

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: ACTIQ SALES AND
MARKETING PRACTICES
LITIGATION**

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CIVIL ACTION

NO. 07-4492

MEMORANDUM AND ORDER

Tucker, J.

May , 2009

Presently before this Court is Defendant's Motion for Judgment on the Pleadings as to the Racketeer Influenced and Corrupt Organizations ("RICO") Counts of Plaintiffs' First Amended Consolidated Class Action Complaint. For the reasons stated below, this Court will grant Defendant's Motion.

BACKGROUND

Plaintiffs bring this class action to recover damages for payments to Defendant Cephalon, Inc. as a result of Defendant's allegedly unlawful marketing of the drug Actiq. Plaintiffs Employers Mutual Casualty Company, EMCASCO Insurance Company, Union Insurance Company, and Indiana Carpenters Welfare Fund are insurers responsible for paying all or a portion of costs of prescription drug purchases by their members and beneficiaries. Am. Compl. ¶¶ 10-11. Plaintiff Pennsylvania Turnpike Commission provides group medical benefits for eligible employees as a party to a contract, issuer of a policy, or sponsor of a plan. Am. Compl. ¶ 12). Plaintiffs all allege that through various contracts, policies, or plans, they paid some portion of the cost for Actiq prescriptions during the relevant time period.

Defendant Cephalon is a pharmaceutical company that manufactures and sells several prescription drugs, including Actiq. Am. Compl. ¶ 13. Actiq is a prescription drug approved by the United States Food and Drug Administration (“FDA”) for the purpose of managing breakthrough cancer pain in patients with malignancies who are already receiving and tolerant to opioid therapy for their underlying cancer pain.

Plaintiffs allege that Actiq is a potent painkiller that was FDA approved solely for cancer patients whose pain could not be managed with other drugs. Am. Compl. ¶ 2. Plaintiffs further allege that because of Actiq’s high potential for abuse, the FDA expressly required Defendant to display a warning that the drug was not approved for any off-label uses. According to Plaintiffs, Defendant was aware that the cancer community was a limited market for Actiq, and consequently, for financial gain, Defendant pursued a deceptive marketing scheme which included marketing to a wide range of practitioners for off-label uses such as back pain, head aches, and migraines. Plaintiffs aver that the unlawful, off-label marketing of Actiq caused sales to increase from \$15 million in 2000 to \$471 million in 2006. Am. Compl. ¶ 34. Plaintiffs allege that Defendants encouraged general practitioners to prescribe Actiq even though this drug was inappropriate, medically unnecessary, and not FDA approved for treatment of these conditions. Am. Compl. ¶ 41-46. Plaintiffs further allege that as a result of unlawful marketing activities, Defendant pled guilty to violating the Federal Food, Drug and Cosmetic Act, and agreed to pay a \$425 million settlement resulting from Federal and State Medicaid Claims. Am. Compl. ¶ 62. Plaintiffs contend that class members were injured by payment of excessive prescription costs for off-label uses of Actiq, and now seek to recover excess payments.

In response, Defendant argues that Plaintiffs’ claims overlook several intervening

decision-makers, whose acts affect Plaintiffs' alleged injuries. Examples of the decision-makers referenced by Defendant are physicians with the independent medical judgment regarding what the appropriate course of treatment is for an individual patient, the judgment of pharmacy benefit managers to cover Actiq in their plan, and Plaintiffs' policies regarding coverage and reimbursement of Actiq prescriptions. Essentially, Defendant asserts that the various intervening decision-makers negate causation, and therefore Defendant's liability.

Plaintiffs filed three separate complaints in October, November, and December of 2007, all alleging that Defendant's devised an unlawful marketing scheme and asserting claims for violation of consumer-protection statutes and unjust enrichment. Defendant moved to dismiss the complaints and this Court denied the motions, and consolidated the three cases. Plaintiffs filed their first Amended Consolidated Class Action Complaint on May 16, 2008, which reasserts the allegations in the original complaints and raises two new claims RICO claims. Defendant moved for judgment on the pleadings as to the RICO counts pursuant to Federal Rule of Civil Procedure 12(c) on August 29, 2008.

LEGAL STANDARD

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) is subject to the same standard of review applicable to a motion to dismiss under Rule 12(b)(6). See Turbe v. Gov't of Virgin Islands, 938 F.2d 427, 428 (3d Cir. 1991). In considering a motion to dismiss under Rule 12(b)(6), the Court must accept as true all allegations in the complaint and all reasonable inferences that can be drawn therefrom, viewing them in the light most favorable to the plaintiff. Taliaferro v. Darby Twp. Zoning Bd., 458 F.3d 181, 188 (3d Cir.

2005). A Rule 12(b)(6) motion should be granted only if it appears to a certainty that no relief could be granted under any set of facts that could be proved. Id.

Thus, the allegations in the complaint must transcend the speculative, and instead, state a claim to relief that is plausible on its face. Bell Atl. Corp. v. Twombly, 127 S.Ct. 1955, 1965, 1969, 1974 (2007). Applying the plausibility standard, a court may accept as true only well-pleaded allegations, which does not include bald assertions or legal conclusions. Morse v. Lower Merion Sch. Dist., 132 F.3d 902, 906 (3d Cir. 2007).

