

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

CIPLA USA, INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 22-552-VAC-SRF
)	
IPSEN BIOPHARMACEUTICALS, INC.,)	
)	
Defendant.)	

MEMORANDUM ORDER

At Wilmington this 5th day of August, 2022, the court having considered defendant Ipsen Biopharmaceuticals, Inc.’s (“Ipsen”) motion to stay (D.I. 18), and the briefing and filings associated therewith (D.I. 19; D.I. 22; D.I. 24; D.I. 32), IT IS HEREBY ORDERED that Ipsen’s motion to stay is DENIED for the following reasons:

1. **Background.** Ipsen is a biopharmaceutical drug company. (D.I. 1 at ¶ 1) In August 2007, Ipsen began manufacturing Somatuline® Depot, a drug injection with the active ingredient lanreotide acetate, to treat rare diseases by slowing the growth of tumors. (*Id.*)
2. InvaGen Pharmaceuticals, Inc. (“InvaGen”), an affiliate of plaintiff Cipla USA, Inc. (“Cipla”), submitted a Section 505(b)(2) application to the Food and Drug Administration (“FDA”) to market a lanreotide acetate injection product (“Cipla’s Lanreotide Acetate Product”). (*Id.* at ¶ 2) The FDA approved InvaGen’s application on December 17, 2021. (*Id.* at ¶ 39) The complaint alleges that the active ingredient, route of administration, and strengths of Cipla’s Lanreotide Acetate Product are the same as Somatuline® Depot. (*Id.* at ¶ 40)
3. Following FDA approval of Cipla’s Lanreotide Acetate Product, the complaint alleges that Ipsen’s stock price dropped significantly and Ipsen began making false or misleading statements about Cipla and its product. (*Id.* at ¶¶ 41-47) Among the allegedly false statements

made by Ipsen were allegations that Cipla's Lanreotide Acetate Product falls under a separate healthcare billing code from Ipsen's Somatuline® Depot product under the Healthcare Common Procedure Coding System ("HCPCS"). (*Id.* at ¶ 47) According to Cipla, these false or misleading statements have created market confusion regarding health care coverage and reimbursement for Cipla's Lanreotide Acetate Product, leading to erosion of Cipla's sales and damage to Cipla's reputation and goodwill. (*Id.* at ¶¶ 49-52)

4. Cipla filed this suit on April 27, 2022, alleging causes of action for unfair competition under the Lanham Act, 15 U.S.C. § 1125(a) and Delaware common law; deceptive trade practices under the Delaware Uniform Deceptive Trade Practices Act, 6 *Del. C.* § 2532; tortious interference with economic advantage; and trade libel. (*Id.* at ¶¶ 57-99) On May 4, 2022, the case was assigned to the court's Vacant Judgeship docket (the "VAC docket"). (D.I. 6)

5. On June 3, 2022, Ipsen filed a motion to dismiss for lack of subject matter jurisdiction and failure to state a claim under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6), respectively. (D.I. 16) Ipsen filed the instant motion to stay discovery pending resolution of the motion to dismiss on the same date. (D.I. 18)

6. On July 6, 2022, the Centers for Medicare & Medicaid Services ("CMS") issued a decision creating a new HCPCS Level II code for Cipla's Lanreotide Acetate Product. (D.I. 32, Ex. A at 10)

7. **Legal Standard.** District courts have broad discretion in matters concerning case management and discovery. *See United States v. Schiff*, 602 F.3d 152, 176 (3d Cir. 2010); *Sempier v. Johnson & Higgins*, 45 F.3d 724, 734 (3d Cir. 1995). Included within this broad discretion is a district court's consideration of a motion to stay. *See Dentsply Int'l Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990). Courts generally consider three factors in

