

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

<p>JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.</p>	<p>C.A. No. 21-691-GBW PUBLIC VERSION</p>
<p>JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.</p>	<p>C.A. No. 21-1138-GBW</p>
<p>JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.</p>	<p>C.A. No. 21-1594-GBW</p>

**OPENING BRIEF IN SUPPORT OF PLAINTIFFS'
MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 2
OF NONOBVIOUSNESS OF U.S. PATENT NOS. 11,077,079 AND 11,147,782**

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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 Nos. 11,077,079 (“’079 Patent”) and 11,147,782 (“’782 Patent,” together with the ’079 Patent, “’079/782 Patents”). C.A. No. 21-1138, D.I. 216 at ¶¶ 10, 25-37; C.A. No. 21-1594, D.I. 211 at ¶¶ 10, 24-36. Avadel asserts affirmative defenses and counterclaims of invalidity under 35 U.S.C. § 103 against the ’079/’782 Patents. C.A. No. 21-1138, D.I. 227 at 13 (Second Affirmative Defense), 17-18 (Counterclaim Count II); C.A. No. 21-1594, D.I. 222 at 13 (Second Affirmative Defense), 25 (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 the asserted claims of the ’079/’782 Patents are allegedly invalid for obviousness under 35 U.S.C. § 103.

II. SUMMARY OF ARGUMENT

The Court should grant Jazz summary judgment because Avadel has no evidence of obviousness under the correct legal standard. In particular, Avadel has no evidence that the ’079/’782 Patents would have been obvious to a POSA *without knowledge of the disclosures in the ’079/’782 Patents’ specification and claims*. Its expert admittedly never conducted any such analysis.

Post-AIA 35 U.S.C. § 103 requires obviousness to be analyzed “*before* the effective filing date of the claimed invention.” (emphasis added).¹ It is “axiomatic that a finding of

¹ Pre-AIA 35 U.S.C. § 103 required obviousness to be analyzed “at the time the invention was made.” The standards are the same unless in the pre-AIA context and an earlier time of invention is being sought based on prior conception and diligent reduction to practice. *See*

obviousness cannot be founded on knowledge or teaching provided by the patentee's invention itself." *Procter & Gamble Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 592 (D. Del. 1997).

Avadel's alleged obviousness expert, Dr. Alexander Klibanov, made clear both in his expert reports and deposition that he is offering his obviousness opinions *solely subject to certain assumptions*. One assumption Dr. Klibanov was asked to make by Avadel's counsel is that the '079/'782 Patents' asserted claims have adequate written description support and are enabled. Dr. Klibanov admitted, however, that a person of ordinary skill in the art ("POSA") would have needed access to the '079/'782 Patents' specification and claims to make the same assumption he did for his obviousness analysis. Dr. Klibanov further admitted that a POSA would not have had that access. Indeed, by statute, a POSA *could not* have that access. Instead, a POSA must conduct the obviousness analysis before the '079/'782 Patents' specification and claims existed.

Avadel has no evidence that the '079/'782 Patents would have been obvious to a POSA "before the earliest effective filing date." There is therefore no genuine dispute that Avadel cannot prove obviousness. Accordingly, Jazz is entitled to summary judgment on this issue.

III. AVADEL CANNOT PROVE OBVIOUSNESS OF THE '079/'782 PATENTS' ASSERTED CLAIMS

A patent is obvious "if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing

Webastro Thermo & Comfort N. Am., Inc. v. Bestop, Inc., No. 16-13456, 2019 WL 2417070, at *3 (E.D. Mich. June 10, 2019), *aff'd sub nom.* No. 16-13456, 2019 WL 4892417 (E.D. Mich. July 29, 2019). That is not at issue here. Regardless, pre-AIA obviousness legal standards apply equally to the post-AIA statute. *See Merck & Cie v. Watson Lab'ys, Inc.*, 125 F. Supp. 3d 503, 512 (D. Del. 2015), *rev'd on other grounds*, 822 F.3d 1347 (Fed. Cir. 2016).

date of the claimed invention to a [POSA].” 35 U.S.C. § 103.² Patents are presumed valid and Avadel must therefore prove obviousness by clear and convincing evidence. 35 U.S.C. § 282(a); *Microsoft Corp. v. i4i Ltd. P’ship*, 564 U.S. 91, 95, 101-02 (2011).

