

United States District Court
District of Massachusetts

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Meijer, Inc. and Meijer)		
Distribution, Inc. on behalf of)		
themselves and all others)		
similarly situated,)		
)		
Plaintiffs,)	Civil Action No.	
)	15-11828-NMG	
v.)		
)		
Ranbaxy Inc. and Sun)		
Pharmaceutical Industries Ltd.,)		
)		
Defendants.)		
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MEMORANDUM & ORDER

GORTON, J.

This case involves a putative class action brought by plaintiffs Meijer, Inc. and Meijer Distribution, Inc., (jointly, "Meijer" or "plaintiffs") against Ranbaxy, Inc. and related entities ("Ranbaxy") and Sun Pharmaceutical Industries, Ltd. ("Sun Pharma") (jointly, "defendants") for antitrust and Racketeer Influenced and Corrupt Organizations Act ("RICO") violations.

In September, 2015, defendants filed a motion to dismiss for failure to state a claim pursuant to Fed. R. Civ. P. 12(b)(6), which was referred to United States Magistrate Judge M. Page Kelley for a Report and Recommendation ("R&R"). The R&R was filed with this session on June 16, 2016. It was accepted

and adopted whereby defendants' motion to dismiss was denied. On October 7, 2016, defendants filed a motion requesting that this Court certify that Order for interlocutory appeal. For the following reasons, the motion will be allowed.

I. Background

In May, 2015, plaintiffs brought this action on behalf of themselves and as representatives of a direct purchaser class. Their complaint contains four counts against defendants: violations of the Sherman Act, 15 U.S.C. § 2, (Counts I and II) and violations of RICO, 18 U.S.C. § 1962(c) and (d) (Counts III and IV, respectively).

In September, 2015, defendants moved to dismiss plaintiffs' allegations for failure to state a claim upon which relief can be granted, pursuant to Fed. R. Civ. P. 12(b)(6). They sought dismissal of plaintiffs' claims by asserting, inter alia, that the claims were precluded by the Federal Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 et. seq. In support of that proposition, defendants relied on the decision of the United States Supreme Court in Buckman Co. v. Plaintiff's Legal Comm., 531 U.S. 341 (2001) and 21 U.S.C. § 337(a).

In Buckman, the plaintiffs brought state-law tort claims against a consultant for injuries caused by orthopedic bone screws, alleging that the defendant made fraudulent representations to the Food and Drug Administration ("FDA") in

the course of obtaining approval to market the screws. 531 U.S. at 343. The Supreme Court found that federal law preempted state-law tort claims for fraud on the FDA. Id. at 349.

Here, defendants assert that Buckman should be read expansively to prohibit all claims predicated on fraud on the FDA, not just state-law claims. They note that the Supreme Court in Buckman focused on the explicit bar against private action in 21 U.S.C. § 337(a).

Furthermore, defendants emphasize the Supreme Court's reasoning that state-law fraud-on-the-FDA claims would conflict with and burden the FDA in ways not contemplated by Congress. They contend that this rationale is applicable regardless of whether the claims are based on state or federal law. By their reading, the key distinction in Buckman is between private litigants and the federal government, not the underlying source of the claims.

In January, 2016, this Court referred the motion to dismiss to Magistrate Judge M. Page Kelley. After hearing, she entered a R&R, recommending that the motion be allowed on all counts against Ranbaxy Laboratories Limited and Ranbaxy USA, Inc. Plaintiffs did not oppose that dismissal. Magistrate Judge Kelley also recommended that the motion to dismiss be denied as to all counts against Ranbaxy and Sun Pharma. On September 7, 2016, after considering the parties' objections, this session

accepted and adopted the R&R, granting, in part, and denying, in part, defendants' motion to dismiss.

In accepting and adopting the R&R, this Court concluded that plaintiffs' Sherman Act and RICO claims against Ranbaxy and Sun Pharma ought to proceed. Although their claims presented a matter of first impression for which Supreme Court precedent was not precisely on point, this Court found that the Sherman Act and RICO claims were not precluded by the FDCA under Buckman's preemption analysis. Instead, the Court agreed with plaintiffs and applied POM Wonderful LLC v. Coca-Cola Co., 134 S.Ct. 2228 (2014).

In POM, the Supreme Court analyzed the overlap of the Lanham Act, 15 U.S.C. § 1125, and the FDCA as a matter of statutory interpretation not preclusion. POM Wonderful LLC, 134 S.Ct. at 2236. It noted that

when two statutes complement each other, it would show disregard for the congressional design to hold that Congress nonetheless intended one federal statute to preclude the operation of the other.

Id. Accordingly, in this case, after finding that the relevant statutes do not conflict and that plaintiff appropriately alleged violations of the Sherman Act and RICO, defendants' motion to dismiss was denied.

Defendants now move this Court to certify to the First Circuit Court of Appeals ("First Circuit") whether 21 U.S.C.

§ 337(a) and the Supreme Court's decision in Buckman preclude plaintiffs' fraud-on-the-FDA RICO and antitrust claims.

