8-10-2015

Travelers Indemnity Co v. Cephalon Inc

NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

_____

No. 14-4261

_____

THE TRAVELERS INDEMNITY COMPANY, and its various property casualty affilliates and subsidiaries; TRAVELERS CASUALTY & SURETY COMPANY, and its various property casualty affilliates and subsidiaries; ST. PAUL FIRE & MARINE INSURANCE COMPANY, and its various property casualty affilliates and subsidiaries; THE STANDARD FIRE INSURANCE COMPANY,
and its various property casualty affilliates and subsidiaries,
Appellants

v.

CEPHALON, INC.; TEVA PHARMACEUTICALS USA, INC.; TEVA PHARMACEUTICAL INDUSTRIES LIMITED; ABC CORPORATIONS 1 THROUGH 5; FICTITIOUS NAMES

_____

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Civ. Action No. 2-12-cv-04191)
District Judge: Honorable Mary A. McLaughlin

_____

Submitted Under Third Circuit L.A.R. 34.1(a)
July 14, 2015

_____

Before: SMITH, GREENAWAY, JR., and SHWARTZ, *Circuit Judges*.

(Opinion Filed: August 10, 2015)

OPINION*

GREENAWAY, JR., *Circuit Judge*.

Plaintiff-Appellants ("Plaintiffs"), several workers' compensation insurance providers, are Travelers Indemnity Company, Travelers Casualty & Surety Company, St. Paul Fire & Marine Insurance Company, and the Standard Fire Insurance Company. Defendant-Appellees ("Defendants") are Cephalon, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd.[1] Plaintiffs brought claims against Defendants for intentional misrepresentation, negligent misrepresentation, violations of state consumer protection laws, and unjust enrichment, and seek damages and an injunction.

The District Court dismissed Plaintiffs' claims for lack of standing under Federal Rule of Civil Procedure 12(b)(1) and for failure to state a claim under Rule 12(b)(6). Because Plaintiffs have failed to set out their fraud claims with sufficient specificity under Federal Rule of Civil Procedure 9(b) and have failed to plead the necessary elements under Connecticut's Unfair Trade Practices Act ("CUTPA"), Conn. Gen. Stat.

* This disposition is not an opinion of the full Court and pursuant to I.O.P. 5.7 does not constitute binding precedent.

[1] Plaintiffs do not address the District Court's dismissal of claims against Teva USA and Teva Ltd. in their opening brief. Thus, any argument with respect to those Defendants is waived. *See In re Surrick*, 338 F.3d 224, 237 (3d Cir. 2003).

Ann. §§ 42-110a, we will affirm the District Court's dismissal for failure to state a claim. Plaintiffs also appeal the District Court's denial of their motion to amend the judgment of dismissal and for leave to file an amended complaint. We will affirm that denial because amendment would have been futile.

I. BACKGROUND

Actiq and Fentora are powerful painkillers approved by the Food and Drug Administration ("FDA") to manage breakthrough pain in cancer patients who were already receiving and were tolerant to opioid pain medications. Both Actiq and Fentora include warning labels indicating that they are only for the treatment of persistent cancer pain in patients who are tolerant to opioid therapy, and that they are contraindicated for acute or post-operative pain management in opioid non-tolerant patients. Plaintiffs allege that Cephalon marketed Actiq and Fentora for off-label uses, specifically by promoting these medications to doctors for use in non-cancer patients for the treatment of non-cancer pain. Plaintiffs allege that Cephalon's marketing "goes beyond mere off-label promotion of Actiq [and Fentora] and includes untruthful, factually inaccurate, incomplete and/or otherwise misleading promotion of the drug[s], and the promotion of Actiq [and Fentora] for contraindicated uses." (Am. Compl. ¶ 80.) Plaintiffs also allege that they and their claimants spent more than $18 million on Actiq and Fentora since 2004. Plaintiffs provide illustrative examples of claimants who were prescribed Actiq and Fentora for off-label uses and the amount of money Plaintiffs paid for the medications prescribed in these examples. However, Plaintiffs do not allege that they or

their claimants heard or relied on fraudulent statements or misrepresentations. Rather, they allege that Cephalon directed its off-label marketing at doctors treating claimants whose claims would be reimbursed by Plaintiffs. Plaintiffs identify five doctors who prescribed Fentora to Plaintiffs' claimants and who also "received payments/benefits from Cephalon" during the same time period. (Am. Compl. ¶ 162.) Plaintiffs also identify one claimant who received Actiq prescriptions from a doctor who attended "field rides" with Cephalon representatives, Am. Compl. ¶ 94, though Plaintiffs allege neither that this doctor received payments or benefits from Cephalon, nor that misleading or fraudulent information was provided or relied upon.

