IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
January 25, 2011

Lyle W. Cayce
Clerk

No. 10-20022

RONALD FUNK,

Plaintiff - Appellant

v.

STRYKER CORPORATION; STRYKER SALES CORPORATION; HOWMEDICA OSTEONICS CORP., doing business as Stryker Orthopaedics,

Defendants - Appellees

Appeal from the United States District Court
for the Southern District of Texas

Before JOLLY, DeMOSS, and DENNIS, Circuit Judges.

E. GRADY JOLLY, Circuit Judge:

In this medical device products liability case, Ronald Funk appeals the district court's judgment granting Stryker Corporation's ("Stryker") Rule 12(b)(6) motion to dismiss for failure to state a claim that overcomes a preemption defense. Before us on appeal, the relevant pleadings asserted are Funk's first amended complaint and a proposed second amended complaint, which the court denied leave to file. He did not appeal that order. Thus the only complaint before us is Funk's first amended complaint. Based upon the issues over which we have appellate jurisdiction, we hold that the district court committed no error

in assessing Funk's pleadings, nor in its application of judicial notice. Accordingly, we affirm the district court's dismissal of the case.

I.

On March 26, 2007, Ronald Funk underwent a total hip replacement during which his surgeon implanted a Trident System artificial hip replacement ("Trident"). Stryker produces Trident, which is comprised of several component parts, including an: acetabular cup, ceramic liner, ceramic femoral ball, and femoral stem. Following surgery, Funk experienced ongoing pain in his right hip. His surgeon attributed Funk's pain to loosening of the acetabular cup, caused by a lack of boney ingrowth that would ordinarily secure the device to his hip. Funk underwent another surgery to remove and replace the loose cup, apparently successfully as far as this record shows.

Trident is a Class III device under the Federal Food, Drug, and Cosmetic Act (the "FFDCA"). Section 360 of the Medical Device Amendments of 1976 prohibits states from establishing "safety or effectiveness" standards that are "different from, or in addition to" the requirements under the FFDCA. 21 U.S.C. § 360. Section 360 preemption only applies to Class III devices approved through the Food and Drug Administration's (the "FDA") pre-market approval ("PMA") process, rather than the less-rigorous § 510(k) approval process. Still, however, § 360 allows "parallel" state actions – state law claims that are based on federal regulations. Trident received PMA on February 3, 2003; a question Funk attempts to present here, however, is whether the PMA process applied to one of the Trident's component parts, the acetabular cup.[1]

[1] This opinion does not address whether the independent components of Trident - including the acetabular cup - underwent PMA. For jurisdictional reasons outlined below, that issue is not properly before the court.

II.

On December 13, 2009, the district court granted Stryker's Rule 12(b)(6) motion to dismiss, finding that Funk failed to state a claim upon which relief could be granted (the "December Judgment"). Based upon the first amended complaint and the responsive pleadings, the district court held that Trident underwent PMA, and that Funk's design defect claims were therefore preempted by § 360. To reach this holding, the court took judicial notice of a letter from the FDA to Stryker indicating that Trident underwent the PMA process, noting that the approval process was a matter of public record. The district court held that finding that Trident received PMA was consistent with both parties' pleadings. Finally, the court noted that many district court cases addressing preemption claims indicated that Trident underwent the PMA process.[2] On these bases, the court held that Trident underwent PMA approval, that Funk's claims were preempted, and that the complaint failed to state a claim upon which relief could be granted. The court therefore dismissed Funk's complaint.

After the district court entered its judgment, Funk appealed to this court. Almost simultaneously with his appeal of the December Judgment, he also filed a motion for reconsideration with the district court, along with a motion for leave to file a proposed second amended complaint. The district court denied both of these motions on January 13, 2010 ("the January Order"). Funk did not file a notice of appeal with respect to the January Order; nor did he amend his earlier notice to include the January Order, as is required by Federal Rule of Appellate Procedure Rule 4(a)(4)(B)(ii).[3]

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[2] We do not evaluate this finding.

[3] After oral arguments, we asked the parties to provide letter briefs addressing appellate jurisdiction over claims pled after the December Judgment.

III.

A.

