

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS  
FOR THE ELEVENTH CIRCUIT

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No. 13-12709

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D.C. Docket No. 8:10-cv-02008-VMC-TGW

LAKELAND REGIONAL MEDICAL CENTER, INC., on behalf of itself and all  
others similarly situated,

Plaintiff – Appellant,

versus

ASTELLAS US, LLC and ASTELLAS PHARMA US, INC.,

Defendants – Appellees.

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Appeal from the United States District Court  
for the Middle District of Florida

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(August 15, 2014)

Before ANDERSON, Circuit Judge, and EBEL,<sup>\*</sup> Circuit Judge, and UNGARO,<sup>\*\*</sup>  
District Judge.

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<sup>\*</sup> Honorable David M. Ebel, United States Circuit Judge for the Tenth Circuit, sitting by  
designation.

<sup>\*\*</sup> Honorable Ursula Ungaro, United States District Judge for the Southern District of Florida,  
sitting by designation.

EBEL, Circuit Judge:

Defendants-Appellees Astellas US, LLC and Astellas Pharma US, Inc. (collectively “Astellas”) holds patents on a cardiac test and sells its unpatented pharmaceutical product, Adenoscan, for use during that test. Plaintiff-Appellant Lakeland Regional Medical Center, Inc. (the “Medical Center”), which conducts these cardiac tests, alleges that Astellas is able to overcharge the Medical Center for the Adenoscan product by unlawfully tying the patented right to perform the patented cardiac test to the purchase of the unpatented Adenoscan in violation of Section 1 of the Sherman Act, 15 U.S.C. § 1. At issue in this appeal is the district court’s refusal to certify the Medical Center’s tying claim as a class action. We AFFIRM.

### **BACKGROUND**

Healthcare providers often test for coronary artery disease using a procedure called myocardial perfusion imaging (“MPI”). This test is most accurate when carried out while the heart is stressed by, for example, administering adenosine to the patient during the procedure. Adenosine is a naturally occurring chemical compound that causes selective blood vessels to dilate. Astellas has held two patents for performing an MPI using adenosine; the first patent expired in March 2009 and the second will expire in March 2015. Astellas does not offer healthcare

providers a freestanding license to perform its patented MPI procedure. Instead, healthcare providers obtain an implied license to perform the MPI procedure by purchasing Astellas's unpatented adenosine product, Adenoscan, for use during the procedure.

When this litigation began, Adenoscan was the only adenosine product that the Food and Drug Administration ("FDA") had approved for use during an MPI. There are other adenosine products available in the market, however, and healthcare providers are not bound by the FDA's approval ruling, but can, instead, use any adenosine product during an MPI that the healthcare providers, in their medical judgment, deem appropriate. Exercising that prerogative, the Medical Center began using chemically-identical adenosine products that were cheaper than Adenoscan during MPIs performed at the Medical Center. Astellas responded by threatening to sue the Medical Center for performing Astellas's patented MPI procedure without a license.

The Medical Center sued Astellas first for, among other claims, violating federal antitrust laws by illegally tying the implied license to perform MPIs involving adenosine to the purchase of Adenoscan. See 15 U.S.C. § 1.<sup>1</sup> According

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<sup>1</sup> Section 1, United States Code Title 15, provides in pertinent part that "[e]very contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal." A tying arrangement—"an agreement by a party to sell one product but only on the condition that the

to the Medical Center, this unlawful tying arrangement enabled Astellas to charge 450% more for Adenoscan than the price for other, chemically-identical adenosine products. As relief, the Medical Center sought 1) treble damages for the amount Astellas had overcharged the Medical Center for Adenoscan, and 2) injunctive and declaratory relief. See 15 U.S.C. §§ 15(a), 26.

