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**

OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT NO. 1

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I. NATURE AND STAGE OF THE PROCEEDINGS

Avadel CNS Pharmaceuticals, LLC ("Defendant" or "Avadel") moves for summary judgment of lack of written description support for the Sustained Release Patents. Br. 4-14.[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 genuine material factual disputes exist as to both: (1) whether the Sustained Release ("SR") Specification directs a POSA to use the claimed methacrylic acid-methyl methacrylate ("MAMM") co-polymer formulations; and (2) whether the SR Specification discloses common structural features to achieve the claimed dissolution profiles. Indeed "regardless of what the expert testimony will ultimately prove, whether the[re] . . . are 'blaze marks' on the trees in the forest of those skilled in the art is a factual matter to be decided at trial." *Alza Corp. v. Mylan Lab'ys, Inc.*, 349 F. Supp. 2d 1002, 1018-19 (N.D.W. Va. 2004). And summary judgment is inappropriate where, as here, "there is a genuine dispute as to the scope of the genus described in the claims and whether a skilled artisan could envision the claimed genus with reference to its structural features alone." *Bioverativ Inc. v. CSL Behring LLC*, No. 17-914, 2020 WL 1066019, at *4 (D. Del. Mar. 5, 2020). Accordingly, Avadel's motion should be denied.

III. FACTUAL BACKGROUND

As explained below, the SR Specification directs a POSA to use the claimed MAMM co-polymers and discloses common structural features to achieve the claimed dissolution profiles. Avadel, of course, has a different version of the facts, but that just proves that summary

[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).

judgment is inappropriate. Indeed, in certain instances, Avadel's experts *agree* with Jazz on facts that indicate that written description is satisfied.

A. The SR Specification Does Not Disclose An "Enormous Genus Of Potential Formulations"

1. The SR Specification directs a POSA to use polymers to control the release of drug from the formulation

The SR Specification explains that the inventors discovered sustained release formulations comprised of a controlled release ("CR") core that contains the active pharmaceutical ingredient (gamma-hydroxybutyrate or "GHB") and a functional coating over the CR core. CoF No. 1. The invention is a sustained release GHB formulation where a functional coating over a GHB-comprised core works to deliver sustained release of GHB with the claimed dissolution profiles. As Avadel's expert (Dr. William Charman) opined, "[t]he [SR] specification describes the purpose of the functional coating of the CR core [is] to 'preserve the integrity of the unit dosage [form] for post-administration and serve[] to facilitate controlled release of drug from the CR core.'" CoF No. 2. Jazz's expert (Dr. Christian Moreton) agrees that the "type of controlled release formulations described [in the SR Specification] are coated formulations. . . . So they have a coating over the drug which controls the rate of release of the drug from [the] formulations." *Id.*

Avadel argues there are a long list of ingredients in the SR Specification that make up "a vast universe of possible formulations." Br. 5. The record, however, demonstrates otherwise. The ingredients Avadel focuses on—"such as binders, fillers, diluents, disintegrants, colorants, buffering agents, coatings, surfactants, wetting agents, lubricants, glidants, or other suitable excipients" (*id.* at 5)—are *not* components of the inventive functional coating described for

controlling release of drug in the SR Specification.[2] Instead, they are part of the CR core. CoF No. 3. No expert has opined that the SR Specification describes using ingredients within the CR core (as opposed to the functional coating) to control the release of GHB. *See* CoF No. 4 ("The patent describes the use of [the] pore formers in the coating, and that's where – the functional coating, and that's where the controlled release control [is] centered.").

