

United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 12, 2002 Decided May 14, 2002

No. 01-7163

In Re: Lorazepam & Clorazepate Antitrust Litigation

Appeal from the United States District Court
for the District of Columbia
(No. 99ms00276)

John G. Roberts, Jr. argued the cause for petitioners. With him on the briefs were Catherine E. Stetson, Michael R. Grynberg, Christopher K. Tahbaz, Irving Scher and David A. Hickerson. James B. Weidner entered an appearance.

Michael D. Hausfeld argued the cause for respondents. With him on the brief were Arthur M. Kaplan and Thomas Campbell.

Before: Ginsburg, Chief Judge, Rogers and Garland,
Circuit Judges.

Opinion for the Court filed by Circuit Judge Rogers.

Rogers, Circuit Judge: This appeal presents for the first time in this circuit the threshold question of when interlocu-

tory review of a class certification decision is appropriate under Federal Rule of Civil Procedure 23(f). We take the opportunity to offer general guidance on the scope of our discretion under Rule 23(f) in considering the petition for Rule 23(f) review by Mylan Laboratories, Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc., Profarmaco S.r.l., Cambrex Corporation, and GYMA Laboratories of America, Inc. (collectively "Mylan"), of the district court's certification of a class of direct purchasers of the generic anti-anxiety drugs lorazepam and clorazepate from Mylan or UDL. Mylan contends that the district court erred in ruling that despite the Federal Trade Commission's ("FTC") procurement of a settlement against Mylan on behalf of a class of indirect purchasers, a class of direct purchasers had antitrust standing under *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), and, in the alternative that the certified class consists of both direct and indirect purchasers in violation of *Illinois Brick*. We conclude that interlocutory appeal pursuant to Rule 23(f) typically is appropriate in three circumstances: (1) when there is a death-knell situation for either the plaintiff or defendant that is independent of the merits of the underlying claims, coupled with a class certification decision by the district court that is questionable, taking into account the district court's discretion over class certification; (2) when the certification decision presents an unsettled and fundamental issue of law relating to class actions, important both to the specific litigation and generally, that is likely to evade end-of-the-case review; and (3) when the district court's class certification decision is manifestly erroneous. Applying these standards we deny Mylan's petition for interlocutory review.

I.

The class action now pending in the district court was preceded by two lawsuits brought by the FTC and several States' Attorneys General against Mylan that were ultimately consolidated and ended in a settlement. On December 21, 1998, the FTC filed suit, pursuant to ss 5 and 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. ss 45, 53(b), against Mylan, Cambrex, Profarmaco, and GYMA Lab-

oratories, seeking injunctive and equitable relief, including disgorgement of \$120 million plus interest. *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25, 32, 34 (D.D.C. 1999). The amended complaint alleged that the defendants had engaged in unfair methods of competition in violation of s 5(a) of the FTC Act, 15 U.S.C. s 45(a), by Mylan's entering into exclusive licensing agreements with the other defendants, allowing Mylan to control the supply of the active pharmaceutical ingredients ("API") for generic lorazepam and clorazepate tablets so that Mylan could increase the price of these generic drugs. On December 22, 1998, the Attorneys General of ten States, later joined by an additional 22 States and the District of Columbia, brought suit against the same defendants and SST Corporation, seeking equitable relief and treble damages for violations of ss 1 and 2 of the Sherman Act, 15 U.S.C. ss 1, 2, and various State antitrust laws. *Mylan*, 62 F. Supp. 2d at 32; see also *In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 369, 373 (D.D.C. 2002). As to the FTC, the district court denied the defendants' motion to dismiss, which argued that the district court lacked subject matter jurisdiction because the FTC was not authorized to seek either monetary relief or a permanent injunction in an antitrust case. *Mylan*, 62 F. Supp. 2d at 35-37. As to the States, the district court partially granted the defendants' motion to dismiss, inter alia, narrowing the States' federal claims to claims under s 4 of the Clayton Act for direct purchases and limiting restitution and disgorgement on behalf of indirect purchasers on a State-by-State basis. *Id.* at 37-53; see also *FTC v. Mylan Labs., Inc.*, 99 F. Supp. 2d 1, 4-10 (D.D.C. 1999). Subsequently, the parties entered into a settlement agreement, which the district court approved on February 1, 2002. *Mylan*, 205 F.R.D. at 402. The settlement agreement provided, in part, that Mylan would pay disgorgement in the amount of \$71,782,017 to satisfy the consumer claims in the States' lawsuit and \$28,217,983 to satisfy the States' agency claims. The settlement agreement also provided that the FTC, States, State agencies, and consumers who did not

