Nos. 2014-1282, 2014-1291

United States Court of Appeals for the Federal Circuit

APOTEX INC.,

Plaintiff-Appellant,

v.

DAIICHI SANKYO, INC. AND DAIICHI SANKYO CO., LTD.,

Defendants-Appellees,

and

MYLAN PHARMACEUTICALS INC.,

Movant-Cross-Appellant.

Appeals from the United States District Court for the Northern District of Illinois, Case No. 12-cv-09295, Judge Sharon Johnson Coleman

REPLY BRIEF OF CROSS-APPELLANT MYLAN PHARMACEUTICALS INC.

Michael D. Shumsky
John K. Crisham
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 879-5000

Counsel for Movant/Cross-Appellant Mylan Pharmaceuticals Inc.

November 17, 2014

CERTIFICATE OF INTEREST

Pursuant to Fed. Cir. R. 47.4, I hereby certify as follows:

1. The full name of every party represented by me in this appeal is:

Mylan Pharmaceuticals Inc.

2. The name of the real party in interest, if different from the above, is:

Not applicable.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc.

4. The names of all attorneys and law firms whose partners or associates have appeared for the party identified above in the lower tribunal or who are expected to appear for the party in this appeal are:

D. Joseph Piech
Sarah P. Herlihy
KIRKLAND & ELLIS LLP
300 North LaSalle Street
Chicago, IL 60654

Michael D. Shumsky
John K. Crisham
Stephen S. Schwartz
KIRKLAND & ELLIS LLP
655 Fifteenth Street N.W.
Washington, D.C. 20005

Jay P. Lefkowitz, P.C.
Steven J. Menashi
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022

/s/ Michael D. Shumsky
Michael D. Shumsky
KIRKLAND & ELLIS LLP

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INTRODUCTION

Apotex's three-page response to Mylan's cross-appeal does not remotely justify the district court's denial of Mylan's intervention.

Apotex first asserts that Mylan's interest in this litigation is "moot" because the district court granted Daiichi's motion to dismiss. But that position is frivolous in light of the fact that Apotex has appealed the district court's dismissal of its lawsuit to this Court—and thereby seeks to continue its mission to destroy Mylan's statutory right to 180-day exclusivity. As a result, Mylan's interests are just as "live" today as they were on the day Apotex filed this lawsuit.

Apotex nonetheless claims that Mylan need not intervene because Daiichi adequately protects Mylan's interests. But that argument—which Apotex raises for the first time—is foreclosed by well-settled caselaw holding that competitors cannot be forced to rely on each other to defend their respective interests, even when both seek the same outcome.

Finally, Apotex claims that Mylan has no interest in this litigation because Apotex merely seeks a judgment of non-infringement—not a court decision declaring Mylan's exclusivity forfeited. Indeed, Apotex

asserts, this lawsuit is merely a "predicate" to some future proceeding where the question of Mylan's exclusivity will be resolved (perhaps in Apotex's favor, perhaps in Mylan's) if Apotex happens to prevail.

That assertion—which Apotex also raises for the first time—is triply flawed. It contradicts both the allegations of Apotex's amended complaint and the relief the amended complaint expressly sought. It in any event ignores Mylan's interest in avoiding the uncertainty and expense of the further proceedings Apotex says would follow from the entry of a final judgment in this case. And, most important, it distinguishes this case from the Federal Circuit precedents Apotex relies upon—where there was no dispute that a successful declaratory judgment would in fact trigger the first-filer's exclusivity as to the challenged patents and thereby remediate the asserted injuries. In its apparent desperation to prevent Mylan from intervening, Apotex instead has confirmed that it lacks standing to pursue this case.

ARGUMENT

A. Mylan's Interests Are Not "Moot."

Apotex first contends that the district court's intervention ruling should be affirmed because Mylan's interests are "moot." Apotex Yellow Br. 34. This is so, Apotex claims, because "the relief for which Mylan

seeks intervention … already was granted by the district court on Daiichi's own motion." *Id.* But as we previously explained, that position is absurd given that Apotex's appeal seeks to overturn the district court's decision to dismiss its case—and thereby eliminate the very predicate for Apotex's mootness argument. *See* Mylan Red Br. 28-32. Apotex cannot credibly maintain that the district court's decision moots Mylan's interests for all time at the same time it seeks to overturn that decision.

