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. 1

CONCISE STATEMENT OF FACTS

A-1. The Sustained Release Patents are part of the same patent family and share a common specification. Ex. 8 (2nd Supp. Op. Charman Rep.) ¶ 120; Ex. 13 (Moreton Reb. Rep.) ¶ 14; *see generally* Ex. 1, U.S. Patent Nos. 10,758,488 (the "'488 Patent"), Ex. 2, 10,813,885 (the "'885 Patent"), Ex. 3, 10,959,956 (the "'956 Patent"), and Ex. 4, 10,966,931 (the "'931 Patent") (together, the "Sustained Release Patents").

A-2. The Asserted Claims of the Sustained Release Patents recite formulations in which the sustained release portion has a functional coating comprising "one or more methacrylic acid-methyl methacrylate co-polymers." *See e.g.,* '488 Patent at claims 1, 9, 12; '885 Patent at claims 1, 7; '956 Patent at claims 1, 9, 11, 12, 20, 25; '931 Patent at claims 1, 7.

A-3. The Asserted Claims of the Sustained Release Patents recite formulations in which the functional coating is "deposited over the core [which] comprises at least one pharmaceutically active ingredient selected from gamma-hydroxybutyrate and pharmaceutically acceptable salts of gamma-hydroxybutyrate." *See e.g.,* '488 Patent at claims 1, 9, 12; '885 Patent at claims 1, 7; '956 Patent at claims 1, 9, 11, 12, 20, 25; '931 Patent at claims 1, 7.

A-4. The Asserted Claims of the Sustained Release Patents recite formulations in which "the sustained release portion releases greater than about 40% of its gamma-hydroxybutyrate by about 4 to about 6 hours when tested in a dissolution apparatus 2 in deionized water at a temperature of 37°C. and a paddle speed of 50 rpm." *See e.g.,* '488 Patent at claims 1, 9, 12; '885 Patent at claims 1, 7; '956 Patent at claims 1, 9, 11, 12, 20, 25; '931 Patent at claims 1, 7.

A-5. The specification of the Sustained Release Patents ("SR Specification") discloses a "controlled release core" that "includes at least one drug substance to be delivered," but also

explains that it can also include other things, "such as binders, fillers, diluents, disintegrants, colorants, buffering agents, coatings, surfactants, wetting agents, lubricants, glidants, or other suitable excipients." '488 Patent at 9:46-11:52. Dr. Moreton testified that "the only thing [the SR Specification] says [] is that the core includes at least one drug substance." Ex. 18 (Moreton Dep. Tr.), 67:6-13.

A-6. The SR Specification discloses 22 options for binders. '488 Patent at 10:37-46. Dr. Moreton testified that a POSA would know that any of those binders could be used and that the specification does not state any preference for any of those binders over any others. Dr. Moreton also testified that the use of a binder is optional and that a POSA would understand that the specification is not limiting. Dr. Moreton also testified that more than one binder may be used. Ex. 18 (Moreton Dep. Tr.), 74:19-76:8, 78:19-79:5; '488 Patent at 10:35-39 (referencing "one or more binders" and "at least one binder").

A-7. The SR Specification discloses that if a binder is used, it can be included in amounts from 1 to 10% of the total weight of the core. '488 Patent at 10:49-55. Dr. Moreton testified that the specification doesn't give a preference for one percentage over another. Ex. 18 (Moreton Dep. Tr.), 78:1-18.

A-8. The SR Specification lists 12 potential lubricants. '488 Patent at 10:56-11:9. Dr. Moreton testified that "there are not many more" approved for pharmaceutical use. He further testified that the inclusion of a lubricant is optional and that the SR Specification does not express a preference for any particular lubricant. Ex. 18 (Moreton Dep. Tr.), 79:6-80:9.

A-9. The SR Specification also lists surfactants, fillers, and compression aids that may be used in the disclosed formulation. '488 Patent at 11:29-52. Dr. Moreton testified that the inclusion of surfactants and fillers is entirely optional. Ex. 18 (Moreton Dep. Tr.), 83:14-86:20.

A-10. The SR Specification discloses that the functional coating may include one or more base polymers, one or more pore formers, one or more plasticizers, and/or one or more anti-tack agents. '488 Patent at 12:40-14:4. The specification provides specific examples of each of these categories. *Id.* Dr. Moreton testified that the SR Specification does not express a preference for any of these. Ex. 18 (Moreton Dep. Tr.), 101:14-18; 105:21-106:9.