exclude themselves from the settlement, would release their claims against the defendants.

On August 16, 1999, the Judicial Panel on Multidistrict Litigation transferred to the United States District Court for the District of Columbia a Northern District of Illinois lawsuit pending against Mylan. This lawsuit was consolidated, on March 9, 2000, with a lawsuit brought by St. Charles Rehabilitation Center against Mylan. The named plaintiffs in the consolidated action were Advocate Health Care, St. Charles Hospital and Rehabilitation Center, Dik Drug Company, and Harvard Pilgrim Health Care, and they sought class certification as direct purchasers of lorazepam and clorazepate. The amended complaint alleged that Mylan had engaged in price fixing and monopolization in violation of ss 1 and 2 of the Sherman Act, and the plaintiffs sought treble damages pursuant to s 4 of the Clayton Act. Mylan moved to dismiss the complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), on the ground that the plaintiffs' proposed class of direct purchasers lacked antitrust standing to assert their claims. In *Illinois Brick*, the Supreme Court held that, with narrow exceptions, only direct purchasers may recover damages for illegal overcharges under s 4 of the Clayton Act. *Illinois Brick*, 431 U.S. at 746-47. Essentially, Mylan argued that the usual direct purchaser rule of *Illinois Brick* should not apply because the FTC had won a monetary recovery for the benefit of a class of indirect consumer purchasers pursuant to s 13(b) of the FTC Act for alleged antitrust violations, and to allow both purchaser classes to obtain relief would undermine the policy rationales behind *Illinois Brick*. In the alternative, Mylan opposed the class certification arguing, *inter alia*, that the class consisted of direct and indirect purchasers in violation of *Illinois Brick*'s direct purchaser rule. On July 2, 2001, the district court denied the motion to dismiss, and, in accord with the plaintiffs' request, certified the following class:

All persons and entities in the United States who purchased generic lorazepam tablets and/or generic clorazepate tablets directly from Defendants Mylan and UDL

during the period January 12, 1998 through the present, excluding Defendants, their respective parents, subsidiaries and affiliates, any co-conspirators of Defendants, and all governmental entities.

In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12, 21 (D.D.C. 2001). The district court appointed Advocate Health Care, St. Charles Hospital, Dik Drug, and Harvard Pilgrim as class representatives.

Mylan now petitions for interlocutory review of the district court's denial of its Rule 12(b)(6) motion to dismiss and the district court's certification of a class of direct purchasers. Asserting that "[t]his is not the typical case," Petitioners' Br. at 16, Mylan contends that, in light of the flexible standards for review developed in the circuits, appellate review of its petition under Rule 23(f) is warranted: not only does Mylan's petition raise the novel issue of law of "how properly to calibrate antitrust standing where two antitrust cases collide," *id.* at 20, the outcome of which is potentially dispositive of the case, but also the district court's decision is particularly susceptible to challenge and there may be no further opportunity to review its decision. Reviving its Rule 12(b)(6) contention, Mylan challenges the district court's certification decision by contending first that under *Illinois Brick*, the FTC's 13(b) enforcement action on behalf of the ultimate consumers of lorazepam and clorazepate precludes suit by a direct purchaser class. Allowing a direct purchaser class to sue the same defendants for antitrust damages following the FTC's suit and settlement would, in Mylan's view, "topple every rationale" supporting *Illinois Brick*'s rule confining potential antitrust plaintiffs to one level of purchasers. *Id.* at 17. In "these uncommon circumstances," Mylan concludes, "the direct purchaser class should be denied recovery." *Id.* Second, as to the certified class, Mylan maintains that, even if direct purchasers may sue for antitrust damages in addition to the consumer class, the district court erred in ruling that the class had antitrust standing under the direct purchaser rule and its narrow exceptions. According to Mylan, many members of the class, including three of the four class representatives, bought lorazepam and clorazepate, not from