Instead, when it comes to the inventive functional coating used to control the release of GHB, the SR Specification's focus is on polymers. As Avadel's expert (Dr. Charman) opines, the SR Specification states that "[t]he 'functional coating compositions as disclosed herein may include one or more base polymer and at least one pore-former.'" CoF No. 5. All of the SR Specification's "Examples" of sustained release formulations use polymeric functional coatings, including with polymeric pore formers. *Id.*; *see also* Br. 8. The SR Specification explains that pore formers work by "dissolv[ing] and form[ing] pores or channels in the coating through which the drug is released." *See id.* The SR Specification further explains that the pore formers are to be used at about 20% to about 50% by weight of the functional coating. CoF No. 5. "The base polymer is described as ranging from about 50% to about 80% by weight of the coating composition," excluding certain non-polymeric materials. *Id.*

Dr. Charman admits that the SR Specification lists only three classes of pore formers, two of which are polymers. *See* CoF No. 6. Dr. Moreton also testified that "[t]he patent describes the use of the – the pore formers in the coating, and that's where – the functional coating, and that's where the controlled release control [is] centered." *Id.* Therefore, the SR Specification

[2] To the extent Avadel implies that the disclosure of optional ingredients weighs in favor of lack of written description, that is not the law. *See, e.g., Amgen v. Hoechst Marion Roussel*, 314 F.3d 1313, 1333 (Fed. Cir. 2003) (holding that Federal Circuit precedent establishes that a patentee need only describe the invention as claimed, and need not describe unclaimed elements).

discloses that the use of a polymeric functional coating, and in particular pore formers within that coating, is an inventive feature of the claims.

With respect to the two remaining categories of potential functional coating excipients that Avadel mentions—plasticizers and anti-tack agents (Br. 6)—no expert has opined that those ingredients alone can control release. While non-polymeric materials may be included within the functional coating (CoF No. 7), neither plasticizers nor anti-tack agents are required by the asserted claims of the Sustained Release Patents.

2. The SR Specification directs a POSA to use MAMM co-polymers for formulations with a pH-sensitive start-up lag time

Avadel does not—because it cannot—dispute that the SR Specification expressly discloses the use of the claimed MAMM co-polymers within the functional coating at the claimed percentage. *See* Br. at 8. In fact, Avadel's own expert agrees that "one embodiment" described in the SR Specification is a sustained release formulation with a functional coating comprised of the claimed MAMM co-polymers. CoF No. 8.

Moreover, Dr. Moreton opines (and Dr. Charman agrees) that MAMM co-polymers are part of a very limited universe (only three enteric materials) that the SR Specification teaches to use to achieve a pH-sensitive start-up lag time. CoF No. 9. Indeed, the SR Specification discloses a "*particular embodiment*"[3] to control the release of GHB where the "dosage form may be formulated such that controlled release formulation exhibits a start-up time lag." CoF No. 12 (emphasis added). What this means is that GHB does not "start" to release from the sustained release portion until after release of GHB from the immediate release portion is substantially

[3] Avadel appears to take issue with the SR Specification not describing the MAMM co-polymers embodiment as a "preferred embodiment." Br. 10. But the SR Specification does not disclose *any* "preferred embodiments." It does, however disclose a very limited number of "particular embodiments," one of which is the pH-sensitive lag-time embodiment at issue here.

complete. CoF No. 11. The SR Specification further teaches a POSA that, "[w]here a start-up lag time is desired, an enteric coating may be applied over the controlled release component" and that "[u]se of enteric pore-formers would also impart a start-up lag." CoF No. 12. An enteric pore-former is a formulation component that may be used as part of a functional coating. It works by "dissolv[ing] and form[ing] pores or channels in the coating through which the drug is released." *See id.*

The SR Specification names *only three* enteric materials that can be used to impart a start-up lag time: cellulose acetate phthalate, polyvinyl acetate phthalate, and the claimed MAMM co-polymers. CoF No. 9. And the SR Specification teaches that when an enteric pore former is used, it should comprise from about 20% to about 50% by weight of the functional coating. CoF No. 5. At bottom, the SR Specification teaches that if a POSA "desire[s]" a GHB formulation with a pH-sensitive start-up lag time, then the POSA is directed to use one of three options, including the claimed MAMM co-polymers at the claimed weight percentage.

B. The SR Specification Discloses Structural Features To Achieve The Claimed Dissolution Release Profiles

As noted above, the claimed MAMM co-polymers work by "dissolv[ing] and form[ing] pores or channels in the coating through which the drug is released." CoF No. 5. Dr. Moreton explained in his expert report that, although the SR Specification does not include working examples with MAMM co-polymers as the pore formers, the SR Specification includes sufficient data to inform a POSA that the claimed dissolution release profiles would be achieved through the use of water-soluble pore formers, like MAMM co-polymers. CoF No. 13.