Apotex offers no answer to that straightforward point, which is dispositive. After all, "a case becomes moot only when it is impossible for a court to grant any effectual relief whatever to the prevailing party," *Knox v. Serv. Employees Int'l Union, Local 1000*, 132 S. Ct. 2277, 2287 (2012) (citation and internal quotation marks omitted), or "the parties lack a legally cognizable interest in the outcome." *Chafin v. Chafin*, 133 S. Ct. 1017, 1023 (2013) (quoting *Already, LLC v. Nike, Inc.*, 133 S. Ct. 721, 726 (2013) (some internal quotation marks omitted)). So long as Apotex continues to pursue this case, Mylan has the same legally cognizable interest that led it to seek intervention below (preserving its statutory right to 180-day marketing exclusivity) and

the courts retain authority to enter effectual relief (barring Apotex from pursuing its claims, by affirming the district court's dismissal of Apotex's amended complaint).[1]

B. Daiichi Cannot Adequately Represent Mylan's Interests.

Apotex next argues—for the first time—that intervention is unwarranted because Mylan's "interests are adequately protected by Daiichi." Apotex Yellow Br. 33. This is so, Apotex says, because "Mylan and Daiichi … share the same competitive interests in maintaining Mylan's eligibility to 180-day exclusivity period [*sic*] and stand to benefit from no additional generic competition." *Id.*

That argument proves too much. Because litigants almost always intervene in support of one party or the other, holding that an intervenor's interest in achieving the same result advocated by an

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[1] Apotex's "*Cf.*" reference to *Chapman v. Manbeck*, 931 F.2d 46 (Fed. Cir. 1991), is bizarre. Though Apotex suggests that case bars intervention in patent cases unless "the proposed intervenors' patents []or their products are actually at issue in the case," Apotex Yellow Br. at 34-35, *Chapman* held no such thing. Instead, it held only that intervention in that case was inappropriate because the proposed intervenor's interests would not be impaired "as a practical matter" since it already was protecting those interests in concurrently-pending

(Continued…)

existing party effectively would end intervention as we know it. That cannot be right.

And it isn't. As Mylan explained in its opening brief, it is well settled that competitors do not adequately represent each other's interests even when they share the same ultimate objective—including cases that have reached that conclusion in Hatch-Waxman litigation. *See* Mylan Red Br. at 34-35 (citing *inter alia Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1076 (D.C. Cir. 1998) (holding that brand manufacturer was entitled to intervene as of right because a generic manufacturer could not represent its interests: "Mova is a generic drug manufacturer, and therefore might have strategic reasons not to press certain arguments available to Upjohn in anticipation of (perhaps) finding itself in Mylan's situation in a future case."); *Lake Investors Dev. Grp., Inc. v. Egidi Dev. Grp.*, 715 F.2d 1256, 1261 (7th Cir. 1983) (explaining that although plaintiff and proposed intervenor "have the same ultimate objective," plaintiff could not adequately represent the proposed intervenor because they were "directly in competition")).

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litigation. 931 F.2d at 48. Needless to say, that factual scenario bears no relationship to this case.

That rule has particular force here. Mylan and Daiichi are direct competitors who engaged in lengthy, costly, and acrimonious patent litigation over the right to market the very product at issue in this case. Though both companies now agree Apotex's lawsuit should be dismissed, they self-consciously have raised distinct legal arguments for reaching that result—differences driven in no small part by their divergent statuses as a brand manufacturer (on one hand) and generic company (on the other), who have had to craft their positions in light of the fact that they are repeat players in this space and therefore must balance their positions to account for their respective product portfolios and pending litigation dockets. To the extent there is any doubt about the parties' divergent interests, it is resolved by Daiichi's repeated refusal to consent to Mylan's intervention (including the fact that Daiichi even proposed the mootness rationale ultimately relied upon by the district court to deny Mylan's intervention, *see* Daiichi Sankyo's Resp. to Mylan's Mot. to Intervene and Dismiss, D. Ct. Dkt. No. 41 at 1 ("Mylan's motion to dismiss should be treated as an *amicus* brief. If this Court grants Daiichi Sankyo's motion—as it should—Mylan's motion to intervene is moot.")).

Neither of the cases Apotex cites supports its apparent belief that direct competitors like Daiichi and Mylan can stand in each other's shoes simply because they share a given objective. In *Shea v. Angulo*, 19 F.3d 343 (7th Cir. 1994), the court merely held that the interests of the plaintiff (Shea) and proposed intervenor (Butzen) did not meaningfully diverge because their ancillary dispute—over whether and how to allocate any proceeds from an eventual recovery in plaintiff Shea's case against the defendant (FCA)—could be resolved in follow-on litigation between Shea and Butzen and because Butzen offered no credible basis for thinking that Shea would not seek to maximize the recovery that later might have to be divided with Butzen. *Id.* at 347-48.

Apotex's reliance on *Wolfsen Land & Cattle Co. v. Pac. Coast Fed'n of Fisherman's Ass'ns*, 695 F.3d 1310 (Fed. Cir. 2012), is equally far afield. That case did not involve direct competitors, but instead turned on "the presumption that the government as sovereign can adequately represent [an aligned intervenor's] interests." *Id.* at 1317. That presumption of course has no application here, and *Wolfsen* in any event found that the intervenor had not overcome that presumption because it "has shown no argument that the government would leave

aside but [the proposed intervenor] would not, or any reason to believe the government would be unwilling to pursue some theory that [the proposed intervenor] would pursue in order to defeat Wolfsen's claim." *Id.* A simple comparison of the briefs filed by Daiichi and Mylan in this case reveals precisely the opposite: While both parties advocate the same outcome, each has advanced its own unique rationales for reaching that result.

