United States District Court
District of Massachusetts

Iron Workers District Council of New England Health and Welfare Fund et al.,	)	
Plaintiffs,	)	**Civil Action No. 23-11131-NMG**
v.	)	
Teva Pharmaceutical Industries Ltd. et al.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

This lawsuit arises out of allegations that defendants, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Branded Pharmaceutical Products R&D, Inc. (collectively, "Teva") and Norton (Waterford) Ltd. (collectively, "defendants"), engaged in illegal, anti-competitive practices to block introduction of a generic drug that competes with its QVAR and QVAR Redihaler lines of inhaler products.

Plaintiffs are labor union health and welfare funds representing a putative class of entities and individuals that allegedly overpaid for prescription asthma medication because of defendants' purported practices. Pending before the Court is

defendants' motion for judgment on the pleadings and defendants' accompanying motion to stay the proceedings. For the reasons that follow, the motion for judgment on the pleadings will be allowed, in part, and denied, in part, and the motion to stay will be denied.

I. Background

This Court outlined the complex factual, procedural and regulatory background of this case in a prior order. See Iron Workers Dist. Council of New Eng. Health & Welfare Fund v. Teva Pharm. Indus. Ltd., No. CV 23-11131-NMG, 2024 WL 2025572, at *1-*3 (D. Mass. May 7, 2024). As such, the following will address only those facts necessary to resolve the motion at issue.

This case concerns Teva's prescription asthma treatment products known as QVAR and QVAR Redihaler. Those products contain beclomethasone dipropionate, a corticosteroid, as well as a hydrofluoroalkane ("HFA") which is an aerosol propellant. Teva acquired the rights to QVAR in 2006, and a 2023 decision from the District of New Jersey upheld its patents. Plaintiffs allege that beginning in 2014, the year before the last patent claiming beclomethasone dipropionate was to expire, Teva began a multifaceted, anticompetitive scheme to delay for as long as possible the entry into the market of generic competition to QVAR.

One component of the purported monopolization scheme relevant here was an alleged reverse payment, or "pay-for-delay", deal. Plaintiffs assert that in January, 2020, Amneal Pharmaceuticals ("Amneal") filed the first application for a generic version of QVAR. Teva did not sue Amneal but by the end of 2020, Amneal's plans to secure approval for the generic purportedly "fell silent". Based upon those circumstances, plaintiffs contend that Teva agreed to pay Amneal to delay launching a generic version of QVAR. Teva rejoins that it made no such payment and decided not to sue Amneal because of an FTC order incorporated into an asset purchase agreement. That order ostensibly forbids Teva from suing Amneal and thus explains its failure to do so.

Plaintiffs filed an expansive amended complaint in September, 2023, asserting a claim for injunctive relief under 15 U.S.C. §2 (the Sherman Antitrust Act), a plethora of claims under state antitrust and consumer protection statutes and a claim for unjust enrichment. Defendants moved to dismiss the complaint in its entirety for failure to state a claim. This Court allowed, in part, and denied, in part, that motion. In response to this Court's partial denial of dismissal, defendants filed an answer with 32 accompanying exhibits. In conjunction with that answer and the exhibits, defendants now move for judgment on the pleadings.

II. Legal Standard

A motion for judgment on the pleadings under Fed. R. Civ. P. 12(c) is governed by the same legal standard as a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), except that the Court considers the pleadings as a whole rather than just the plaintiff's complaint. Aponte-Torres v. Univ. of Puerto Rico, 445 F.3d 50, 54-55 (1st Cir. 2006).

To survive such a motion, the subject pleading must contain sufficient factual matter to state a claim for relief that is actionable as a matter of law and "plausible on its face." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim is plausible if, after accepting as true all non-conclusory factual allegations, the Court can draw the reasonable inference that the defendant is liable for the misconduct alleged. Ocasio-Hernandez v. Fortuno-Burset, 640 F.3d 1, 12 (1st Cir. 2011).

In considering the merits of such a motion, the Court must accept all factual allegations in the complaint as true and draw all reasonable inferences in the plaintiff's favor. R.G. Fin. Corp. v. Vergara-Nunez, 446 F.3d 178, 182 (1st Cir. 2006). The Court may also consider documents that the parties provide alongside their pleadings if 1) the parties do not dispute their authenticity, 2) they are "central to the plaintiffs' claim" or 3) they are "sufficiently referred to in the complaint." Curran

v. Cousins, 509 F.3d 36, 44 (1st Cir. 2007) (quoting Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993)).[1]

III. Analysis

In its motion for judgment on the pleadings, defendant contends that the answer and exhibits it provided render plaintiff's complaint implausible on two fronts: 1) because it does not sufficiently allege a reserve payment scheme between Teva and Amneal and 2) because it fails to assert causation for purposes of antitrust standing. The Court addresses each contention seriatim.

