IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC., Plaintiff, v. AUROBINDO PHARMA LIMITED, et al., Defendants.	Civil Action No. 20-985-RGA

MEMORANDUM OPINION

James D. Taylor, Jr., SAUL EWING ARNSTEIN & LEHR LLP, Wilmington, DE; Chad J. Peterman (argued), Scott F. Peachman, Rebecca A. Hilgar, PAUL HASTINGS LLP, New York, NY,

Attorneys for Plaintiff.

R. Touhey Myer, KRATZ & BARRY LLP, Wilmington, DE; Timothy H. Kratz, Michael P. Hogan, KRATZ & BARRY LLP, Atlanta, GA,

Attorneys for Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.

Nathan R. Hoeschen, SHAW KELLER LLP, Wilmington, DE; Ivan M. Poullaos (argued), Katherine D. Hundt, WINSTON & STRAWN LLP, Chicago, IL,

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

David A. Bilson, PHILLIPS, MCLAUGHLIN & HALL, P.A., Wilmington, DE; Timothy F. Peterson, LOCKE LORD LLP, Chicago, IL,

Attorneys for Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited.

James S. Green, Jr., SEITZ, VAN OGTROP & GREEN, P.A., Wilmington, DE; Yixin H. Tang, UPADHYE TANG, LLP, Chicago, IL,

Attorneys for Defendants MSN Laboratories Private Limited and MSN Pharmaceuticals, Inc.

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ANDREWS, U.S. DISTRICT JUDGE:

Before me is the issue of claim construction of multiple terms in U.S. Patent No. 10,449,185 ("the '185 patent"), U.S. Patent No. 10,646,480 ("the '480 patent"), and U.S. Patent No. 10,849,891 ("the '891 patent") ("the asserted patents").[1] The parties submitted a Joint Claim Construction Brief (D.I. 137) and Appendix (D.I. 138), and I heard oral argument on February 23, 2022 (D.I. 145).

I. BACKGROUND

The asserted patents share a common specification. These patents are directed to capsules containing 34 mg of pimavanserin. ('480 patent, 1:65–67). Pimavanserin is the active ingredient in Nuplazid®, which is "approved for treatment of hallucinations and delusions associated with Parkinson's disease psychosis at a dose of 34 mg." (*Id.*, 1:22–25). Nuplazid® was originally a 17 mg tablet formulation, which required patients to take two tablets daily. (D.I. 138, Ex. 2, at 2). Plaintiff then developed the 34 mg formulation of Nuplazid® as disclosed in the asserted patents, which allows patients to take one capsule daily. (*Id.*, Ex. 3, at 2).

The following claims are most relevant for purposes of this Markman, and I have italicized the disputed terms:

Claims 14 and 20 of the '480 patent

> **14.** A pharmaceutically acceptable capsule for orally delivering 34 mg of pimavanserin to a patient, wherein the capsule has a size 3 or 4 capsule shell that contains a blended pimavanserin composition comprising:
>
> *40 mg granulated pimavanserin tartrate* wherein the bulk density of *the granulated pimavanserin tartrate* of 0.4 g/ml to 0.6 g/ml as determined by USP<616>, method 1; a filler and optionally a lubricant.

[1] At argument, there seemed to be an understanding that the '185 patent had dropped out of the case (*see* D.I. 145 at 6–7), but the record appears to reflect that the '185 patent is still asserted against one Defendant group—Zydus and Cadila (*see* D.I. 151 at 2 ¶ 3).

20. The pharmaceutically acceptable capsule of claim 14, wherein *the granulated pimavanserin* has a Carr's index of 24 as determined by USP<1174>.

Claim 8 of the '891 patent

8. A pharmaceutically acceptable capsule for orally delivering 5-34 mg of pimavanserin to a patient, wherein the capsule contains a blended pimavanserin composition comprising:

granulated pimavanserin or a pharmaceutically acceptable salt thereof, wherein the bulk density of the *granulated pimavanserin or pharmaceutically acceptable salt thereof* is 0.4 g/ml to 0.6 g/ml as determined by USP<616>, method 1; a filler and optionally a lubricant.

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321

(internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 331 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

III. CONSTRUCTION OF AGREED-UPON TERMS

I adopt the following agreed-upon constructions:

Claim Term	**Construction**
"a blended pimavanserin composition" (claim 1 of the '185 patent; claims 1, 5, 12, and 14 of the '480 patent; and claims 1 and 8 of the '891 patent)	"a mixture of pharmaceutical ingredients including pimavanserin or a pharmaceutically acceptable salt thereof and one or more excipients mixed together"
"the blended pimavanserin composition" (claims 3, 6, 7, 12, and 16 of the '480 patent; claims 7 and 11 of the '891 patent)	The term "the blended pimavanserin composition" refers to the term "a blended pimavanserin composition" which is recited in the same claim or in a parent claim

