

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

TAKEDA PHARMACEUTICALS U.S.A.,
INC.,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.,

Defendant.

Civil Action No. 19-2216-RGA

MEMORANDUM ORDER

Before me is Plaintiff Takeda's Motion for a Rule 54(b) Final Judgment as to Takeda's Claims and to Stay Mylan's Counterclaims. (D.I. 251). I have considered the parties' briefing. (D.I. 252, D.I. 254, D.I. 255). For the reasons set forth below, this motion is DENIED in part and DISMISSED as moot in part.

I. BACKGROUND

Takeda and Mylan entered into a License Agreement in 2017. (D.I. 2 Ex. 1). The License Agreement provided that Mylan would not enter the market with its generic colchicine product until certain enumerated events occurred. (*Id.* §1.2). Takeda sued Mylan, alleging that Mylan prematurely launched and sold its generic colchicine product, thus breaching the License Agreement. (D.I. 2 at 1, 25). Takeda also brought patent infringement claims. (*Id.* at 1, 27-40). Mylan brought two counterclaims that Takeda breached the License Agreement by bringing this lawsuit. (D.I. 164 at 32-34).

I bifurcated the case to first hear Takeda's breach of contract claim and Mylan's express license defense. (D.I. 198). All other claims and issues, including Mylan's counterclaims, were

stayed. *Id.* In due course, I granted summary judgment in favor of Mylan. I held that Mylan did not breach the License Agreement. (D.I. 245). The parties agree that the only claims remaining in dispute are Mylan’s two counterclaims. (D.I. 252 at 3, D.I. 254 at 1). Takeda now moves for Rule 54(b) final judgment on the Breach of the License Agreement claim and to stay Mylan’s two counterclaims until the Federal Circuit reviews the summary judgment decision. (D.I. 251).

II. LEGAL STANDARD

In any case involving multiple claims, “the court may direct entry of a final judgment as to one or more, but fewer than all, claims . . . if the court expressly determines that there is no just reason for delay.” Fed. R. Civ. P. 54(b). In considering whether to enter a Rule 54(b) judgment, courts use a two-step analysis. *See Curtiss-Wright Corp. v. Gen. Elec. Co.*, 446 U.S. 1, 7–8 (1980). A court must first decide, as a matter of law, whether a judgment is final. *Id.* at 7. If the requirement of finality is met, the court must determine whether, in its discretion, there is any just reason for delay. *Id.* at 8.

A judgment “includes a decree and any order from which an appeal lies.” Fed. R. Civ. P. 54(a). To satisfy Rule 54(b), “[i]t must be a ‘judgment’ in the sense that it is a decision upon a cognizable claim for relief, and it must be ‘final’ in the sense that it is ‘an ultimate disposition of an individual claim entered in the course of a multiple claims action.’” *Curtiss-Wright*, 446 U.S. at 7 (citation omitted).

To determine whether there exists a just reason for delay, the Third Circuit has set forth five factors:

(1) the relationship between the adjudicated and unadjudicated claims; (2) the possibility that the need for review might or might not be mooted by future developments in the district court; (3) the possibility that the reviewing court might be obliged to consider the same issue a second time; (4) the presence or absence of a claim or counterclaim which could result in set-off against the judgment sought to be made final; [and] (5)

miscellaneous factors such as delay, economic and solvency considerations, shortening the time of trial, frivolity of competing claims, expense, and the like.

Berkeley Inv. Grp., Ltd. v. Colkitt, 455 F.3d 195, 203 (3d Cir. 2006).

Courts have discretion to grant a stay. *Cost Bros. v. Travelers Indem. Co.*, 760 F.2d 58, 60 (3d Cir. 1985). “The standard for granting a stay involves consideration of three factors: (1) whether granting a stay will simplify the issues for trial; (2) whether discovery is complete and a trial date is set; and (3) whether granting a stay would cause the non-moving party to suffer undue prejudice from any delay, or a clear tactical disadvantage.” *Huvepharma Food v. Associated British Foods, PLC*, 2019 WL 3802472, at *1 (D. Del. Aug. 13, 2019).

III. DISCUSSION

The judgment is final. Neither party disputes that. (D.I. 252 at 7, D.I. 254 at 7-15). At issue is only whether there is a just reason for delay. I go through each of the *Berkeley* factors in turn and conclude I should not enter a Rule 54(b) judgment.

First, Plaintiff argues there is no overlap between Takeda’s adjudicated claims and Mylan’s unadjudicated counterclaims. (D.I. 252 at 8). Plaintiff contends the breach of License Agreement claim was based on pre-litigation facts while the counterclaims are based on post-litigation conduct. *Id.* Plaintiff also argues the claim and counterclaims were based on entirely different sections of the License Agreement (§ 1.2(d) and §§ 1.7 & 1.12, respectively) which have hardly any factual or legal overlap. (D.I. 255 at 2). Defendant contends that the claim and counterclaims are interrelated because they involve the same parties, License Agreement, colchicine product, and colchicine patents. (D.I. 254 at 10).