At the outset, we will summarize our holding today, which affirms the district court's dismissal of Funk's complaint for failure to state a claim: (1) We do not have appellate jurisdiction to consider whether the district court erred in denying Funk's motion for leave to file a second amended complaint and motion for reconsideration, because he did not appeal the January Order; (2) Funk's allegation of his component theory under the PMA approval process is not before us, as it was not pleaded in district court prior to the only appealed judgment; (3) the district court correctly dismissed Funk's claim because neither his original complaint nor first amended complaint satisfies required pleading standards to set forth a cognizable claim; and (4) the district court's application of judicial notice did not transform the motion to dismiss into a motion for summary judgment. For these reasons, the district court order is affirmed.

B.

First we must begin with the jurisdictional questions—which were briefed only after oral argument—because two of Funk's major arguments presented in his appellate brief concern the January Order. First, he contends that the district court erred in denying his motion for reconsideration and motion for leave to file a second amended complaint; these rulings were contained only in the January Order. Second, Funk draws extensively upon the allegations he presented in his proposed second amended complaint as support for why he believed the district court erred in dismissing his complaint under Rule 12(b)(6). In this respect, Funk's primary contention is that the district court's reasoning was erroneous because the acetabular cup received § 510(k) approval, not PMA. This "component theory" suggests that the acetabular cup underwent a different approval process than the rest of Trident, and was thus subject to different preemption standards. However, as noted by Stryker, this court is foreclosed

from considering this argument on appeal because it was not raised until after the entry of the December Judgment; these issues were presented to the district court only in the motion for reconsideration and in the proposed second amended complaint addressed in the January Order, which Funk did not appeal. Thus, Funk is foreclosed from presenting in this appeal the arguments based on allegations asserted in the proposed second amendment.

Although the Fifth Circuit liberally construes issues on appeal, we are bound by specific jurisdictional requirements. The Supreme Court has held that the timely notice of appeal in a civil case is a jurisdictional requirement, to which courts cannot create equitable exceptions. *Bowles v. Russell*, 551 U.S. 205, 214 (2007). An appellant must amend his notice of appeal to challenge orders subsequent to the final judgment. *Taylor v. Johnson*, 257 F.3d 470, 474 (5th Cir. 2001). Although "a brief may serve as the 'functional equivalent' of an appeal" if it is filed within the time specified by Federal Rule of Appellate Procedure Rule 4, it may only do so if it gives the notice provided under Federal Rule of Appellate Procedure Rule 3, which requires, in relevant part, "designating the judgment, order, or part thereof being appealed." *Id*. at 475; FED. R. APP. P. 3(c)(1)(B). Funk did not appeal the January Order, nor amend his earlier appeal, nor specifically designate that he was appealing the order in his appellate brief.

Moreover, neither exhaustive review of the record nor the letter brief submitted by Funk identifies a single concrete instance in which Funk pled the component theory before the entry of the December Judgment. Funk's first amended complaint noted that Stryker obtained approval to market the Trident "under *either* a 510(k) procedure *or* a pre-market approval."[4] (emphasis added).

[4] Funk's original complaint alleges that "Plaintiff believes that Defendant obtained approval from the [FDA] to market the hip prostheses under a 510(k) procedure and not under a [PMA] procedure." This allegation was amended in the first amended complaint, which instead read: "Defendant obtained approval from the [FDA] to market the hip prostheses

In its ruling, the district court held that it was consistent with both parties' pleadings to find that Trident received PMA. We repeat ourselves to conclude that the arguments Funk raises in the appellate brief concerning the component theory cannot be considered, as they were not presented to the district court until after it entered the December Judgment, the only judgment before us today.

Because Funk did not file a notice of appeal for the January Order, we have appellate jurisdiction to consider neither the argument that the district court erred in denying his motions for reconsideration and leave to amend nor the arguments presented in his proposed second amended complaint on appeal.

C.

Funk has two claims stemming from the December Judgment, over which the court has jurisdiction: (1) whether the court erred in finding that Funk did not adequately plead manufacturing defect claims parallel to the requirements of federal regulations; and (2) whether the 12(b)(6) motion was converted to a motion for summary judgment because the district court considered extrinsic evidence through the use of judicial notice to recognize a publically-available letter. We consider each of these claims below.

1.