II. Legal Analysis

A. Legal Standard

District courts may certify an otherwise non-appealable order for interlocutory review by the Court of Appeals if the order 1) involves a controlling question of law 2) as to which there are grounds for a substantial difference of opinion and 3) an immediate appeal would materially advance the ultimate termination of the litigation. 28 U.S.C. § 1292(b); Carabello-Seda v. Municipality of Hormigueros, 395 F.3d 7, 9 (1st Cir. 2005). Generally, the First Circuit will not certify interlocutory appeals from a denial of a motion dismiss. Carabello-Seda, 395 F.3d at 9. Interlocutory appeals may be necessary, however, "in long-drawn-out cases, such as antitrust and conspiracy cases." Milbert v. Bison Lab., 260 F.2d 431, 433 (3rd Cir. 1958) (citing House Report No. 1667, 85 Cong. 2d Sess., pp. 1, 2).

B. Application

1. Controlling Question of Law

A question of law is "controlling" if reversal would terminate the action. Phillip Morris Inc. v. Harshbarger, 957 F. Supp. 327, 330 (D. Mass. 1997). Such questions typically implicate a pure legal principle that can be resolved without

extensive consultation to the record. S. Orange Chiropractic Ctr., LLC v. Cayan LLC, No. 15-13069, 2016 WL 3064054, at *2 (D. Mass. May 31, 2016).

Here, all of plaintiffs' claims are predicated on fraud on the FDA. If the First Circuit finds those claims precluded by the FDCA, they will be dismissed, thereby terminating the action. Resolution of the preclusion question is therefore "controlling". See Philip Morris, 957 F. Supp. at 330 (finding this element satisfied where a reversal by the Court of Appeals would likely terminate the action).

Moreover, the First Circuit can make such a determination with minimal review of the factual record because it only requires statutory and case law interpretation. See Ahrenholz v. Bd. of Tr. of Univ. of Ill., 219 F.3d 674, 676 (7th Cir. 2000) (concluding that "question of law" refers to "a question of the meaning of a statutory or constitutional provision, regulation, or common law doctrine").

2. Materially Advance the Termination of Litigation

The requirement that an appeal will materially advance the ultimate termination of the litigation is "closely tied" to the controlling-question-of-law element. Philip Morris, 957 F. Supp. at 330. This condition is satisfied if reversal of the Court's decision advances the termination of the litigation. United Air Lines, Inc. v. Gregory, 716 F. Supp. 2d 79, 92 (D. Mass. 2010).

As explained above, if the First Circuit decides that the rationale underlying Buckman also precludes federal claims alleging fraud on the FDA, the present case would be terminated.

3. Substantial Ground for a Difference of Opinion

A substantial ground for a difference of opinion arises where an issue involves "one or more difficult and pivotal questions of law not settled by controlling authority." Phillip Morris Inc., 957 F. Supp. at 330 (quoting McGillicuddy v. Clements, 746 F.2d 76, 76 n.1 (1st Cir. 1984)). The issue must involve a legal principle rather than an application of a legal principle to a unique set of facts. United Air Lines Inc., 716 F. Supp. 2d at 92.

As far as this Court can discern, this is the first time a party has brought antitrust claims predicated on fraud on the FDA. The viability of such claims raises a question not precisely controlled by precedent. Defendants rely on Buckman which is arguably distinguishable from this matter because the Supreme Court found plaintiffs' state-law claims preempted by the FDCA. See Buckman, 531 U.S. at 353. Here, state law is not implicated. The question is whether the FDCA, a federal statute, precludes claims based on two other federal statutes, the Sherman Act and RICO.

Although, plaintiffs rely on POM, which address the intersection of two federal statutes as a matter of statutory

interpretation, the Supreme Court in POM makes no explicit reference to Buckman, the case does not involve fraud on the FDA and it does not address the scope of 21 U.S.C. § 337(a). See generally POM Wonderful, 134 S.Ct. 2228. The issue raised by defendants in their motion to dismiss is sufficiently novel and not necessarily resolved under the onerous McGillicuddy standard. See Phillip Morris Inc., 957 F. Supp. at 330 (granting interlocutory appeal where a new statute and the question of its preemption had not yet been resolved).

Preemption has been recognized as “naturally appropriate” for interlocutory review. Id. And preclusion, like preemption, addresses important questions of federal law and policy as to competing legislative goals. Accordingly, the preclusion question here raises the kind of issue suitable for interlocutory review. See id.

Finally, defendants point to this Court’s decision in United Air Lines, asserting that there are no substantial grounds for a difference of opinion. In that case, this Court found that the movants challenged the application of a well-settled legal standard to a novel set of facts. United Air Lines Inc., 716 F. Supp. 2d at 92. Concluding that such a question did not present a unique or pivotal question of law, this Court declined to allow interlocutory review. In contrast, here the question is which legal principle applies: a broad reading of

Buckman that prohibits fraud-on-the-FDA claims based on federal statutes or a narrow reading that restricts its holding to state-law fraud-on-the-FDA claims. Unlike the issue in United Air Lines, this is squarely a legal question, which, for the reasons already stated, is appropriate for interlocutory review.

ORDER

For the foregoing reasons, defendants' motion (Docket No. 103) to certify this Court's September 7, 2016 Order for interlocutory appeal (Docket No. 80) is **ALLOWED**.

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated March 28, 2017