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

REPLY BRIEF OF PLAINTIFFS-APPELLANTS

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I. INTRODUCTION

Appellee, Shire,[1] gives short shrift to the Supreme Court's decision in *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013) which rejected the "scope of the patent test," arguing that the Supreme Court's holding is "inapposite" to the district court's decision below granting Shire's motion to dismiss. *See* Brief for Defendants-Appellees ("Defs. Bf.") at 11. The district court, however, expressly relied on the scope of the patent test set forth in *In re Tamoxifen Citrate Antitrust Litig.*, 466 F.3d 187 (2d Cir. 2006) to dismiss Plaintiffs' antitrust claim that Shire violated its duty to deal by refusing to comply with the licensing and supply terms of litigation settlements it had negotiated with its generic competitors because Plaintiffs had not alleged that the settlement agreements exceeded the scope of Shire's patents. As the district court stated,

> 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 (emphasis added).[2] The district court reasoned that because under the scope

[1]Shire refers to Defendants-Appellees Shire LLC and Shire U.S. Inc. (collectively "Shire").

[2] As described in Plaintiffs' opening brief, Plaintiffs allege that Shire settled Hatch-Waxman patent infringement litigation that threatened to end its monopoly over the drug Adderall XR by licensing its generic competitors, Teva Pharmaceuticals USA, Inc. ("Teva") and Impax Laboratories, Inc. ("Impax") (collectively the

of the patent test Shire could "simply have opted to offer Teva and Impax other compensation under the settlement agreements while refusing to license its patents without running afoul of the antitrust laws," its conduct under those licenses could not give rise to an antitrust claim. JA-136.

In *Actavis*, however, the Supreme Court expressly rejected the "scope of the patent" test and its corollary that any anticompetitive effects of an agreement that fall within the scope of the exclusionary potential of the patent are immune from antitrust attack. *Actavis*, 133 S. Ct. at 2230. *Actavis* instructed that the antitrust question is not answered merely by asking what the holder of a valid patent could do, (*id.* at 2230-31), but rather, by "considering traditional antitrust factors such as likely anticompetitive effects, redeeming virtues, market power, and potentially offsetting legal considerations[.]" *Id.* at 2231. Therefore, the district court erred when it held that, regardless of Shire's conduct as alleged in the complaint, Shire cannot be subject to an antitrust duty to deal claim as set forth in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985) unless the agreement that gave rise to the duty to deal exceeded the scope of Shire's patent.

"Generics") and agreeing to supply them with all of their product requirements ("AXR Product") starting in 2009.

Now that the underpinnings of the district court's legal analysis have been removed by *Actavis*, Shire seeks to present this case as something it is not - an isolated stand-alone commercial licensing agreement that can have no antitrust implications because under patent law Shire had no obligation to license its patents or supply its product to anyone. But that argument begs the very question presented in *Actavis*. To refer simply to what the holder of a *valid* patent could do does not by itself answer the antitrust question because the patent may or may not be valid and may or may not be infringed. *Actavis*, 133 S. Ct. at 2230-31. Indeed, even in the case of a *valid* patent, patent license agreements are not *per se* immune from antitrust scrutiny *See e.g.*, AREEDA & HOVENKAMP, ANTITRUST LAW, ¶ 2046 at 330 (3d ed. 2012); *Actavis*, 133 S. Ct. at 2232-33 ("both within the settlement context and without, the Court has struck down overly restrictive patent licensing agreements . . . These cases do not simply ask whether a hypothetically valid patent's holder would be able to charge . . . . 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").