A. The “Premise” Of Dr. Klivanov’s Obviousness Opinions Is Based On Disclosures That Would Not Have Been Available To A POSA

Dr. Klivanov testified at deposition that his only basis for alleged invalidity for the ’079/’782 Patents is “obviousness based on certain assumptions that are clearly and repeatedly stated in [his operative opening expert report].” SOF 5. In his operative opening report, Dr. Klivanov stated in no uncertain terms that his “opinions herein are premised” on the assumption that disclosures in Jazz’s ’079/’782 Patents provide adequate written description support for and enable the asserted claims of those patents. SOF 6. He confirmed the same at deposition. *Id.*

But Dr. Klivanov also confirmed at deposition that the written description and enablement analyses for Jazz’s ’079/’782 Patents “are based on the entirety of the [’079/’782] patent[s], both the specification and the – and the claims.” SOF 7. He further testified that, for the purpose of offering his obviousness opinions in the case, he used an assumption that a POSA would have had access to and knowledge of the specification and claims of the ’079/’782 Patents, and that his assumption “depends on the existence of those patents.” SOF 8, 11. Dr. Klivanov admitted, however, that a POSA in February 2016 (before the effective filing date of the ’079/’782 Patents) would not have had access to the ’079/’782 Patents. SOF 11.

Although Dr. Klivanov testified, “I don’t know what assumption a POSA would or would not have had” (*id.*; SOF 22), a POSA could not have employed the same assumption that

² The ’079/’782 Patents are post-AIA patents because their effective filing date is after March 1, 2013. SOF 1.

Dr. Klibanov did regarding written description and enablement. By statute, a POSA cannot have access to, or knowledge of, the disclosures of the specification and claims of the patents-in-suit because those patents do not exist at the time of the POSA's analysis.

Post-AIA 35 U.S.C. § 103 states a patent is invalid for obviousness “if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious *before* the effective filing date of the claimed invention to a [POSA].” (emphasis added). It is, therefore, “axiomatic that a finding of obviousness cannot be founded on knowledge or teaching provided by the patentee's invention itself.” *Procter & Gamble*, 989 F. Supp. at 592. Consistent with this principle, the Federal Circuit has held that it is error to use the teachings in the challenged patent for the purpose of finding obviousness. *See, e.g., Univ. of Strathclyde v. Clear-Vu Lighting LLC*, 17 F.4th 155, 165 (Fed. Cir. 2021) (“Clear-Vu argues that support [for the obviousness findings] can be found in the [challenged] patent itself. . . . But [t]he inventor's own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the [POSA] would have followed, as evidenced by the pertinent prior art.”); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983) (“It is wrong to use the patent in suit as a guide through the maze of prior art references, combining the right references in the right way so as to achieve the result of the claims in suit.”).

Here, Dr. Klibanov readily admitted to his hindsight-based analysis at deposition. Dr. Klibanov testified “I certainly reviewed the – the [’079/’782 Patents], both the claims and specification . . . *before* I started reviewing the prior art.” SOF 10 (emphasis added). Dr. Klibanov further testified that the reason he searched the prior art for particular disclosures that allegedly fall within the scope of the ’079/’782 Patents' asserted claims is because he “wasn't engaged in some open-ended exercise.” SOF 9. Instead, his “analysis started with

reviewing the [’079/’782 Patents], including their specifications and the claims, and you know, also at some point I reviewed their prosecution history. . . . And I used the references that are – in my judgment were particularly relevant to conducting the analysis that I’ve been asked to conduct.” SOF 10. Dr. Klibanov testified, “I was specifically tasked by counsel for Avadel to [opining] whether the asserted claims of the [’079/782] patents are obvious under certain assumptions that I repeatedly state in my expert reports.” SOF 9.

As noted above, the referenced assumptions include that a POSA would have had knowledge of the disclosures in the ’079/’782 Patents’ specification and claims. This is precisely the hindsight analysis that the statute and precedent preclude. *See, e.g., Janssen Pharms., Inc. v. Teva Pharms. USA, Inc.*, No. 18-734, 2021 WL 5323737, at *10, n.25 (D.N.J. Nov. 16, 2021) (“Dr. Wermeling also appeared to rely on impermissible hindsight in forming his obviousness opinion” because “Dr. Wermeling conceded that he ‘formed [his] opinions on obviousness’ by ‘look[ing] at the ’906 Patent claims first,’” and that concession “undermine[s] his obviousness opinion.”); *Cheese Sys., Inc. v. Tetra Pak Cheese & Powder Sys., Inc.*, 725 F.3d 1341, 1352 (Fed. Cir. 2013) (“Obviousness cannot be based on the hindsight combination of components selectively culled from the prior art to fit the parameters of the patented invention.”).