As Dr. Moreton explained, the pore former used in Examples 1-3 of the SR Specification is hydroxypropyl cellulose. CoF No. 14. Hydroxypropyl cellulose, like MAMM co-polymers, is a water-soluble pore former. *Id.* Dr. Moreton opines, and Dr. Charman does not dispute, that

Examples 1-3 provide data falling within the claimed dissolution release profiles. *Id.* Dr. Moreton further opines that, "based on the disclosures in the Sustained Release Specification, a POSA would expect a [MAMM] co-polymer coating in the context of the claimed GHB sustained release formulations to behave similarly as compared to the hydroxypropyl cellulose coating described in Example 2, with the only exception being that the [MAMM] co-polymer formulation would include a start-up lag for the release of its sustained release portion." CoF No. 15. In fact, Dr. Moreton testified at deposition that he would be "confident" that he could use the SR Specification's disclosed pore formers to achieve the dissolution release characteristics described in the examples and in the claims. *Id.*

IV. ARGUMENT

A. Legal Standards

"Written description is a question of fact, judged from the perspective of one of ordinary skill in the art as of the relevant filing date." *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1063 (Fed. Cir. 2020) (internal cites and quotations omitted). "A party must prove invalidity for lack of written description by *clear and convincing evidence*." *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015) (emphasis added).

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he 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." 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).

Where, like here, the moving party fails to meet "its burden to establish that 'no finder of fact could reasonably determine that the asserted claims of the patents-in-suit contained an adequate written description,'" summary judgment is "inappropriate." *Idenix Pharms. LLC v. Gilead Scis., Inc.*, No. 13-1987, 2016 WL 6802481, at *8-9 (D. Del. Nov. 16, 2016).

B. Genuine Material Factual Disputes Preclude Summary Judgment

1. Genuine material factual disputes exist as to whether the SR Specification provides a reason to use the claimed MAMM co-polymers

Avadel argues that summary judgment is warranted because the SR Specification purportedly describes "a large genus of potential formulations," and a POSA "would have no reason to select the claimed 20-50% MAMM copolymers from the multitude of other potential excipients." Br. 8; *see also id.* at 9 (arguing no "blaze marks to steer the POSA toward the claimed combination"). Avadel, however, has failed to carry its burden to show an absence of genuine material factual disputes; the record establishes significant material disputes of fact.

First, Avadel incorrectly argues that "[t]here is no dispute" that the SR Specification discloses "a large genus of potential formulations" that result in a "forest of possibilities." Br. 5-6, 8. The record does not support this assertion. *See supra* § III.A.1. Both parties' experts agree that the SR Specification describes controlling the release of GHB with a functional coating that is applied to a CR core. CoF Nos. 1-2. The vast majority of the formulation options Avadel focuses upon to create a "forest" are *not* part of what the SR Specification describes as the necessary functional coating to control the release of GHB. *See* CoF Nos. 3-7, 9-15. Without Avadel's artificially-created "forest," the potential options for that functional coating are small. *Id.* The functional coating necessarily includes polymeric materials; no expert has opined otherwise. CoF Nos. 5-6. And the polymeric materials for the functional coating described in the SR Specification include pore formers. *Id.* In fact, each of the Examples of sustained release

formulations in the SR Specification uses a polymeric functional coating, including polymeric pore formers. CoF No. 5. And while other ingredients such as plasticizers and anti-tack agents can also be included in the functional coating, no expert has opined that those ingredients *alone* are described in the SR Specification as controlling the release of GHB. CoF No. 7.

Second, Avadel incorrectly argues that "a POSA reading the as-filed specification would have no reason to select the claimed 20-50% MAMM copolymers from the multitude of other potential excipients in the claimed formulation." Br. 8. As an initial matter, and as described above, the "potential excipients" for use are not as broad as Avadel attempts to make them seem. *See supra* § III.A.1. Moreover, Dr. Moreton opines, and the SR Specification states that, if a pH-sensitive start-up lag time is "desired," then the SR Specification directs a POSA to use one of *only three* enteric materials, including MAMM co-polymers. *See supra* § III.A.2.