DISCUSSION

18 U.S.C. § 1962(c) makes it unlawful for any person employed by or associated with any enterprise to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity. In order to state a RICO claim under 18 U.S.C. § 1962, a plaintiff must first demonstrate statutory standing under RICO. A civil RICO plaintiff is required "to make two related but analytically distinct threshold showings: (1) that the plaintiff suffered an injury to business or property; and (2) that the plaintiff's injury was proximately caused by the defendant's violation of 18 U.S.C. § 1962." Maio v. Aetna, Inc., 221 F.3d 472, 483 (3d Cir. 2000). If statutory standing is met, plaintiff must then allege facts to establish the following: (i) the existence of an enterprise engaged in or affecting interstate commerce; (ii) that the defendant was employed by or associated with the enterprise; (iii) that the defendant participated, directly or indirectly, in the conduct or the affairs of the enterprise; and (iv) that the defendant participated through a pattern of racketeering activity that must include the allegation of at least two racketeering acts. See Sedima, S.P. R. L. v. Imrex Co., 473 U.S. 479, 496 (1985).

This renders the existence of an enterprise central to any RICO claim.

A. Standing

It is well established that proximate cause “is a flexible concept that does not lend itself to ‘a black letter rule that will dictate the result in every case.’” Bridge v. Phoenix Bond & Indem. Co., 128 S. Ct. 2131, 2142 (2008) (quoting Holmes v. Sec. Inv. Prot. Corp., 503 U.S. 258 (1992)). Rather, “proximate cause is a generic label called on to describe the judicial tools used to limit a person’s responsibility for the consequences of that person’s own acts. . . .” Id. As discussed above, a plaintiff must adequately plead proximate cause to proceed with a civil RICO action. To determine whether a plaintiff has met this burden, the United States Court of Appeals for the Third Circuit evaluates three factors: (1) the directness of the injury; (2) whether there would be any difficulty in apportioning damages; and (3) whether a plaintiff’s claim is more appropriately brought by a different party. Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 933 (3d Cir. 1999). Both the Supreme Court of the United States and the Third Circuit have held that a RICO complaint should be dismissed at the Rule 12(b)(6) stage if it appears that the alleged injury is indirect. Id. at 934. Further, a complaint that fails to demonstrate the first factor, the directness of the injury, should be dismissed, even if the other two factors are met. See Allegheny Gen. Hosp. v. Philip Morris, Inc., 228 F.3d 429, 444 (3d Cir. 2000).

Directness of the Injury

In the present case, Defendant insists that there is a lack of direct injury, specifically

because the acts of doctors and various other third parties constitute intervening acts, all of which were allegedly unforeseeable and independent of Defendant's actions. In response, Plaintiffs argue that while intervening acts can break the chain of causation, such acts must be independent and completely unforeseeable, and that given Defendant's alleged deceptive marketing scheme which involves widespread dissemination of inaccurate information about the safety of these drugs, Defendant's cannot reasonably allege that acts beyond their own are either unforeseeable or completely independent. Rather, Plaintiffs contend that the acts of the physicians and other third parties were foreseeable and intended by Defendant as a result of its marketing scheme. See In re Lupron Mktg. & Sales Practices Litig., 295 F. Supp.2d 148, 175 (D. Mass. 2003). This Court finds Plaintiffs' reasoning persuasive.

The notion that Defendants' comprehensive marketing scheme had no effect on physicians and third parties, such that their selection of Actiq was wholly unforeseeable by Defendant, is unrealistic. Indeed, Defendant markets aggressively with the intent that, as a result of their efforts, physicians will prescribe their product. Moreover, Plaintiffs' allegations that Defendant's marketing scheme induced them to make substantial overpayments for Actiq is sufficient to satisfy RICO's causation requirement at the pleading stage. Id.

Difficulty in Apportioning Damages

Defendant also contests Plaintiffs' standing on the grounds that apportioning damages would be exceptionally difficult. Relying on Desiano v. Warner-Lambert Co., 326 F.3d 339 (2d Cir. 2003), Plaintiffs counter that "there is no apportionment problem here as each [health benefit provider] and its patient co-payer has its own, segregable claim for economic harm, to the extent

of their respective co-pay.” This Court agrees with Plaintiffs’ position, and finds that the respective payment made by each Plaintiff can be feasibly determined.

Appropriate Enforcers

Defendant argues that any enforcement action related to Actiq should be brought by the Food and Drug Administration (“FDA”), rather than by Plaintiffs. In response, Plaintiffs allege that Defendant has misconstrued the purpose of Plaintiffs action, in that Plaintiffs do not seek to enforce any FDA regulation, but instead seek to hold Defendant responsible for its allegedly deceptive marketing scheme.