In Funk's first amended complaint (the complaint before the district court at the time it issued its December Order) he alleged that even if Trident was approved via PMA, Funk's claims survive preemption because his complaint alleges that Stryker failed to meet the manufacturing requirements of the FDA. Although Funk correctly understands the law regarding parallel state claims, his claim that Stryker violated FDA manufacturing requirements when

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under either a 510(k) procedure or a [PMA] procedure. Pursuant to this approval, Defendant was required to comply with the FDA's standards and requirements established through the PMA process." The district court correctly considered the first amended complaint.

producing Trident was not legally cognizable as set out in his pleadings before the district court. The district court held that "Funk provides no facts in support of his conclusory allegations, instead relying on the doctrine of *res ipsa loquitur* - a doctrine that would seem to be soundly refuted by *Riegel*." R. at 289. The district court's holding is borne out by our review of the pleading. In the first amended complaint, Funk offered the following allegations:

> *Manufacturing Defect*.
>
> [3.] The hip prostheses contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues and bacteria remained on the prosthesis in violation of the FDA standards and requirements and in violation of the manufacturing processes and design approved by the FDA.
>
> [4.] The hip prostheses deviated, in its construction or quality, from the specifications or planned output. As more particularly set forth below, Plaintiff invokes the doctrine of res ipsa loquitur as to the manufacturing defect contained in the hip prosthesis.

R. at 260. This complaint is impermissibly conclusory and vague; it does not specify the manufacturing defect; nor does it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor does the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process. It instead relies on *res ipsa loquitur* to suggest only that the "that the thing speaks for itself." *See Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (noting that in order to survive a 12(b)(6) motion to dismiss, the plaintiff must plead enough facts to "state a claim that is plausible on its face.") (citation and quotation omitted); *Delaney v. Stryker Orthopedics*, 2009 WL 564243, at *6 (D. N.J. March 5, 2009) (dismissing a manufacturing claim because plaintiff did not point "to a defect or deviation from the FDA-reviewed Trident manufacturing

specifications regarding the Trident implanted in him" or "allege that 'something was wrong' with the product").

Comparing the first amended complaint with the proposed second amended complaint shows how the first is lacking: The second amended complaint specifies with particularity what went wrong in the manufacturing process and cites the relevant FDA manufacturing standards Stryker allegedly violated. But, alas for Funk, the second amended complaint is not part of this appeal and is not before us. Left to consider only the conclusory pleading of the first amended complaint, we hold that the district court did not err in finding that Funk's claim of manufacturing defects failed to state a manufacturing defect in Trident.

2.

Funk finally contends that the court erred when it failed to convert Stryker's motion to dismiss into a motion for summary judgment because, he argues, the district court considered extrinsic evidence. The district court took judicial notice of public records indicating that the Trident received PMA to reach the holding that Funk's claims were preempted by § 360k. Although the district court did not identify the specific record(s) upon which it based its findings, the parties appear to agree that the court referenced Record P000013, which includes a letter from the FDA dated February 3, 2003, granting PMA to the Trident.

When reviewing a motion to dismiss, a district court "must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (citations omitted). A district court's use of judicial notice under Federal Rule of Evidence 201 is reviewed for abuse of discretion. *See Taylor v.*

Charter, 162 F.3d 827, 829 (5th Cir. 1998). The district court abuses its discretion when its ruling is based on an erroneous view of the law or a clearly erroneous assessment of the evidence. *Nunez v. Allstate Ins. Co.*, 604 F.3d 840, 844 (5th Cir. 2010). "A judicially noticed fact must be one not subject to reasonable dispute in that it is either (1) generally known within the territorial jurisdiction of the trial court or (2) capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b).

The district court appropriately used judicial notice in accordance with these standards. In the pleadings before the December Judgment, there was no actual asserted factual dispute (Funk's complaint specified the hip prosthesis was approved "under either a 510(k) procedure or a pre-market approval (PMA) procedure."). *See* R. at 229. Further, the district court took appropriate judicial notice of publically-available documents and transcripts produced by the FDA, which were matters of public record directly relevant to the issue at hand. *Norris v. Hearst Trust*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("it is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record."). Accordingly, we hold that it was appropriate for the court to take judicial notice, under Rule 12(b)(6), of the PMA the FDA granted to Stryker for marketing its Trident System.

IV.

We conclude by summarizing our holding today: We have held that we lack appellate jurisdiction over the January Order of the district court denying Funk's motion to reconsider its December Judgment and denying his motion to file a second amended complaint because he failed to file a notice of appeal from that order; the only judgment over which we have appellate jurisdiction is the December Judgment, dismissing the complaint for failure to state a claim; that the district court did not err in taking judicial notice of the PMA; and finally that

the district court did not err in dismissing the complaint on the grounds that it failed to plead a legally cognizable claim. Accordingly, the judgment of the district court is

AFFIRMED.