I think the claims and counterclaims are related. Mylan’s first counterclaim is for breach of § 1.7. (D.I. 171 at 11). Section 1.7 states that Takeda covenants not to sue unless there is a material breach by Mylan. (D.I. 2 Ex. 1 § 1.7). Takeda claimed there was a material breach of §

1.2(d) of the License Agreement. (D.I. 2 at 25). Mylan's second counterclaim is for a breach of § 1.12. (D.I. 171 at 12). Section 1.12 states in relevant part that Takeda will not interfere with Mylan's efforts to sell Mylan's ANDA product. (D.I. 2 Ex. 1 § 1.12). Mylan argues that Takeda kept Mylan's generic colchicine product off the market with this litigation. (D.I. 254 at 4). Both counterclaims arise out of the same License Agreement and involve the same parties and product. The Federal Circuit would need to consider largely the same factual background for both the claim and counterclaims if they were appealed separately or together.

Second, Plaintiff argues there is no possibility the need for appellate review will be mooted by future developments in the district court. (D.I. 252 at 9). Mylan does not directly respond to this argument. (D.I. 254). I think Plaintiff is right, because there is nothing further to litigate about whether Takeda breached the contract.

Third, Plaintiff argues that the Federal Circuit will not need to consider the breach of contract a second time. *Id.* Even if the counterclaims are also later appealed to the Federal Circuit, Plaintiff contends that appeal would raise separate issues. *Id.* This is probably true.

Fourth, Plaintiff argues the counterclaims will not result in a set-off against the final judgment on the breach of contract claim because they arose from a different set of facts. (D.I. 252 at 10). Mylan does not directly respond to this argument. (D.I. 254). Plaintiff lost; it has no money judgment. Thus, the counterclaims will not result in a set-off.

Finally, Plaintiff argues that entry of a final judgment will promote judicial efficiency. *Id.* Plaintiff argues that I bifurcated the trial to hear the license defense first, and that Respondent stated this would be efficient. *Id.* Mylan contends that the trial was bifurcated to separate the contract claims from the patent claims, and to avoid unnecessary discovery on damages. (D.I. 254 at 13; D.I. 253 Ex. A 31:1-8, 35:12-15, 39:1-8). Mylan argues the counterclaims were never

discussed in the hearing resulting in bifurcation (D.I. 253 Ex. A), and thus the bifurcation was not endorsing entry of final judgment and subsequent appeal of the breach of contract claim. (D.I. 254 at 12). To be candid, it came as a surprise to me to learn that ruling on the breach of contract did not resolve this case in this Court.¹ I bifurcated the trial because Plaintiff was asserting seventeen patents and it seemed likely based on the preliminary injunction proceedings that the patents would never become an issue. (D.I. 253 Ex. A 30:16-31:11, 43:12-44:5). So, doing patent discovery would likely be a colossal waste of time and money. *Id.*

Plaintiff argues that if the Federal Circuit reverses the summary judgment decision, then the counterclaims would fail. (D.I. 252 at 10). Plaintiff contends that therefore entry of final judgment to allow for appeal would make proceedings more efficient. *Id.* Mylan argues that the Federal Circuit has already found “the final judgment in the West-Ward Litigation likely triggers Section 1.2(d) of the License Agreement, permitting Mylan to market its generic colchicine product.” (D.I. 254 at 9; *Takeda Pharms. U.S.A., Inc. v. Mylan Pharms. Inc.*, 967 F.3d 1339, 1345 (Fed. Cir. 2020)). Therefore, Mylan contends the Federal Circuit is unlikely to reverse the summary judgment decision. (D.I. 254 at 9). I agree with Mylan. Given that the Federal Circuit has already considered the interpretation of § 1.2 and found against Takeda, albeit using a deferential standard of review, entry of a final judgment would probably make the proceedings inefficient. Entering a Rule 54(b) judgment would likely result in piecemeal appellate review.

On balance, the *Berkeley* factors weigh against entering a Rule 54(b) judgment on the breach of contract claim. Takeda’s breach of contract claim and Mylan’s breach of contract counterclaims overlap. Entry of a Rule 54(b) judgment would thus lead to inefficient litigation. I

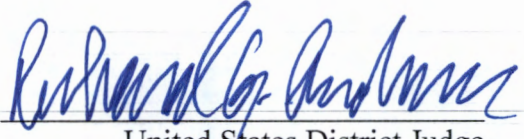
¹ I don’t think anything ever happened in this case that made me aware that the counterclaims existed. But even if there was such an event, it made no lasting impression on me.

thus DENY Plaintiff's motion to enter a Rule 54(b) judgment, and I DISMISS as moot the motion to stay Mylan's two counterclaims.

The parties should meet and confer and within two weeks jointly propose a schedule for moving forward.

IT IS SO ORDERED.

Entered this 23rd day of January, 2024


United States District Judge