

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

LAKELAND REGIONAL MEDICAL CENTER,
INC.,

Plaintiff,

v.

Case No. 8:10-cv-2008-T-33TGW

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

Defendants.

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ORDER

This cause comes before the Court pursuant to Plaintiff Lakeland Regional Medical Center's Motion and Brief in Support of Class Certification (Doc. # 116), which was filed on July 13, 2012. Defendants Astellas US, LLC and Astellas Pharma US, Inc. (collectively, "Astellas") filed a Response and Brief in Opposition to Class Certification (Doc. # 138) on August 27, 2012, and Lakeland Regional filed a Reply Memorandum (Doc. # 144) on September 4, 2012. For the reasons that follow, the Court denies Class Certification in this antitrust case.

I. Background

Lakeland Regional, a full-service hospital, is a not-for-profit Florida corporation with its headquarters in Lakeland, Florida. (Doc. # 11 at ¶ 7). Astellas, incorporated in Delaware with its headquarters in Deerfield, Illinois, is the exclusive licensee of two relevant patents involving

adenosine, a naturally occurring substance found in the human body. Id. at ¶ 8. Lakeland Regional alleges that Astellas has engaged in unlawful, anticompetitive, monopolistic, and exclusionary activity with respect to adenosine in violation of the Sherman Antitrust Act, 15 U.S.C. §§ 1 and 2, the Clayton Antitrust Act, 15 U.S.C. § 14, Florida antitrust law, and Florida common law.

A. The Patents

Physicians use a test known as myocardial perfusion imaging to diagnose a condition known as cardiac artery disease, one of the leading causes of death in the United States. (Doc. # 11 at ¶ 9). Myocardial perfusion imaging is usually done while the patient is placed under "stress" in order to maximize the accuracy of the test. Id. at ¶ 10. Physicians induce stress by requiring patients to exercise on a treadmill. Id. When patients are unable to exercise on a treadmill, physicians create "pharmacological stress" through the administration of adenosine. Id. Adenosine is a naturally occurring compound that induces the dilation of blood vessels. Id. at ¶ 12.

Even when patients are capable of exercise, physicians often use adenosine to further stress the heart, in order to increase the accuracy of the stress test. Id. Administration

of adenosine is the medically recognized standard of care when pharmacologic stress is required to perform myocardial perfusion imaging. Id.

During the time relevant to the present suit, the use of adenosine during myocardial perfusion imaging has been covered by two separate method of use patents: the 5,070,877 patent and the 5,731,296 patent. (Levitt Decl. Doc. # 138-3 at ¶ 4). The '877 Patent expired on May 18, 2009. (Berneman Rpt. at ¶ 16).¹ The '296 Patent will not expire until March 24, 2015. (Levitt Decl. Doc. # 138-3 at ¶ 4). Astellas is the exclusive licensee of such Patents. Id. Therefore, any health care provider who administers adenosine to a patient during myocardial perfusion imaging must have a license to do so from Astellas. Id.

Astellas sells an adenosine drug known as Adenoscan, and it is the only drug approved by the United States Food and Drug Administration for use during myocardial perfusion imaging. (Berneman Rpt. at ¶ 15). Adenoscan was launched in 1995, and by 2001, it had become the most commonly used drug

¹ A majority of the parties' submissions regarding class certification were filed under seal. The Court has accordingly referred to such materials by title, rather than by a docket number.

for inducing stress for myocardial perfusion imaging. (McQuire Rpt. at ¶ 97).

B. Astellas's Communications with Lakeland Regional

Lakeland Regional does not dispute the validity of the '296 Patent, but, nevertheless, began using an adenosine product other than Adenoscan during myocardial perfusion imaging. On July 31, 2008, Astellas transmitted a letter to Lakeland Regional indicating that Lakeland Regional must purchase Adenoscan for use in myocardial perfusion imaging procedures and that use of "generic" adenosine during such procedures would constitute infringement of the '296 Patent. (Doc. # 11 at ¶ 24). Among other things, Astellas' letter stated:

[S]ale of . . . an Adenoscan substitute for that use [in myocardial perfusion imaging] is currently protected by two independent United States patents When Adenoscan is purchased from Astellas, the purchaser is given permission to use the drug as an adjunct for [myocardial perfusion imaging]. But when adenosine from an unauthorized source is used for [myocardial perfusion imaging] . . . the seller and the user are infringing both the '877 and the '296 patents and thus could be liable for patent infringement [E]ven after May 18, 2009, only Astellas . . . will be legally permitted to use adenosine as an adjunct for [myocardial perfusion imaging].

Id. at ¶ 26.