Under the reasoning of *Actavis*, Shire cannot ignore the context and circumstances under which its duty to deal arose. As described in Plaintiffs'

opening brief (and as alleged in the complaint), in 2006 Shire settled Hatch-Waxman patent infringement litigation that threatened to end its monopoly over the drug Adderall XR by licensing the Generics and agreeing to supply them with all of their AXR Product requirements starting in April and October 2009, respectively. JA-23-24. By agreeing to enter into the license and requirement contracts in order to avoid *the risk that its patent could be declared invalid or not infringed*, thereby ensuring that its patent monopoly would continue for three years, Shire assumed a duty to deal and surrendered any exclusionary patent rights it could assert against the Generics, even assuming it otherwise had no duty to deal. Then, after having reaped the benefit of three more years of monopoly profits, Shire, starting in 2009, violated its duty to deal and refused to provide the Generics with all their AXR Product requirements (even though adequate supply was available), permitting Shire to unlawfully maintain its monopoly beyond 2009 and continue to charge supracompetitve prices for the product it sold.

Shire cannot confine the effect or significance of its conduct to a mere contractual dispute between private parties regardless of the impact on competition and consumers. As the Court recognized in *Actavis* (and in other Hatch-Waxman cases), Hatch-Waxman was intended to "speed the introduction of low-cost generic drugs to market," *Actavis*, 133.S Ct. at 2228 (quoting *Caraco Pharm., Labs., Ltd.*

v. Novo Nordisk A/S, 132 S. Ct. 1670, 1676 (1990)), and when a generic is improperly delayed from coming to market, the consumer loses. *Actavis*, 133 S. Ct. at 2226. Perversely for consumers, what Shire has engineered here is no different than if it had paid the Generics to stay off the market: (1) Shire induced the Generics to drop their patent challenges in return for license and requirement contracts that would permit their unconstrained market entry in 2009; and then (2) when generic entry was set to occur, Shire breached its duty to deal, limiting the Generics' ability to enter the market and permitting Shire to continue to charge higher prices.[3]

Finally, the allegations in the complaint sufficiently state a cognizable refusal to deal claim as set forth in *Aspen*. *See also Eastman Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451, n. 12 (1992) ("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 is a legitimate competitive reason for the refusal").

[3]In fact, Shire reports in its brief that it has "resolved" its contract disputes with Teva and Impax, (*see* Defs. Bf. at 13 n. 8), and an Impax press release discloses that Shire paid Impax $48 million pursuant to the settlement. *See* (http://investors.impaxlabs.com/Media-Center/Press-Releases/Press-Release-Details/2013/Impax-and-Shire-Settle-Litigation-Concerning-Supply-of-Authorized-Generic-Adderall-XR1133482/default.aspx). Had Shire simply paid Impax $48 million dollars to settle the Hatch-Waxman lawsuit and to stay off the market beyond 2009, there would be no question that the settlement would be an anticompetitive reverse payment agreement.

Shire's suggestion that "[a]t most, Shire *partially* refused to deal with Teva and Impax for AXR Product," (*see* Defs. Bf. at 16), is not a defense. There is no requirement that to be actionable, a refusal to deal must be absolute. *See infra* at n. 6. In any event, this case concerns Shire's refusal to comply with a requirements contract as opposed to a fixed-quantity contract. By intentionally limiting supply to the Generics (who sell the product at lower prices) to create an artificial market shortfall, and then filling that shortfall with higher-priced identical brand product, Shire caused consumer harm that forms the basis of the antitrust challenge here. To suggest that Shire's partial performance is a defense to this action ignores the antitrust claim and the injury occasioned by its conduct.

Shire's further argument that *Aspen* is not applicable because in *Aspen*, there was a long-existing course of dealing between the competitors does not help Shire. To the contrary, in *Aspen*, the basis for the duty to deal had to be inferred circumstantially from evidence of the long-existing relationship between the parties. Here, however, the basis for the duty to deal could not be more explicit: it was contained in written agreements between the parties.

For these reasons, the district court's decision and order dismissing Plaintiffs' complaint must be reversed.