The Medical Center brought its case as a class action on behalf of all healthcare providers who had purchased Adenoscan during a four-year period, from September 2006 through September 2010. But the district court refused to certify the class, ruling, among other things, that the Medical Center was not a viable class representative because 1) the direct purchaser rule, see Illinois Brick Co. v. Illinois, 431 U.S. 720, 729, 736 (1977), precluded the Medical Center's own treble damages claim since the Medical Center had purchased Adenoscan, not directly from Astellas, but instead from several independent pharmaceutical distributors; and 2) the Medical Center's requests for declaratory and injunctive relief were, or soon would be, moot because, after the initiation of this suit, the FDA had approved a generic version of Adenoscan for use during MPIs and because the Medical Center insufficiently articulated the class-wide injunctive

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buyer also purchases a different (or tied) product"—may be unlawful under § 1. Eastman Kodak Co. v. Image Technical Servs., Inc., 504 U.S. 451, 461-62 (1992) (internal quotation marks omitted). In this case, the Medical Center alleges that the tying product is the implied license to perform MPIs involving adenosine, and the tied product is the Adenoscan.

relief that it reasonably could obtain.

Although the district court's denial of class certification was not a final, appealable order, see Coopers & Lybrand v. Livesay, 437 U.S. 463, 464-65 (1978), the ruling effectively foreclosed the Medical Center's tying claim. The Medical Center thus stipulated to the entry of final judgment against it on all of its claims while preserving its right to appeal the district court's denial of class certification. See Dorse v. Armstrong World Indus., Inc., 798 F.2d 1372, 1376-77 (11th Cir. 1986). Exercising jurisdiction under 28 U.S.C. § 1291, we AFFIRM.

## DISCUSSION

**I. Because the direct purchaser rule precludes the Medical Center's own treble damages claim, the district court did not abuse its discretion in refusing the Medical Center's request to certify a class seeking damages against Astellas for unlawful tying**

### **A. Relevant legal principles**

This appeal involves the interaction between law governing claims for unlawful tying and antitrust standing principles. The Medical Center has claimed a classic tying arrangement.<sup>2</sup> Its allegations are as follows: Astellas is the source of two products. First, Astellas has a patent on performing MPIs that use adenosine

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<sup>2</sup> See Eastman Kodak, 504 U.S. at 460-61 ("A tying arrangement is an agreement by a party to sell one product but only on the condition that the buyer also purchases a different (or tied) product," which violates antitrust laws "if the seller has appreciable economic power in the tying product market and if the arrangement affects a substantial volume of commerce in the tied market.") (internal quotation marks omitted); see also Phillip Areeda & Herbert Hovenkamp, IX Antitrust Law § 1700a (3d ed. 2011).

to stress the patient's heart during the procedure. Healthcare providers wanting to perform that procedure, therefore, need a license from Astellas to do so. Second, Astellas sells Adenoscan which, at the time this litigation began, was the only adenosine product that the FDA had approved for use during the patented MPI procedure, although there were other adenosine products available on the market that could perform the same function as Adenoscan. According to the Medical Center's allegations, Astellas leveraged its power in the testing market to overcharge for Adenoscan. The Medical Center contends that it was injured by this tying arrangement because the only way it could obtain the tying product that it needed—a license from Astellas to perform MPIs involving adenosine—was to overpay for Adenoscan. The Medical Center further contends that, by requiring it to buy the overpriced Adenoscan in order to get the process license it wanted, Astellas foreclosed the Medical Center from purchasing other adenosine products at much lower prices for use during the MPIs. The Medical Center measures its tying damages, then, by the amount it overpaid for Adenoscan when compared with the amount it could have paid to purchase another adenosine product.<sup>3</sup>

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<sup>3</sup> The appropriate measure of damages in a tying case is the amount the purchaser overpaid for the unlawfully tied bundle of products or services when compared to the amount the purchaser would have paid to purchase those products or services separately. See Kypta v. McDonald's Corp., 671 F.2d 1282, 1285 (11th Cir. 1982). Here, however, the Medical Center alleges that Astellas charged nothing for the implied use license it tied to the sale of Adenoscan, and further alleges that, even if Astellas had offered a stand-alone license separate from the Adenoscan,

But it is well-settled that not everyone who is injured by an antitrust violation can recover (treble) damages.<sup>4</sup> Under the direct purchaser rule, only the customer who purchased the goods or services at issue directly from the alleged antitrust violator can recover damages. See Illinois Brick, 431 U.S. at 729, 736; see also Kansas v. UtiliCorp United, Inc., 497 U.S. 199, 203-04 (1990). In other words, even if Astellas’s alleged tying arrangement injured purchasers all along the distribution chain for either the tying (implied process license) or the tied (Adenoscan) product, the direct purchaser rule only permits the first purchaser to recover damages from Astellas for any unlawful overcharge. The reasons for this rule are threefold, see UtiliCorp, 497 U.S. at 208-16: permitting only the direct purchaser to recover damages 1) “eliminate[s] the complications of apportioning overcharges between direct and indirect purchasers,” id. at 208; 2) eliminates the possibility that direct and indirect purchasers could seek duplicative recoveries against the antitrust violator, id. at 212; and 3) best “promote[s] the vigorous enforcement of the antitrust laws” by permitting only the best-situated purchaser to sue for damages, id. at 214.

