**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| JAZZ PHARMACEUTICALS, INC.,<br>Plaintiff,<br>v.<br>AVADEL CNS PHARMACEUTICALS, LLC,<br>Defendant. | C.A. No. 21-691-GBW<br>**PUBLIC VERSION** |
| JAZZ PHARMACEUTICALS, INC., et al.,<br>Plaintiffs,<br>v.<br>AVADEL CNS PHARMACEUTICALS, LLC,<br>Defendant. | C.A. No. 21-1138-GBW<br>**PUBLIC VERSION** |
| JAZZ PHARMACEUTICALS, INC., et al.,<br>Plaintiffs,<br>v.<br>AVADEL CNS PHARMACEUTICALS, LLC,<br>Defendant. | C.A. No. 21-1594-GBW<br>**PUBLIC VERSION** |

**OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT NO. 2**

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## I. NATURE AND STAGE OF THE PROCEEDINGS

Avadel CNS Pharmaceuticals, LLC ("Defendant" or "Avadel") moves for summary judgment of invalidity for lack of enablement of the '079/'782 Patents. Br. 14-27.[1] Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Ltd. ("Plaintiffs" or "Jazz") oppose.

## II. SUMMARY OF ARGUMENT

Avadel's motion for summary judgment should be denied because Avadel fails to address the necessary "weighing [of] many factual considerations" that the Federal Circuit requires for determining whether a defendant can carry its burden on enablement. *Cephalon, Inc. v. Watson Pharms., Inc.*, 707 F.3d 1330, 1336 (Fed. Cir. 2013) (describing the eight *Wands* factors test). As explained below, genuine disputes of material fact exist as to nearly all of the eight factors (including disputes among Avadel's own experts).

Avadel argues that the Court should grant summary judgment because the '079/'782 Patents purportedly "fail[] to teach a POSA how to make and use at least non-resinate embodiments of the claimed invention." Br. 15.[2] Specifically, Avadel argues that "it is undisputed that the compound at issue [oxybate] is particularly difficult to formulate and a POSA would have to test hundreds of thousands of formulations to figure out which ones might work." *Id.*; *see also id.* at 23 (arguing that a POSA would be left with only "trial and error" experimentation). Yet Avadel fails to even mention all *Wands* factors, analyze the evidence on

[1] As used herein, "Br." refers to Avadel's "Brief in Support of Defendant's Summary Judgment and Daubert Motions" (C.A. No. 21-691, D.I. 407).

[2] Avadel states in a footnote that it "believes that the specification of the '079 and '782 patents fails to enable the full scope of GHB resinate-based formulations," (Br. 15 n.4), but does not develop that argument. Jazz disagrees, but need not respond. "Arguments raised only in footnotes . . . are waived." *Otsuka Pharm. v. Sandoz, Inc.*, 678 F.3d 1280, 1294 (Fed. Cir. 2012).

each of these factors, or explain how the factors in this instance should be balanced. While Avadel focuses on one factor—quantity of experimentation—Jazz's expert (Dr. Steven R. Little) and Avadel's expert (Dr. William Charman) disagree on whether even this single factor favors Avadel. In fact, at least one of Avadel's other experts (Dr. Robert Langer) *agrees* with Jazz's expert Dr. Little that a POSA would not view the quantity of experimentation to be as great as Avadel claims. Dr. Langer also characterizes what Avadel calls undue as "routine." And at least six of the other eight underlying factual inquiries also remain in dispute between Drs. Little and Charman. Because genuine material facts remain in dispute (even among Avadel's own experts), Avadel's motion should be denied.

## III. ARGUMENT

### A. Legal Standards

"The burden of proof here is on [Avadel] to show that the ['079/'782] patents are invalid for lack of enablement by *clear and convincing evidence*." *Cephalon*, 707 F.3d at 1336 (emphasis added). The enablement "requirement is met when at the time of filing the application one skilled in the art, having read the specification, could practice the invention without 'undue experimentation.'" *Id.* (citing *In re Wands,* 858 F.2d 731, 736-37 (Fed. Cir. 1988)). "Whether undue experimentation is required is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *Id.* Those many factual considerations that must be weighed are the *Wands* factors: "(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims." *Id.*

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). As the moving party, Avadel bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). The court is to "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc*., 530 U.S. 133, 150 (2000).