Mylan, but from pharmaceutical wholesalers, who also purport to be members of the direct purchaser class. Mylan asserts that this purchasing chain makes these class members who purchased from intermediaries "quintessential indirect purchasers," who, under Illinois Brick, cannot sue for antitrust damages. Hence, Mylan maintains, the district court erred in not determining, prior to certifying the class, whether the class and its representatives had antitrust standing under Illinois Brick.

We first set forth the standards that we will ordinarily apply in exercising our discretion under Rule 23(f), and then we address the contentions in Mylan's petition.

II.

Rule 23(f), added by amendment in 1998, provides that "[a] court of appeals may in its discretion permit an appeal from an order of a district court granting or denying class action certification under this rule if application is made to it within ten days after entry of the order." Fed. R. Civ. P. 23(f). Although other circuit courts of appeals have addressed the scope of Rule 23(f) review, this is a question of first impression for this court. The advisory committee's note to Rule 23(f) states that "[a]ppeal from an order granting or denying class certification is permitted in the sole discretion of the court of appeals" and is "akin to the discretion exercised by the Supreme Court in acting on a petition for certiorari." Fed. R. Civ. P. 23(f) advisory committee's note. The advisory committee's note also indicates that not all class certification issues warrant review, noting that "many suits with class-action allegations present familiar and almost routine issues that are no more worthy of immediate appeal than many other interlocutory rulings" and accordingly directs the "courts of appeals [to] develop standards for granting review that reflect the changing areas of uncertainty in class litigation." Id. The advisory committee's note offers this further guidance:

Permission to appeal may be granted or denied on the basis of any consideration that the court of appeals finds

persuasive. Permission is most likely to be granted when the certification decision turns on a novel or unsettled question of law, or when, as a practical matter, the decision on certification is likely dispositive of the litigation.

Id. Thus, the advisory committee's note identifies two instances in which Rule 23(f) review would likely be appropriate: (1) when a class certification decision as a practical matter terminates the litigation; and (2) when a class certification decision raises a novel issue of law. Relying on this guidance, other circuits have examined the appropriate scope of Rule 23(f).

First among the circuits to address the scope of appellate review pursuant to Rule 23(f), was the Seventh Circuit in *Blair v. Equifax Check Services, Inc.*, 181 F.3d 832 (7th Cir. 1999). In *Blair*, the Seventh Circuit rejected the adoption of a bright-line rule as imprudent and, looking to the reasons for the addition of Rule 23(f), identified three categories of cases in which appellate review would be appropriate. *Id.* at 834. First, for some cases, denial of class status would sound the "death knell" of the litigation because the "representative plaintiff's claim is too small to justify the expense of litigation." *Id.* Second, the grant of class status can put substantial pressure on the defendant to settle independent of the merits of the plaintiffs' claims. *Id.* Third, an appeal may facilitate the development of the law of class actions. *Id.* at 835. Regarding the first two categories, the Seventh Circuit added that the petitioner must demonstrate that the district court's certification decision was "questionable" and "must do this taking into account the discretion the district judge possesses in implementing Rule 23, and the correspondingly deferential standard of appellate review." *Id.* It explained, if the district court's decision is "impervious to revision," there is no point to an interlocutory appeal no matter how "dramatic the effect of the grant or denial of class status [is] in undercutting the plaintiff's claim or inducing the defendant to capitulate." *Id.* Regarding the third category of cases, which it noted is likely to include fundamental issues about class actions that have been poorly developed because so many class actions settle or are resolved in a manner that

overtakes procedural matters, *id.*, the Seventh Circuit observed that it is less important to show that the district court's certification decision is questionable, explaining that law can be advanced through affirmances as well as reversals; rather, the more important the question under the second factor is and the "greater the likelihood that it will escape effective disposition at the end of the case," the more appropriate the appeal. *Id.*