The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, "regulates the manufacturing, marketing and sale of prescription drugs, and provides that a drug cannot be sold in interstate commerce unless it is approved by the FDA for the specific medical use, or 'indication,' listed on the drug's labeling." *In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239 (3d Cir. 2012) (citing 21 U.S.C. § 355(a)). Although "[p]rescription drugs frequently have therapeutic uses other than their FDA-approved indications[,] [t]he FDCA . . . generally prohibits manufacturers from marketing, advertising, or otherwise promoting drugs for such unapproved or 'off-label' uses." *Id.* at 239-40 (citing 21 U.S.C. § 331(a) and (d)). However, "[b]ecause the FDCA does not regulate the practice of medicine, physicians may lawfully prescribe drugs for off-label uses." *Id.* at 240 (citing *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001)). Furthermore, "violations of the

FDCA do not create private rights of action." *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994).

II. ANALYSIS[2]

A. Plaintiffs' Fraud Claims Are Not Pled with Sufficient Particularity Under Rule 9(b)

Plaintiffs' claims are premised upon Cephalon's allegedly fraudulent scheme to mislead doctors with respect to the proper use and effectiveness of Actiq and Fentora, thereby causing those doctors to improperly prescribe those drugs to Plaintiffs' claimants. Because this theory sounds in fraud, Plaintiffs' pleadings must satisfy the "stringent" Rule 9(b) requirements for particularity.[3] *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007); *see* Fed. R. Civ. P. 9(b) ("In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake."). "In order to satisfy Rule 9(b), plaintiffs must plead with particularity 'the "circumstances" of the alleged

---

[2] The District Court had jurisdiction under 28 U.S.C. § 1332. This Court has jurisdiction pursuant to 28 U.S.C. § 1291. "We exercise plenary review over the District Court's dismissal of the Amended Complaint[]," under Federal Rule of Civil Procedure 12, sections (b)(1) and (b)(6). *Schering Plough*, 678 F.3d at 243. "We review the District Court's denial of a Rule 59(e) motion to amend the complaint for abuse of discretion, but we review the District Court's underlying legal determinations *de novo* and factual determinations for clear error." *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 220 (3d Cir. 2011) (internal citations omitted).

[3] *See In re Westinghouse Sec. Litig.*, 90 F.3d 696, 717 (3d Cir. 1996) (Even when "fraud is not a necessary element of a claim . . . claims that do sound in fraud must be pled with particularity."). Thus, all of Plaintiffs' claims alleging fraudulent activity—i.e., Plaintiffs' claims for intentional and negligent misrepresentation, unjust enrichment and an injunction—must be pled with sufficient particularity under Rule 9(b).

fraud in order to place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior.'" *Lum v. Bank of Am.*, 361 F.3d 217, 223-24 (3d Cir. 2004) (quoting *Seville Indus. Mach. Corp. v. Southmost Mach. Corp.*, 742 F.2d 786, 791 (3d Cir. 1984)), *abrogated in part on other grounds by Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007). "Plaintiffs also must allege who made a misrepresentation to whom and the general content of the misrepresentation." *Id.* at 224.

Here, Plaintiffs' conclusory allegations that Cephalon's marketing and promotion of Actiq and Fentora were deceptive, improper, false or misleading do not satisfy that burden.[4] Indeed, Plaintiffs' argument boils down to an assertion that Cephalon's off-label promotion of Actiq and Fentora was inherently fraudulent and created a private cause of action. However, Plaintiffs fail to identify any specific fraudulent statements, omissions, or misrepresentations that were made to doctors who prescribed Actiq and Fentora. We agree with the District Court that Plaintiffs fail to allege "the contents of these statements and materials"[5] and do not "specify when, where, or to whom any sales

[4] Plaintiffs' argument that the Rule 9(b) particularity requirements should be relaxed here because certain information was exclusively within Defendants' control fails. Defendants did not have exclusive control over significant information, such as the reasons that the doctors prescribed Actiq and Fentora, or whether Plaintiffs' claimants who received those prescriptions benefitted from them.

[5] The District Court noted that one document title provided by Plaintiffs, "Actiq for Migraine," suggests the content of this document. (App. 32, n. 18.) This alone is insufficient to satisfy the particularity requirement.

pitch was made." (App. 32, n. 18.) Because Plaintiffs have not alleged the particular facts surrounding the alleged fraud, as required under Rule 9(b), their claims sounding in fraud cannot stand. Thus, we will affirm the District Court's dismissal of those claims.