### B. Genuine Material Factual Disputes On The *Wands* Factors Preclude Summary Judgment

#### 1. Genuine material factual disputes exist as to the nature of the invention and the predictability of the art

Avadel begins its argument by implying that the predictability of the art favors summary judgment. But Avadel ignores a main point of dispute between the parties' experts, including with respect to the nature of the invention. Avadel misleadingly argues that "Jazz's experts agree that oxybate is a particularly challenging drug to formulate *for controlled release*." Br. 17 (emphasis added). The conclusion Avadel wants the Court to draw is that a POSA would not know how to control the release of oxybate as of the '079/'782 Patents' February 2016 filing date. However, neither the cited testimony, nor Avadel's relied-upon portions of the Sustained Release Patents' ("SR") Specification or the '079/'782 Specification, support that conclusion.

*First*, Avadel cites to Dr. Christian Moreton's report and states that "a POSA at the time of the invention 'would have found the creation of a controlled release GHB formulation to be both a complicated and unpredictable endeavor.'" *Id.* But as Avadel acknowledges (*id.*, n.5), Dr. Moreton's opinions are for the Sustained Release Patents—not the '079/'782 Patents for which Avadel seeks summary judgment. The "time of invention" for the Sustained Release Patents is March 2011—*five years before* the '079/'782 Patents' filing date. By February 2016,

the known methods of controlling/modifying release of oxybate were far more developed. In fact, Dr. Moreton's testimony is premised on a POSA "starting from scratch," without the disclosures of the Sustained Release Patents. Resp. to SMF ¶ B-3. And Avadel omits the very next sentence of Dr. Moreton's report. There Dr. Moreton continues: "But what Dr. Charman's position overlooks, in my opinion, is that the inventors explain in the Sustained Release Specification how they overcame those difficulties and, in so doing, provided further information to a POSA, including the type of *in vitro* release targeted with the claimed [MAMM] copolymers." Resp. to SMF ¶ B-3. Dr. Moreton's testimony does not support Avadel's position.

*Second*, Avadel cites Dr. Little's testimony regarding "complexities associated with formulating oxybate *into a finished dosage form*." Br. 17 (emphasis added). As an initial matter, Avadel omits that Dr. Little, like Dr. Moreton, then goes on in the same paragraph of the report Avadel cites to explain how the teachings of the '079/'782 Specification demonstrate that Jazz overcame those complexities. Resp. to SMF ¶ B-2. Moreover, Avadel overlooks the impact of the "finished dosage form" part of Dr. Little's testimony. As Dr. Little explains, the '079/'782 Specification demonstrates that the claimed inventions are focused on administrability (i.e., the dosage form) of controlled/modified release oxybate. *See, e.g.*, CoF Nos. 1-4. This is different than simply controlling the release of oxybate. Instead, Dr. Little opines that Jazz's formulation of controlled/modified release oxybate in a sachet (required in the '079 Patent's claims) and with a viscosity enhancing agent and acid separate from the oxybate particles (required in the '782 Patent's claims) allowed Jazz to overcome prior-art administrability issues with controlled/modified release oxybate dosage forms (i.e., the inventions claimed in the '079 and '782 Patents improve upon the administration of controlled/modified release oxybate to the end

user). *Id.* While Dr. Charman disagrees with Dr. Little's "administrability" opinions (CoF No. 2), that is a genuine dispute regarding the breadth of the claims that is further discussed below.

*Third*, Avadel focuses on the SR Specification's and the '079/'782 Specification's discussion of certain challenges of working with oxybate. But again Avadel overlooks a key point. Both specifications set forth solutions to the challenges after those discussions. The SR Specification states: "Despite the challenges noted, formulations and unit dosage forms providing controlled release of GHB are described herein." CoF No. 3. The '079/'782 Specification then provides the solution of formulating oxybate as an oral suspension, including in a sachet and with a viscosity enhancing agent and acid separate from the oxybate particles. A0621 5:37-6:11; A0625, 13:57-14:30; A2508, ¶ 24; A2509, ¶ 26; A2513-A2514, ¶¶ 34-35; A2548, ¶ 115; A2550-A2551, ¶ 118.