deciding how to exercise their discretion in the context of a motion to stay: (1) whether a stay will simplify the issues for trial; (2) the status of the litigation, particularly whether discovery is complete and a trial date has been set; and (3) whether a stay would cause the non-movant to suffer undue prejudice from any delay or allow the movant to gain a clear tactical advantage. *See Am. Axle & Manuf., Inc. v. Neapco Holdings LLC*, C.A. No. 15-1168-LPS, 2021 WL 616992, at *2 (D. Del. Feb. 17, 2021); *Harvey v. McBride*, C.A. No. 19-1861-CFC *et al.*, 2021 WL 372511, at *3 (D. Del. Feb. 3, 2021). However, consideration of these factors “is not a rigid template for decision[,]” and the court retains discretion to consider the totality of circumstances “beyond those captured by the three-factor stay test.” *British Telecommc ’ns PLC v. IAC/InterActiveCorp*, C.A. No. 18-366-WCB, 2020 WL 5517283, at *5 (D. Del. Sept. 11, 2020) (quoting *Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1362 (Fed. Cir. 2016)). The movant bears the burden to show that the circumstances support an exercise of the court’s discretion to stay. *RideShare Displays, Inc. v. Lyft, Inc.*, C.A. No. 20-1629-RGA-JLH, 2021 WL 7286931, at *1 (D. Del. Dec. 17, 2021) (citing *Clinton v. Jones*, 520 U.S. 681, 708 (1997)).

8. Analysis. Based on the court’s consideration of the totality of the circumstances in this case, Ipsen’s motion to stay is DENIED. The court’s exercise of its discretion over case management is guided by Standing Order No. 2022-VAC-1, dated March 9, 2022 (“Standing Order”), which governs cases such as this one that are assigned to the VAC docket during the current judicial vacancy. The Standing Order specifies that “[t]he filing of a motion shall not be grounds to prevent the case, including discovery, from progressing” until the case is assigned to an Article III Judge. Standing Order at ¶ 5(f). Ipsen’s proposal to stay discovery until resolution of the pending motion to dismiss would require a deviation from the Standing Order. In the

context of the overarching guidance provided by the Standing Order, the court turns to an analysis of the three stay factors.

9. ***Simplification of issues for trial.*** The first factor does not weigh heavily for or against a stay at this stage of the proceedings. *See Kaavo Inc. v. Cognizant Tech. Sols. Corp.*, C.A. No.14-1192-LPS-CJB *et al.*, 2015 WL 1737476, at *2 (D. Del. Apr. 9, 2015) (explaining that the court must assess “*all* of the possible outcomes of the . . . inquiry . . . not just the potential outcome most favorable to the party seeking the stay.”). Ipsen argues the court’s consideration of its motion to dismiss is likely to result in dismissal of the entire case, and Cipla disputes Ipsen’s position. (D.I. 19 at 8-10; D.I. 22 at 10-11) While the case would be “greatly simplified” if the motion to dismiss is granted, “little efficiency gain would be realized” if the motion is denied or granted-in-part. *Kaavo*, 2015 WL 1737476, at *2.

10. Consideration of the first factor on a motion to stay should not entail an evaluation of the legal merits of the motion to dismiss. *See Kaavo*, 2015 WL 1737476, at *2 n.4. Moreover, Ipsen’s focus on the merits of the underlying motion falls outside the scope of the referral to the Magistrate Judge under the Standing Order. *See* Standing Order at ¶ 5(a).¹

11. Ipsen contends that the CMS coding decision further supports its position that the issues will be simplified by a stay, noting that courts routinely stay litigation when the court’s decision would be aided by an agency’s decision. (D.I. 19 at 10; D.I. 32 at 3-4) But the CMS decision does not undermine Cipla’s allegations that Ipsen made multiple misrepresentations about HCPCS coding for Cipla’s Lanreotide Acetate Product which resulted in commercial harm to Cipla. At the time Ipsen made the alleged misrepresentations about the proper coding of

¹ The parties may at any time consent to the jurisdiction of the Magistrate Judge, limited to resolution of a dispositive motion. *See* Form AO85A.

