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No. 09-6273

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

TRINA EMERSON, substituted on behalf of Tim Crews, deceased,

Plaintiff-Appellant,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE

_____/

Before: MARTIN, BOGGS, and COOK, Circuit Judges.

BOYCE F. MARTIN, JR., Circuit Judge. Trina Emerson appeals the district court's grant of summary judgment in favor of Novartis Pharmaceuticals Corporation. The district court held that Emerson failed to rebut Florida's statutory presumption that because Zometa and Aredia were properly approved by the Food and Drug Administration, they were not defectively dangerous. While the voluminous record may have contained some evidence that might have created a material question of fact sufficient to rebut this presumption and defeat Novartis's motion for summary judgment, Emerson failed to specifically identify and argue those facts to the district court. Because the only arguments Emerson made were not relevant to rebutting this statutory presumption, we **AFFIRM** the district court's grant of summary judgment.

I.

This case arises out of a series of lawsuits filed by individuals who developed osteonecrosis of the jaw, a severe bone disease affecting the jaw, allegedly as a result of taking Zometa and Aredia. Zometa and Aredia are prescription bisphosphonate[1] drugs produced by Novartis that are given intravenously most often to patients with cancerous conditions. The drugs are effective at preventing pathological fractures, spinal cord compression, and other bone pains. Although the Food and Drug Administration approved both drugs, many individuals claim to have developed osteonecrosis of the jaw as a result of receiving this medication. Osteonecrosis of the jaw results in the gums being eaten away until the bone is exposed.

Emerson is the surviving adult daughter and personal representative of Tim Randall Crews, who filed suit against Novartis after developing osteonecrosis of the jaw. Crews initially filed this lawsuit in the Middle District of Florida, and the Judicial Panel on Multidistrict Litigation transferred the case to the Middle District of Tennessee for consolidated pretrial proceedings.

The district court granted Novartis's motion for summary judgment on the basis of Florida's government-rules defense, which provides a rebuttable presumption that certain products that have received proper regulatory approval are not defectively dangerous. Although the district court denied Novartis's litigation-wide motion for summary judgment, it found that Emerson had not rebutted this presumption because her only arguments were preempted.

II.

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[1]Bisphosphonates are a class of drugs that derive their name from their chemical structure, which contains two phosphonate groups (PO_3) covalently bonded to a carbon atom.

A. Summary Judgment Standard.

"We review the district court's grant of summary judgment de novo." *Stansberry v. Air Wisconsin Airlines Corp.*, – F.3d —, No. 09-2499, 2011 WL 2621901, at *3 (6th Cir. July 6, 2011) (citing *Bentkowski v. Scene Magazine*, 637 F.3d 689, 693 (6th Cir. 2011). Summary judgment is appropriate where the pleadings, depositions, answers to interrogatories, admissions on file, and affidavits show "that there is no genuine dispute as to any material fact and that the movant is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(a). "The moving party has the initial burden of proving that no genuine issue of material fact exists," and the court must draw all reasonable inferences in the light most favorable to the nonmoving party. *Vaughn v. Lawrenceburg Power Sys.*, 269 F.3d 703, 710 (6th Cir. 2001). When a motion for summary judgment is properly made and supported and the nonmoving party fails to respond with a showing sufficient to establish an essential element of its case, summary judgment is appropriate. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986).

Rule 56 places an affirmative duty on the nonmovant to cite to "particular parts of materials in the record" to establish that a particular fact cannot be supported or is genuinely disputed. Fed. R. Civ. P. 56(c)(1); *see Chicago Title Ins. Corp. v. Magnunson*, 487 F.3d 985, 995 (6th Cir. 2007). District courts need not independently comb through the record and establish that it is bereft of a genuine issue of material fact before granting summary judgment. *Chicago Title Ins.*, 487 F.3d at 995; *Street v. J.C. Bradford & Co.*, 886 F.2d 1472, 1479-80 (6th Cir. 1989). Although we review a district court's decision granting or denying summary judgment de novo, we generally will not

consider facts that were not brought to the district court's attention. *Chicago Title Ins.*, 487 F.3d at 995; *Guarino v. Brookfield Twp. Trs.*, 980 F.2d 399, 404 (6th Cir. 1992).

B. Whether Emerson Rebutted the Statutory Presumption That Zometa is Not Defectively Dangerous.

Florida has adopted a government-rules defense, which creates a rebuttable presumption that certain products are not defective or unreasonably dangerous. Fla. Stat. Ann. § 768.1256 (West 2010). The statute provides that:

> (1) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm:
>
> (a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury;
>
> (b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and
>
> (c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product.