A-11. None of the 13 working examples provided in the SR Specification describe a formulation comprising a functional coating with MAMM co-polymers or any other of the identified enteric pore formers. '488 Patent at 19:10-27:14; Ex. 18 (Moreton Dep. Tr.), 139:14-19; Ex. 8 (2nd Supp. Op. Charman Rep.) ¶ 255; Ex. 12 (Gray Rep.) ¶¶ 55-57.

A-12. Dr. Moreton testified that the SR Specification does not place any limitations on the polymers that could be used as part of a functional coating. Ex. 18 (Moreton Dep. Tr.), 97:10-19; *id.* 98:17-99:9. Dr. Moreton testified that the SR Specification does not place any limitation on the amount of base polymer that may be present. *Id.* 99:10-17. Dr Moreteon testified that the SR Specification describes the pore former as optional and, if used, expresses no preference for the use of anything in particular as a pore former. *Id.* 101:14-102:2; *id.* 104:9-15. Dr. Moreton testified that in its description of the functional coating, the SR Specification was "listing different materials that can be used, no preference." *Id.* 105:21-106:9.

A-13. In response to the question "[D]o you understand there to be any restrictions that are being placed in the specification of the '488 patent on the polymers that could be included within a functional coat?," Dr. Moreton answered "no, only that they must be approved for . . . pharmaceutical use." Ex. 18 (Moreton Dep. Tr.), 98:17-99:9.

A-14. Jazz's original Sustained Release utility patent application was filed March 2011 with 108 claims. Ex. 20 ('369 App.), Mar. 24, 2011 Claims. None of these claims mention methacrylic acid-methyl methacrylate, USP apparatus 2, or deionized water. *Id.*

A-15. From March 2011 to July 2018, Jazz's claims were directed to "controlled release" formulations and made no mention of any enteric pore formers or any in vitro testing conditions whatsoever. Ex. 20 ('369 App.), 3/6/2011 claims, 3/24/2011 claims, 5/28/2013 claims, 1/27/2014 claims, 9/16/2014 claims, 5/19/2015 claims, 4/4/2016 claims, 1/18/2017 claims, 10/4/2017 claims.

A-16. In July 2018, Jazz filed a new set of claims requiring "one or more methacrylic acid-methyl methacrylate co-polymers that are from about 20 to 50% by weight of the functional coating," and certain dissolution characteristics measured using USP apparatus 2. Ex. 8, (2nd Supp. Op. Charman Rep.) ¶¶ 148-149.

A-17. Flamel's U.S. Patent Application No. 2018/0021284 published in January 2018 and claims formulations using methacrylic acid-methyl methacrylate as well as in vitro testing performed in USP apparatus 2. Ex. 21, (U.S. Patent App. No. 2018/0021284) claims 26, 39, 40.

[redacted]

A-18. In March 2020, Jazz modified the claims pending in the '487 application, replacing "controlled release" with "sustained release." According to this examiner, this was done to make the invention "distinct from the delayed release formulations of Liang." Ex. 8 (2nd Supp. Op. Charman Rep.) ¶¶ 157, 165; Ex. 7('488 File History), Mar. 6, 2020 Amendments to the Claims; Summary of Apr. 2, 2020 Examiner Interview.

A-19. Methacrylic acid-methyl methacrylate co-polymers appear only once in the SR Specification, where they are disclosed as one potential enteric pore former. Ex. 8 (2nd Supp. Op. Charman Rep.) ¶¶ 197, 243; Ex. 22 (Pl. Apr. 1, 2022 Validity Contentions) at 88. The specification states that "it is possible to use an enteric component as part or all of the pore former in the coating composition," "[h]owever, incorporating enteric components in the film may result in delivery characteristics that exhibit some level of sensitivity to gastric and intestinal transit times." '488 Patent at 13:26-34. The specification discloses more than a dozen pore formers in several classes, including polymeric pore formers ('488 Patent at 12:61-66), small-molecule pore formers ('488 Patent at 12:66-13:4), expanding/swelling pore formers ('488 Patent at 13:4-13), and enteric components ('488 Patent at 13:26-32). *See generally*, '488 Patent at 12:55-13:34. Dr. Moreton testified that there are two other possible enteric coatings not mentioned in the specification. Ex. 18 (Moreton Dep. Tr.), 103:13-104:8.

A-20. Dr. Moreton testified that nothing in the specification would direct a POSA to use MAMM over any of the other pore formers identified and that the use of any pore former is entirely optional. Ex. 18 (Moreton Dep. Tr.), 101:14-102:2.

A-21. The SR specification does not explain what excipients should be included or omitted from the formulation to achieve the claimed release profiles. '488 Patent at 19:10-27:14; Ex. 8 (2nd Supp. Op. Charman Rep.) ¶¶ 198, 243, 255, 261.

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