

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

JAZZ PHARMACEUTICALS, INC.,

Plaintiff,

v.

AVADEL CNS PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 21-691-GBW

PUBLIC VERSION

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 21-1138-GBW

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 21-1594-GBW

**OPENING BRIEF IN SUPPORT OF PLAINTIFFS'
MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 4
OF NO ANTICIPATION OF U.S. PATENT NO. 11,077,079**

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I. NATURE AND STAGE OF THE PROCEEDINGS

Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Ltd. (“Plaintiffs” or “Jazz”) allege that Avadel CNS Pharmaceuticals, LLC (“Defendant” or “Avadel”) infringes six patents, including U.S. Patent No. 11,077,079 (“’079 Patent”). C.A. No. 21-1138, D.I. 216 at ¶¶ 10, 25-37. Avadel asserts an affirmative defense and counterclaim of invalidity under 35 U.S.C. § 102 against the ’079 Patent. C.A. No. 21-1138, D.I. 227 at 13 (Second Affirmative Defense), 17-18 (Counterclaim Count II). Fact and expert discovery are closed and the parties are proceeding to a five-day jury trial beginning on February 26, 2024. Jazz moves herein for partial summary judgment against one of Avadel’s twenty-five-plus invalidity defense theories: that U.S. Patent Application Publication US 2006/0210630A1 (“Liang” or “Liang 2006”) allegedly anticipates the asserted claims of the ’079 Patent under 35 U.S.C. § 102.

II. SUMMARY OF ARGUMENT

The Court should grant Jazz summary judgment because both parties’ experts agree, as did Avadel in submissions to the United States Patent and Trademark Office (“PTO”) before it was sued by Jazz, that Liang does not disclose several required elements of the ’079 Patent’s asserted claims. Because there is no genuine dispute that Liang does not disclose all elements of the asserted claims of the ’079 Patent, Liang cannot anticipate the asserted claims. Jazz is therefore entitled to summary judgment on that portion of Avadel’s defense and counterclaim.

III. AVADEL CANNOT PROVE THAT LIANG ANTICIPATES THE ASSERTED CLAIMS OF THE ’079 PATENT

To prove anticipation based on Liang, Avadel must prove by clear and convincing evidence that Liang discloses, either expressly or inherently, each and every limitation of the ’079 Patent’s asserted claims. *See* 35 U.S.C. § 102(a); *HTC Corp. v. Cellular Commc'ns Equip.*,

LLC, 877 F.3d 1361, 1368 (Fed. Cir. 2017). If any claim limitation is not disclosed in Liang, then Liang cannot anticipate as a matter of law. *Id.*

A. The '079 Patent's Asserted Claims All Share Common Claim Elements

All asserted claims of the '079 Patent require, among other elements, “opening a sachet containing a solid oxybate formulation,” “mixing the formulation with water,” and “orally administering the mixture to the patient.” SOF 3.

B. There Is No Genuine Dispute That Liang Does *Not* Disclose The Asserted Claims' Common Claim Elements

Before Jazz brought suit against Avadel, Avadel made arguments to the PTO that directly contradict the arguments that Avadel makes in this case. Avadel contends in this case that Liang anticipates the asserted claims of the '079 Patent. For Avadel's contention to be correct, Avadel must argue that Liang discloses “opening a sachet containing a solid oxybate formulation,” “mixing the formulation with water,” and “orally administering the mixture to the patient.” But Avadel already took the exact opposite position at the PTO during the prosecution of its own patent.

During prosecution of its own patent, and before it was sued by Jazz, Avadel argued to the PTO that “Liang do[es] not expressly disclose opening a sachet containing a gamma hydroxybutyrate formulation, mixing the formulation with water and orally administering the mixture.” SOF 4-7. These arguments are equally applicable to each of the '079 Patent asserted claims. SOF 3, 6. And Avadel's own expert, Dr. Charman, agrees with the position Avadel previously took in front of the PTO. Dr. Charman agrees that Liang does *not* disclose the above-recited claim elements. SOF 9.