The factual premise at the heart of Avadel's motion—that the SR Specification purportedly provides no reason to use MAMM co-polymers within a functional coating—is a hotly-debated material factual dispute between Jazz's and Avadel's experts. Drs. Moreton and Charman specifically debate whether the SR Specification would teach a POSA away from (as Dr. Charman asserts) formulations with a pH-sensitive start-up lag time.

Dr. Charman alleges that there is a "caution highlighting the downside of using enteric polymers," that the SR Specification "describes the significant limitations of the two possible applications of using enteric materials to create a start-up lag," and that the SR Specification "teach[es] away from the use of enteric polymers." CoF No. 16.[4] *By contrast*, Dr. Moreton

[4] Dr. Charman claims that the "Sustained Release Specification states that a 'less pH-sensitive start-up lag time is desired,'" when it actually provides a discussion of "*where* a less pH-sensitive lag time is desired." CoF No. 18. The SR Specification is giving the option for either a pH-sensitive lag time or a less pH-sensitive lag time, not saying the less pH-sensitive one is more preferrable, as Dr. Charman implies in misquoting the SR Specification.

opines that a POSA would not see the SR Specification as having any "warning or 'caution' against using [MAMM] co-polymers." CoF No. 17. He testified that the SR Specification "doesn't say that there are any deficiencies" with the described lag time and "if you want a lag time, [MAMM] is the way to go." *Id.*

In view of these genuine material factual disputes, Avadel's motion must be denied. Here, the parties' experts dispute whether the SR Specification provides a reason to use the claimed MAMM co-polymers. "[S]ummary judgment is inappropriate where issues of material fact are disputed by experts." *Ford v. Panasonic Corp. of N. Am.*, 284 F. App'x 901, 903 (3d Cir. 2008) (internal cite omitted); *see also, e.g.*, *Alza*, 349 F. Supp. 2d at 1018-19 ("[R]egardless of what the expert testimony will ultimately prove, whether the release rates in Alza's '355 patent are 'blaze marks' on the trees in the forest of those skilled in the art is a factual matter to be decided at trial."). As Judge Stark held in denying summary judgment due to alleged lack of written description, where "a reasonable factfinder could agree with [the plaintiff's expert] that there is not 'nothing' or 'no disclosure'" in the specification, then "[s]ummary judgment is therefore inappropriate." *Idenix*, 2016 WL 6802481, at *8-9; *see also Transcenic, Inc. v. Google, Inc.*, No. 11-582, 2014 WL 7275835, at *2 (D. Del. Dec. 22, 2014) (collecting cases and denying summary judgment where the "motions present a 'battle of the experts' that is not amenable to resolution prior to the presentation of evidence, including testimony").

And to be sure, the dispute between Drs. Moreton and Charman is material to the outcome of Avadel's defense. Where, like here, a patent specification gives a POSA a reason to select from a small number of options to achieve a particular claimed embodiment, then that teaching "is a clear 'blaze mark' providing in *ipsis verbis* support" for the claim. *Singh v. Brake*, 317 F.3d 1334, 1344 (Fed. Cir. 2003). In *Singh*, the Federal Circuit found adequate written

description support for a claimed sub-genus where its defining characteristic was one of five choices that had been described. *See id.* Here, the MAMM co-polymers are one of only three choices available for developing a GHB formulation with a pH-sensitive start-up lag time. That is a "clear blaze mark" under Federal Circuit precedent. *Id.*; *see also Immunex*, 964 F.3d at 1065 (rejecting argument that specification lacked the "required blaze marks" where "the specification identified four preferred fusion proteins, including the claimed p75-IgG1 fusion protein").

