

**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. 4
OF NO ANTICIPATION OF U.S. PATENT NO. 11,077,079**

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I. INTRODUCTION

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

1. Dr. Charman's anticipation opinions are premised entirely on Jazz's written description contentions for the '079 Patent. Avadel's Counterstatement of Facts ("ACoF") D-1; Jazz's Statement of Fact ("SOF") 9 n.1; Avadel's Resp. to Jazz's Statement of Facts ("RSoF") 9.
2. Jazz's contentions rely upon "the '079 patent disclosures." ACoF D-1.
3. The premise for Dr. Charman's anticipation opinions depends on the existence of the '079 Patent. SOF 9 n.1; RSoF 9; ACoF D-1.
4. A POSA in February 2016 would not have had access to the '079 Patent. SOF 1.

Dr. Charman did not offer *any opinion* that the '079 Patent's claims are anticipated *without relying on disclosures from that patent*. Since anticipation cannot be based on disclosures from the challenged patent, summary judgment is warranted.

II. ARGUMENT

A. Dr. Charman's Opinions Rely On The '079 Patent's Disclosures

In his expert report, Dr. Charman stated that he "agree[s]" with the position that Avadel previously took in front of the PTO that Liang does *not* disclose the claim elements of opening a sachet containing a gamma-hydroxybutyrate formulation, mixing the formulation with water, and orally administering the mixture that are common to Jazz's '079 Patent and Avadel's U.S. Patent No. 10,952,986 ("the '986 Patent"). SOF 9. Now, in opposing Jazz's motion for summary judgment based on Dr. Charman's agreement that the prior art does not disclose those claim elements, Avadel argues that Dr. Charman "is simply accepting Jazz's litigation position at face value and applying Jazz's views about how a POSA would have understood and interpreted a patent disclosure to the prior art." C.A. No. 21-691, D.I. 418 ("Opp.") 26. As Avadel describes it, "Jazz took a position [in its written description contentions] regarding how a POSA, as of the '079 patent's alleged priority date, would have understood such sparse disclosures, and Dr.

Charman applied the same approach as Jazz in forming his anticipation opinion.”¹ *Id.* at 25. But the permissible evidence for written description and anticipation is different. For written description, the disclosure of the asserted patent forms the basis of the inquiry, but for anticipation, the disclosure of the asserted patent cannot be used because *it is not part of the prior art*. Dr. Charman’s reliance on Jazz’s written description support for his anticipation opinions leaves Avadel with no evidence of anticipation.

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) (emphasis added). Anticipation, on the other hand, requires that “the four corners of a single, *prior art document* describe every element of the claimed invention.” *NetMoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (emphasis added). It is error to use the teachings in the challenged patent for purposes of finding anticipation. *See* C.A. No. 21-691, D.I. 401 (“Opening Brief”) at 4. Indeed, no case Avadel cites holds that a POSA can look to the challenged patent’s specification for purposes of proving anticipation.² Unlike written description, a POSA does not have access to the patent-in-suit’s specification for anticipation.

Dr. Charman’s opinions are *not* based on *only* the prior art *without* the ’079 Patent’s disclosures. Indeed, Avadel states in its opposition that Dr. Charman is relying on disclosures from “the four corners of the specification of the ’079 patent” for anticipation. Opp. 26. Thus, Avadel has admitted that Dr. Charman has done exactly what Federal Circuit precedent forbids:

¹ Jazz disagrees that it relied on only the specifically called out disclosures in the ’079 Patent for purposes of Section 112 support and also disagrees with Avadel’s characterization of those disclosures. *See* Opp. 25-26. However, that need not be addressed to resolve this motion.

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

base his anticipation opinions on the challenged patent itself. *NetMoneyIN*, 545 F.3d at 1369.

B. Avadel’s Anticipation 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 3. That, however, is what Avadel seeks to do here. Avadel also cites no case law that would permit its shifting positions.

Avadel’s experts use February 18, 2016 as the ’079 Patent’s effective filing date. SOF 1. Avadel’s patents have a *later* effective filing date of July 22, 2016. SOF 5; RSoF 5. Avadel alleges that Jazz “cop[ied] its claims from Avadel’s patent publications.” Opp. 24.³ Therefore, if Dr. Charman unconditionally opined that Jazz’s ’079 Patent’s claims were anticipated, then under Avadel’s allegation, Avadel’s own ’986 Patent claims would be anticipated as well.

Avadel, however, maintains the validity of its ’986 Patent and vigorously argued against the positions Dr. Charman now takes against Jazz’s patents when pursuing its own patent at the PTO. *See* SOF 5-9. Avadel argues that its prior inconsistent statements were made “in a different context.” Opp. 25. Avadel provides no explanation of what that “different” context allegedly was, and Dr. Charman opined that the only distinction is that he is relying on the ’079 Patent’s disclosures (the written description support). SOF 9 n.1; RSoF 9; ACoF D-1. As a result, it is clear that Dr. Charman’s anticipation opinions necessarily (and improperly) depend on the disclosures of the ’079 Patent itself. That leaves Avadel with no evidence of anticipation, 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 summary judgment of no anticipation of the '079 Patent's asserted claims based on Liang.

Dated: December 22, 2023

Respectfully submitted,

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