IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: MALLINCKRODT PLC, *et al.*,	:	Chapter 11
	:	
Debtors.	:	Case No. 20-12522-JTD

ATTESTOR LIMITED and HUMANA INC.,	:	
	:	
	:	
Appellants,	:	Civ. No. 21-1780-TLA
v.	:	
	:	
MALLINCKRODT PLC, *et al.*,	:	
	:	
Appellees.	:	

MEMORANDUM OPINION

October 31, 2022
Wilmington, Delaware

AMBRO, *Circuit Judge*, sitting by designation.

Attestor Limited, on behalf of itself and its affiliated entities, and Humana Inc. (collectively, the "Acthar Claimants") appeal the Bankruptcy Court's Order denying the Acthar Claimants' administrative claims (the "Antitrust Order"). Before briefing on the merits began, the Acthar Claimants moved this Court to certify the Antitrust Order for direct appeal to the Third Circuit Court of Appeals. As the Acthar Claimants have not shown the conditions requiring certification are met, I deny the motion.

The appeal stems from the Chapter 11 bankruptcy case filed by Mallinckrodt plc and 63 of its subsidiaries (collectively, "Mallinckrodt"). In Mallinckrodt's bankruptcy, the Acthar Claimants filed a motion for an order allowing administrative expenses based on damages allegedly caused by post-petition purchases of Acthar Gel (the "Administrative Claims"). They alleged their purchases were at supracompetitive prices that were the result of Mallinckrodt's anticompetitive acquisition of the drug. After a bench trial, the Bankruptcy Court denied the Administrative Claims.

For purposes of this motion, I provide an abbreviated summary of the facts. Two drugs are at center. The first is Acthar, a naturally sourced mixture of adrenocorticothrophic hormone ("ACTH") analogs and other pituitary peptides, that has been produced by Mallinckrodt since 1952. Acthar is not covered by a patent, but its formulation process is a trade secret and there is no generic version of it. The other drug is Synacthen, a slow-release formulation of synthetic ACTH that treats many of the same conditions as Acthar but is not approved in the U.S. Synacthen has no patent protection or trade secret protection.

The Acthar Claimants allege Mallinckrodt's predecessor violated antitrust law when it purchased from Novartis in 2013 the U.S. development, marketing and sale rights to Synacthen. Shortly after this acquisition, the Federal Trade Commission (the "FTC") opened an investigation to determine whether Mallinckrodt violated antitrust law. Meanwhile, two losing bidders for the Synacthen rights sought to develop a synthetic ACTH product. One bidder advanced to manufacturing "proof of concept" batches but eventually abandoned efforts to obtain FDA approval. The other bidder began pursuing FDA approval and, after a 2017 settlement reached in the investigation by the FTC of Mallinckrodt, received a license to sell Synacthen commercially for infantile spasms and nephrotic syndrome. Ultimately, its attempt to bring Synacthen to market failed. Mallinckrodt itself ceased efforts to obtain FDA approval for Synacthen.

In this motion, the Acthar Claimants ask me to certify a direct appeal of the Antitrust Order per 28 U.S.C. § 158(d)(2). Subsection (d)(2)(B) directs a district court, at the request of a party, to certify an order for direct appeal to the court of appeals if it determines: (1) the order involves a question of law as to which there is no controlling decision of the courts of appeals for the circuit or the Supreme Court, or involves a matter of public importance; (2) the order involves a question of law requiring resolution of conflicting decisions; or (3) an immediate appeal from the order may materially advance the progress of the case or proceeding in which the appeal is taken. If a certification is made and the court of appeals authorizes direct appeal, it has jurisdiction of the appeal.

The Acthar Claimants argue a direct appeal should be certified because there is no controlling decision of the Third Circuit or Supreme Court that provides the standard for

antitrust standing in this case. The parties debate whether the Third Circuit's decision in *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132 (3d. Cir. 2017), controls this question of law. In that case, drug purchasers challenged a brand-name drug producer's "reverse payment" settlement with a generic drug producer as anticompetitive. *Id*. Most relevant here, the Court considered whether the generic drug producer could have hypothetically overcome the independent obstacle to its competition that was posed by a third party's patent. *Id*. at 164-170. It held the plaintiffs did not establish antitrust standing because they could not show it was more likely than not the generic producer would have been able to launch its product in spite of the third-party patent. *Id*.