And while Avadel argues that Dr. Moreton testified that there "are another two enteric coating polymers *not mentioned in the specification*" (Br. 9 (emphasis added)), it is unclear how that supports Avadel's argument. Even if there were five types of enteric materials disclosed in the SR Specification (there are not), both *Singh* and *Immunex* instruct that this is still far cry from Avadel's characterization of MAMM co-polymers as being "one of many" options. *See id.*

Avadel cites several Federal Circuit opinions that it argues compel a finding in its favor. Br. 9-11. But none of those cases was decided on similar facts—i.e., where, like here, the specification teaches a POSA to use one of only three options when the claimed embodiment "is desired." CoF Nos. 9-12. For instance, in *Regents of the University of Minnesota. v. Gilead Sciences, Inc.*, the Federal Circuit found *ipsis verbis* disclosure lacking because the specification recited "a compendium of common organic chemical functional groups, yielding a laundry list disclosure . . . ." 61 F.4th 1350, 1357 (Fed. Cir. 2023). Likewise, in *Purdue Pharma L.P. v. Iancu*, the claimed excipients ("gelling agents") were "merely two of many undifferentiated compounds" that fell within a "laundry list" of nearly 40 gelling agents. 767 Fed. App'x 918, 923-24 (Fed. Cir. 2019). In *Fujikawa v. Wattanasin*, the claimed "sub-genus diverge[d] from [the specification's] preferred elements."[5] 93 F.3d 1559, 1571 (Fed. Cir. 1996). And in *FWP IP*

[5] *See supra* n.3.

ApS v. Biogen MA, Inc., the claims were directed to a treatment for multiple sclerosis ("MS") using a particular 480 mg/day dose, but the "specification list[ed] over twenty diseases and conditions, and MS [was] not identified as of any particular interest," such that a POSA would have had to made a further "selection of 480 mg/day from a large range of possible dosages." 749 Fed. App'x 969, 971 (Fed. Cir. 2018).

Here, by contrast, Jazz's expert has testified (and will testify at trial) that the SR Specification gives a reason to select the claimed MAMM co-polymers, which is found in a disclosure of only three choices. That is much different than the undifferentiated laundry lists found in Avadel's cited cases. For the reasons set forth above, a reasonable factfinder certainly could agree with Dr. Moreton that the specification provides a reason to use the claimed MAMM co-polymers, which would provide the requisite "blaze marks" for the claimed formulations.

2. Genuine material factual disputes exist as to whether the SR Specification describes structural features to achieve the claimed dissolution release profiles

Avadel further argues that "the specification does not describe any structural features of a formulation (i.e., specific excipients) sufficient to 'visualize or recognize' all formulations within the scope of the asserted claims." Br. 12; *see also id.* at 13 (asserting that "the specification does not explain which formulations within the scope of the claims will also satisfy the claimed release profiles"). This is also a genuine material factual dispute.

As explained above, Jazz will present evidence at trial that the Examples in the SR Specification and the common structural features of water-soluble pore formers provide support for the claimed dissolution release profiles. *See supra* § III.C. Dr. Charman "disagree[s] with Dr. Moreton's opinion that a POSA would view non-enteric water-soluble polymers as functioning in the same manner as enteric polymers," based on the alleged varying pH of deionized water. SoF No. 19. In Dr. Charman's view, because the pH of deionized water is

unbuffered and because enteric polymers are pH triggered, pH would affect whether the MAMM co-polymer functional coating produces the claimed dissolution release profile. *See id.*

But this is likewise genuinely disputed and, indeed, the record evidence demonstrates that Dr. Charman lacks support for his conclusion. For example, none of Avadel's experts address that the pH of the deionized water will depend on what is dissolving in it; here the GHB. SoF No. 20. Nor have any of Avadel's experts done any testing to determine what the pH of deionized water will be once a GHB formulation is added for dissolution testing. *Id.* For these reasons and others, Dr. Moreton disagrees with Dr. Charman's purported concerns about any alleged variance in the pH of the deionized water. *Id.*

This battle of the experts precludes summary judgment. *See Ford*, 284 Fed. App'x at 903. The question of whether a POSA would visualize the dissolution profiles of the claimed MAMM co-polymer formulations based on the SR Specifications' Examples 1-3 is both material to the outcome of Avadel's defense and clearly in dispute. The Federal Circuit has found adequate written description based on examples "substantially equivalent" to what has been claimed. *Nalpropion Pharms., Inc. v. Actavis Labs. FL, Inc*., 934 F.3d 1344, 1350 (Fed. Cir. 2019). The relevance of the Examples to the claims is genuinely disputed here and, thus, summary judgment is inappropriate. *See Bioverativ*, 2020 WL 1066019, at *4 (D. Del. Mar. 5, 2020) (denying summary judgment for lack of written description where "there is a genuine dispute as to the scope of the genus described in the claims and whether a skilled artisan could envision the claimed genus with reference to its structural features alone").

