IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS, INC., Plaintiff, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	**REDACTED PUBLIC VERSION FILED DECEMBER 19, 2023** C.A. No. 21-691-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1138-GBW [redacted]
JAZZ PHARMACEUTICALS, INC., et al., Plaintiffs, v. AVADEL CNS PHARMACEUTICALS, LLC, Defendant.	C.A. No. 21-1594-GBW [redacted]

DEFENDANT AVADEL CNS PHARMACEUTICALS, LLC'S CONCISE STATEMENT OF FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT NO. 2

B-1. Dr. Charman opines in the Charman Opening Rpt. that formulation science is complex, difficult, and often unpredictable. *See, e.g.*, Ex. 8, ¶¶ 342, 389, 800.

B-2. Dr. Little's May 5, 2023 rebuttal report regarding the '079 and '782 patents (Little Rebuttal Rpt.) states: "I agree that formulation science is complex and often unpredictable. And I agree that because oxybate is a difficult drug to work with, the complexities associated with formulating oxybate into a finished dosage form only increase." Ex. 10 ¶ 99.

B-3. Dr. Moreton's May 2, 2023 Rebuttal Report ("Moreton Rebuttal Rpt.") states: "I agree that, at the time of invention for the Sustained Release Patents, the inventors recognized certain difficulties in working with GHB, and that, if starting from scratch, a POSA would have found the creation of a controlled release GHB formulation to be both a complicated and unpredictable endeavor." Ex. 13 ¶ 125.

B-4. Dr. Little opines that Allphin 2012, which shares a specification with the sustained release patents, is incorporated by reference into the '079 and '782 patents' specification. Ex. 10 ¶ 29.

B-5. In his Rebuttal Rpt., Dr. Little relies on the disclosures of Allphin 2012 as support for his opinion that non-resinate multiparticulate formulations of GHB are described and enabled by the specification of the '079 and '782 patents. Ex. 10 ¶¶ 30, 79.

B-6. Dr. Charman's Opening Rpt. states: "For a POSA to be able to make and use a non-resinate controlled release component, a POSA would need much more information than is provided in the '079 patent. . . . A POSA would also need to know information about the materials used to create other types of controlled release forms. . . . Further, a POSA would need specific information about how to make a non-resinate drug composition, such as the ratios of the various materials to each other and to oxybate, how the materials should be combined to create the formulation. . . ." Ex. 8 ¶ 756.

B-7. Dr. Charman's Opening Rpt. states his opinion that the specification of the '079 and '782 patents "does not provide any of the information a POSA would need to know to create a non-resinate drug formulation. . . . For example, the specification does not identify any other possibilities besides resinates for controlling release of oxybate. Nor does the specification describe any of the materials or ingredients that would be needed to create a non-resinate controlled release oxybate dose, the relative amounts of those materials that should be used, how the materials should be configured or mixed with drug product, the means of loading/coating/injecting/instilling the drug product into a formulation, or any of the conditions required for formulation of a non-resinate oxybate dose." Ex. 8 ¶ 788.

B-8. Dr. Charman's Opening Rpt. states the basis for his opinions that the purported incorporation by reference of Allphin 2012 into the specification of the '079 and '782 patent specification does not remedy the deficiencies in the specification '079 and 782 patents with respect to enablement. Ex. 8 ¶¶ 815-819, 943-946.

B-9. Dr. Charman's Opening Rpt. states: "The theoretical universe of materials that could be used to control drug release is extensive, as are the possible types of controlled release profiles." Ex. 8 ¶¶ 780, 942.

B-10. When addressing the breadth of the claims of the '079 and '782 patents, Dr. Little does not identify any specific materials that can be used to control the release of oxybate that are not within the scope of the asserted claims. Ex. 10 ¶¶ 92, 151.

B-11. Dr. Little's April 25, 2023 Rebuttal Report on the SR patents states that the prior discloses far more than a finite number of options of coating materials to choose from. Ex. 11 ¶¶ 6, 62, 66.

B-12. In response to the question "And then the next paragraph of the specifications says that there are 29 different levels that a POSA can toy with or experiment with for the surfactant alone.

Do you see that?" Dr. Little answered "Well, it says inclusive of all ranges in between, so that would be infinity, if that's what you mean." Ex. 17, 227:1-10.

B-13. The claims of the '079 and '782 patents encompass both resinate and non-resinate embodiments. Ex. 10 ¶¶ 22, 27.

B-14. When asked "But you could have, according to the specification, any combination of those excipients, right?" Dr. Moreton responded "what this -- what -- the way I read it, you can have a filler, a lubricant, a surfactant. You choose them --" Ex. 18, 87:3-8.

B-15. When asked if Column 13 of the '488 patent specification reads "The functional coating may include a plasticizer, right?" Dr. Moreton responded "Yes." Ex. 18, 106:13-24.

B-16. At his deposition, Dr. Moreton stated that there are "probably a dozen or more" different kinds of water soluble polymers approved for pharmaceutical use and "four or five" different kinds of water insoluble polymers approved for pharmaceutical use. Ex. 18, 96:10-18.

B-17. When asked "Do you understand there to be any limitations that are being placed in the '488 specification on any sol -- any soluble or insoluble polymers that could be used as part of a functional coat? Dr. Moreton answered "It just - - it just lists polymers that could be used. When asked "No restrictions?" he answered "not that I can see." Ex. 18, 97:10-19.

B-18. Dr. Moreton agreed that Column 12 of the specification of the '488 patent lists nine materials that can be used as pore formers. Ex. 18, 102:17-103:9.

