**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**TAMPA DIVISION**

RUTH DOPSON-TROUTT et al.,

Plaintiffs,

vs. Case No.: 8:06-CV-1708-T-24-EAJ

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.
_____/

**ORDER**

This cause comes before the Court on Defendant Novartis Pharmaceuticals Corporation ("Novartis")'s Motion for Judgment as a Matter of Law. (Dkt. 276.) Plaintiff Ruth Dopson-Troutt opposes. (Dkt. 282.) The Court orally granted in part and denied in part the motion in open court on April 8, 2014. The purpose of this order is to clarify and elaborate on the Court's oral pronouncements.

## I. BACKGROUND

Plaintiff was diagnosed with breast cancer, which later metastasized to her hip and pelvic bones. Her oncologist, Dr. Arthur Feldman, prescribed Aredia and Zometa, which are bisphosphonate drugs that Novartis produced, sold, and marketed. From 1999 to 2005, Plaintiff was infused with Aredia and/or Zometa, with her last Zometa infusion occurring on May 12, 2005. Plaintiff had her tooth extracted sometime in 2004, after which she began experiencing jaw pain she attributed to osteonecrosis of the jaw ("ONJ").

This case went to trial beginning on March 24, 2014 on Plaintiff's negligent failure to warn claim (count III) and breach of express warranty claim (count IV).[1] As to the express warranty claim, Plaintiff's complaint alleged that Novartis breached an express warranty because Aredia and Zometa were "not safe and were unfit for the uses for which they were intended." (*Id*.) Plaintiff's proposed jury instructions, however, claimed that Novartis breached an express warranty because Novartis failed to provide an adequate warning. (Dkt. 195 at 10, 16.) The Court asked Plaintiff to identify the specific express warranty allegedly breached. (Dkt. 223.) In response, Plaintiff claimed the express warranty was that the drugs would strengthen bones:

> Novartis warranted that **the effect of its drugs Aredia and Zometa was to strengthen bones, not to weaken them**. That is their "fit and proper use" referenced in Plaintiff's Complaint. *See* Complaint, ¶ 39. This was the warranty relied upon by Mrs. Dopson-Troutt and her healthcare provider. *Id.*, ¶ 40. At her deposition Mrs. Dopson-Troutt explained she was told exactly what is in Novartis packaging, namely that Aredia strengthens bones not weakens them. *See* Deposition of Ruth Dopson-Troutt, Vol. 1, 112:12-24 (Jul. 20, 2011) (excerpt attached hereto as Exhibit B). In these cases, fact bound as the Supreme Court noted common law is, the drug did the *exact opposite* of what it was claimed to do.

(Dkt. 226.)

## II. LEGAL STANDARD

Under Rule 50, a court should render judgment as a matter of law when there is no "legally sufficient evidentiary basis" for a reasonable jury to find for that party on that issue. Fed. R. Civ. P. 50. The court must view the facts in the light most favorable to the non-movant. *Wideman v. Wal-Mart Stores*, 141 F.3d 1453, 1454 (11th Cir. 1998).

[1] On April 9, 2014, the jury returned a verdict for Novartis on the negligent failure to warn claim. (Dkt. 287.)

## III. BREACH OF EXPRESS WARRANTY CLAIM[2]

Novartis moved for judgment as a matter of law as to Plaintiff's breach of express warranty claim, arguing that: (1) the claim is barred as a matter of Pennsylvania law; and (2) Plaintiff presented no evidence that Novartis provided an express warranty. The Court denied Novartis' motion to the extent it argued the claim was barred as a matter of Pennsylvania law but granted it on the substantive argument that there was insufficient evidence presented by Plaintiff on which a jury could find for Plaintiff on the breach of express warranty claim.