II. ARGUMENT

A. The District Court's Application of the "Scope of the Patent Test" to Dismiss Plaintiffs' Antitrust Complaint Was Reversible Error

The district court applied *Tamoxifen* to dismiss Plaintiffs' complaint, reasoning that if the anticompetitive effects of the settlement agreements between Shire and the Generics could not be subject to antitrust scrutiny, any conduct by Shire relating to its obligations under the agreements was necessarily also immune from the antitrust laws. In *Actavis*, however, the Supreme Court rejected the scope of the patent test, holding that simply because the challenged anticompetitive effects of a patent settlement fall within the scope of the exclusionary potential of a patent does not immunize reverse payment settlements from antitrust attack.[4] *Actavis*, 133 S. Ct at 2230. To the contrary, the Court stated that "it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law policy, rather than by measuring them against procompetitive antitrust policies as well." *Id.* at 2231. Accordingly, the Supreme Court held that patent-related settlement agreements that do not exceed the exclusionary potential of the patent are not *per se* immune to antitrust

[4] *Actavis* considered the scope of the patent test as articulated by the Eleventh Circuit in *FTC v. Watson Pharms., Inc.*, 677 F.3d 1298 (11th Cir. 2012) – namely, that "absent sham litigation or fraud in obtaining the patent, a reverse payment settlement is immune from antitrust attack so long as its anticompetitive effects fall within the scope of the exclusionary potential of the patent." *Id.* at 1312. That standard is virtually identical to the test adopted by this court. *See Tamoxifen*, 466 F.3d at 212-213.

scrutiny. Rather, their legality should be assessed under traditional rule-of reason analysis. *Id*. at 2237-38.

While Shire now argues that "*Actavis* is inapposite because it dealt with an entirely different issue," (*see* Defs. Bf. at 22), *Tamoxifen's* "scope of the patent" test was, in fact, the linchpin of the district court's analysis. The district court repeatedly stated its view that unless *Tamoxifen* could be distinguished, Plaintiffs could not state an antitrust action under *Aspen*:

> 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.

> 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;

> Thus, neither *Safeway* nor the other refusal-to-deal cases cited by LWD would alter the Court's conclusion that, notwithstanding 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, LWD's claims fail.

JA-142.

Accordingly, since the district court below determined that satisfying the scope of the patent test was a condition precedent to Plaintiffs' alleging an antitrust claim under *Aspen*, the dismissal of the complaint must be reversed.

B. Shire's Argument that Federal Patent Law Immunizes its Conduct is Inconsistent with *Actavis* and is Otherwise Contrary to Law

Now that the scope of the patent test has been rejected, Shire argues that, nevertheless, under patent law it "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." *See* Defs. Bf. at 18. Shire contends further that "[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." *Id.* at 19. As the Supreme Court advised in *Actavis*, however, statements such as Shire's that reflect *conclusions* about whether a particular restraint lies beyond the patent monopoly do nothing to inform the required analysis. Moreover, Shire's supposition that its patents conferred absolute monopoly power either prior to, or after, entering into the settlement agreements is directly contrary to the analysis in *Actavis* which recognizes that patent rights are probabilistic: "to refer [] simply to what the holder of a valid patent could do does not by itself answer the antitrust question. The

patent here may or may not be valid, and may or may not be infringed." *Actavis*, 133 S. Ct. at 2230-31. Accordingly, the antitrust question in this case should not be answered merely by measuring the theoretical length or amount of a restriction solely against the length of the patent's term and it cannot be answered on a motion to dismiss. Even were the analysis limited to patent law (contrary to what *Actavis* instructs, *id.* at 2230-31), "[i]t would be difficult to reconcile the proposed right with the patent-related policy of eliminating unwarranted patent grants so the public will not 'continually be required to pay tribute to would-be monopolists without need or justification.'" *Id.* at 2233 (quoting *Lear, Inc. v. Adkins*, 395 US 653, 670 (1969)).