The First Circuit in *Waste Management Holdings, Inc. v. Mowbray*, 208 F.3d 288 (1st Cir. 2000), agreed that Blair "captured the essential principles on which Rule 23(f) rests." *Id.* at 293. However, because of the ease with which issues of law can be characterized as "fundamental," *id.* at 294, and because so many class certification decisions turn on "familiar and almost routine issues," *id.* (quoting Fed. R. Civ. P. 23(f) advisory committee's note), the First Circuit narrowed the third category to include only "those instances in which an appeal will permit the resolution of an unsettled legal issue that is important to the particular litigation as well as important in itself and likely to escape effective review if left hanging until the end of the case." *Id.* At the same time, however, the First Circuit duly noted the broad discretion ceded to the appellate courts by the rule, and cautioned that:

While we hope that these general comments will be helpful to parties deciding whether to pursue applications under Rule 23(f), we do not foreclose the possibility that special circumstances may lead us either to deny leave to appeal in cases that seem superficially to fit into one of these three pigeonholes, or conversely, to grant leave to appeal in cases that do not match any of the three described categories.

Id. Stating as well that it "intend[s] to exercise [its] discretion judiciously," however, the First Circuit observed that "[b]y their nature, interlocutory appeals are disruptive, time-consuming, and expensive," and that notwithstanding the access to the appellate courts provided by Rule 23(f), the court "should err, if at all, on the side of allowing the district court an opportunity to fine-tune its class certification order, rather than opening the door too widely to interlocutory

appellate review." *Id.* (citing Fed. R. Civ. P. 23(c)(1)). The Second Circuit, in *In re Sumitomo Copper Litigation*, 262 F.3d 134 (2d Cir. 2001), appears to have adopted the approach set forth in *Mowbray*. *Id.* at 139-40. It stated that Rule 23(f) petitioners ordinarily must show either that the certification order (1) "will effectively terminate the litigation and there has been a substantial showing that the district court's decision is questionable," or (2) "implicates a legal question about which there is a compelling need for immediate resolution." *Id.* at 139.

Other circuits have elaborated on the *Mowbray* approach. The Eleventh Circuit, in *Prado-Steiman v. Bush*, 221 F.3d 1266 (11th Cir. 2000), adopted five guideposts for Rule 23(f) review: (1) whether the certification ruling is likely to sound the death knell of the litigation; (2) whether the district court's certification decision contains a substantial weakness, such that it likely was an abuse of discretion; (3) whether the appeal presents an unsettled legal question that is of specific and general importance, e.g., issues likely to evade review, issues that are involved in related actions, and interests that affect the public interest; (4) the nature and status of the litigation before the district court, e.g., the status of discovery, the pendency of relevant motions, and how long the matter has been pending; and (5) the likelihood that future events will make immediate appellate review more appropriate, e.g., a change in financial status of a party or ongoing settlement negotiations. *Id.* at 1274-76. The second factor serves as a sliding scale: the more questionable the district court's decision, the less the remaining four factors need weigh in. *Id.* at 1274-75 & n.10. The Eleventh Circuit recognized the possibility that when the district court's certification decision is clearly wrong, Rule 23(f) review "may be warranted even if none of the other factors supports granting the Rule 23(f) petition." *Id.* at 1275. The Fourth Circuit, in *Lienhart v. Dryvit Systems, Inc.*, 255 F.3d 138 (4th Cir. 2001), adopted the Eleventh Circuit's approach with the sliding scale, but firmly stated that when a class certification decision is manifestly erroneous, review is warranted regardless of the remaining factors. *Id.* at 145-46. The court

