]

As explained in *Actavis*, the Court's concern with applying a scope-of-the-patent test to immunize a reverse payment agreement from antitrust scrutiny rested upon the fact that such agreements were being used to settle litigations involving allegations that a patent was invalid or not infringed, and the scope-of-the-patent test, as applied in the context of Hatch-Waxman-related settlements, assumed that the challenged patent was valid and infringed. *Id*. at 2230-31. If these assumptions were wrong, the patentee making a substantial settlement payment to

[11] The Court granted the FTC's certiorari petition "[b]ecause different courts have reached different conclusions about the application of the antitrust laws to Hatch-Waxman-related patent settlements." 133 S. Ct. at 2230. In *Tamoxifen* , this Court applied a standard similar to that applied by the Eleventh Circuit. 466 F.3d at 206-209; *see also Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98, 105-06 (2d Cir. 2010). The district court cited *Tamoxifen* and *Bayer AG* in its opinion. While *Actavis* abrogates the holdings of those decisions, it does not, for the reasons discussed in this section and Section I.A, *supra*, support the conclusion that the district court's Rule 12(b)(6) dismissal should be reversed.

the alleged infringer could, in effect, be buying itself an unlawful patent monopoly. *Id.* at 2234-35.

No such concern is present here. As noted above, Plaintiffs do not challenge the validity of the Adderall XR Patents or Teva's and Impax's infringement of those Patents. They do not allege that Shire's settlements with those companies somehow extended the scope of Shire's Patents or were in any way unlawful. Indeed, their claim depends upon those settlements being entirely lawful, including the supply agreement component. Thus, the antitrust situation here is very different from the one presented in *Actavis*.

Moreover, in *Actavis*, the Court did nothing to undermine a patentee's protection from antitrust liability when it unilaterally refuses to deal in a product covered by its valid patent. Indeed, the Court expressly recognized that "a valid patent excludes all except its owner from the use of the protected process or product." *Id.* at 2231 (quoting *United States v. Line Material Co.*, 333 U.S. 287, 308 (1948)). The Court also reaffirmed that "courts must balance the privileges of [the patent holder] and its licensees under the patent grants with the prohibitions of the Sherman Act against combinations and attempts to monopolize." *Id*. at 2231 (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364, 390-91 (1948)). To strike that balance, courts should ask whether '"the patent statute specifically gives a right' to restrain competition in the manner challenged; and whether

'competition is impeded to a greater degree' by the restraint at issue than other restraints previously approved as reasonable." *Id*. (quoting *Line Material*, 333 U.S. at 311). As discussed above, the Patent Act gives the holder of a valid patent the right to exclude others fully from making or selling its patented product, and courts have approved such complete refusals. Here, as alleged in the Complaint, Shire is not even exercising its right to exclude others entirely from selling AXR Product, rather Shire has enabled Teva and Impax to sell generic versions of AXR Product and gain at least 50 to 60 percent of the sales of that product. Further, Shire's alleged partial refusal to deal falls far short of the type of exclusionary conduct courts have found to constitute monopolization. Thus, nothing in *Actavis* supports the conclusion that Shire's conduct violated Section 2 of the Sherman Act.[12]

C. PLAINTIFFS' ALLEGATIONS FAIL TO STATE A VALID MONOPOLIZATION CLAIM UNDER *ASPEN SKIING*

Plaintiffs argue that: (i) by entering into the AXR Product supply agreements with Teva and Impax, Shire somehow waived the right afforded it by patent law to exclude others from making or selling the Product; and (ii) by not providing Teva and Impax with all of the generic AXR Product they demanded,

[12] The Court may take judicial notice of the fact that on August 26, 2013, months after the *Actavis* decision, the FTC closed its investigation into whether the 2006 Barr (now Teva) and Impax AXR Product settlement agreements violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, without taking any action. *See* http://www.ftc.gov/os/closings/comm/130826shirelabshireltr.pdf.

which would have given the generics 90 percent of the DEA quota for AXR Product and with which demands Shire disagreed, Shire somehow engaged in monopolization. Plaintiffs rely heavily upon *Aspen Skiing Co.* to support their extraordinary claim. Nothing in *Aspen*, however, which itself is "at or near the outer boundary of Section 2 liability," *Trinko*, 540 U.S. at 409, provides any basis for Plaintiffs' monopolization claim.[13]