Shire's attempt to characterize its conduct as involving nothing more than an isolated contract dispute between the parties ignores the allegations in the complaint, and Shire cannot so easily dismiss the significance of the circumstances which gave rise to its duty to deal. As the complaint alleges, Shire was engaged in Hatch-Waxman patent infringement litigation that threatened the existence of its Adderall XR monopoly. Rather than risk a court decision that could invalidate its patents or hold that the Generics did not infringe, which would immediately open the market to generic competition, Shire, in 2006, entered into substantively identical settlement agreements that resolved the litigation. As described by the

district court:

> Each settlement had the same structure: the [Generics] agreed not to launch any of their own products…for roughly three years, thereby preserving Shire's market share. In return, Shire agreed to grant [the Generics] patent licenses to sell generic Adderall XR once the three year no-competition window closed, and further agreed to supply all of [the Generics] needs for generic Adderall XR under separate requirements contracts with each. . .
>
> [W]hile Shire continued to enjoy monopoly power through 2009 under the agreements, and it granted patent licenses to [the Generics], it failed to meet the terms of its requirements contracts with the [Generics]. LWD alleges that Shire, instead of supplying each entity with all the Adderall XR they demanded, intentionally breached the contracts to keep supplies artificially low and prices artificially high.

JA-123-24. Accordingly, the anticompetitive effects and legality of Shire's conduct cannot be evaluated merely by looking at what happened in 2009. Rather, Shire's conduct in 2006, when, in return for three more years of unchallenged monopoly sales, Shire agreed to license its patents and supply the Generics with AXR Product, giving rise to Shire's duty to deal, must also be considered.

Similarly, Shire cannot describe Plaintiffs' allegations as a mere commercial dispute between private parties that has no impact on competition. As the Supreme Court described in *Actavis*, the Hatch-Waxman Act was intended to speed the introduction of low-cost generic drugs to market, and where a settlement keeps a generic out of the market, the patentee and challenger gain, but the consumer loses.

Actavis, 133 S. Ct. at 2228, 2234-35. Here, the effect of Shire's conduct by refusing to meet the Generics' supply requirements is no different than if Shire had paid the Generics to stay off the market beyond the 2009 agreed-upon entry date.[5] Even though the Supreme Court held that a patent settlement can have anti-competitive effects on consumers and violate the antitrust laws, Shire asks for a *per se* rule that a pharmaceutical company's refusal to abide by its obligations under such an agreement is immune from antitrust scrutiny.

It is for these reasons that the cases Shire relies on are readily distinguished. The dispute in *SCM Corp. v. Xerox Corp.*, 645 F.2d 1195 (2d Cir. 1981), for example, arose over Xerox's acquisition and subsequent refusal to license certain of its patents to a competitor. Here, in contrast, Shire agreed to relinquish its patent monopoly by voluntarily granting licenses to the Generics to settle Hatch-Waxman litigation, then breached the contractual duty to deal it undertook to avoid the potential invalidation of its patents. Further, in *SCM Corp.*, there was no challenge to the validity or infringement of the patent. Instead, SCM argued that it was foreseeable that Xerox would ultimately obtain monopoly power, and therefore Xerox should have been forced to license its patents. *Id.* at 1207. In short, *SCM Corp.* dealt with the limits of what a monopolist can do, having legally acquired

[5]And as described in n. 3, *infra*, Shire has apparently paid Impax $48 million dollars to compensate Impax for its limited market entry in 2009.

monopoly power. *Id.* at 1206-07. Accordingly, the broad proposition for which Shire cites *SCM Corp.* (*see* Defs. Bf. at 17), "simply stated, a patent holder is permitted to maintain his patent monopoly through conduct permissible under the patent laws," (*SCM Corp.*, 645 F. 2d at 1204), does nothing to immunize Shire from antitrust scrutiny in this case, and is directly at odds with *Actavis*'*s* construction that merely asking what "the holder of a valid patent could do does not by itself answer the antitrust question." *Actavis*, 133 S. Ct. at 2230-31.