The determination of the appropriate enforcer is related to the directness of the injury requirement. See Phoenix Bond, 128 S. Ct. at 2142 (quoting Holmes, 503 U.S. at 269-70). Here, as health benefit providers covering all or a portion of the cost for Actiq prescriptions that were arguably medically unnecessary, Plaintiffs have alleged sufficient facts to demonstrate a direct economic injury. As such, this Court finds that Plaintiffs are appropriate enforcers, and having met all three factors relevant to the issue of standing, that Plaintiffs indeed have standing to pursue a RICO action against Defendant.

B. The Existence of an Enterprise

A RICO enterprise is defined as “any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity.” 18 U.S.C. § 1961(4). To establish the existence of an enterprise, or an association-in-fact enterprise, a plaintiff must show evidence of an ongoing organization, formal or informal;

evidence that the various associates of the enterprise function as a continuing unit; and evidence that the enterprise has an existence separate and apart from the pattern of activity in which it engages. United States v. Ricobene, 709 F.2d 214, 221 (3d Cir. 1983).

Courts have determined that an association-in-fact can satisfy the first element requiring the existence of an enterprise, however, there must be allegations allowing an inference that some sort of structure exists for decision-making, whether hierarchical or consensual, or some mechanism for controlling and directing group affairs on a continuous rather than ad hoc basis. Ricobene, 709 F.2d at 222. Yet, allegations which merely state that individual members performed particular roles and were aware of each other's activities, without more, is insufficient to plead the existence of an enterprise. Seville, 742 F.2d at 790 n. 5). Essentially, while Plaintiffs need not allege facts in their Complaints sufficient to prove the existence of an enterprise, at a minimum, Plaintiffs must identify the enterprise and provide details about its structure in more than vague terms. Id.

Under the rules of notice pleading, a plaintiff need not specifically allege all of the facts necessary to establish these three enterprise elements in the complaint. Seville Indus. Mach. Corp. v. Southwest Mach. Corp., 742 F.2d 786, 790 (3d Cir. 1984). However, the allegations of the complaint must not affirmatively negate any of these elements. Id. at 790. Further, there must be sufficient allegations to allow the existence of the three elements to be inferred. See Lorenz v. CSX Corp., 1 F.3d 1406, 1412 (3d Cir. 1991).

Here, Plaintiffs have failed to establish facts sufficient to infer the existence of an enterprise as required by the statute. First, Plaintiffs have failed to set forth sufficient details in more than vague terms to identify the alleged enterprise. Plaintiffs state that "the enterprise is an

association-in-fact consisting of Defendant . . . and pain management specialists, CME speakers, paid speakers, and doctors paid to publish studies and the marketing and publication firms employed by Defendant to promote Actiq for off-label uses.” Am. Compl. at ¶ 82. Plaintiff further states that “Defendant and the other members of the Enterprise created and maintained systematic links for a common purpose to aid in marketing Actiq for off-label uses. Am. Compl. at ¶ 83. Yet, these statements are merely conclusory and open-ended, such that they fail to sufficiently identify the structure of the alleged entity, as well as names or titles of the individuals involved. Courts have established that the mere statement that individuals performed a particular roles and were aware of each other’s roles will not suffice to plead the existence of an enterprise. The allegations of the Amended Complaint simply do not provide sufficient details which support the existence of an ongoing organization which functions as a continuous unit.

Second, Plaintiffs have not established that the alleged enterprise has an existence separate and apart from the pattern of activity in which it engages. Plaintiffs assert that “the enterprise was created precisely to make it appear to the public that Defendant did not have a hand in any discussions or promotion of off-label use.” Am. Compl. at ¶ 94. Such a statement establishes both that the enterprise that Plaintiffs allege existed has no legitimate purpose beyond the racketeering activity, but further that Plaintiffs have affirmatively negated that which they attempt to prove, namely that the enterprise existed beyond committing the alleged predicate acts. Consequently, Plaintiffs have failed to plead adequate facts to support the existence of a RICO enterprise.

C. § 1962(d) RICO Conspiracy Claim

Plaintiffs also allege that Defendant violated 18 U.S.C. § 1962(d) when it allegedly engaged in a conspiracy to violate RICO. 18 U.S.C. § 1962(d) provides that it is “unlawful for any person to conspire to violate any of the provisions of subsection (c) of this section.

However, “any claim under § 1962(d) based on a conspiracy to violate the other subsections of § 1962 necessarily must fail if the substantive claims themselves are deficient.” Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1192 (3d Cir. 1993).

In the present case, Plaintiffs have failed to plead sufficient facts to establish that the alleged enterprise has a separate existence apart from the pattern of activity in which it engages. Without such facts, Plaintiffs’ substantive RICO claims are deficient. Therefore, Plaintiffs’ § 1962(d) conspiracy claim must fail as a matter of law.

CONCLUSION

Given that Plaintiffs’ allegations must consist of more than bald assertions or legal conclusions, and this Court’s conclusion that Plaintiffs’ allegations concerning the existence of enterprise are insufficient to state a RICO claim, Plaintiffs’ RICO allegations cannot survive a motion for judgment on the pleadings pursuant to Fed. R. Civ. P. 12(c). Therefore, this Court will grant Defendant’s motion for judgment on the pleadings and dismiss the RICO counts of Plaintiffs’ First Amended Consolidated Class Action Complaint.

An appropriate order follows.