B. Connecticut Unfair Trade Practices Act[6]

The District Court dismissed Plaintiffs' claims under CUTPA on the grounds that Plaintiffs' did not adequately establish a cognizable injury. However, we will not reach the question of injury because even assuming arguendo that Plaintiffs had established injury, they have failed to sufficiently plead causation, as required by CUTPA. Thus, we will affirm for that reason.[7] *See Stevenson Lumber Co.-Suffield v. Chase Assocs.*, 932 A.2d 401, 406 (Conn. 2007) ("[I]n order to prevail in a CUTPA action, a plaintiff must establish both that the defendant has engaged in a prohibited act *and* that, 'as a result of' this act, the plaintiff suffered an injury. The language 'as a result of' requires a showing that the prohibited act was the proximate cause of a harm to the plaintiff." (quoting Conn. Gen. Stat. Ann. § 42-110g)). "Proximate cause is an actual cause that is a substantial factor in the resulting harm." *Artie's Auto Body, Inc. v. Hartford Fire Ins. Co.*, 947 A.2d 320, 330 (Conn. 2008) (alterations, citations and internal quotation marks omitted).

---

[6] The District Court held that because Plaintiffs did not plead facts alleging economic injury in any state besides Connecticut, CUTPA is the only consumer protection law under which Plaintiffs have standing. On appeal, Plaintiffs have made no argument that their claims should have been considered under other states' consumer protection laws, thus this argument is waived. *See Surrick*, 338 F.3d at 237.

[7] "We may affirm the District Court on any grounds supported by the record." *Nicini v. Morra*, 212 F.3d 798, 805 (3d Cir. 2000) (citation omitted).

Here, the allegations in the Amended Complaint fail to establish proximate cause. Indeed, Plaintiffs did not allege that any doctor relied on Defendants' alleged misrepresentations in prescribing Actiq or Fentora, or that these prescriptions would not have been written if these physicians had not received the allegedly fraudulent information from Cephalon. Thus, Plaintiffs have not sufficiently pleaded causation, as required by CUTPA, and we will affirm the District Court's dismissal of the CUTPA claims.

C. Amendment

Plaintiffs also appeal the District Court's denial of their motion to partially amend the judgment of dismissal pursuant to Federal Rule of Civil Procedure 59(e) and for leave to file a Second Amended Complaint ("SAC"). The District Court denied this motion because Plaintiffs had already filed one amended complaint and had discovery, the motion to dismiss had been pending for over a year, and the District Court had already heard argument on it. The District Court found that Plaintiffs strategically delayed filing their SAC to see if their Amended Complaint survived Defendants' Motion to Dismiss. The District Court also reviewed the SAC and determined that it "fail[ed] to cure the deficiencies" that the District Court identified in dismissing the Amended Complaint. (App. 47.) Thus, amendment would have been futile. *See In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1434 (3d Cir. 1997) ("Among the grounds that could justify a denial of leave to amend . . . [is] futility.").

We agree that amendment would have been futile and will affirm on that ground.

Although Plaintiffs did include additional detail in the proposed SAC, such as information regarding conferences sponsored by Cephalon, and physician attendees who later prescribed Actiq, the SAC still fails to satisfy causation, which is a required element of each of Plaintiffs' claims. *See Sturm v. Harb Dev., LLC*, 2 A.3d 859, 872 (Conn. 2010) (requiring party claiming intentional misrepresentation "'to have suffered harm as a result of . . . reliance [on the false representation]'" (quoting *Suffield Dev. Assocs. P'ship v. Nat'l Loan Investors, L.P.*, 802 A.2d 44 (Conn. 2002)); *Platinum Funding Servs., LLC v. Petco Insulation Co.*, No. 3:09-CV-1133, 2011 WL 1743417, at *10 (D. Conn. May 2, 2011) ("A plaintiff asserting an unjust enrichment claim must show . . . that the plaintiff suffered a detriment as a result of the defendant's failure to pay the plaintiff."); *Stevenson*, 932 A.2d at 406 (requiring a showing of proximate causation under CUTPA). Allegations that physicians attended presentations and interacted with Cephalon sales representatives do not sufficiently demonstrate that these interactions *caused* the physicians to write the prescriptions at issue. Because the facts alleged in the SAC do not create a sufficient causal connection between Defendants' alleged actions and the alleged injury suffered by Plaintiffs, amendment would have been futile. Thus, we will affirm the District Court's denial of Plaintiff's motion to amend the judgment of dismissal and for leave to file an SAC.

III. CONCLUSION

For the foregoing reasons, we will affirm the final judgment of the District Court.