The Supreme Court has stated that “where a party assumes a certain position in a legal proceeding, and succeeds in maintaining that position, he may not thereafter, simply because his

interests have changed, assume a contrary position” *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001). District courts, therefore, routinely estop litigants from making arguments before the court that are clearly inconsistent with previous arguments made before the PTO. *See, e.g., Yeda Res. & Dev. Co. Ltd. v. Imclone Sys. Inc.*, 443 F. Supp. 2d 570, 623 (S.D.N.Y. 2006) (“During the course of their patent prosecution, defendants specifically represented to the PTO that Figure 1(B) of the 1988 paper . . . discloses element (iii) of Claim 1 They now take the position that Figure 1(B) does not disclose Element (iii) However, because the PTO adopted their argument that Figure 1(B) supports Element (iii), we conclude that defendants are judicially estopped from now arguing that the Weizmann scientists did not disclose Element (iii) in the 1988 paper.”); *Health Advocate, Inc. v. Health Advocates, LLP*, No. 03-4277, 2005 WL 8176688, at *5 (E.D. Pa. July 14, 2005) (noting that “this Court will exercise its discretion to apply the equitable doctrine of judicial estoppel and bar Plaintiff from asserting that the ‘Health Advocates’ [trade]mark is generic” where plaintiffs had taken the opposite position before PTO).

Perhaps because Avadel is aware of this legal precedent, Avadel’s expert, Dr. Charman, focuses his validity opinions on an alleged lack of written description, and not on alleged anticipation based on Liang. In fact, as noted above, Dr. Charman agrees with the arguments Avadel made in front of the PTO regarding the lack of an express disclosure in Liang of “opening a sachet containing a gamma hydroxybutyrate formulation, mixing the formulation with water and orally administering the mixture.” SOF 9. So does Jazz’s expert, Dr. Davies. SOF 11-12. And Dr. Charman confirmed that he is not offering any inherent anticipation opinions. SOF 10. Therefore, Dr. Charman and Dr. Davies *agree* that Liang does not disclose, expressly or inherently, the ’079 Patents’ common claim elements of “opening a sachet containing a solid oxybate formulation,” “mixing the formulation with water,” and “orally

administering the mixture to the patient.” SOF 9-12. That should be the end of the anticipation inquiry.

But Avadel and its expert Dr. Charman want to argue that, if Dr. Charman is incorrect in his alleged lack of written description opinions, then Dr. Charman can change his opinions regarding the disclosures in Liang. Specifically, Dr. Charman wants to change his opinions in order to opine on anticipation as well, stating that “my opinion is that if it is deemed that the ’079 patent has an adequate written description, then the comparable disclosures in Liang 2006 likewise discloses [the above-recited claim limitations].” SOF 9, n.1. But “[a]s [the Federal Circuit] ha[s] stated numerous times . . . in order to demonstrate anticipation, the proponent must show that *the four corners of a single, prior art document* describe every element of the claimed invention.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (internal quotations and citation omitted) (emphasis added). As noted above, it is Dr. Charman’s opinion that the common claim elements of the ’079 Patent are *not* disclosed in the four corners of Liang. And Avadel cannot “assume a contrary position” “simply because [its] interests have changed” once unsuccessful on written description. *New Hampshire*, 532 U.S. at 749.

In sum, both parties’ experts agree, as did Avadel during the prosecution of its own patent, that Liang does not disclose the ’079 Patent’s common claim elements of “opening a sachet containing a solid oxybate formulation,” “mixing the formulation with water,” and “orally administering the mixture to the patient.” Consequently, as a matter of law, Liang cannot anticipate the ’079 Patent’s asserted claims.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Jazz partial summary judgment on Avadel’s Second Affirmative Defense and Counterclaim Count II.

Dated: November 30, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 30, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on November 30, 2023, upon the following in the manner indicated:

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