explained that stringent standards for review are inappropriate as "Rule 23(f)'s purpose [was] to eliminate the unduly restrictive review practices which obtained when mandamus was the only available means to review a class certification prior to final judgment in the absence of a district court's decision to voluntarily certify the issue for immediate review...." *Id.* at 145. Hence, the Fourth Circuit observed that "[i]n addition to addressing 'death knell' situations and promoting the resolution of legal questions of general importance, a careful and sparing use of Rule 23(f) may promote judicial economy by enabling the correction of certain manifestly flawed class certifications prior to trial and final judgment." *Id.* at 145. Following the Eleventh and Fourth Circuits' decisions, the Third Circuit, in *Newton v. Merrill Lynch, Pierce, Fenner & Smith*, 259 F.3d 154 (3d Cir. 2001), identified four categories of cases in which Rule 23(f) would be appropriate: the three set forth by the Seventh Circuit in *Blair* and the advisory committee's note plus the Eleventh and Fourth Circuits' inclusion of a category of likely erroneous class certification decisions. *Id.* at 165.

The differences among the circuits, which are subtle, are of three types. First, two circuits permit appeal if the district court's decision is erroneous, regardless whether the other factors governing appeal under Rule 23(f) are present. Compare *Newton*, 259 F.3d at 165; and *Lienhart*, 255 F.3d at 145-46; with *Mowbray*, 208 F.3d at 293-94; and *Blair*, 181 F.3d at 834-35. Second, two circuits allow appeal when a petition raises an unsettled and fundamental question of law, regardless whether the district court likely erred. See *Mowbray*, 208 F.3d at 293; *Blair*, 181 F.3d at 835. Third, those same circuits caution that interlocutory appeal of an unsettled question of law is appropriate only when that question may evade effective appellate review at the end of the trial court proceedings. See *Mowbray*, 208 F.3d at 293-94; *Blair*, 181 F.3d at 835.

In our view, interlocutory appellate review under Rule 23(f) is properly directed by the guidance set forth in the advisory committee's note. The note reflects, on balance, a reluctance to depart from the traditional procedure in which claimed

errors by the district court are reviewed on appeal only upon the conclusion of the proceedings in the district court. Although the rule ceded broad discretion to the appellate courts, it is understood, if not presumed, that appellate courts will act with cognizance of both the concerns underlying interlocutory appeals generally and the specific purposes for the allowance of interlocutory appeals of class certification decisions in Rule 23(f). Delay caused by interlocutory appeals under Rule 23(f) may be less of a concern because filing a petition does not automatically stay the litigation, see Blair, 181 F.3d at 835; in the instant case, the docket indicates that the case proceeded until the district court granted Mylan's motion for a stay on April 15, 2002. Still, interlocutory appeals are generally disfavored as "disruptive, time-consuming, and expensive" for both the parties and the courts, Mowbray, 208 F.3d at 294, and the more so in a complex class action where the district court may reconsider and modify the class as the case progresses. Prado-Steiman, 221 F.3d at 1276-77; Fed. R. Civ. P. 23(c)(1). As the Eleventh Circuit aptly commented, the exception provided by Rule 23(f) should be exercised in a manner that avoids both micromanagement of complex class actions as they evolve in the district court and inhibition of the district court's willingness to revise the class certification for fear of triggering another round of appellate review. See Prado-Steiman, 221 F.3d at 1273-74. Thus, petitions for Rule 23(f) review are likely to be granted sparingly in cases that fall within neither the guidelines in the advisory committee's note nor the standards we adopt today. Nonetheless, the circuit courts addressing Rule 23(f) are in agreement that restrictions on review should not preclude review in special circumstances that neither the advisory committee's note nor the courts foresaw. See, e.g., Mowbray, 208 F.3d at 294; Blair, 181 F.3d at 834.

