

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

**REPLY 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. INTRODUCTION

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

1. Dr. Klibanov’s obviousness opinions are premised entirely on Jazz’s written description and enablement contentions for the ’079/’782 Patents. Avadel’s Counterstatement of Facts (“ACoF”) B-8, B-9; Jazz’s Statement of Fact (“SOF”) 6; Avadel’s Resp. to Jazz’s Statement of Facts (“RSoF”) 6.
2. Jazz’s contentions rely upon “information from the ’079[/'782] Patent[s]’ specification.” ACoF B-9.
3. The premise for Dr. Klibanov’s obviousness opinions depends on the existence of the ’079/’782 Patents. SOF 10, 11; RSoF 10, 11.
4. A POSA in February 2016 would not have had access to those patents (*id.*), and Dr. Klibanov therefore could not testify that a POSA would have made the same assumption he did for the premise of his opinions (SOF 22; RSoF 22).

Dr. Klibanov did not offer *any opinion* that the ’079/’782 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

A. Dr. Klibanov’s Opinions Rely On The ’079/’782 Patents’ Disclosures

Avadel argues that “Dr. Klibanov conducted a proper obviousness analysis premised on accepting Jazz’s written description arguments at face value and applying the same disclosure standard to the prior art.” C.A. No. 21-691, D.I. 418 (“Opp.”) 14. As Avadel describes it, Jazz argued that “disclosures of certain claim elements in the ’079/’782 patents . . . are sufficient to meet the written description requirement,”¹ and Dr. Klibanov took “the same standard applied by Jazz in evaluating written description support and applied them to evaluating the disclosures in the prior art.” *Id.* at 10-11. But the permissible evidence for written description and obviousness

¹ Jazz disagrees that it relied on only the specifically called out disclosures in the ’079/’782 Patents for purposes of Section 112 support and also disagrees with Avadel’s characterization of those disclosures. *See id.* 10-13. However, that need not be addressed to resolve this motion.

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*. Dr. Klibanov's reliance on Jazz's written description support for his 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. 396 ("Opening Brief") at 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.² Unlike written description, a POSA does not have access to the patent-in-suit's specification for obviousness.

Dr. Klibanov's opinions are *not* based on *only* the prior art and knowledge of a POSA *without* the '079/'782 Patents' disclosures. If they were, then there would be no reason for Dr. Klibanov to premise his opinions on the disclosures of the '079/'782 Specification. Because of that premise, however, Dr. Klibanov opines that the prior art only discloses claim element "X" if the '079/'782 Specification supports claim element "X." Dr. Klibanov is therefore necessarily using the '079/'782 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).

² Dicta in the unreported *In re Stauffer* case does not change binding Federal Circuit precedent.

B. Avadel's Obviousness Argument Contradicts Its Position Before The PTO

Avadel fails to mention, let alone distinguish, Jazz's cited cases holding that a party cannot advance a position in litigation that is inconsistent with the position that party advanced (and benefited from) at the PTO. Opening Brief at 6. That, however, is what Avadel seeks to do here. Avadel also cites no case law that would permit its shifting positions.

Dr. Klibanov uses February 18, 2016 as the '079/'782 Patents' effective filing date. SOF 1. Avadel's patents have a *later* effective filing date of July 22, 2016. SOF 12, 16; RSoF 12, 16. Avadel alleges that Jazz "cop[ied] Avadel's patent claims into its own patents." Opp. 13.³ Therefore, if Dr. Klibanov unconditionally opined that Jazz's '079/'782 Patents' claims were obvious, then under Avadel's allegation, Avadel's own patent claims would be obvious as well.

Avadel, however, maintains the validity of its patents and vigorously argued against the positions Dr. Klibanov now takes against Jazz's patents when pursuing its own patents at the PTO. *See* SOF 12-22. Avadel argues that its prior inconsistent statements were made "in the context of prosecuting its own patents with their own factual records, which are distinct from the facts in this litigation." Opp. 18. Avadel provides no explanation of what that "distinct" context allegedly was, and Dr. Klibanov opined that the only distinction is that he is relying on the '079/'782 Patents' disclosures (their written description and enablement support). SOF 20-21; RSoF 20-21. As a result, it is clear that Dr. Klibanov's obviousness opinions necessarily (and improperly) depend on the disclosures of the '079/'782 Patents themselves. That leaves Avadel with no evidence of obviousness, and summary judgment is therefore warranted.

³ [T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application." *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 874 (Fed. Cir. 1988).

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 '079/'782 Patents.

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Respectfully submitted,

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