*Fourth*, citing only its own expert's report, Avadel argues that the '079/'782 Specification "does not provide any instructions for how a POSA can make non-resinate controlled release oxybate formulations." Br. 19 (citing SMF ¶¶ B-6, B-7). This is a conclusory assertion that ignores all of the genuine material factual disputes. *See generally* CoF 1-26. "The simple fact that an opinion is offered into evidence by way of expert report does not turn an opinion into a fact." *Leonard v. Stemtech Health Scis., Inc.*, No. 08-067, 2011 WL 6046701, at *23 (D. Del. Dec. 5, 2011), *report and recommendation adopted*, No. 08-067, 2012 WL 1133185 (D. Del. Mar. 28, 2012). And certainly not an undisputed one warranting summary judgment.

**2. Genuine material factual disputes exist as to the breadth of the claims**

There can be no doubt that the breadth of the claims is disputed. When "there remains a genuine dispute of material fact as to the nature of the alleged invention and the scope of the claims," summary judgment of enablement is inappropriate. *See, e.g., Bioverativ Inc. v. CSL Behring LLC*, No. 17-914, 2020 WL 1066019, at *4 (D. Del. Mar. 5, 2020). That exists here.

*First*, as discussed above, whether the crux of the '079/'782 Patents' inventions is administrability is a prime dispute between Drs. Little and Charman. *See supra* III.B.1.

*Second*, Dr. Little disagrees with Avadel's argument that "the structural requirements recited in the claims—sachet, acid, and viscosity enhancing agent—fail to limit the number or types of materials that could be used in the claimed formulation." Br. 19. In fact, he specifically notes this disagreement with Dr. Charman in the portions of his report Avadel cites. CoF No. 5.

*Third*, Avadel misleadingly argues that "Dr. Little repeatedly acknowledged that there are 'far more than a finite number of options' for potential coating materials." Br. 19. In SMF ¶ B-11, Avadel cites to Dr. Little's nonobviousness opinions for the earlier-in-time Sustained Release Patents. There, Dr. Little was opining on the "alleged prior art as a whole" that Avadel's expert asserted for his obviousness opinions. CoF No. 6. There is no requirement that an expert analyze whether the specification enables the prior art as a whole, only the claimed inventions. In fact, it would be error for the expert to do the former. *See Inline Connection Corp. v. AOL Time Warner Inc.*, No. 02-272, 2007 WL 275928, at *4-5 (D. Del. Jan. 29, 2007) (excluding enablement testimony that did not focus on whether the claimed inventions were enabled).

**3. Genuine material factual disputes exist as to the quantity of experimentation necessary and the presence of working examples**

As to the quantity of experimentation, Avadel argues that a POSA would be faced with at least hundreds of thousands of possible formulations to test for controlled/modified release. Br. 19-20. Thus, Avadel argues, a POSA has "no other choice but to engage in a 'trial and error' effort to identify formulations with the desired drug release profile." *Id.* at 23. But where, like here, it is disputed whether the process is truly "trial and error," "a reasonable jury could find that the patent claims are enabled. Thus, summary judgment of no enablement is inappropriate." *Amgen Inc. v. Sanofi*, No. 14-1317, 2019 WL 259099, at *3 (D. Del. Jan. 18, 2019).

*First*, whether a POSA would undertake the multiplication exercise on which Avadel premises its argument (*see* Br. 19-20) is undoubtedly a genuine material factual dispute.

When Avadel pursued this line of questioning at Dr. Little's deposition, Dr. Little disagreed with Avadel's multiplication premise. He explained that "[i]t would be not the way a [POSA] even looks at this. Because, otherwise, every formulation patent I've ever seen has infinite numbers of possibilities, and it's just not the way formulation science works." CoF No. 7. And Dr. Little clearly explained his disagreement with Dr. Charman on this point:

> The difference is very simply between Dr. Charman's view and mine, is that when you look at this particular patent specification, there's guidance and categories of different excipients and different things. That is the classification of formulation, period. You can experiment within that classification, but I disagree that it's millions and trillions of possible combinations that would intimidate a person of ordinary skill in the art. It's just a fundamental difference in the way we look at the specification.

CoF No. 8 (subject to errata at A2492-A2493); *see also* CoF No. 9 ("I think this is the difference in the way that Dr. Charman fundamentally looks at this. . . . A formulator looks at this and is no way intimidated by these numbers, because they realize that each of these is a category of being able to tune. So it's not like they look at every one of these as a particular star in the sky as a universe. That's just not how a formulator looks at the patent at all.").