A. Reverse Payment Scheme

A reverse payment scheme involves allegations that a brand drug manufacturer agreed to pay a potential generic competitor to delay bringing a generic drug to market. See In re Loestrin 24 Fe Antitrust Litig., 814 F.3d 538, 551 (1st Cir. 2016). The alleged payment is subject to antitrust scrutiny under the "rule of reason." Id. Under that analysis, courts must look to

> [the payment's] size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.

[1] Although plaintiffs tacitly take issue with certain documents defendant provided, the Court considers them because plaintiffs do not argue that the documents are unauthenticated or otherwise not central to the claims. See Curran v. Cousins, 509 F.3d 36, 44 n.5 (1st Cir. 2007) (affirming district court's consideration of produced documents in connection with a Rule 12(c) motion where other party "ha[d] not raised any argument . . . as to their authenticity").

Id. (quoting FTC v. Actavis, Inc., 570 U.S. 136, 159 (2013)). The First Circuit has rejected the requirement of alleging exact amounts at the pleading stage and has clarified that non-monetary reverse payments are also subject to the same scrutiny. Id. Instead, to state a reverse payment claim, plaintiffs must

> allege facts sufficient to support the legal conclusion that the settlement at issue involves a large and unjustified reverse payment.

In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552. The complaint must include allegations of "the general contours of when an agreement was made" and "support[] those allegations with a context that tends to make [the] agreement plausible." Evergreen Partnering Grp., Inc. v. Pactiv Corp., 720 F.3d 33, 46 (1st Cir. 2013). An agreement becomes plausible when the payment is so large that it cannot be justified but for the defendant company's "serious doubts about the patent's survival," revealing that "the payment's objective" was to affect an anticompetitive end. In re Asacol Antitrust Litig., 233 F. Supp. 3d 247, 261-62 (D. Mass. 2017) (quoting Actavis, 570 U.S. at 138) (citing King Drug Co. of Florence, Inc. v. Smithkline Beecham Corp., 791 F.3d 388, 410 (3d Cir. 2015)).

Applying that standard to its prior decision on the motion to dismiss, this Court concluded that plaintiffs had presented plausible allegations of a reverse payment scheme between defendant and Amneal. Specifically, the Court found that

allegations of Amneal's announcement of a generic QVAR combined with their unexplained failure to launch the drug and Teva's unexplained failure to sue Amneal created an inference of a reverse payment. The Court perceived no other alternative explanation and thus accepted the reverse payment allegations as plausible.

Now, defendants proffer documentary evidence that Teva did not sue Amneal because it was barred from doing so under a 2016 FTC order. Defendants contend that the subject order renders plaintiffs' reverse payment claim implausible, and specifically, that

1) the FTC order precludes Teva from bringing a patent infringement suit against any entity to which it "divested a product under that order";

2) the products subject to the order included "Beclomethasone" products which is defined to include QVAR;

3) Teva's later Asset Purchase Agreement ("APA") with Impax incorporated by reference the FTC order;

4) the APA also included a term that the agreement would be "binding upon" all "successors and permitted assigns" of Impax;

5) Amneal became a successor to Impax through a merger; and

6) therefore, Teva was prohibited from suing Amneal for any patent infringement claim related to QVAR.

Plaintiffs vigorously dispute defendants' proposed reading of the FTC order and its effect on defendants' decision not to sue Amneal. They claim that the APA and accompanying FTC order

do not negate the plausibility of a reverse payment scheme but they underestimate their burden of pleading. In a motion for judgment on the pleadings, defendants are not compelled to rule out every other possible explanation. Instead, it is incumbent upon them to disprove the plausibility of plaintiff's complaint in light of the facts presented by their answer. See Rivera-Gomez v. de Castro, 843 F.2d 631, 635 (1st Cir. 1988) (explaining that Rule 12(c) requires courts to consider validity of claims brought in plaintiff's complaint based on "contemplation of . . . the pleadings as a whole"); Ruiz Rivera v. Pfizer Pharm., LLC, 521 F.3d 76, 84 (1st Cir. 2008) (accepting Rule 12(c) judgment on the pleadings as viable where plaintiffs' assertions of fact do not "possess enough heft" to show he is "entitled to relief").