In a letter dated September 14, 2009, Astellas explained to Lakeland Regional:

While there is no patent that covers the *composition*, adenosine, this *method of use* patent precludes the use of generic adenosine for [myocardial perfusion imaging] as a substitute for Adenoscan. Astellas is the only party that can authorize the patented use of an adenosine infusion for [myocardial perfusion imaging] studies. Such permission is **only** granted when Adenoscan is purchased . . . from Astellas.

Id. at ¶ 28 (emphasis in original).

C. Lakeland Regional's Complaint

Lakeland Regional initiated this action against Astellas on September 13, 2010, and filed an Amended Class Action Complaint on October 19, 2010. (Doc. ## 1, 11). Lakeland Regional's Amended Complaint arrays the following counts against Astellas: unlawful tying (count one), exclusive dealing (count two), attempt to monopolize (count three), unreasonable restraint of trade (count four), attempted monopolization (count five), and tortious interference with a prospective economic advantage (count six). (Doc. # 11).

Lakeland Regional's expert explains the essence of Lakeland Regional's antitrust claims:

Astellas extends its monopoly by use of a tied sale. A tied sale occurs when the seller of a product or service (*the tying product*) over which it has market or monopoly power requires a consumer to also buy another product (*the tied product*) the

seller produces. . . . In this matter, the tying product/service is Astellas' '296 method of infusing adenosine in connection with [myocardial perfusion imaging] testing; the tied product is adenosine as Adenoscan. Astellas has used the '296 patent for the method of infusing adenosine for [myocardial perfusion imaging] to force Class members to purchase its adenosine (Adenoscan) at prices much above those for other adenosine products.

(McGuire Rpt. at ¶ 63).

Lakeland Regional seeks certification of the following national class pursuant to Rule 23(b)(2), (3), Fed.R.Civ.P.:

All health care providers who were consumer-purchasers of Astellas' adenosine products within four years prior to the filing of this action, and who would have used adenosine sold by a provider other than defendant Astellas for myocardial perfusion imaging (MPI) but for the defendant's claim that generic adenosine could not be used for this procedure (even though it was available on the market).

- (a) Those health care providers referenced above still in business on the date that final judgment is entered in this action;
- (b) Those health care providers referenced above who do not have pending [] against defendant Astellas, on the date of the Court's certification order, any individual action wherein the recovery sought is based in whole or in part on the type of claim asserted herein;
- (c) Health care providers are excluded from the class as to defendant Astellas who have previously obtained a judgment; or settled any claims against the defendant concerning the type [of] claims asserted herein; or have previously executed releases releasing any such claims against the defendant; or who have signed any arbitration agreement with the defendant concerning settlement claims.

(Doc. # 116 at 25). Lakeland Regional also requests certification of a state subclass defined identically but limited to members located in the State of Florida.

After due consideration, the Court denies class certification.

II. Class Action Analysis

A. Legal Standard

As explained in Valley Drug Co. v. Geneva Pharms., Inc., 350 F.3d 1181, 1187 (11th Cir 2003), "Rule 23 establishes the legal roadmap courts must follow when determining whether class certification is appropriate." Under Rule 23(a), a class may be certified only if (1) the class is so numerous that joinder of all members would be impracticable; (2) there are questions of fact and law common to the class; (3) the claims or defenses of the representatives are typical of the claims and defenses of the unnamed members; and (4) the named representatives will be able to represent the interests of the class adequately and fairly. The burden of proof to establish the propriety of class certification rests with the advocate of the class, and failure to establish any one of the four Rule 23(a) factors and at least one of the alternative

requirements of Rule 23(b) precludes class certification. Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 615-18 (1997).²

This Court must conduct a "rigorous analysis" of the Rule 23 prerequisites before certifying a class. Gen. Tel. Co. of the S.W. v. Falcon, 457 U.S. 147, 161 (1982). See also Coopers & Lybrand v. Livesay, 437 U.S. 463, 469 (1978)("[T]he class determination generally involves considerations that are enmeshed in the factual and legal issues comprising the plaintiff's cause of action The more complex determinations required in Rule 23(b)(3) class actions entail even greater entanglement with the merits.")(internal citations omitted).

B. Standing to Assert Claim for Damages and Rule 23(b)(3)

"Any analysis of class certification must begin with the issue of standing." Griffin v. Dugger, 823 F.2d 1476, 1482

² Lakeland Regional seeks certification under Rules 23(b)(2) and (3). Subsection (2) is satisfied 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." Subsection (3) is satisfied if "the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."

(11th Cir. 1987). "Whether the named plaintiffs have standing to assert their claims is a threshold legal issue" that should be addressed prior to delving into the Rule 23(a) analysis of numerosity, commonality, typicality, and adequacy of representation. Hines v. Widnall, 334 F.3d 1253, 1256 (11th Cir. 2003).