With these considerations in mind, we offer the following guidance. Rule 23(f) review will ordinarily be appropriate in three circumstances: (1) when there is a death-knell situation for either the plaintiff or defendant that is independent of the merits of the underlying claims, coupled with a class certifica-

tion decision by the district court that is questionable, taking into account the district court's discretion over class certification; (2) when the certification decision presents an unsettled and fundamental issue of law relating to class actions, important both to the specific litigation and generally, that is likely to evade end-of-the-case review; and (3) when the district court's class certification decision is manifestly erroneous. Whether the district court's decision is questionable need not affect the appropriateness of Rule 23(f) review in the second category, as issues of law can be advanced through affirmances as well as reversals. *Blair*, 181 F.3d at 835. But we conclude, unlike *Mowbray* and *Blair*, that error in certifying a class should not entirely be ignored outside the first category. Where a district court class certification decision is manifestly erroneous, for example, Rule 23(f) review would be warranted even in the absence of a death-knell situation if for no other reason than to avoid a lengthy and costly trial that is for naught once the final judgment is appealed. Although these standards are meant as guidance on when Rule 23(f) review ordinarily will be granted, we caution that the standards represent guidance, not a rigid test.

As is true for all the circuits, we are of the view that Rule 23(f) review should be granted rarely where a case does not fall within one of these three categories. The sheer number of class actions, the district court's authority to modify its class certification decision, see Fed. R. Civ. P. 23(c)(1), and the ease with which litigants can characterize legal issues as novel, all militate in favor of narrowing the scope of Rule 23(f) review. See *Prado-Steiman*, 221 F.3d at 1273-74; see also *Mowbray*, 208 F.3d at 294. At the same time, there necessarily should be some hesitancy in creating a rigid test for the exercise of an appellate court's discretion to grant a Rule 23(f) petition for review because circumstances may arise that cannot now be anticipated in which review would be appropriate, and conversely, in which review would be inappropriate notwithstanding the fact that a petition falls within the categories of cases in which review would ordinarily be appropriate. As the advisory committee's note indicates, the circuit court standards should "reflect the changing areas of uncer-

tainty in class litigation." Fed. R. Civ. P. 23(f) advisory committee's note. Each circuit, thus, has reserved some leeway in its standards. See, e.g., *Newton*, 259 F.3d at 165; *Prado-Steinman*, 221 F.3d at 1276; *Mowbray*, 208 F.3d at 294; *Blair*, 181 F.3d at 834. So do we. That said, we nevertheless conclude that, absent special circumstances, this court's consideration of petitions for interlocutory review under Rule 23(f) should ordinarily fall within the three circumstances that we have identified.

III.

Mylan contends in its Rule 23(f) petition for review that, although certification of a class of direct purchasers is consistent with the direct purchaser rule of *Illinois Brick*, it conflicts with what Mylan regards as the underlying policy of *Illinois Brick*--that only one purchaser class has antitrust standing to sue under s 4 of the Clayton Act--when, as here, the FTC has brought suit and obtained a settlement on behalf of a class of consumer indirect purchasers. Mylan also contends that the certified class consists of both direct and indirect purchasers in contravention of *Illinois Brick* and Rule 23's class certification requirements. Seeking to bring itself within the flexible standards for Rule 23(f) adopted by the circuit courts, Mylan maintains that its petition for review should be granted because "important issues of antitrust standing [are] raised by the District Court's class certification ruling" that are novel, significant, and potentially dispositive, and because the class as certified is particularly suspect and may avoid later review given the potential liability Mylan faces. We conclude that Rule 23(f) review is inappropriate because Mylan's arguments in support of its Rule 12(b)(6) motion to dismiss are unrelated to class certification, and because Mylan's only challenge to the class certification decision falls outside the categories for Rule 23(f) review set forth in Part II.

A.

Rule 23(f) interlocutory review is limited to issues that relate to class certification. See Fed. R. Civ. P. 23(f); *Bertul-*

li v. Indep. Ass'n of Cont'l Pilots, 242 F.3d 290, 294 (5th Cir. 2001); Carter v. W. Publ'g Co., 225 F.3d 1258, 1262 (11th Cir. 2000). Thus, under Rule 23(f), this court can review the merits of an appeal only insofar as they bear upon the propriety of class certification, that is, whether the proposed class satisfies the prerequisites of Rule 23. The threshold requirements of class certification under Rule 23(a) are: (1) numerosity (a large enough class such that "joinder of all members is impractical"); (2) commonality ("questions of law or fact common to the class"); (3) typicality ("claims or defenses of the representative parties are typical of the claims or defenses of the class"); and (4) adequacy of representation ("representative parties will fairly and adequately protect the interests of the class"). Fed. R. Civ. P. 23(a); Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 613 (1997). The rule also limits class actions to cases where: (1) separate actions would risk "establish[ing] incompatible standards of conduct for the party opposing the class" or individual adjudications "which would as a practical matter be dispositive of the interests" of nonparty members or "substantially impair or impede their ability to protect their interests"; (2) injunctive or declaratory relief is sought and "the party opposing the class has acted or refused to act on grounds generally applicable to the class"; or (3) "the court finds that the questions of law or fact common to the members of the class predominate over any questions affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Fed. R. Civ. P. 23(b)(1), (2), & (3); Amchem, 521 U.S. at 614-16.