### A. Pennsylvania law does not bar breach of express warranty claims against pharmaceutical drug manufacturers.

Novartis argued first that Pennsylvania law bars breach of express warranty claims against pharmaceutical drug manufacturers. Novartis' argument is based on its interpretation of the Pennsylvania Supreme Court's decision in *Hahn v. Richter,* 673 A.2d 888 (Pa. 1996), where the court was presented with a failure-to-warn claim, and explained that "where the adequacy of warnings associated with prescription drugs is at issue . . . the manufacturer's negligence, is the only recognized basis of liability." *Id.* at 891. Novartis contends *Hahn* means that pharmaceutical drug manufacturers can only be held liable under a theory of negligence.

Federal district courts in Pennsylvania are split on this issue. *See Doughtery v. C.R. Bard, Inc.*, 2012 WL 2940727, at *8 (E.D. Pa. July 18, 2012) (collecting cases); *Tatum v. Takeda Pharm. N. Am., Inc.*, 2012 WL 5182895, at *3 (E.D. Pa. Oct. 19, 2012). Some district courts have concluded that Pennsylvania bars express warranty claims against pharmaceutical drug manufacturers. *See Salvio v. Amgen, Inc.*, 810 F. Supp. 2d 745, 755-56 (W.D. Pa. 2011) (collecting cases). These courts, like Novartis, read *Hahn* broadly to mean that Pennsylvania law bars all non-negligence claims against prescription drug manufacturers. *Id.*

[2] The Court previously held that Pennsylvania law governs this diversity action. (Dkt. 110.)

Other district courts have reached the opposite conclusion, finding that nothing in *Hahn* bars a breach of express warranty claim against prescription drug manufacturers. *Doughtery,* 2012 WL 2940727, at *9; *Tatum*, 2012 WL 5182895, at *3. Specifically, the issue in *Hahn* was whether a failure to warn claim was based on a theory of strict liability or negligence. The *Hahn* court did not consider other theories of liability, such as the contractual theory underlying a breach of express warranty claim. The Court agreed with the reasoning of those latter courts, and denied Novartis' Rule 50 motion on this basis.

**B. There was no evidence that an express warranty was created or breached.**

Secondly, Novartis contended Plaintiff presented no evidence that Novartis provided an express warranty that Aredia and Zometa would strengthen bones, not weaken them. In arguing that "Novartis warranted its drugs to strengthen bones, not to weaken them," (Dkt. 282 at 19), Plaintiff identified a statement in the "Clinical Pharmacology" section of the package inserts[3] for Aredia and Zometa.[4] As for Aredia's package insert, Plaintiff identified the statement—"In animal studies, at doses recommended for the treatment of hypercalcemia, Aredia inhibits bone resorption apparently without inhibiting bone formation and mineralization"—which appears in the following section of the package insert:

> The principal pharmacologic action of Aredia is inhibition of bone resorption. Although the antiresorptive mechanism is not completely understood, several factors are thought to contribute to this action. Aredia adsorbs to calcium phosphate (hydroxyapatite) crystals in bone and may directly block dissolution of this mineral component of bone. In vitro studies also suggest that inhibition *of* osteoclast activity contributes to inhibition of bone resorption. **In animal studies, at doses recommended for the treatment of hypercalcemia, Aredia inhibits bone resorption apparently without inhibiting bone formation and mineralization**. Of relevance to the treatment of hypercalcemia of malignancy

[3] For the purpose of Novartis' Rule 50 motion on Plaintiff's breach of express warranty claim, the terms "package insert," "label," and "prescribing information," were used interchangeably and had the same meaning.

[4] Plaintiff had not identified these statements as the alleged warranty during this case until her written response in opposition to Novartis' Rule 50 motion.

> is the finding that Aredia inhibits the accelerated bone resorption that results from osteoclast hyperactivity induced by various tumors in animal studies.

PX-2000A at 2 (Aredia April 1999 label) (emphasis added). As for Zometa, Plaintiff identified the statement—"Zoledronic acid also blocks the osteoclastic resorption of mineralized bone and cartilage through its binding to bone"—in the following section of the package insert:

> The principal pharmacologic action of zoledronic acid is inhibition of bone resorption. Although the antiresorptive mechanism is not completely understood, several factors are thought to contribute to this action. *In vitro,* zoledronic acid inhibits osteoclastic activity and induces osteoclast apoptosis. **Zoledronic acid also blocks the osteoclastic resorption of mineralized bone and cartilage through its binding to bone**. Zoledronic acid inhibits the increased osteoclastic activity and skeletal calcium release induced by various stimulatory factors released by tumors.