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Astellas would have charged nothing for that license. In this tying case, then, the Medical Center is measuring its damages by the amount Astellas was able to overcharge the Medical Center for the Adenoscan, by tying it to the implied license, as compared to the price at which the Medical Center could have obtained other, comparable adenosine products.

<sup>4</sup> Because this tying claim is before us on standing, we do not reach its merits and so we do not express any opinion regarding the claim’s merits.

**B. The district court correctly determined that the direct purchaser rule bars the Medical Center's damages claim**

We review de novo the district court's application of the direct purchaser rule to the Medical Center's damages claim. See Sunbeam Television Corp. v. Nielsen Media Research, Inc., 711 F.3d 1264, 1270 (11th Cir. 2013). Applying that rule here, there is no doubt that the distributors who purchased Adenoscan from Astellas and then resold it to the Medical Center are the direct purchasers and, therefore, the only parties under Illinois Brick that can recover tying damages from Astellas. Because, according to the Medical Center, neither the distributors nor the Medical Center ever paid Astellas anything for the implied license to perform the patented MPI procedure, it was the distributors who first bore all the damages from the alleged unlawful tying, which was the overcharged price of Adenoscan.

Although the distributors may have passed on to the Medical Center some or all of the overcharge that they paid to Astellas, the Medical Center cannot recover damages from Astellas for that overcharge because it was the second purchaser of that tied product. Indeed, to allow the Medical Center to maintain a damages claim for this particular tying arrangement would give rise to the very problems that the direct purchaser rule seeks to avoid. It would complicate the calculation of damages resulting from any overcharge by Astellas by requiring an apportionment



of that overcharge throughout the Adenoscan distribution chain, between the direct purchasers (the distributors) and the indirect purchasers (like the Medical Center); it would create the possibility that both the distributors and the indirect Adenoscan purchasers like the Medical Center could recover from Astellas for the same allegedly unlawful tying arrangement; and it would discourage vigorous private-citizen enforcement of the antitrust laws by making it more difficult for the best-suited plaintiffs, the distributors, to bring an unlawful tying claim.<sup>5</sup> See UtiliCorp, 497 U.S. at 208-16. For these reasons, then, only the distributors, as the direct purchasers of Adenoscan who first paid the inflated tied price for that product, can recover damages from Astellas for that alleged overcharge resulting from Astellas's alleged tying behavior.

**C. The Medical Center's argument to the contrary is unavailing**

The Medical Center's primary argument against applying the direct purchaser rule to preclude its damages claim is that the distributors are not the best plaintiffs to assert the tying claim at issue here because they have no use for the tying product, which is the implied license to perform an MPI using adenosine;

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<sup>5</sup> Applying the direct purchaser rule here serves all of the purposes underlying that rule. See UtiliCorp, 497 U.S. at 208-16. But even if the rule's application in this particular case did not serve the rule's underlying purposes, the Supreme Court has directed courts to apply the rule nonetheless: "even assuming that any economic assumptions underlying the Illinois Brick rule might be disproved in a specific case, we think it an unwarranted and counterproductive exercise to litigate a series of exceptions." Id. at 216.

indeed, according to the Medical Center, the distributors never even receive that license.<sup>6</sup> According to the Medical Center, in other words, Astellas does not exert tying pressure on the distributors, coercing them to buy the tied product (Adenoscan) in order to get the tying product (the implied license) because the distributors have no use for the implied license. And if there is no pressure on the distributors to buy the tied product, so argues the Medical Center, the distributors have no incentive to bring the tying claim.