Although Mylan is correct that whether a class of direct purchasers has antitrust standing under the particular circumstances at issue is a novel question of law, the question is unrelated to class certification under Rule 23. As Mylan styled its filing in the district court, its novel question of law is properly raised in a Rule 12(b)(6) motion to dismiss; the denial of a motion to dismiss is generally not subject to interlocutory review under Rule 23(f) because whether the plaintiffs state a cause of action is only relevant to class

certification to the extent the inquiry relates to the requirements of Rule 23. See *Gen. Tel. Co. of the Southwest v. Falcon*, 457 U.S. 147, 160 (1982); *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 177-78 (1974). Mylan's effort to recast its Rule 12(b)(6) arguments as a challenge to class certification on the ground that a class of direct purchasers lacks antitrust standing, is to no avail. That Mylan's argument as to antitrust standing may dispose of the class as a whole and thereby preclude a lawsuit by direct purchasers goes well beyond the purpose of Rule 23(f) review because it is unrelated to the Rule 23 requirements. The fact that Mylan's challenge would be dispositive of the class action is not unlike a variety of issues of law on the merits of a class action because of the very nature of commonality, see *Fed. R. Civ. P. 23(a)(2)*; review of such issues would expand Rule 23(f) interlocutory review to include review of any question raised in a motion to dismiss that may potentially dispose of a lawsuit as to the class as a whole. This result would inappropriately mix the issue of class certification with the merits of a case, which do not warrant interlocutory review pursuant to Rule 23(f). What matters for purposes of Rule 23(f) is whether the issue is related to class certification itself, and Mylan makes no showing that its antitrust standing claim is so related.

The cases on which Mylan relies do not advance its cause. To the extent that appellate courts have considered constitutional standing pursuant to Rule 23(f), the inquiry has been limited to whether the court has subject matter jurisdiction to review the class certification issue, or whether the claims of the representatives of the class have the requisite typicality. Neither inquiry is applicable to the antitrust standing issue that Mylan presents. In the first category of cases cited by Mylan is *Bertulli v. Independent Association of Continental Pilots*, 242 F.3d 290 (5th Cir. 2001), in which the Fifth Circuit explained that, because Article III standing is one element of the court's subject matter jurisdiction, this requirement must be met before the court can even examine whether the class has met the Rule 23 requirements. *Id.* at 294; see also *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315, 319 (5th Cir.

2002); *Isaacs v. Sprint Corp.*, 261 F.3d 679, 682-83 (7th Cir. 2001). Unlike constitutional standing, this court's jurisdiction does not turn on antitrust standing. See *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 535 n.31 (1983). The question of constitutional standing, which is a prerequisite to Rule 23 class certification because it goes to the court's jurisdiction, is not at issue here. In the second category of cases cited by Mylan is *Prado-Steiman*, in which the Eleventh Circuit considered, pursuant to Rule 23(f), whether the named representatives had constitutional standing, explaining that the question of standing was appropriate for review under Rule 23(f) only to the extent it was relevant to Rule 23's typicality requirement for "[w]ithout individual standing to raise a legal claim, a named representative does not have the requisite typicality to raise the same claim on behalf of a class." *Prado-Steiman*, 221 F.3d at 1279-80; see also *Piazza v. EBSCO Indus., Inc.*, 273 F.3d 1341, 1346-55 (11th Cir. 2001); *Carter*, 225 F.3d at 1262-63. The court thus only considered Article III standing to the extent that it was relevant to Rule 23 class certification. Unlike constitutional standing, whether the class representatives have antitrust standing because they are direct purchasers does not go to the typicality of the claims of the representatives of the class, which is composed entirely of direct purchasers. See Fed. R. Civ. P. 23(a)(3); *Prado-Steiman*, 221 F.3d at 1279 & n.14. Hence, the issue of antitrust standing is beyond the scope of the court's Rule 23(f) review. The only case to which Mylan points in which a court considered antitrust standing to be a necessary predicate to certifying the class is *In re NASDAQ Market-Makers Antitrust Litigation*, 169 F.R.D. 493 (S.D.N.Y. 1996), but there the court appears to have viewed antitrust standing as being relevant to its subject matter jurisdiction; it was only on this basis that the court considered antitrust standing to be a prerequisite to class certification. See *id.* at 504-05.