PX-2000G at 1 (Zometa March 2004 label) (emphasis added); PX-2000F at 1 (Zometa Sept. 2003 label) (emphasis added).

Based on those statements, Plaintiff contended Novartis stated that the drugs would provide "bone mineralization," which in turn constituted an express warranty that the drugs would strengthen bones, not weaken them. Plaintiff argued that Plaintiff's testimony and the records of the prescribing physician, Dr. Feldman, showed they relied on an express warranty that the drugs would strengthen bones, not weaken them.[5]

To prevail on a claim for breach of warranty under Pennsylvania law, Plaintiff must prove that: (1) an express warranty was created; (2) a breach of warranty occurred; and (3) the breach was the cause of the specific damages sustained. *Yurcic v. Purdue Pharma, L.P.*, 343 F. Supp. 2d 386, 394 (M.D. Pa. 2004) (citing *Price v. Chevrolet Motor Div. of Gen. Motors Corp*., 765 A.2d 800, 809 (Pa. Super. Ct. 2000)). Pennsylvania's Uniform Commercial Code provides that a seller may create express warranties as follows:

[5] Dr. Feldman did not testify in the trial and his records were destroyed in the flood. However, a small number of his records had been forwarded to Dr. Jude Pierre, a treating physician in Florida, and introduced through that witness.

> (1) Any affirmation of fact or promise made by the seller which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
>
> (2) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

13 Pa. Cons. Stat. § 2313(a). To satisfy the "basis of the bargain" requirement, Plaintiff must prove that she "read, heard, saw or knew" the statement she alleges constituted a warranty. *Cipollone v. Liggett Grp., Inc.*, 893 F.2d 541, 567 (3d Cir. 1990), *rev'd on other grounds*, 505 U.S. 504 (1992); *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 574 (E.D. Pa. 2011).

The Court found no legally sufficient evidentiary basis from which a reasonable jury could find that Novartis created an express warranty that Aredia and Zometa strengthens bones, not weakens them. Plaintiff provided no evidence, expert testimony or otherwise, that the statements in the drugs' package insert regarding "bone mineralization" amounted to an affirmation of fact, promise, or description that Aredia and Zometa will "strengthen bones," not weaken them. In fact, Plaintiff never even identified these statements as the express warranty until her written response to Novartis' Rule 50 motion. Although some of Dr. Feldman's records (from Plaintiff's follow-up visits on the remission of her metastatic breast cancer) indicate that the purpose of prescribing the drugs was to maintain "bone mineralization," no evidence was presented by Dr. Feldman, by expert witnesses, or by any witness that Dr. Feldman read and understood the package insert's statements regarding bone mineralization to be a warranty that the drugs would strengthen bones. And while Plaintiff testified that she understood the drugs would strengthen her bones, no evidence connected her understanding to the package insert's statements regarding bone mineralization.

Even if the Court were to have assumed that the statements regarding bone mineralization constituted an express warranty, Plaintiff did not prove the express warranty was breached. Plaintiff identified no evidence establishing that Aredia, in fact, does not inhibit bone resorption

without inhibiting bone mineralization (as it "apparently" did in animal trials at doses recommended for treatment of hypercalcemia) or that Zometa does not block "osteoplastic resorption of mineralized bone."

The record lacks any evidence from which a reasonable jury could find that Novartis created, and breached, an express warranty. Accordingly, the Court granted Novartis' motion for judgment as a matter of law as to Plaintiff's breach of express warranty claim.

**DONE** and **ORDERED** at Tampa, Florida, this 11th day of April, 2014.

Susan C. Bucklew

SUSAN C. BUCKLEW
United States District Judge

Copies to: Counsel of Record