Similarly, in *Miller Insituform, Inc. v. Insituform of North America, Inc.*, 830 F.2d 606 (6th Cir. 1987), there was no question of the patent's validity, or claim that the sublicense had been granted to avoid a patent challenge. Further, the sublicensee did not contend that its termination had an adverse effect on competition, *id.* at 609, rather it complained because its territory had been assigned to another sublicensee. *Id.* at 607. The law is well-settled, of course, that the antitrust laws were enacted for the protection of competition, not competitors. *Brown Shoe Co. v. United States*, 370 U.S. 294, 320 (1962).

C. The Complaint Sufficiently Alleges a Monopolization Claim Based on Shire's Refusal to Supply its Generic Competitors With All of their AXR Product Requirements

The complaint sufficiently alleges a Section 2 claim as set forth in *Aspen* based on Shire's refusal to supply the Generics with all of their AXR Product

requirements as Shire agreed to do in settling Hatch-Waxman litigation. *Verizon Communications, Inc. v. Law Offices of Curtis v. Trinko, LLP*, 540 U.S. 398, 408 (2004) ("[u]nder certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate § 2") (quoting *Aspen*); *Eastman Kodak* 504 U.S. 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"); *Pac. Bell Tel. Co., v. Linkline Communications, Inc.*, 555 U.S. 438, 448 (2009) (citing *Aspen* 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").

Other than recycle its argument that a patentee can never be subject to a refusal to deal claim (which Plaintiffs have demonstrated is not the case here), Shire does little to contest that Plaintiffs have at least stated a claim. Shire argues that *Aspen* is not applicable because the defendant in that case did not have a patent, but then attempts to distinguish *Safeway Inc. v. Abbott Labs.*, 761 F. Supp. 2d 874 (N.D. Cal 2011), which sustained a refusal to deal claim regarding a patented drug product, because the plaintiffs there also asserted a "classic case" of monopoly leveraging, without explaining why the additional claim should alter the analysis. Shire then argues that *Aspen* is further distinguishable because in *Aspen*

"there was a long-existing competitive market that allowed the ski slopes to compete against each other," but, as explained earlier, that long-standing relationship was the basis for inferring a duty to deal. Here, the Court or jury need not review circumstantial evidence to infer a duty to deal: the duty is explicitly stated in the settlement agreements.

Finally, Shire argues that there can be no actionable "*Aspen*-type refusal-to-deal claim" unless there is a complete refusal to deal. *See* Defs. Bf. at 28. Shire offers no support for this distinction, and in fact the refusal to deal in *Aspen* was not complete. *Aspen*, 472 U.S. at 594.[6] Moreover, in this case it was the intentional shortfall created by Shire which forms the basis of the antitrust claim. Focusing on partial compliance totally ignores the complained-of wrongs.

III. CONCLUSION

For the above reasons, this Court should reverse the order of the district court.

[6] In *Aspen Skiing*, the defendant "accepted" the plaintiff's redesigned "Adventure Pack" good on all Aspen ski slopes. *See Aspen Skiing*, 472 U.S. at 594. However, the defendant then made a change in its price structure which made the redesigned "Adventure Pack" unprofitable to the plaintiff. *Id.* at 594 n. 15. *See also Safeway Inc. v. Abbott Labs.*, 2010 U.S. Dist. LEXIS 2145, *20-21 (N.D. Cal. Jan. 12, 2010) (offer to deal only on unreasonable terms amounts to practical refusal to deal); *MetroNet Svcs. Corp. v. Qwest Corp.*, 383 F.3d 1124, 1132 (9th Cir. 2004) (same). In any event, as noted above, because of the very nature of the agreements here, Shire's refusing to supply the Generics' full requirements constitutes an absolute refusal to deal, as anything less than the whole subverts the very essence of the agreements.

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Respectfully submitted,

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