Astellas asserts that the Motion for Class Certification should be denied because Lakeland Regional lacks standing to assert antitrust claims for money damages against Astellas under the holding of Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977). Even if the required elements of numerosity and commonality are satisfied, Lakeland Regional's claims cannot be "typical" of the class if Lakeland Regional lacks standing to pursue such claims. Likewise, Lakeland Regional cannot adequately represent the class as its representative if Lakeland Regional lacks standing.

Lakeland Regional's case rests on the position that it was overcharged for Astellas' Adenoscan product. However, Lakeland Regional's corporate representative, Linda Nelson, testified that Lakeland Regional has never purchased Adenoscan directly from Astellas; all purchases of Adenoscan were from two wholesalers. (Nelson Dep. at 13:22-14:8; 19:22-20:6; 25:11-16). Regardless of how Lakeland Regional has

characterized its claim, the crux of Lakeland Regional's damages claim is inevitably that Astellas charged the wholesalers excessively for Adenoscan, and the wholesalers passed the overcharge on to Lakeland Regional.

Lakeland Regional's "pass on" claim is precisely the kind addressed by and barred by Illinois Brick, 431 U.S. at 735. Pursuant to Illinois Brick, only direct purchasers may bring a claim for overcharges in the context of the antitrust laws, with only narrow exceptions that do not apply in this case. The Supreme Court reaffirmed the reasoning of Illinois Brick in Kansas v. Utilicorp United, Inc., 497 U.S. 199, 216 (1990), where the Court characterized Illinois Brick as a brightline rule barring pass-on claims by indirect purchasers. The Utilicorp case also held that only direct purchasers have standing to bring federal antitrust claims, even where the direct purchasers may pass the entire unlawful overcharge to downstream purchasers. 497 U.S. at 206-09.

It should be noted that in its July 25, 2011, Order denying Astellas' Rule 12(b)(6) motion to dismiss, this Court held that Illinois Brick did not bar Lakeland Regional's antitrust claims at the pleadings stage. (Doc. # 66). At that point in the proceedings, the Court's analysis was confined to the four corners of the Amended Complaint, and Lakeland

Regional's Amended Complaint contained allegations of direct purchase of Adenoscan from Astellas. In contrast, at the present juncture, the Court has before it the deposition testimony of Nelson, in which she clearly states that Lakeland Regional has never purchased Adenoscan directly from Astellas.³ This uncontested fact eviscerates Lakeland Regional's standing and its ability to meet the requirements of Rule 23(a). Lakeland Regional is not a direct purchaser and therefore has no antitrust standing to pursue damages claims against Astellas, as a class representative or otherwise.

A number of courts have come to the same conclusion in the context of cases in which health care providers desire to sue drug manufacturers for antitrust injuries, but purchase the relevant drugs and medical devices from third parties. See

³ In its prior Order at the motion to dismiss stage, the Court also noted that Lakeland Regional's claims may survive the Illinois Brick rule pursuant to Lowell v. American Cyanamid Co., 177 F.3d 1228 (11th Cir. 1999). In Lowell, the Eleventh Circuit reversed the district court's application of Illinois Brick to dismiss an antitrust action. The Eleventh Circuit reasoned, among other things, that because the complaint contained no allegations of "pass on" overcharges, the holding of Illinois Brick did not apply. At this juncture, Lakeland Regional's claims have been crystallized and the Court ascertains that Lakeland Regional does sue based on "pass on" overcharges. Accordingly, Lowell does not preclude application of the Illinois Brick rule in this case.

In re Hypodermic Prods. Antitrust Litig., No. 11-cv-3122, 2012 WL 1995047, at *4-5 (3d Cir. June 5, 2012)(reversing district court's finding that a health care provider was a direct purchaser of medical device when the record showed that the health care provider purchased the medical devices from a distributor and health care provider's claim was therefore barred by Illinois Brick); Warren Gen. Hosp. v. Amgen, Inc., 643 F.3d 77, 79-80 (3d Cir. 2011)(affirming dismissal of antitrust action pursuant to Illinois Brick when plaintiff hospital purchased drugs from a wholesaler, rather than directly from the antitrust defendant); Delaware Valley Surgical Supply, Inc. v. Johnson & Johnson, 523 F.3d 1116, 1122-24 (9th Cir. 2008)(affirming district court's application of Illinois Brick to find that a health care provider who purchased drugs from a third-party distributor did not have standing to pursue an antitrust claim against such drug manufacturer). The result here is no different.

As Lakeland Regional has not cleared the first hurdle by establishing its standing, the Court denies the Motion for Class Certification to the extent Lakeland Regional seeks to certify a class action pursuant to Rule 23(b)(3) for money damages.