Since Dr. Klibanov conducted a legally incorrect analysis, Avadel has no evidence that the ’079/’782 Patents would have been obvious to a POSA “before the earliest effective filing date.” Therefore, there is no genuine dispute that Avadel cannot prove obviousness of the ’079/’782 Patents’ asserted claims. Thus, Jazz is entitled to summary judgment.

B. Avadel’s Arguments To The PTO Before This Case Began Directly Contradict Its Obviousness Arguments In This Case

The reason Avadel is having its expert employ a premise for his obviousness opinions that renders them legally incapable of proving obviousness is clear. Before Jazz brought suit

against Avadel, Avadel made arguments to the United States Patent and Trademark Office (“PTO”) that directly contradict the arguments that Avadel makes in this case. Avadel, thus, cannot take any position on obviousness that would actually be needed to prove its case.

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 Rsch. & 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 Advoc., Inc. v. Health Advocs., 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).

In this case, Avadel contends that the ‘079/’782 Patents’ asserted claims would have been obvious. For Avadel’s contention to be correct, Avadel must argue that the prior art by *February 2016* (SOF 1) would have rendered the ‘079/’782 Patents’ claims obvious. But several elements in the ‘079/’782 Patents’ claims overlap with elements in Avadel’s patent claims that were not filed until *July 2016*—*five months after* Jazz’s February 2016 filing date. SOF 1, 12-13, 16-17;

see also SOF 3-4. And at the PTO before it was sued by Jazz, Avadel argued that the prior art would *not* have rendered its claims obvious. SOF 13-14, 17-18.

Avadel's arguments before the PTO directly contradict any argument for obviousness it would need to prove its case. For example, and relevant to the '079 Patent, Avadel argued to the PTO that the prior art does "not expressly disclose opening a sachet containing a gamma hydroxybutyrate formulation, mixing the formulations with water and orally administering the mixture." SOF 14. Avadel further argued to the PTO that prior art "teaches away from a sachet," and to abandon a "problematic" sachet formulation "in favor of a purely liquid formulation." *Id.* The PTO found Avadel's arguments "persuasive" and allowed issuance of Avadel's patent. SOF 15. The '079 Patent's asserted claims each require "opening a sachet containing a solid oxybate formulation," "mixing the formulation with water," and "orally administering the mixture to the patient." SOF 3. Avadel's arguments to the PTO are equally applicable to each '079 Patent asserted claim.

As another example, and relevant to the '782 Patent, Avadel argued to the PTO that the prior art does not "disclose or suggest a formulation having a suspending/viscosifying agent and an acidifying agent that are separate and distinct from the immediate release component and delayed/controlled release component of the formulation." SOF 18. Avadel further argued to the PTO that "a [POSA] would not have been prompted by the disclosure of [the prior art] to modify the dosage forms disclosed therein and arrived at the claimed formulation." *Id.* Once again, the PTO found Avadel's arguments "persuasive" and allowed issuance of Avadel's patent. SOF 19. The '782 Patent's asserted claims each require "a viscosity enhancing agent" "and an acid," "wherein the viscosity enhancing agent and the acid are separate from the immediate

release particles and the modified release particles.” SOF 4. Avadel’s arguments to the PTO are equally applicable to each ’782 Patent asserted claim.

Avadel’s need to change positions explains why Avadel had Dr. Klibanov employ a legally flawed premise for obviousness. Indeed, when confronted with Avadel’s prior statements to the PTO during deposition, Dr. Klibanov claimed that Avadel’s statements were made “in a different context.” SOF 20. When asked “[w]hat’s the different context,” Dr. Klibanov immediately fell back on his legally impermissible premise for analyzing obviousness: “The different context is that, first of all, in – in my case, in my analysis, I’ve been specifically instructed to assume that there is enablement and adequate written description.” SOF 21.

Avadel’s contradictory positions before the PTO and this Court concerning the subject matter claimed in the ’079/’782 Patents have forced Dr. Klibanov into the untenable position of asserting obviousness based on the assumption that the ’079/’782 Patents have adequate written description support and are enabled. But, described above, Avadel’s conundrum has led to Dr. Klibanov providing a legally improper analysis and has left Avadel without evidence of obviousness.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Jazz partial summary judgment on Avadel’s Second Affirmative Defense and Counterclaim Count II for the ’079/’782 Patents.

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.

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