We are unpersuaded. While admittedly the distributors have no need for a license that permits them to perform MPIs, that license has economic value for the distributors who seek to resell Adenoscan to their healthcare customers, who do need that license. In fact, because the distributors could only market and sell Adenoscan for its FDA-approved use—that is, in conjunction with an MPI involving adenosine—the distributors needed to be able to assure their

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<sup>6</sup> No one questions that Astellas tied the implied process license to the purchase of Adenoscan. But there are two ways to view that arrangement. One way is to suppose that the implied license came directly from the purchase of Adenoscan and thus flowed down the Adenoscan distribution chain, from Astellas to the distributor to the Medical Center. This is what Astellas contends, and that is consistent with its, Astellas's, own assertions in letters it sent to healthcare providers, including the Medical Center. The other way to view the arrangement is that Astellas linked the right to obtain an implied license to the purchase of Adenoscan, even though healthcare providers like the Medical Center, in exercising that right, actually obtained the implied license directly from Astellas. That is the Medical Center's contention. As we see it, it does not matter because, either way, Astellas undoubtedly conditioned its granting of the implied license on the purchase of Adenoscan, and here the entire tying damages came from the enhanced price of Adenoscan, the tied product, which was first paid by the distributors to Astellas.

customers—the hospitals—that they could use the Adenoscan that the distributors were selling. Thus, Adenoscan, tied to the implied license, had a greater resale value for the distributors than other adenosine products which Astellas would not allow to be used with its patented MPI process. Therefore, regardless of whether or not the distributors themselves actually received or used the implied license, they were still susceptible to the coercion of the tying arrangement and were still injured by any unlawful overcharge that Astellas was able to command for Adenoscan. To conclude otherwise would be to ignore the economic realities of the transactions at issue here. See United States v. Concentrated Phosphate Export Ass’n, 393 U.S. 199, 208 (1968) (“In interpreting the antitrust laws, . . . [w]e must look at the economic reality of the relevant transactions.”); see also Eastman Kodak, 504 U.S. at 466-67 (“Legal presumptions that rest on formalistic distinctions rather than actual market realities are generally disfavored in antitrust law.”).

Our conclusion is bolstered by several cases from other circuits which, although not controlling here, are helpful. Though not a tying case, Kloth v. Microsoft Corp., 444 F.3d 312 (4th Cir. 2006), is perhaps most helpful. In Kloth, Microsoft sold computer manufacturers a license to “pre-install” Microsoft software onto the manufacturers’ computers and the right to charge consumers for

the option to purchase licenses to use the software from Microsoft. Id. at 318-19, 321-22. After consumers bought the computers from the manufacturer or a retailer, the consumers had the option of either accepting Microsoft's license to use the software already installed on the computer or rejecting the license and receiving a refund directly from Microsoft. Id. at 318, 320. Applying Illinois Brick, the Fourth Circuit held that the consumers were indirect purchasers of Microsoft's software licenses, even if the consumers actually acquired the software licenses directly from Microsoft, because the consumers paid the computer manufacturers or retailers (and not Microsoft) for the licenses as part of the computer's purchase price. Id. at 320-21. In reaching that conclusion, the Fourth Circuit rejected the consumers' contrary suggestion that they were direct purchasers, stating that they

fail[ed] to recognize both the role of the [computer manufacturer] or the retailer in the licensing chain and the economic realities of the transaction. Although Microsoft does not sell title to its software, it does sell licenses to use its software, and plaintiffs [consumers] could have acquired licenses directly from Microsoft. . . . But the plaintiffs in this case acquired their licenses by purchases from [computer manufacturers] and retailers, paying them, not Microsoft, for their licenses at prices set by the [manufacturers] and retailers. Because the plaintiffs purchased their products from intermediaries and not Microsoft, they are indirect purchasers within the meaning of that term as defined in Illinois Brick and UtiliCorp, and the recoveries they would have from Microsoft would present the very problems that those cases sought to avoid.

Id.