Although the question of whether a class of direct purchasers has antitrust standing when, in Mylan's terms, "two antitrust cases collide" relates neither to this court's subject

matter jurisdiction nor to any aspect of Rule 23 class certification, there may be occasions when threshold issues (e.g., statute of limitations), jurisdictional issues (e.g., Article III constitutional standing), or issues on the merits (e.g., affirmative defenses or the elements of a cause of action, see, e.g., *West v. Prudential Securities, Inc.*, 282 F.3d 935, 937 (7th Cir. 2002); *Newton*, 259 F.3d at 172; *Mowbray*, 208 F.3d at 295-99), would be appropriate for interlocutory review pursuant to Rule 23(f). In such circumstances, however, those issues would relate in some manner to the certification of the class or the court's jurisdiction. We have no occasion to describe the precise contours of the relationship, for here there is no such relation.

B.

Mylan's challenge to the composition of the certified class as assertedly, and improperly, consisting of both direct and indirect purchasers also is inappropriate for Rule 23(f) review.

First, Mylan has not shown that certification of the class would sound the death knell of the litigation. Other than mere assertions, Mylan makes no showing that it will be unduly pressured to settle because of the class's certification. Mylan failed to submit any evidence that the damages claimed would force a company of its size to settle without relation to the merits of the class's claims. See *Prado-Steiman*, 221 F.3d at 1274; *Mowbray*, 208 F.3d at 294-95.

Second, Mylan's challenge presents no unsettled question of fundamental importance to the law of class actions. Mylan argues that the district court erred in applying the standards of Rule 23 to the facts of this case, but Mylan does not aver that the district court lacked established law to guide it in that task. Insofar as Mylan's objection is based upon the district court's conclusion that the class representatives are direct purchasers, the law guiding that decision also is well settled. See *Illinois Brick*, 431 U.S. at 735-36.

Third, Mylan has not made a showing that, in light of the district court's discretion, see *Hartman v. Duffey*, 19 F.3d

1459, 1471 (D.C. Cir. 1994), the class certification was manifestly erroneous. Mylan contends the certified class does not meet the requirements of Rule 23(a)(2-4), namely, predominance, typicality, and adequacy of representation, because members of the class occupy different levels of a distribution relationship with Mylan. Upon the record before us, however, we can not conclude that there is manifest error in the district court's determination that the class representatives have standing under Illinois Brick or in the findings of fact underlying that conclusion. As the district court comes to know more about the relationships among Mylan, the pharmaceutical wholesalers, and the class plaintiffs, it may further refine the class, see Fed. R. Civ. P. 23(c)(1)--a possibility that supports our conclusion that immediate appeal is not warranted here.

Accordingly, we hold, upon applying the standards that we have outlined in defining when Rule 23(f) review is ordinarily appropriate, that Mylan's challenges to the class certification do not warrant interlocutory review pursuant to Rule 23(f). Although Mylan would nonetheless have the court reach the merits of the district court's certification decision as well as the merits of its Rule 12(b)(6) motion to dismiss because the issues have been carefully briefed, review under Rule 23(f) is not warranted. Therefore, we deny the petition for review.