A reasonable jury could agree with Dr. Little. In fact, another of Avadel's experts, Dr. Langer, offered strikingly similar testimony to Dr. Little on this issue. Specifically, when asked whether he knew the number of combinations possible for pH-sensitive polymers across various percentage weights in a patent, Dr. Langer testified that any patent, including his own, could have "billions of combinations" *if read the way the question suggested*. CoF No. 10. Thus, whether a POSA would even undertake Avadel's multiplication exercise is genuinely disputed.

*Second*, the District of New Jersey recently agreed with Dr. Little's view that the multiplication exercise Avadel attempts here is divorced from reality. In support of a non-enablement argument there, the defendant created a large universe of possible formulations by multiplying different possible excipients and particle sizes. *See Janssen Pharms. v. Mylan Labs.*, No. 20-13103, 2023 WL 3605733, at *35 (D.N.J. May 23, 2023). The court found that "a POSA would *not* view the [challenged] Patent's disclosures . . . as encompassing 10 million individual formulations" and rejected defendant's lack of enablement theory. *Id.* (emphasis added). Given that a court rejected such a theory, certainly a reasonable jury could reject it, too.

*Third*, that same court continued that, "even if the Asserted Claims did encompass millions of individual formulations, a POSA would be able to make any one of those formulations . . . without undue experimentation." *Id.* (alteration in original).[3] Here, Dr. Little never testified that the amount of experimentation would be undue. Instead, Dr. Little testified that the experimental work would be "common" formulation work for a POSA. CoF No. 11. Nothing in Dr. Little's testimony cited in SMF ¶ B-31 (Br. 23) demonstrates anything different.

And notably, Avadel's expert (Dr. Langer) *agrees* with Dr. Little. The '079/'782 Patents explain that a POSA can test for controlled release with dissolution testing. CoF No. 12. Avadel recognizes as much. Br. 23. Dr. Langer could not have been clearer in testifying that, what Avadel implies is "undue," is what a POSA would consider "routine":

> Q. Okay. What do you consider to be routine experimentation in terms of dissolution testing?
>
> A. Well, I mean maybe I should ask you to clarify, but why don't I try to start at a high level. Like what often happens in this kind of area is people you know, they do what is called preformulation and formulation, and they try different things. They try different

[3] Moreover, "inventors [are] not required to provide a detailed recipe for preparing every conceivable permutation of the compound they invented to be entitled to a claim covering that compound." *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 555 F. App'x 961, 967 (Fed. Cir. 2014).

> percentages, and they see what the, you know, release kinetics are. I think that is generally routine. And if you, when you do that, you know, changing percentages of materials, of polymers to get desired kinetics, I think that is fairly routine experimentation, if that helps.

CoF No. 12. Thus, what is routine experimentation is disputed (even among Avadel's experts).

*Fourth*, the fact that experimentation may be extensive or complex does not make it undue where the art typically engages in such experimentation. *See GlaxoSmithKline v. Hikma Pharm.*, No. 12-1965, 2012 WL 3561970, at *29 (D.N.J. Aug. 16, 2012) (finding "significant experimentation is not uncommon in the context of finding effective solutions in the pharmaceutical industry" …. "the state of the art at the time was unpredictable, and that one of skill in the art would anticipate extensive experimentation and be prepared to conduct such experimentation"). Avadel never addresses Dr. Charman's testimony that "[t]he [experimentation] threshold required for GHB formulation would be somewhat higher due to the challenges posed by GHB as a drug to be formulated." CoF No. 14. As Dr. Little opined, especially considering the higher threshold, a POSA would not think that even a greater level of experimentation was undue. CoF No. 15. And as the Federal Circuit has held in reversing a non-enablement judgment, even "extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques." *Cephalon*, 707 F.3d at 1338. Again, Dr. Little opined the techniques are "common" and Dr. Langer called them "routine." CoF Nos. 11-13.

*Fifth*, Avadel does not address the working examples of non-resinate controlled/modified release formulations present in Allphin 2012, which as explained below, are incorporated by reference into the '079/'782 Patents. Allphin 2012 discloses both USP 2 type dissolution testing

and pharmacokinetic testing results, demonstrating controlled release. CoF No. 16.[4] As Avadel correctly recognizes (Br. 23-24), both of these tests are specifically disclosed for determining release of oxybate in the '079/'782 Patents. CoF No. 16.