The three cases that Avadel cites (*see* Br. 12-13) do not support a grant of summary judgment on the facts here. In *Allergan USA v. MSN Laboratories*, the asserted claims covered "formulations of eluxadoline using *any* filler and *any* disintegrant with the claimed amounts,

which is a broad genus." No. 19-1727, 2023 WL 6295496, at *15 (D. Del. Sept. 27, 2023) (emphasis added). Despite that broad genus, the specification "only disclose[d] formulations made with the same disintegrant (crospovidone) and fillers (mannitol and SMCC). Indeed, the specification is explicit about using these specific excipients, not functional groups." *Id.* Here, the claims are limited to specific percentage MAMM co-polymer formulations with other structural limitations. The SR Specification further instructs the POSA to choose from only three enteric materials (including the claimed MAMM co-polymers) where a formulation with a pH-sensitive lag time is "desired."

The Federal Circuit's decision in *Idenix Pharmaceuticals v. Gilead Sciences* is likewise readily distinguished. There, "billions and billions" of compounds met the structural limitations of the claim. 941 F.3d 1149, 1157 (Fed. Cir. 2019). And with respect to compounds that met the claimed efficacy limitation, a reasonable jury could have concluded that at least "many, many thousands" would exist. *Id.* Despite that breadth, the patent provided "no method of distinguishing effective from ineffective compounds for the compounds reaching beyond the [18] formulas disclosed." *Id.* at 1164. At bottom, the specification did "not explain what makes [any claimed compound] effective, or why." *Id.* Here, by contrast, the SR Specification explains how formulations with the enteric material achieve sustained release. As Jazz's experts will testify, the SR Specification describes in detail the structural elements of the functional coating that are relevant to facilitating the desired release profile, including the use of water-soluble pore formers such as MAMM co-polymers at the claimed percentage. *See supra* § III.B.

Finally, Judge Bryson's decision in *Lipocine v. Clarus Therapeutics* is inapposite. There, the claims "cover *any* oral method using almost *any* formulation administered within that broad range of doses, followed by titration if needed, as long as the method works." 541 F. Supp. 3d

435, 462 (D. Del. 2021) (emphasis added). Here, the claims are not so broad as to cover any formulation that meets the functional limitations; there are clearly structural requirements (including the core and 20-50% MAMM co-polymer limitations), something missing from the claims addressed in *Lipocine*. In fact, another court in this District recently distinguished *Lipocine* on this basis in denying a motion for summary judgment, explaining that, in that case, the claims described the invention in "purely functional terms." *10x Genomics, Inc. v. NanoString Techs., Inc.*, No. 21-653, 2023 WL 5805585, at *6 (D. Del. Sept. 7, 2023). But where, like here, the claimed inventions have structural limitations described in the specification, summary judgment for lack of written description is inappropriate. *Id.*

At bottom, it is "common for patentees to disclose a range of possible embodiments," and a "patentee is free to selectively claim one particular embodiment without running afoul of the written description requirement." *Erfindergemeinschaft UroPep GbR v. Eli Lilly & Co*., 276 F. Supp. 3d 629, 656 (E.D. Tex. 2017), *aff'd*, 739 Fed. App'x 643 (Fed. Cir. 2018). Here, the parties have a genuine material factual dispute as to whether a POSA would understand the claimed dissolution profiles result from the common structural features of MAMM co-polymers and the information set forth in Examples 1-3. Summary judgment is therefore inappropriate.

V. CONCLUSION

For the foregoing reasons, Avadel's motion for summary judgment of invalidity for the Sustained Release Patents based on alleged lack of written description support 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.

I further certify that I caused copies of the foregoing document to be served on December 15, 2023, upon the following in the manner indicated:

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