

**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. 3
OF NONOBVIOUSNESS OF THE SUSTAINED RELEASE PATENTS**

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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. 10,758,488, 10,813,885, 10,959,956, and 10,966,931 (collectively, “the Sustained Release Patents”). C.A. No. 21-691, D.I. 325 at ¶¶ 1, 24-75. Avadel asserts affirmative defenses and counterclaims of invalidity under 35 U.S.C. § 103 against the Sustained Release Patents. C.A. No. 21-691, D.I. 336 at 21-22 (Second Affirmative Defense), 29 (Counterclaim Count II), 31 (Counterclaim Count IV), 33 (Counterclaim Count VI), 35 (Counterclaim Count VIII). 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 Sustained Release 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 fact, both parties’ experts agree that the alleged prior art, as properly viewed by a POSA, does not disclose a required element of the Sustained Release Patents’ asserted claims. Avadel’s expert only reaches a different conclusion when she admittedly (and improperly) uses the disclosures in the Sustained Release Patents’ specification and claims as the bases for her obviousness opinions.

Each asserted claim of the Sustained Release Patents requires, among other elements, one or more deionized water dissolution release profiles for the sustained release portion of the claimed formulation—what Ms. Gray calls “the Claimed Dissolution Limitation.” SOF 3-4. An entire section of Ms. Gray’s opening expert report was devoted to her opinion that “the prior art

taught the Claimed Dissolution Limitation.” SOF 6. Ms. Gray reversed course, however, in her reply expert report and at deposition. Therein, Ms. Gray stated that she “agree[d]” with Jazz’s experts that, “[a]s properly viewed by a POSA with experience in dissolution profiles,” “the references I cited to in my Opening Report *do not disclose* the claimed dissolution limitations.” SOF 6-8 (emphasis added). Thus, there is no genuine dispute that those limitations of the Sustained Release Patents’ asserted claims are not disclosed in the prior art.

Given this lack of a dispute, Ms. Gray has stated that her obviousness opinions are premised on the “assum[ption] that the Sustained Release Patents’ description of different formulations tested under different dissolution conditions would reasonably convey to a POSA that the inventors were in possession of the claimed subject matter.” SOF 9. In other words, Ms. Gray is basing her obviousness opinions on a POSA’s knowledge of the disclosures in the patents-in-suit’s specification and claims. But pre-AIA 35 U.S.C. § 103 requires obviousness to be analyzed “*at the time the invention was made.*” (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 Co. v. Paragon Trade Brands, Inc.*, 989 F. Supp. 547, 592 (D. Del. 1997).

Avadel has no evidence that the Sustained Release Patents would have been obvious to a POSA “at the time the invention was made.” 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 SUSTAINED RELEASE PATENTS’ ASSERTED CLAIMS

A patent is obvious “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time

the invention was made to a [POSA].” Pre-AIA 35 U.S.C. § 103.¹ 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).

In her reply report and at deposition, Ms. Gray “agree[d]” with Jazz’s experts that, “[a]s properly viewed by a POSA with experience in dissolution profiles,” “the references I cited to in my Opening Report do not disclose the claimed dissolution limitations.” SOF 6-8. Given this undisputed fact, Ms. Gray made clear in her reply report that her only basis for alleged obviousness of the Sustained Release Patents is premised on the “assum[ption] that the Sustained Release Patents’ description of different formulations tested under different dissolution conditions would reasonably convey to a POSA that the inventors were in possession of the claimed subject matter.” SOF 9. To make such an assumption, however, Ms. Gray’s POSA would necessarily have to have had access to, and to have relied upon, the disclosures in the specification and claims of the patents-in-suit. A POSA *could not* have had that access.

Ms. Gray’s obviousness opinions are flawed as a matter of law. By statute, the patents-in-suit are unavailable to a POSA at the time of the obviousness analysis. Pre-AIA 35 U.S.C. § 103 states a patent is invalid for obviousness “if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious *at the time the invention was made* 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

¹ The Sustained Release Patents are pre-AIA patents because their effective filing date is before March 1, 2013. SOF 1.

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 the inventor’s own path itself never leads to a conclusion of obviousness; that is hindsight. What matters is the path that the person of ordinary skill in the art would have followed, as evidenced by the pertinent prior art.”) (internal citation and quotations omitted); *Orthopedic Equip. Co., Inc. v. U.S.*, 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.”).

Since Ms. Gray conducted a legally incorrect analysis, Avadel has no evidence that the Sustained Release Patents would have been obvious to a POSA “at the time the invention was made.” In fact, Ms. Gray agrees with Jazz’s experts that they would not have been obvious ‘as properly viewed by a POSA.’ SOF 6-8. There can therefore be no genuine dispute that Avadel cannot prove obviousness of the Sustained Release Patents’ asserted claims. Thus, Jazz is entitled to summary judgment.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Jazz partial summary judgment on Avadel’s Second Affirmative Defense, and Counterclaim Counts II, IV, VI and VIII for the Sustained Release 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.

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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