The situation in Kloth is analogous to the circumstances presented here and supports our conclusion that the direct purchaser rule precludes the Medical Center's damages claim.<sup>7</sup> As in Kloth, here the distributor paid Astellas for the Adenoscan and the license (or the right to obtain the license); and the Medical Center then, in turn, paid the distributor (and not Astellas) for both the Adenoscan and the license (or the right to obtain the license). The Medical Center, therefore, was only an indirect purchaser of both from the alleged antitrust violator, Astellas.<sup>8</sup>

In a second case supporting our decision, Warren General Hospital v. Amgen Inc., 643 F.3d 77 (3d Cir. 2011), the Third Circuit applied the direct purchaser rule to preclude a hospital's tying claim against a pharmaceutical company. There, the hospital claimed that the drug manufacturer, Amgen, was unlawfully tying the sale of two drugs over which Amgen had a monopoly (the "tying" products) to the sale of a third, more expensive Amgen drug (the "tied" product). Id. at 80-81. The alleged tying scheme specifically involved Amgen

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<sup>7</sup> The Medical Center attempts to distinguish Kloth because, in that case, 1) both the computer hardware and software came together from the computer manufacturers to the consumer; and 2) Microsoft leveraged its power in the computer operating system market to compel the manufacturers to install its software onto the computers. But those facts do not meaningfully distinguish Kloth from the circumstances presented here.

<sup>8</sup> Recall that under the Medical Center's theory, no one actually paid anything for the implied license.

offering healthcare providers price rebates on the tying drugs based upon the volume of purchases that healthcare providers made of the tied drug. Id. Even though Warren General Hospital bought all three drugs through independent distributors, the plaintiff hospital claimed that it had directly purchased the drugs from Amgen because it contracted with Amgen directly for the rebates and it received those rebates directly from Amgen. Id. at 87-88. The Third Circuit rejected that argument, concluding that the hospital was still only an indirect purchaser of Amgen's drugs because the hospital ordered the drugs from independent distributors and paid those distributors for the drugs at a price set by the distributors. Id. at 88-89. According to the court, it was irrelevant that the rebates came directly from Amgen: while there "were some direct interactions between Amgen and the hospital relating to the rebate program and the volume of Amgen drugs the hospital required," those interactions were insufficient to make the hospital a direct purchaser of the drugs from Amgen when the drugs themselves were in fact purchased from the independent distributors. Id. at 88.

The same could be said about the products here: even if the license might be viewed as coming directly from Astellas, see supra n. 4, that does not change the fact that the Medical Center purchased Adenoscan, which carried the right to obtain permission to use it in MPIs and which constituted the entire overcharge

forming the basis of the treble damages claim, directly from the distributors, not Astellas.

Finally, the Tenth Circuit's decision in Sports Racing Services, Inc. v. Sports Car Club of America, Inc., 131 F.3d 874 (10th Cir. 1997) lends further support to our decision. In Sports Racing Services, an amateur car racer, Freeman, sued Sports Car Club of America, alleging that Sports Car Club illegally tied its sale of the right to race in Club-sponsored races to the purchase of cars and parts for the races from Sports Car Club. 131 F.3d at 878-79, 886. Although Freeman bought the tying product, the right to race, directly from Sports Car Club, he had to buy the tied products, Sports Car Club's cars and parts, from an independent distributor. Id. at 878, 883, 887. The Tenth Circuit held that the direct purchaser rule may not bar Freeman's tying claim against Sports Car Club,<sup>9</sup> even though he was only an indirect purchaser of the tied products (the cars and parts), because Freeman was the first party in either distribution chain (of the tied and tying products) that was "the direct victim of the anticompetitive activity [the tying arrangement] and the first person with a cause of action" for tying. Id. at 889.

That reasoning is consistent with our conclusion here: the distributors were the first entities in the Adenoscan distribution chain subjected to the tying arrangement's

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<sup>9</sup> The case came to the Tenth Circuit on a summary judgment decision. See Sports Racing Servs., 131 F.3d at 878. Ultimately the court remanded the case to the district court for further factual finding. Id. at 890-91.

coercive force because they were compelled to pay the overcharge for Adenoscan, which was the source of the alleged tying damages claim and the Medical Center was downstream of that tying damage.

The Tenth Circuit, in Sports Racing Services, concluded that the cars/parts distributor in that case did not have a tying claim because the distributor was not subjected to the coercive effect of the tying arrangement since it had no connection to, and no use for, the tying product—the right to race in Club-sponsored races.<sup>10</sup> While the distributor in Sports Racing Services paid for the tied products, the cars and parts it resold to the racers, the distributor did not pay for the tying product, the right to race. Because it was the racer who first paid for both, therefore, he was the only party who could claim tying damages, measured as the difference between the price the racer paid for the bundled products and services against the price he would have paid for them separately, had Sports Car Club not unlawfully tied them together.