In their amended complaint, plaintiffs do not dispute the existence of the FTC order or the APA, nor their purported effects upon Teva's right to sue Amneal. Cf. In re Loestrin 24 Fe Antitrust Litig., 814 F.3d at 552; Evergreen Partnering, 720 F.3d at 46. Instead, plaintiffs argue ad ignorantiam: because there is no other explanation for the failure to sue, there must have been a reverse payment scheme. The Court is thus left with two explanations for Teva's failure to sue Amneal: 1) the unsubstantiated allegations in plaintiffs' complaint and 2)

defendants' answer, substantiated by allegedly valid documentary evidence.

In light of the governing Rule 12(c) standard, plaintiffs' conjecture regarding an alleged reverse payment scheme is rendered implausible in the face of defendant's documents. See Clorox Co. v. Proctor & Gamble Com. Co., 228 F.3d 24, 32 (1st Cir. 2000) (indicating that facts supported by documentary evidence "trump" unsupported allegations for purposes of deciding Rule 12(c) motion) (quotations omitted)). At the motion to dismiss stage, the Court was left to presume that Amneal's unexplained failure to launch the generic alternative to QVAR plausibly resulted from a reverse payment. Based on defendants' responsive pleading, however, mere conjecture is not enough. Cf. In re Asacol Antitrust Litig., 233 F. Supp. at 263 (finding reverse payment claim plausible where plaintiff alleged existence of settlement agreement in which infringer "effectively provided [patent holder] with a $101 million profit" and patent holder offered no alternative explanation for payment alleged). Accordingly, plaintiffs' reverse payment claim will be dismissed.

B. Causation for Antitrust Standing

To sustain an antitrust action as a private party, a plaintiff must successfully demonstrate that he has "antitrust standing," Vazquez-Ramos v. Triple-S Salud, Inc., 55 F.4th 286,

293 (1st Cir. 2022), which, in turn, depends on six factors that courts must balance:

> (1) the causal connection between the alleged antitrust violation and harm to the plaintiff; (2) an improper motive; (3) the nature of the plaintiff's alleged injury and whether the injury was of a type that Congress sought to redress with the antitrust laws ("antitrust injury"); (4) the directness with which the alleged market restraint caused the asserted injury; (5) the speculative nature of the damages; and (6) the risk of duplicative recovery or complex apportionment of damages.

Serpa Corp. v. McWane, Inc., 199 F.3d 6, 10 (1st Cir. 1999) (citing Sullivan v. Tagliabue, 25 F.3d 43, 46 (1st Cir. 1994)). Defendants challenge plaintiff's here only as to whether they have properly alleged causation.

Causation, for purposes of antitrust standing, requires the plaintiff to show that the antitrust violation alleged was a "material cause" of his injury, even if it was not the sole cause of that injury. Engine Specialties, Inc. v. Bombardier Ltd., 605 F.2d 1, 14 (1st Cir. 1979) (citing Zenith Radio Corp. v. Hazeltine Rsch. Inc., 395 U.S. 100, 114 n.9 (1969)). The First Circuit has interpreted this "material" connection as, in effect, a proximate cause requirement. In re Neurontin Marketing & Sales Practices Litig., 712 F.3d 21, 35 (1st Cir. 2013). The First Circuit has also emphasized that the first and fourth of standing factors which "require causation between the alleged violation and the alleged harm" are paramount. See RSA Media, Inc. v. AK Media Grp., Inc., 260 F.3d 10, 14 (1st Cir. 2001).

Whether this essential element of causation has been met is usually, though not always, a consideration for the finder of fact. Exxon Co., U.S.A. v. Sofec, Inc., 517 U.S. 830, 840-41 (1996) ("The issues of proximate causation and superseding cause involve application of law to fact, which is left to the factfinder, subject to limited review."); Swift v. United States, 866 F.2d 507, 510 (1st Cir. 1989) ("Application of the legal cause standard to the circumstances of a particular case is a function ordinarily performed by, and peculiarly within the competence of, the factfinder."); Peckham v. Continental Cas. Ins. Co., 895 F.2d 830, 837 (1st Cir. 1990) ("Causation questions . . . are normally grist for the jury's mill.").

In applying this standard to defendants' prior motion to dismiss, the Court concluded that plaintiffs had sufficiently alleged causation to maintain standing as private parties to this antitrust matter. The fact that a previous decision validated defendants' patents, see Teva Branded Pharma. Prod. R&D, Inc. v. Cipla Ltd., 678 F. Supp. 3d 559 (D.N.J. 2023), provided an insufficient basis to warrant dismissal of plaintiffs' antitrust claim for lack of causation.