C. Rather Than Support The District Court's Intervention Decision, Apotex's Assertion That This Litigation May Not Trigger The Loss Of Mylan's Exclusivity Forecloses This Court's Jurisdiction.

Finally, Apotex argues that Mylan need not intervene because the requested judgment is merely a "predicate to forfeiture of Mylan's eligibility to first filer exclusivity" which "ultimately will be [determined] by FDA." Apotex Yellow Br. 34. That argument does not justify the denial of Mylan's intervention, and indeed only underscores the lack of Article III jurisdiction over Apotex's lawsuit.

First, while Apotex *now* seeks to cast doubt on whether the requested declaratory judgment would cause the forfeiture of Mylan's exclusivity, the amended complaint expressly alleges that the requested declaratory judgment will in fact cause such a forfeiture. Indeed, that

allegation is the very basis for Apotex's claim to standing: "Apotex's injury can be redressed by the requested relief: a declaratory judgment of noninfringement would trigger first applicant Mylan's exclusivity period." App. 51 (Am. Compl. ¶ 40); *see also* App. 52 (Am. Compl. Prayer For Relief ¶ C) (seeking entry of a judgment "[d]eclaring that the [FDA] may approve Apotex's [ANDA] whenever that application is otherwise in condition for approval," *i.e.*, without respect to Mylan's exclusivity). Given Apotex's explicit allegation that its lawsuit would in fact cause Mylan to lose exclusivity, Apotex cannot now turn around and assert that Mylan lacks an interest in defending the legally protected right that Apotex's lawsuit expressly aims to thwart.

Second, this argument would provide no basis for denying Mylan's right to intervene even if the outcome of further proceedings before FDA were uncertain. After all, Mylan has an obvious interest in avoiding the expense, effort, and uncertainty associated with further litigation over the issues that Apotex's lawsuit puts in play. That alone is sufficient to grant Mylan standing to intervene. *See, e.g.*, *Supreme Beef Processors, Inc. v. U.S. Dep't of Agriculture*, 275 F.3d 432, 438 (5th Cir. 2001) (holding that "[t]he interest in avoiding piecemeal litigation is … served

by allowing NMA's intervention") (citing *Goodman v. Heublein*, 682 F.2d 44, 47 (2d Cir. 1982) (granting motion to intervene in part to avoid piecemeal litigation)).

There is, however, a far more important point here: To the extent Apotex now casts doubt on whether its lawsuit would in fact cause the forfeiture of Mylan's exclusivity—and thereby suggests that even a favorable judgment might not allow Apotex to enter the market any earlier than the status quo otherwise would permit—there is no basis for exercising jurisdiction over this lawsuit. After all, Article III standing requires the plaintiff to show that "it is likely, as opposed to merely speculative, that [its purported] injury will be redressed by a favorable decision." *Friends of the Earth, Inc. v. Laidlaw Environ. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000); *see also Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1148 (2013) ("[Plaintiffs'] theory of standing, which relies on a highly attenuated chain of possibilities, does not satisfy the requirement that the threatened injury must be certainly impending.") (citations omitted).

The fact that Apotex itself now doubts whether its lawsuit would redress its alleged exclusion from the market—doubts that are well-

founded for the reasons set forth in Mylan's opening brief, at 42-45—is reason alone to dismiss this case. Indeed, the company's late-breaking equivocation on this key point makes this lawsuit quite different from the prior precedents in which this Court has allowed declaratory judgment actions to proceed: In each of those cases, it was *undisputed* that the requested judgment would in fact trigger the first-filer's exclusivity as to the challenged patents and thereby remediate the plaintiffs' asserted injury. Rather than support the denial of Mylan's intervention, Apotex's last-ditch effort to keep Mylan out of this case fatally undermines the very predicate for this litigation.

CONCLUSION

For the foregoing reasons, this Court should reverse the district court's denial of Mylan's motion to intervene.

November 17, 2014

Respectfully submitted,

/s/ Michael D. Shumsky

Michael D. Shumsky
John K. Crisham
KIRKLAND & ELLIS LLP
655 Fifteenth Street, N.W.
Washington, D.C. 20005
(202) 879-5000

Counsel for Movant/Cross-Appellant Mylan Pharmaceuticals Inc.

CERTIFICATE OF COMPLIANCE

1. I hereby certify that this brief complies with the type-volume limitation of Fed. R. App. P. 28.1(e)(2)(B)(i) because it contains 2,102 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

2. I hereby certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010, in 14 point Century Schoolbook font.

November 17, 2014

/s/ Michael D. Shumsky
Michael D. Shumsky

CERTIFICATE OF SERVICE

The undersigned certifies that on this 17th day of November 2014, he caused an electronic copy of the Reply Brief of Cross-Appellant Mylan Pharmaceuticals Inc. to be served on all counsel of record via this Court's CM/ECF filing system.

November 17, 2014 /s/ Michael D. Shumsky
Michael D. Shumsky