Here, on the other hand, the Adenoscan distributors, as we have already explained, were subject to the coercive effect of Astellas's allegedly unlawful tying arrangement because both the tying product, the implied license, and the tied

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<sup>10</sup> The distributor was not itself buying the cars to race them and, when it resold the cars, it did not do so with a license that the buyer could race them in a Club-sponsored race. The buyer independently had to qualify and pay directly to Sports Car Club for the right to race in a sponsored race. There was no suggestion that when the distributor bought the car from Sports Car Club, that it was also buying an implied right to race that car in a Club-sponsored race.



product, Adenoscan, were valuable to the distributors and useful to them on resale. Moreover, the purchase of the Adenoscan automatically conveyed an implied license to perform the patented MPI procedure using adenosine. Furthermore, according to the Medical Center, neither it nor the distributors paid anything for the automatically conveyed implied license. Unlike in Sports Racing Services, then, the distributors in this case bore the full brunt of the tying arrangement and they were the first entities who suffered the full amount of the tying damages, measured in this case as the overcharge Astellas was able to demand for Adenoscan. Unlike in Sports Racing Services, then, it follows that the distributors in this case were injured by the tying arrangement in the same manner as the Medical Center and they, rather than the Medical Center, are the first entities in the Adenoscan distribution chain to have a tying damages claim against Astellas. It follows, therefore, that only the distributors, as the direct purchasers of Adenoscan, can recover damages from Astellas; the Medical Center cannot.

**D. Conclusion as to the district court's refusal to certify a class for purposes of the Medical Center's damages claim**

For these reasons, then, we agree with the district court that the direct purchaser rule precludes the Medical Center, as an indirect purchaser of Adenoscan, from recovering damages from Astellas for its allegedly unlawful tying arrangement. As such, the Medical Center would not be an adequate

representative for a class seeking damages for the alleged unlawful tying and the district court, therefore, did not abuse its discretion in denying the Medical Center's request to certify a class for the damages claim, see Ault v. Walt Disney World Co., 692 F.3d 1212, 1216 (11th Cir. 2012), cert denied, 133 S. Ct. 1806 (2013).

## **II. The district court also did not abuse its discretion in refusing to certify the class for purposes of seeking injunctive and declaratory relief**

The direct purchaser rule does not apply to claims for injunctive and declaratory relief. See In re Beef Indus. Antitrust Litig., 600 F.2d 1148, 1167 (5th Cir. 1979).<sup>11</sup> Nevertheless, the district court also declined to certify the class for purposes of seeking injunctive and declaratory relief against Astellas because 1) such relief in this case would soon be moot; and 2) the Medical Center did “not sufficiently brief[] the Court as to the substance of its claims for declaratory or injunctive relief to justify class certification pursuant to [Fed. R. Civ. P.] 23(b)(2).” (Doc. 150 at 13.) We disagree with the first reason, but affirm on the second.

### **A. The Medical Center's claims are not moot**

We review questions of mootness de novo. See Doe v. Wooten, 747 F.3d 1317, 1321-22 (11th Cir. 2014). It was Astellas's burden, as the party asserting

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<sup>11</sup> This court, in Bonner v. City of Prichard, 661 F.2d 1206, 1207 (11th Cir. 1981) (en banc) adopted as binding precedent all decisions of the former Fifth Circuit issued prior to October 1, 1981.

that the Medical Center's claims would soon be moot, to come forward with information to support that assertion. See Cardinal Chem. Co. v. Morton Int'l, Inc., 508 U.S. 83, 98 (1993) (addressing mootness on appeal).