Now, defendants reiterate that the Cipla decision which found an inhaler design in violation of Teva's patents vitiates causation for purposes of antitrust standing. More broadly,

defendants rely on In re Nexium (Esomeprazole) Antitrust Litig., 842 F.3d 34 (1st Cir. 2016) and In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No. CV 14-MD-02503, 2018 WL 563144 (D. Mass. Jan. 25, 2018) to assert that, in claims involving patented and generic versions of medical products, a plaintiff cannot properly allege causation if the patent at issue is valid. Defendants, however, overestimate the applicability of those cases to the case at bar.

Both Nexium and Solodyn involved disputes about causation that arose well beyond the pleading stage. In Nexium, the First Circuit upheld a finding that the absence of "evidence" that any of the patents "would be adjudicated invalid" or otherwise could have been designed around warranted judgment as a matter of law in favor of defendant on the causation issue. 842 F.3d at 63. Similarly, in Solodyn, the District Court found that the absence of "evidence" that a patent could be proven invalid warranted summary judgment. 2018 WL 563144 at *13-*14. The Nexium decision went on, however, to expressly distinguish between the necessary proof of antitrust causation at the summary judgment stage but not at the pleading stage. 842 F.3d at 62. The First Circuit cited a Sixth Circuit decision for the proposition that plausible allegations based on some reasons other than a given patent's invalidity at the pleading stage was not fatal and merely "raise a disputed issue of fact." Id. (quoting In re

Cardizem CD Antitrust Litig., 332 F.3d 896, 900 (6th Cir. 2003) (alteration omitted)).

Although neither the First Circuit nor other sessions of this Court have since confined their reading of Nexium to its procedural posture, cf. In re Asacol Antitrust Litig., 907 F.3d 42, 52 (1st Cir. 2018) (applying Nexium to class certification issue), decisions from other federal courts support a conclusion that Nexium's stricter evidentiary requirement does not extend to the pleading stage. In In re Xyrem (Sodium Oxybate) Antitrust Litig., 555 F. Supp. 3d 829 (N.D. Cal. 2021), for example, the Northern District of California concluded that Nexium on its facts applied to a decision made post-trial and that it "expressly distinguished [necessary] allegations of antitrust injury at the Rule 12(b)(6) stage." Id. at 875 (quotation omitted). As in Nexium itself, the court highlighted decisions that have found patent validity and the ability to design around a patent a disputed issue of fact that does not warrant dismissing a case at the pleading stage. Id.; see also Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, plc, No. 15 CIV. 6549 (CM), 2018 WL 7197233, at *31 (S.D.N.Y. Dec. 26, 2018) (reading Nexium's evidentiary requirement as based on application of judgment as matter of law standard).

Because defendants' motion here is at the pleading stage, plaintiffs' allegations of antitrust standing suffice to survive

judgment on the pleadings just as it survived the motion to dismiss. Cf. 4MVR, LLC v. Hill, No. 12-cv-10674, 2015 WL 3884054, at *6 (D. Mass. June 24, 2015) ("Motions for dismissal and judgment on the pleadings are governed by the same standard."). Defendants' answer and accompanying documents do not alter this Court's earlier conclusion: the Cipla decision proves only that the specific design at issue violated Teva's patents, not that there is no plausible way for another company to design a different product without infringement. There remains a genuine dispute of material fact as to whether a generic manufacturer could design a generic QVAR inhaler product around defendants' upheld patents.

This case is therefore distinguishable from both Nexium and Solodyn. 2018 WL 563144, at *13. In both cases, the court required "evidence" for a claim to survive a motion for summary judgment or a motion for judgment as a matter of law. In re Nexium, 842 F.3d at 63; Solodyn, 2018 WL 563144, at *13 (citing Borges ex rel. S.M.B.W. v. Serrano-Isern, 605 F.3d 1, 5 (1st Cir. 2010)). At the pleading stage, however, all that is required of a claim is plausibility, see Nexium, 842 F.3d at 62 (citing Cardizem, 332 F.3d at 900); Iqbal, 556 U.S. at 678, and nothing in defendants' answer warrants a change in the Court's previous finding that plaintiffs plausibly alleged causation for purposes of antitrust standing. Accord Xyrem, 555 F. Supp. 3d at

875 (distinguishing Nexium in applying Rule 12(b)(6)). Consequently, the Court is unpersuaded by defendants' arguments that plaintiffs' claims should be dismissed in their entirety for want of antitrust standing. Furthermore, because this case will not be dismissed at the pleading stage, the Court will deny defendants' motion to stay.

ORDER

For the foregoing reasons, defendants' motion for judgment on the pleadings (Docket No. 63) is, as to plaintiffs' reverse payment claim, **ALLOWED** but is otherwise **DENIED**. Defendants' motion to stay the proceedings (Docket No. 66) is **DENIED**.

So ordered.

Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated: November 6 2024