

**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

**PUBLIC VERSION**

JAZZ PHARMACEUTICALS, INC., et al.,

Plaintiffs,

v.

AVADEL CNS PHARMACEUTICALS, LLC,

Defendant.

C.A. No. 21-1594-GBW

**PUBLIC VERSION**

**REPLY BRIEF IN SUPPORT OF PLAINTIFFS'  
MOTION FOR PARTIAL SUMMARY JUDGMENT NO. 3  
OF NONOBVIOUSNESS OF THE SUSTAINED RELEASE PATENTS**

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## I. INTRODUCTION

The following material facts underlying Jazz's motion are not in dispute:

1. Ms. Gray's obviousness opinions are premised entirely on Jazz and its experts' written description arguments for the Sustained Release Patents. Avadel's Counterstatement of Facts ("ACoF") C-3, C-4; Jazz's Statement of Fact ("SOF") 9; Avadel's Resp. to Jazz's Statement of Facts ("RSoF") 6, 8.
2. Jazz and its experts rely upon "reasons .... for why the Sustained Release Specification does provide sufficient written description." ACoF C-4.
3. The premise for Ms. Gray's obviousness opinions depends on the existence of the Sustained Release Patents. SOF 9; RSoF 9.
4. A POSA in March 2011 would not have had access to the Sustained Release Patents. SOF 1.

Ms. Gray did not offer *any opinion* that the Sustained Release Patents' claims would have been obvious *without relying on disclosures from those patents*. Since obviousness cannot be based on disclosures from the challenged patents, summary judgment is warranted.

## II. ARGUMENT

Avadel argues that "Ms. Gray makes clear in her report .... that, if the trier of fact accepts Jazz's arguments that a POSA would have been able to find sufficient written description in the specification of the Sustained Release patents, then the claimed dissolution profiles would have thereby been taught by the prior art." C.A. No. 21-691, D.I. 418 ("Opp.") 21. As Avadel describes it, "Jazz's experts offered [opinions] regarding how a POSA would have understood, and extrapolated from, the disclosures of the Sustained Release patents," regarding written description and Ms. Gray "applied that same standard to her analysis of the prior art." *Id.* at 20. But the permissible evidence for written description and obviousness is different. For written description, the disclosure of the asserted patent forms the basis of the inquiry, but for obviousness, the disclosure of the asserted patent cannot be used because *it is not part of the scope and content of the prior art*. Ms. Gray's reliance on Jazz's written description support for

her obviousness opinions leaves Avadel with no evidence of obviousness.

Written description is based on “an objective inquiry into the four corners of the [patent-in-suit’s] specification” and “the [patent-in-suit’s] specification must describe [the] invention.”

*Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

Obviousness, on the other hand, must be “guided *only* by the prior art references and the *then-accepted* wisdom in the field.” *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999) (emphasis added). It is error to use the teachings in the challenged patent for purposes of finding obviousness. *See* C.A. No. 21-691, D.I. 398 (“Opening Brief”) at 3-4. Indeed, neither *Graham*, nor any case Avadel cites, holds that a POSA can look to the challenged patent’s specification for purposes of proving obviousness. Unlike written description, a POSA does not have access to the patent-in-suit’s specification for obviousness.<sup>1</sup>

Ms. Gray’s opinions are *not* based on *only* the prior art and knowledge of a POSA *without* the Sustained Release Patents’ disclosures. If they were, then there would be no reason for Ms. Gray to premise her opinions on the disclosures of the Sustained Release Specification. Because of that premise, however, Ms. Gray opines that the prior art only discloses the claimed dissolution profile elements if the Sustained Release Specification supports the claimed dissolution profile elements. Ms. Gray is therefore necessarily using the Sustained Release Specification improperly “as a guide” to match up with the prior art. *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1012 (Fed. Cir. 1983). Accordingly, there is no genuine dispute that Avadel cannot prove obviousness of the Sustained Release Patents’ asserted claims.

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<sup>1</sup> *Biogen* invokes the *opposite* standard compared to what Avadel seeks to invoke here. In *Biogen*, the Court found no written description (relying on the disclosures of the patent-in-suit’s specification). 18 F.4th 1333, 1341-42 (Fed. Cir. 2021). The Court did *not* find obviousness by relying on the disclosures of the patent-in-suit’s specification. *Id.* at 1346

### **III. CONCLUSION**

For the foregoing reasons and those set forth in Jazz's Opening Brief, the Court should grant Jazz summary judgment of nonobviousness for the Sustained Release Patents.

Dated: December 22, 2023

Respectfully submitted,

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