Astellas grounded its mootness argument on its prediction that a generic version of Adenoscan would be available in October 2012, just a week after the district court denied class certification. But that prediction proved wrong, and generic Adenoscan did not become available during the time this case remained pending in the district court.<sup>12</sup> Moreover, the record does not indicate what effect, if any, the presence of this single generic might have on the Adenoscan market. We cannot conclude, therefore, that the controversy at issue here is at an end, see Atheists of Fla., Inc. v. City of Lakeland, 713 F.3d 577, 593-94 (11th Cir. 2013), or that it is currently impossible to provide the Medical Center with meaningful injunctive or declaratory relief, see Rich v. Sec'y, Fla. Dep't of Corr., 716 F.3d 525, 531 (11th Cir. 2013). Indeed, on appeal, Astellas does not argue to the contrary. The district court thus erred in denying class certification on the ground that the Medical Center's declaratory and injunctive claims might soon become

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<sup>12</sup> Astellas now asserts that the FDA approved a generic form of Adenoscan a year later, in August 2013, after the Medical Center initiated this appeal, but that information is not part of the appellate record.

moot.<sup>13</sup>

**B. The district court did not abuse its discretion in refusing to certify the class because the Medical Center failed to justify certification**

In addition to mootness, the district court also refused to certify the class for purposes of declaratory and injunctive relief because the Medical Center failed to justify certification. We review that determination for an abuse of discretion. See Ault, 692 F.3d at 1216. “As long as the district court’s reasoning stays within the parameters of Rule 23’s requirements for the certification of a class, the district court decision will not be disturbed.” Heffner v. Blue Cross & Blue Shield of Ala., Inc., 443 F.3d 1330, 1337 (11th Cir. 2006) (internal quotation marks omitted).

Rule 23(b)(2) provides that a class can be certified for purposes of seeking injunctive or declaratory relief if “the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.” “The key to the (b)(2) class is the indivisible nature of the injunctive or declaratory remedy warranted.” Wal-Mart Stores, Inc. v. Dukes, 131 S. Ct. 2541, 2557 (2011) (internal quotation marks omitted). Thus, “Rule 23(b)(2) applies only when a single injunction or declaratory judgment would provide relief to each member of

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<sup>13</sup> It may be that the district court did not conclude as a jurisdictional matter that the Medical Center’s claims were, or soon would be, moot. Instead, the district court may have decided not to exercise its discretion to certify the class under these circumstances. If so, the denial of class certification was an abuse of discretion, for the same reasons stated above.

the class.” Id. It was the Medical Center’s burden to “affirmatively demonstrate” that class certification was appropriate under Rule 23(b)(2). Id. at 2551. The Medical Center failed to meet that burden, in two ways.

First, it never identified exactly what injunctive or declaratory relief it was seeking. In its complaint, the Medical Center requested only “such declaratory and injunctive relief as appropriate in order to compel and ensure defendant Astellas’ future compliance with law.” (Doc. 11 at 19.) In the twenty-two months between the time the Medical Center filed its complaint and the time it moved for class certification, Astellas tried unsuccessfully to pin the Medical Center down as to exactly what declaratory and injunctive relief it was seeking. Specifically, Astellas wanted to know whether the Medical Center was seeking an order requiring it to offer healthcare providers a stand-alone license to perform MPIs involving adenosine. When the Medical Center moved for class certification, it suggested only that the district court “could” order Astellas to provide access to and use of its patent without threat of litigation and without requiring the purchase of a product from Astellas. (Doc. 115 at 13.) This statement was insufficient to permit the district court to assess adequately whether the injunctive and declaratory relief the Medical Center was seeking could provide relief to each member of the class, see Wal-Mart Stores, 131 S. Ct. at 2557.

Second, even if the Medical Center adequately explained the injunctive and declaratory relief it sought, and assuming that relief included an injunction requiring Astellas to offer healthcare providers a stand-alone license to perform MPIs involving adenosine, the Medical Center failed to prove that such an order would provide relief to each class member. See id. at 2551, 2557. Astellas asserted that no other member of the putative class had ever asked for a stand-alone license; that, according to Astellas, it was likely a stand-alone license combined with generic adenosine would cost class members at least as much, if not more, than the implied license currently bundled with Adenoscan; and that, even if it would be less expensive to purchase a stand-alone license and generic adenosine, healthcare providers might still choose to use Adenoscan because the FDA had approved only Adenoscan for use during MPIs and Medicare would reimburse providers only for using Adenoscan but not for using the generic version of adenosine. The Medical Center failed to offer any evidence to counter Astellas's assertions. The district court, therefore, did not abuse its discretion in refusing to certify the class for purposes of seeking declaratory and injunctive relief against Astellas.

## **CONCLUSION**

For the foregoing reasons, we **AFFIRM** the district court's decision denying

the Medical Center class certification on its claims seeking treble damages and injunctive and declaratory relief.