Wellbutrin controls the standing issue here. It recognized that a "regulatory or legislative bar" independent of a defendant's conduct could break the chain of causation needed to establish a plaintiff's antitrust standing. *Id.* at 165. The Acthar Claimants' argument—that *Wellbutrin* is distinguishable because the alleged obstacle to competition independent of a defendant's conduct was patent law, rather than FDA regulation—is not compelling. The Acthar Claimants also appear to suggest I certify the appeal because the Third Circuit should consider whether the causation standard announced in the D.C. Circuit's decision in *U.S. v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001), controls antitrust standing here.[1] Yet, both *Microsoft* and the one Third Circuit decision to invoke its "significant contribution" standard, *U.S. v. Dentsply Intern., Inc.*, 399 F.3d 181, 187 (3d. Cir. 2005), involved Government enforcement actions seeking equitable remedies.

[1] *Microsoft*'s causation standard asked whether (1) "the exclusion of nascent threats is the type of conduct that is reasonably capable of contributing significantly to a defendant's continued monopoly power" and (2) "the [potential competitors] reasonably constituted nascent threats at the time" of the anticompetitive conduct. 253 F.3d at 79.

Here, *Wellbutrin* speaks directly to the issue of antitrust standing in private causes of action and provides a standard to apply.

Continuing on, the Acthar Claimants assert I should certify a direct appeal because the Antitrust Order involves a matter of public importance, that is, "a legal question the resolution of which will advance the cause of jurisprudence to a degree that is usually not the case." *In re Am. Home Mortg. Inv. Corp.*, 408 B.R. 42, 44 (D. Del. 2009). Other authorities suggest it is "doubtful" a matter of public importance can exist if there is controlling precedent. COLLIER ON BANKRUPTCY ¶ 5.06[4][b] (16th ed.). This appeal does not involve a matter of public importance sufficient to require direct appeal. First, *Wellbutrin* is controlling precedent and currently provides a standard to be applied in cases like this. Second, concerns about the implications of the allegedly anticompetitive acquisition are softened, as the FTC already settled antitrust claims against Mallinckrodt.

The Acthar Claimants contend as well that a direct appeal should be certified because the standing test applied in the Antitrust Order conflicts with District Court decisions in this Circuit and this conflict requires resolution by the Court of Appeals. However, the pre-*Wellbutrin* decisions cited by the Acthar Claimants may well have been overridden by *Wellbutrin*. Even if they were not, their context is less akin than this case to *Wellbutrin*; hence applying it does not conflict with those decisions. They involved settlements, litigation, and citizen petitions, acts that directly interfered with a pending FDA approval process defendants claimed independently delayed competition. In our case, as in *Wellbutrin*, the defendants' alleged bad actions are more separable from the alleged independent bar to their competition. And to the extent the decisions cited by the Acthar

Claimants that postdate *Wellbutrin* conflict with it, this case more closely resembles *Wellbutrin*. As for the two District Court decisions reciting the *Microsoft* causation standard in cases involving private plaintiffs—*Roxul USA, Inc. v. Armstrong World Indus., Inc.,* No. 17-cv-1258, 2019 WL 1109868 (D. Del. March 8, 2019), and *In re Ductile Iron Pipe Fitting Direct Purchaser Antitrust Litig.*, No. 12-cv-711, 2013 WL 812143 (D.N.J. Mar. 5, 2013)—*Wellbutrin* does not conflict with these decisions. In any event, nothing requires resolution by the Third Circuit of *Wellbutrin*'s standing test at this time.

Lastly, the Acthar Claimants argue a direct appeal will materially advance the progress of the case. The implication is why have a district court decide an appeal when that decision is but a way station to a further appeal to the circuit court. But the presumption is otherwise. Where there is "nothing extraordinary or urgent about [the] situation that recommends departing from the standard appellate process," courts have declined to certify direct appeal. *In re Conex Holdings, LLC*, 534 B.R. 606 (D. Del. 2015). A primary reason is that circuit courts often benefit (we hope) from the analysis done by their district court colleagues. The Acthar Claimants' efficiency argument ignores that.

I close with Mallinckrodt's outstanding motion to dismiss the underlying appeal as equitably moot. Principles underlying the equitable mootness doctrine suggest that it is preferable, to the extent possible and practicable, for a court to become familiar with the merits of an appeal before issuing a decision on equitable mootness. *See In re Tribune Media Co.*, 799 F.3d 272, 278 (3d. Cir. 2015). In that context, I reserve judgment on Mallinckrodt's motion.

For these reasons stated, I deny the motion for certification.