*Sixth*, whether working examples are even necessary for enablement here is also a disputed issue. Two of Avadel's experts (Dr. Langer and Dr. Alexander Klibanov) testified that they found prior art references to be enabling for controlled/modified release oxybate where one had no human data and the other had no data of any kind. CoF No. 17. Dr. Langer further testified that "[t]here is no human data in most pharmaceutical, you know, patent[s]," and that "lots and lots of patents I have seen, including my own, and I imagine a number of the Jazz ones, don't have human data in them." CoF No. 18. He continued: "And a lot of patents are gotten when there is not even animal data. It is on the formulation itself." *Id.* Here, Allphin 2012 has both *in vitro* data and human data. It is far ahead of "most pharmaceutical . . . patent[s]." *Id.*

**4. Genuine material factual disputes exist as to the amount of direction or guidance in the specification and the state of the prior art**

Avadel also fails to show the absence of a genuine material factual dispute for these factors. *First*, citing its own expert's report, Avadel argues that "[n]othing in the specification of the '079 and '782 patents itself teaches a POSA how to address the problems it identifies with 'conventional,' non-resinate formulations or how to make a controlled release GHB formulation using conventional formulation approaches." Br. 21. Again, opinions from an expert report are not undisputed facts. *Leonard*, 2011 WL 6046701, at *23. Moreover, Dr. Little disagrees. He opines that Jazz's formulation of controlled/modified release oxybate in a sachet (required in the '079 Patent's claims) and with a viscosity enhancing agent and acid separate from the

[4] For at least this reason, Avadel's unsupported statement regarding testing necessary for the "single daily dose" limitation of the '079 Patent lacks merit. *See* Br. 24.

oxybate particles (required in the '782 Patent's claims) allowed Jazz to overcome prior-art administrability issues with controlled/modified release oxybate dosage forms. CoF Nos. 1-4.

*Second*, Avadel asserts that Dr. Little relies exclusively on the '079/'782 Specification's incorporation by reference of Allphin 2012—the published application that led to the Sustained Release Patents—for the disclosure of non-resinate multiparticulate formulations of oxybate. Br. 21; *see also id.* (arguing that Dr. Moreton's analysis of the SR Specification is the only support Dr. Little offers.). Not so. Dr. Little offers support within the '079/'782 Patents even without the incorporation by reference. CoF No. 19.

*Third*, again citing only its own expert's report, Avadel argues that a POSA would disregard the disclosures of Allphin 2012 because the '079/'782 Patents allegedly "disparage[]" it. Br. 21-22. This is another genuine material factual dispute. Allphin 2012 is incorporated by reference in its "entire[ty] for all purposes" and discussed in the '079/'782 Patents at least six times. CoF No. 20. "Patents that are incorporated by reference are effectively part of the host patents as if they were explicitly contained therein. Incorporation by reference of a patent renders the entire contents of that patent's disclosure a part of the host patent." *Finjan LLC v. ESET, LLC*, 51 F.4th 1377, 1382 (Fed. Cir. 2022) (internal cites and quotations omitted). Therefore, Dr. Little relies on Allphin 2012 as further support for his opinions. And Dr. Little disputes the disparagement opinions Dr. Charman offers and discusses examples of non-resinate controlled/modified release oxybate formulations in Allphin 2012. CoF No. 21.

While Avadel argues that Dr. Little "concedes that the specification of the '079 and '782 patents is entirely silent on how to discern which approaches will and will not work" (Br. 26), Dr. Little offered testimony on this issue in his report. CoF No. 22. Dr. Little further testified "I don't think I've ever seen a patent go through all of the things that wouldn't work." CoF No. 23.

Moreover, Dr. Little testified that Allphin 2012 doesn't "ha[ve] a section of precluded formulations," but instead "[i]t focuses on formulations that would provide the desired behavior." *Id.* Thus, Dr. Little offered testimony that a reasonable jury could adopt.

*Fourth*, Avadel argues that "controlling authority requires that the '079 and '782 patents themselves contain an enabling disclosure." Br. 22. But as noted above, Allphin 2012 is part of the '079 and '782 Patents themselves. *See Finjan*, 51 F.4th at 1382. But even if it were not incorporated by reference, Avadel recognizes it is part of the prior art. *See* Br. 22. "It is well-established . . . that a specification need not disclose what is well-known in the art." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012). Here, it is Dr. Little's opinion that, by the time of the '079/'782 Patents, formulating non-resinate controlled/modified release oxybate was known; what is novel is the improved administrability through the use of the claimed sachet (for the '079 Patent) and the claimed viscosity enhancing agent and acid separate from the oxybate particles (for the '782 Patent). CoF Nos. 1-4. Avadel disagrees. Thus, "[t]he record reveals a genuine dispute of material fact at least regarding whether the ['079/'782] patent's disclosure is sufficiently enabling given the knowledge and understanding of a [POSA]." *Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, No. 14-28, 2017 WL 123457, at *2 (D. Del. Jan. 12, 2017).