B-19. Dr. Moreton agreed that Column 13 of the specification of the '488 patent states that "it's also possible to use an enteric component as part of a pore former" and agreed that the specification provides examples of entire components that can be used as enteric pore formers including cellulose acetate phthalate, methacrylic acid, methyl methacrylate, and polyvinyl acetate phthalate. Ex. 18, 103:13-25.

B-20. When asked "How many other such materials are there that could be used as a pore former?" Dr. Moreton answered "For enteric coating polymers, there is another two." Ex. 18, 104:3-12.

B-21. When asked whether it was correct that "there's nothing in here, in the specification, that expresses a preference for the use of anything in particular as a pore former" Dr. Moreton responded "Correct." Ex. 18, 104:9-15.

B-22. When asked "So a [POSA] would have known that a range of about 20 percent to about 50 percent was a reasonable range for the use of a pore former" Dr. Moreton answered "Yes." Ex. 18, 105:16-20.

B-23. Dr. Little's Rebuttal Rpt. states: "As I explained above, the '079 patent contains a written description of nonresinate forms of a 'controlled release component.' *See supra* at ¶¶ 21-42. In my opinion, that written description would teach a POSA how to make and use the claimed inventions, including non-resinate controlled release components." Ex. 10 ¶ 79.

B-24. Section VI.B.2(b) of Dr. Little's Rebuttal Report, entitled "The '079 patent contains an enabling disclosure of 'non-resinate controlled release components'" is comprised of one paragraph. Ex. 10 ¶ 79.

B-25. Dr. Little relies on Dr. Moreton's analysis of the sustained release patents in support of his opinion that the '079 and '782 patents contain adequate written description support and an enabling disclosure. Ex. 10 ¶¶28-42, 79, 115.

B-26. In Dr. Little's enablement analysis of non-resinate controlled release components at ¶ 79, Dr. Little cites to paragraphs 21-42 of his report, which address written description of non-resinate controlled release components. Paragraphs 21-27 explain Dr. Little's opinion that the '079 patent is not specific to resinate embodiments, and relies on the Court's claim construction order.

Paragraphs 28-42 explain the basis for Dr. Little's opinion that the '079 patent specification describes non-resinate controlled release components. Ex. 10 ¶¶ 79, 21-42.

B-27. When asked "Was there anything in [Column 11:54 through Column 13:47] that provided information as to the content of the functional coating that would not already be known to a person of skill in the art?" Dr. Moreton answered: "[] they're listing different materials that can be used, no preference. The materials were known. . . . ." Ex. 18, 105:21-106:12.

B-28. When asked "But, again, there's no explicit teaching in the '488 patent that tells a person of skill in the art how to make that translation from a tablet to a microparticle, right?, Dr. Moreton responded "Not in that detail, no." Ex. 18., 176:18-23.

B-29. When asked "As you sit here today, can you point me to any portion of the sustained release specification that teaches a [POSA] how to adjust coating composition and amounts to account for differences in surface area?" Dr. Moreton said "Not specifically, no." *Id*., 183:21-184:2.

B-30. Dr. Charman's Reply Rpt. states: "against the backdrop of teachings in the specification that explain why both resinate and non-resinate controlled release formulations face myriad problems and challenges . . . [t]here are no teachings or information in the specification that a POSA could use to achieve the full scope of the claims without undertaking undue and rote trial-and-error experimentation." Ex. 9 ¶ 340.

B-31. Dr. Little stated that "I think in that situation that you're describing to me, if the behavior that you're looking for is release behavior, you would use the release behavior under -- you would use an experiment that would show you the release behavior under the desired conditions, and then you could make modifications and observe the outcome." Ex. 17, 101:17-102:4

B-32. Dr. Charman's Reply Rpt. states "As previously discussed, how to test for the claimed dissolution limitations does not teach how to achieve them." Ex. 9 ¶ 180.

B-33. Dr. Charman's Opening Rpt. states "There is no information in the specification that could teach a POSA how to make and use non-resinate controlled release components that could control release over a period of about 2 to about 8 hours. . . " and "the inventors highlight the significant challenges associated with employing non-resinate forms of controlled release for GHB. . . . " Ex. 8 ¶ 754.

B-34. When asked "In the context of the sentence that we just read, what does significantly reduce mean to you as a person of skill in this context?" Dr. Little answered "That it would not allow you to use every formulation strategy." When asked "Does the specification of the '079 patent identify which conventional solubility and diffusivity control technologies do not work with gamma-hydroxybutyrate?" Dr. Little answered "I don't think that it--if I can remember correctly, I don't think that it goes through those specifics." Ex. 17, 71:17-72:3. When asked "how a [POSA] would determine which technologies would and would not work for GHB?" Dr. Little answered "So I think, for instance, you could pick a particular class of formulations and you could--you could prepare a formulation and observe given the principles of the materials and the methods to see. . . .you could observe it. And then you would get an idea in that category of what the limitations of that particular method would be." *Id.* at 72:15-73:2.

B-35. Dr. Charman's Reply Rpt. states "Despite the numerous formulation challenges associated with GHB highlighted by the inventors, the Sustained Release Specification contains no teaching whatsoever that would enable a POSA to overcome these myriad problems. Absent such a teaching, a POSA would have to undertake undue experimentation to overcome each such issue and then to obtain a viable formulation encompassing the full scope of the Asserted Claims. As such the Sustained Release Specification does not provide an enabling disclosure of the full scope of the claims." Ex. 9 ¶ 152.

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