NOT RECOMMENDED FOR FULL-TEXT PUBLICATION
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Nos. 08-5573, 08-5574, 08-5575

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

FILED
Nov 24, 2009
LEONARD GREEN, Clerk

In re: AREDIA AND ZOMETA PRODUCTS LIABILITY LITIGATION,	)	
PATRICIA FRAGOMELI, FRANK BIOCCA, AND JACK CUTHBERT,	)	
Plaintiffs-Appellants,	)	ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE
v.	)	
NOVARTIS PHARMACEUTICALS CORPORATION,	)	
Defendant-Appellee.	)	

Before: MARTIN, COLE, and KETHLEDGE, Circuit Judges.

KETHLEDGE, Circuit Judge. Patricia Fragomeli, Frank Biocca, and Jack Cuthbert ("Plaintiffs") appeal the district court's order granting summary judgment in favor of Novartis Pharmaceuticals Corporation ("NPC") and denying their motion for additional discovery. We affirm.

I.

Plaintiffs' suits are part of multi-district litigation, *In re Aredia & Zometa Products Liability Litigation*, involving claims that the FDA-approved drugs Aredia and Zometa cause osteonecrosis of the jaw ("ONJ"), a disease that results in bone-tissue deterioration. Biocca and Cuthbert filed their suits in the Southern and Eastern Districts of New York in 2006, and Fragomeli filed hers in

the Middle District of Tennessee. In April 2006, the Judicial Panel on Multidistrict Litigation transferred *Biocca* and *Cuthbert* to the Middle District of Tennessee for coordinated-pretrial proceedings with other Aredia and Zometa suits. Plaintiffs were all Michigan citizens when they filed suit against NPC.

NPC thereafter moved for summary judgment, arguing that Plaintiffs' claims were preempted. Plaintiffs opposed NPC's motion and moved for additional discovery under Federal Rule of Civil Procedure 56(f). The district court granted NPC's summary-judgment motion and dismissed Plaintiffs' Rule 56(f) motion as futile.

This appeal followed.

II.

We review a district court's grant of summary judgment *de novo*. *Beecham v. Henderson County*, 422 F.3d 372, 374 (6th Cir. 2005). Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

Michigan law generally immunizes a drug manufacturer from liability for FDA-approved drugs unless the manufacturer intentionally withholds or misrepresents information that would have led the FDA to deny approval or withdraw the drug. Mich. Comp. Laws. § 600.2946(5)(a). Plaintiffs sued under this fraud-on-the-FDA exception, alleging that NPC withheld or misrepresented information about ONJ after the FDA had approved Aredia and Zometa. In this circuit, the federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq*., preempts such claims, unless some federal

agency has already found the requisite fraud on the FDA. *See Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 966 (6th Cir. 2004). There is no such finding here.

But Plaintiffs argue that *Garcia* is distinguishable for two reasons. First, they contend they have merely brought common-law claims that rely on fraud on the FDA to defeat an affirmative defense, rather than an affirmative claim based on such fraud. And second, they contend that *Garcia* is inapplicable to claims arising from *post*-approval fraud. Per *Garcia's* plain terms, however, both distinctions are beside the point: "[S]tate tort remedies requiring proof of fraud committed against the FDA are foreclosed since federal law preempts such claims." *Id.* at 966 (quotation marks and citation omitted). Plaintiffs' claims undisputedly require proof of fraud committed against the FDA. Plaintiffs have no federal finding to that effect. Under this circuit's binding precedent, therefore, Plaintiffs' claims are preempted.

Plaintiffs also argue that the district court erred in denying their Rule 56(f) motion for additional discovery. We review the denial of that motion for an abuse of discretion. *See Lewis v. ACB Bus. Servs., Inc.*, 135 F.3d 389, 409 (6th Cir. 1998). A court does not abuse its discretion in denying a Rule 56(f) motion if further discovery cannot remedy legal or factual deficiencies in the movant's claims or defenses. *CenTra, Inc. v. Estrin*, 538 F.3d 402, 420 (6th Cir. 2008).

Here, plaintiffs sought further discovery of NPC and FDA records related to Aredia and Zometa. In light of *Garcia*, that discovery would be futile. The district court did not abuse its discretion, therefore, in denying the Rule 56(f) motion.

The judgment of the district court is affirmed.