*Fifth*, Avadel repeats its "laundry list of excipients" multiplication argument and relies on only its own expert's report to argue that "absent from the SR specification is any meaningful guidance as to how those well-known excipients should be combined to achieve the claimed release profile." Br. 22. Jazz already addressed this argument above. *See supra* III.B.3. And opinions in Dr. Charman's report are not undisputed facts. *Leonard*, 2011 WL 6046701, at *23.

*Sixth*, citing Dr. Moreton's written description testimony, Avadel argues that the SR Specification does not "provide any instructions on how to apply its teachings regarding tablet dosage forms to microparticle dosage forms." Br. 22. But all Dr. Moreton did was agree with Avadel's counsel that there was no "explicit teaching." SMF ¶ B-28. "In order to satisfy the written description requirement, the disclosure as originally filed does not have to provide *in haec verba* support for the claimed subject matter at issue . . . ." *Pozen Inc. v. Par Pharm., Inc.*, 696 F.3d 1151, 1167 (Fed. Cir. 2012) (internal cites and quotations omitted). As Dr. Moreton said, it is "reasonably convey[ed]." CoF No. 24. Further, Dr. Moreton opined (citing a patent Dr. Charman relied upon) that this technique would have been well-known in the art. CoF No. 25. And Drs. Little and Charman dispute whether the disclosures in the '079/'782 Patents (minus the incorporated Allphin 2012) also disclose the use of non-resinate microparticles. CoF No. 26. There are several genuine material factual disputes.

**C. The Cases Avadel Cites Do Not Support Summary Judgment Here**

Avadel's cited cases (Br. 24-25) do not indicate that summary judgment should be granted here. In *Amgen*, the plaintiff sought to "monopolize an entire class of things defined by their function—every antibody that both binds to particular areas of the sweet spot of PCSK9 and blocks PCSK9 from binding to LDL receptors." *Amgen Inc. v. Sanofi*, 598 U.S. 594, 613 (2023). Similarly, in *Baxalta*, the claims "cover[ed] all antibodies that (1) bind to Factor IX/IXa; and (2) increase the procoagulant activity of Factor IXa. There [we]re *millions* of potential candidate antibodies." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1366 (Fed. Cir. 2023) (emphasis in original). And the claims in *Enzo* 'encompasse[d] all phosphate-labeled polynucleotides that are hybridizable and detectable." *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1346 (Fed. Cir. 2019). By contrast, here, the breadth of the claims,

including whether the structural limitations of the claims limit that breadth, is a genuine material factual dispute. *See supra* III.B.2.

Furthermore, here, there are not millions of potential antibodies or polynucleotides claimed. Instead, there is one only compound at issue—oxybate. Under similar circumstances, the District of New Jersey recently distinguished the *Amgen* line of cases and rejected an *Amgen*-based enablement defense. In *Orexo AB v. Sun Pharmaceutical Industries Ltd.*, the patentee had a claim that like the '782 Patent's claims recited, among other things, a compound in the form of microparticles and an acid separate from the microparticles. No. 03-12588, 2023 WL 4492095, at *4 (D.N.J. June 30, 2023). The Court nonetheless rejected the *Amgen*-based enablement challenge. The court explained:

> This case involves a patent for a single composition of an opioid dependence drug, not an entire "genus." Orexo does not seek to "monopolize an entire class of things defined by their function," rather Orexo's invention is a narrow composition covering a sublingual tablet containing separate microparticles of buprenorphine and weak acid. []Since the two types of claims are different, and the breadth of the claims are different, *Amgen* is distinguishable from this case.

*Id.* at *24. The *Orexo* reasoning applies equally here.

## IV. CONCLUSION

For the foregoing reasons, Avadel's motion for summary judgment of invalidity for the '079/'782 Patents based on alleged lack of enablement should be denied.

Dated: December 15, 2023

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on December 15, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

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