The parties do not dispute that Novartis is entitled to this presumption that Zometa and Aredia are not defective or unreasonably dangerous. What this presumption actually entails is another story. Florida's statute has not yet been thoroughly interpreted, and the contours and operation of the presumption are still largely unsettled. However, the district court did not need to interpret this area of state law because it held that Emerson's only arguments were preempted. We agree and also do not need to interpret this statute or determine how the presumption operates.

In her brief to the district court, Emerson argued that Novartis was not entitled to the benefit of Florida's statutory presumption because it had defrauded the Food and Drug Administration to gain regulatory approval. However, this type of "fraud-on-the-agency" claim is preempted by federal law. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347 (2001). Therefore, regardless of the intricacies of Florida's statutory presumption, this argument is not sufficient to rebut the presumption that Zometa and Aredia are not defective or unreasonably dangerous.

While Emerson attempted to incorporate facts and arguments from other cases and litigation-wide filings in this multidistrict litigation, she failed to do so with any particularity or develop arguments as to how these materials bore on Florida's statutory presumption. In her briefing before the district court, Emerson began by stating that she adopted "the memorandums of law and fact, expert witnesses' testimony and reports, and the entirety of the case wide discovery and pleadings, as if each were specifically set forth in this Memorandum." Although a party may incorporate other documents by reference, and there are circumstances when it may be expeditious and appropriate to do so, parties still must comply with their duties under Rule 56. Specifically, a party opposing a motion for summary judgment must "cit[e] to particular parts of materials in the record," or show that the facts cited by the movant do not establish the absence of a genuine dispute. Fed. R. Civ. P. 56(c)(1)(A). At the time Emerson filed her brief in district court, the multidistrict litigation contained 2,530 separate docket entries. Many of these entries contained numerous exhibits, and we cannot begin to speculate how many pages Emerson's brief attempted to incorporate. In contrast to the requirements in Rule 56, Emerson's attempt to incorporate this mountain of evidence by

reference fails to identify particular documents in the record, let alone "particular parts of materials in the record."

Based on the district court's other decisions in this litigation, it appears that there might have been evidence in the record sufficient to rebut the presumption and create a material question of fact as to whether Zometa is dangerously defective. However, it was not the district court's duty to track down those facts. The district court denied Novartis's litigation-wide motion for summary judgment, which was made on the basis that it had adequately warned of the risk, holding that there were "a myriad of factual issues." Additionally, in a later case that is part of the same Multidistrict Litigation, the district court denied a motion for summary judgment, holding that, while Novartis is entitled to Florida's statutory presumption that Zometa and Aredia are not defective, the plaintiff identified, in that case, evidence in the record that created a material question of fact as to whether the presumption had been rebutted. 2010 WL 813459, at *1-2 (M.D. Tenn. March 3, 2010). Specifically, the district court distinguished its earlier ruling in Emerson's case, explaining that Emerson had "argued solely that any FDA approvals of Aredia or Zometa were obtained improperly." *Id.* (commenting that the *Emerson* "ruling was limited to the argument asserted by [Emerson] and, therefore, is not preclusive of these Plaintiffs' claims"). The district court's other decisions in these related cases suggest that it might have decided this issue differently if it had been presented with briefing that identified these factual disputes with particularity and contained specific citations to particular portions of the record instead of preempted arguments. However, it was Emerson's job to identify this evidence and craft these arguments and not the district court's.

Because she failed to do so, the district court properly granted summary judgment in favor of Novartis.

Particularly because the district court was faced with a large number of these cases, each with its own complicated legal and factual issues, the district court cannot be faulted for not doing the work of plaintiff's counsel and undertaking a detailed review of the entire record. A district court is not required to "search the entire record to establish that it is bereft of a genuine issue of material fact." *Street*, 886 F.2d 1472, 1479-80. "[J]udges are not like pigs, hunting for truffles" that might be buried in the record. *United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991). The district court considered the arguments that Emerson made and determined that those arguments were preempted and, therefore, insufficient to rebut the statutory presumption. The district court did not need to independently consider whether there were any other arguments or facts that Emerson could have cited to that might have been sufficient to defeat Novartis's summary judgment motion. Similarly, the materials that Emerson attempted to incorporate by reference also do not rebut the statutory presumption because she failed to specifically identify anything in those materials or explain how those materials rebutted Florida's statutory presumption. Therefore, based on the arguments that Emerson presented to the district court, it did not err by granting summary judgment in favor of Novartis.

III.

Emerson's primary argument to overcome the Florida statutory presumption and defeat Novartis's motion for summary judgment was based on a preempted fraud-on-the-agency claim. While Emerson asserted that she was incorporating other materials, this blanket incorporation

without specifically identifying any individual facts or how they operate in conjunction with the presumption is insufficient to defeat Novartis's motion for summary judgment. The district court need not identify arguments and facts that she failed to raise in her briefing. Accordingly, the district court's grant of summary judgment in favor of Novartis is **AFFIRMED**.