Cipla's Lanreotide Acetate Product, the CMS had not yet reached a decision. (D.I. 1 at ¶ 47(a), 59(a)) Yet the complaint alleges Ipsen falsely told customers that their coverage and reimbursement for Cipla's Lanreotide Acetate Product would be impacted by HCPCS coding. (*Id.* at ¶¶ 5, 47(c)-(d)) It is the alleged misrepresentations which form the core of Cipla's complaint. Cipla contends these representations were false because providers can make their own decisions on HCPCS coding before a code is assigned, and the question of coverage is independent from HCPCS coding. (D.I. 1 at ¶¶ 5, 45, 47(c)-(d), 59)

12. Moreover, not all of the alleged misrepresentations identified by Cipla in the complaint involve HCPCS coding or are otherwise impacted by the CMS decision. The complaint alleges Ipsen falsely represented Cipla's position on the therapeutic equivalence of Cipla's Lanreotide Acetate Product and Somatuline Depot®. (D.I. 1 at ¶¶ 5(a), 45, 48, 61, 63) Ipsen does not argue that the CMS decision disposes of this alleged misrepresentation. (D.I. 32 at 3-4)

13. For these reasons, a determination on the simplification of issues for trial is premature prior to the resolution of the motion to dismiss, and the CMS decision does not fundamentally alter the analysis on this factor.

14. ***Status of the litigation.*** This factor weighs in favor of a stay because the case is in its earliest stages, and "the most burdensome stages of the case[] . . . all lie in the future." *IOENGINE, LLC v. PayPal Holdings, Inc.*, C.A. No. 18-452-WCB, 2019 WL 3943058, at *5 (D. Del. Aug. 21, 2019). No scheduling order has been entered, discovery has not yet begun, and no trial date has been set. *See Neste Oil OYJ v. Dynamic Fuels, LLC*, C.A. No. 12-1744-GMS, 2013 WL 3353984, at *5 (D. Del. July 2, 2013).

15. **Undue prejudice.** This factor weighs against a stay. There appears to be no dispute that Cipla and Ipsen are the only competitors in the market for lanreotide acetate products. (D.I. 1 at ¶¶ 1-2; D.I. 24 at 6) “[W]here, as here, the parties are the only two competitors in the relevant market, the Court can more easily draw the inference of the increased chance of undue prejudice from delay related to a stay.” *SenoRx, Inc. v. Hologic, Inc.*, C.A. No. 12-173-LPS-CJB, 2013 WL 144255, at *8 n.10 (D. Del. Jan. 11, 2013).

16. Ipsen’s contention that the parties’ direct competitor status is only relevant in the patent infringement context is not compelling. The complaint in this case alleges loss of market share and a loss of goodwill among customers. (D.I. 1 at ¶¶ 49, 52) Regardless of whether the harm occurs in the context of patent infringement claims or claims for unfair competition, any delay in adjudicating such a case “will have outsized consequences for the party asserting” the claims. *SenoRx*, 2013 WL 144255, at *7; *FMC Corp. v. Summit Agro USA, LLC*, C.A. No. 14-51-LPS-CJB, 2014 WL 3703629, at *5-6 (D. Del. July 21, 2014) (finding some prejudice where parties were direct competitors on a motion to stay Lanham Act claims).

17. The court further recognizes that “delay inherently harms a non-moving party by prolonging resolution of the dispute, even if the party is not currently a direct competitor.” *RideShare Displays, Inc. v. Lyft, Inc.*, C.A. No. 20-1629-RGA-JLH, 2021 WL 7286931, at *1 (D. Del. Dec. 17, 2021) (citing *Neste Oil*, 2013 WL 3353984, at *2).

18. On balance, the totality of the circumstances weighs against the entry of a stay of discovery in this case. A stay of discovery would contravene the case management directives of the Standing Order and is likely to prejudice Cipla.

19. **Conclusion.** IT IS ORDERED that, in the exercise of the court’s discretion over case management of VAC cases, Defendant’s motion to stay is DENIED. (D.I. 18)

21. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to four (4) pages each.

22. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated March 7, 2022, a copy of which is available on the court's website, www.ded.uscourts.gov.



Sherry R. Fallon
United States Magistrate Judge