[13] Plaintiffs also rely upon *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874 (N.D. Cal. 2011). *See* Pltfs' Br. at 21 n.11. *Safeway* involved Norvir, the brand name for a patented protease inhibitor ("PI"), developed by Abbott Laboratories ("Abbott"). It was discovered that Norvir was most efficacious when used as a booster with other PIs, and Abbott eventually began marketing Kaletra, a capsule containing both a PI and Norvir as a booster. Other companies began marketing their PI products to be taken with Norvir as a booster. To protect Kaletra's market share and make the competitors' combination offerings uncompetitive, Abbott increased the wholesale price of Norvir by 400%, while keeping the price of Kaletra constant. Plaintiffs sued under Section 2 of the Sherman Act, claiming that the massive price increase put Abbott's competitors in the untenable position of selling their PIs boosted by Norvir at a price that could not compete with Kaletra, and the court denied Abbott's motion for summary judgment. *Safeway* is distinguishable from the present case on at least two grounds. First, the allegations in *Safeway* involved a classic case of a patentee trying to use its patent monopoly on one product, the booster Norvir, to gain an unfair competitive advantage for another product, Kaletra, not covered by its patent. There are no such allegations here. Second, in *Safeway* plaintiffs offered "evidence that Abbott unilaterally terminated a voluntary course of dealing by increasing the price of Norvir approximately [400%] and did so at some expense." 761 F. Supp. 2d at 894. Conversely here, Plaintiffs' allegations are not that Shire absolutely terminated its course of dealing with Teva and Impax, but rather that Shire partially refused to deal with these companies. This is a key distinction. Finally, Plaintiffs fail to point out that another jurisdiction reviewed the exact same behavior by Abbott and dismissed a Section 2 Sherman Act claim with prejudice pursuant to Rule 12(b)(6) because of Norvir's patent protection. *See Schor v.*

First, in *Aspen*, unlike here, the defendant-petitioner, Aspen Skiing Company ("Ski Co."), did not have a lawful patent monopoly on the downhill skiing services as to which it was refusing to deal. As noted above, the patent laws and longstanding case law expressly recognize a patentee's right to exclude all others from making or selling its patented product. Plaintiffs provide no support for their claim that by entering into a licensing agreement a patentee forfeits that exclusivity right. As discussed above, the Sixth Circuit, citing this Court's decision in *SCM*, expressly rejected any such claim in *Miller Insituform*, as did the district court. *See supra* pp. 18-20.

Second, "the present case does not fit within the limited exception [*Aspen*] recognized" regarding a business's right to refuse to deal with competitors. *Trinko*, 540 U.S at 409. In *Aspen*, there was a long-existing competitive market that allowed plaintiff-respondent, Aspen Highlands Skiing Corp. ("Highlands"), and Ski Co. to compete against each other for down-hill skiing customers by means of an interchangeable ski-lift ticket program, which gave customers the option of skiing at mountains owned by either company. 472 U.S. at 589. Ski Co. caused an important change in that competitive market by refusing to continue in the interchangeable ticket program, thus eliminating Highlands as an effective competitor and depriving customers of access to a service they desired. *Id.* at 592-

Abbott Labs., 378 F. Supp. 2d 850 (N.D. Ill. 2005), *aff'd*, 457 F.3d 608 (7th Cir. 2006).

93. By seeking continuation of the interchangeable ticket program, Highlands was not asking Ski Co. effectively to put itself out of business, but only to stop a complete refusal to deal that significantly diminished Highlands' ability to compete. *Id.*

Here, in contrast, Shire had a lawful patent monopoly on Adderall XR but then granted Teva and Impax patent licenses and provided them with patented AXR Product to sell, thus enabling them to become Shire's competitors with a combined 50 to 60 percent of sales. Shire did not refuse to continue to deal with Teva and Impax, it simply declined to accede to their demands that, in the face of DEA quotas, would have severely diminished Shire as a competitor. In other words, acceding to the demands of Teva and Impax would have caused Shire to have effectively surrendered the market to them. Finally, unlike Ski Co. in *Aspen*, Shire neither forewent short term profits nor showed any intent to monopolize.

Third, the post-*Trinko* cases cited by Plaintiffs to support the continuing vitality of an *Aspen*-type refusal-to-deal claim all involved a complete refusal to deal, whether express or in effect. *See* Pltfs' Br. 16-18, 17 n.8. In contrast, Shire's alleged refusal to deal was only partial and did not prevent Teva and Impax from acquiring 50 to 60 percent of Adderall XR Product sales. At best, according to Plaintiffs, it only prevented those companies from acquiring 90 percent or more of such sales. That is in sharp contrast to *Aspen* where, after Ski Co. began

implementing its refusal to deal, Highlands' market share "declined steadily," its revenues "declined sharply as well," and it basically became a "day ski area in a destination resort." 472 U.S. at 594.

Finally, as discussed above, Plaintiffs' reliance on *Aspen* is simply an attempt, through some kind of alchemy, to change what might be breach-of-contract disputes between Shire and Teva and Impax over the amount and timing of deliveries of DEA-controlled AXR Product into a Sherman Act Section 2 claim. Nothing in *Aspen* supports such a transformation or Plaintiffs' monopolization claim in these actions.

CONCLUSION

For the foregoing reasons, the district court's dismissal of the Complaints pursuant to Rule 12(b)(6) should be affirmed.

October 4, 2013

Respectfully submitted,

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