C. Declaratory and Injunctive Relief and Rule 23(b)(2)

Lakeland Regional correctly asserts that its requests for declaratory and injunctive relief are not barred by the holding of Illinois Brick. See In re Beef Indus. Litig., 600 F.2d 1148, 1167 (5th Cir. Aug. 17, 1979) (“[T]he Illinois Brick rule has no application to claims for injunctive relief”).⁴ However, Lakeland Regional has not sufficiently briefed the Court as to the substance of its claims for declaratory and injunctive relief to justify class certification pursuant to Rule 23(b)(2). Lakeland Regional’s expert devotes all of his opinions to the damages claims and provides no comment on the impact of prospective injunctive or declaratory relief.

In its submissions to the Court concerning certification pursuant to Rule 23(b)(2), Lakeland Regional indicates that “we ask for certification under [Rule 23(b)(2)] in the event that we reach a point where only non-monetary claims remain” (Doc. # 144 at 13). The Court has, indeed, determined that only non-monetary claims remain. Yet, the Amended Complaint is silent as to the details of any requested

⁴ In Bonner v. City of Prichard, 661 F.2d 1206, 1209 (11th Cir. 1981), the Eleventh Circuit adopted all cases decided by the Fifth Circuit Court of Appeals prior to the close of business on September 30, 1981, as binding precedent.

injunctive or declaratory relief sought and asserts only a generic demand for injunctive and declaratory relief.

In its Motion for Class Certification, Lakeland Regional indicates that it seeks "declaratory and injunctive relief preventing Astellas from continuing to tie its method patent to the adenosine used in that method and from continuing to engage in conduct designed to maintain and attain monopoly power in the sale of adenosine and its adjuncts." (Doc. # 116 at 8). In addition, Lakeland Regional asserts that such relief *could* possibly include:

- (1) A declaration that Astellas' conduct, as set forth in Counts I through VI of the First Amended Complaint, is unlawful, in violation of Federal and state antitrust laws, and has caused injury to Lakeland Regional and the class members, and an accompanying order for Astellas to cease such conduct.
- (2) An order to provide and not contest access to and the use of the ['296 Patent] . . . without threat of litigation, and without the requirement to purchase any other product from Astellas, or not to purchase any other product from a competing seller.
- (3) An order declining and providing that Astellas must alternatively notify competing sellers of adenosine that [Lakeland Regional] and class members have the legal right to purchase adenosine from such competing sellers, without threat of litigation by Astellas against the adenosine sellers or [Lakeland Regional] and class members, including a release of any threatened claims by Astellas against [Lakeland Regional], class members, or adenosine sellers.

(Doc. # 116 at 13).

It appears that Lakeland Regional is still developing its theories regarding injunctive and declaratory relief. Lakeland Regional has presented only vague possibilities concerning non-monetary relief, rather than concrete examples supported by expert opinions or other evidence. Neither Lakeland Regional nor its expert has explained with any specificity how injunctive or declaratory relief will benefit the class absent the possibility of recovering money damages. "Rule 23(b)(2) applies only when a single, indivisible remedy would provide relief to each class member." Wal-Mart Stores v. Dukes, 131 S. Ct. 2541, 2545 (2011). Lakeland Regional has not met its burden.

Lakeland Regional has asserted that it seeks \$867 million in damages on behalf of the putative class. This Court agrees with Astellas that "this lawsuit is about the damages claim, and elevating an illusory injunction over a damages claim of \$867 million would be the tail wagging the dog." (Doc. # 138 at 24). The amorphous injunctive and declaratory relief sought appears to be completely incidental to the damages claim - a claim that this Court has determined Lakeland Regional lacks standing to pursue. In addition, the Court questions whether such relief, if granted, would benefit the

class because Astellas has asserted that any claims for injunctive relief will be moot as of October 2012, when a generic version of Adenoscan will be made available: "With or without this lawsuit, a generic version of Adenoscan will be on the market by October, 2012. As a result, the injunction [Lakeland Regional] seeks will become irrelevant long before such relief could ever be ordered by this Court." (Doc. # 138 at 24).

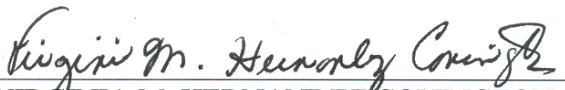
Accordingly, Lakeland Regional has not persuaded the Court that certification of a Rule 23(b)(2) class is appropriate. Based on the submissions before the Court, the Court denies the Motion for Class Certification.

Accordingly, it is

ORDERED, ADJUDGED, and DECREED:

Plaintiff Lakeland Regional's Motion and Brief in Support of Class Certification (Doc. # 116) is **DENIED**.

DONE and **ORDERED** in Chambers, in Tampa, Florida, this 24th day of September, 2012.


VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE

Copies to: All Counsel of Record