IV. CONSTRUCTION OF DISPUTED TERMS

1. "40 mg granulated pimavanserin tartrate" (claim 1 of the '185 patent; claims 1, 5, 12, and 14 of the '480 patent; claim 1 of the '891 patent)

a. *Plaintiff's proposed construction*: "granulation resulting from an act or process in which particles, including 40 mg pimavanserin tartrate, are made to adhere to form larger, multiparticle entities"

b. *Defendants' proposed construction*: "40 mg pimavanserin tartrate granulated alone"

c. *Court's construction*: "40 mg pimavanserin tartrate granulated alone"

The central dispute between the parties is whether the claimed pimavanserin tartrate[2] can be granulated with excipients or whether it must be granulated alone. This dispute depends on whether prosecution history disclaimer applies. Prosecution history disclaimer "requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325–26 (Fed. Cir. 2003).[3] "[A]n applicant's argument that a prior art reference is distinguishable on a particular ground can serve as a disclaimer of claim scope even if the applicant distinguishes the reference on other grounds as well." *Saffran v. Johnson & Johnson*, 712 F.3d 549, 559 (Fed. Cir. 2013) (quoting *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1374 (Fed. Cir. 2007)).

Defendants argue that the patentee clearly and unmistakably disclaimed pimavanserin tartrate granulated with excipients during the prosecution of the relevant patents. (D.I. 137 at

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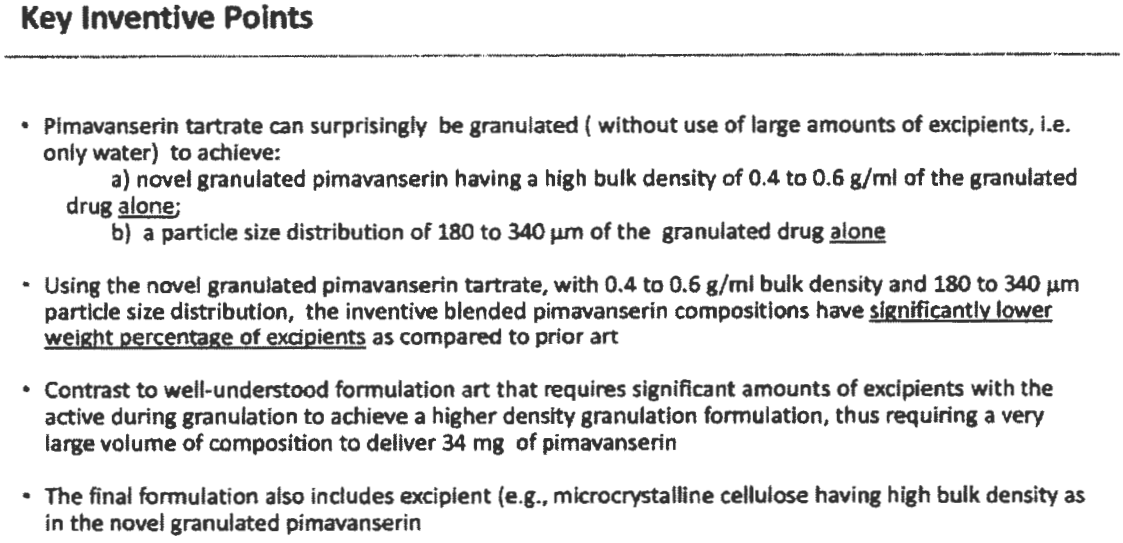
[2] "Forty milligrams of the pimavanserin tartrate is the same as 34 milligrams of pimavanserin." (D.I. 145 at 59:4–5).

[3] I wonder whether something could be unmistakable without also being clear or clear without being unmistakable. In *Omega*, the Court of Appeals quoted cases using "clear" or "clear and unambiguous" as the basis for the "both clear and unmistakable" standard. In probably hundreds of cases arguing about whether there was prosecution disclaimer, I do not think anyone has ever argued that the alleged disclaimer, even if clear, was not unmistakable. Nor has anyone ever argued that even if the alleged disclaimer were unmistakable, it was not clear.

24–29). Plaintiff argues that the statements made by the patentee were ambiguous and do not meet the high burden required to trigger the doctrine of prosecution disclaimer. (*Id.* at 45–48). I agree with Defendants. The prosecution history here is clear. The patentee repeatedly and unambiguously disclaimed pimavanserin tartrate granulated with excipients.

During the prosecution of the '185 patent,[4] the examiner rejected all pending claims as obvious partly because U.S. Patent Publication No. 2007/0264330 ("the '330 Application") disclosed an oral formulation comprising pimavanserin tartrate where "[t]he granulated drug has a bulk density of about 0.56 g/ml." (D.I. 125-4, Ex. D, at 3). This bulk density was within the claimed range of 0.4 to 0.6 g/ml. Before providing a written response, the patentee presented slides detailing the claimed invention to the examiner. (D.I. 125-8, Ex. H). The patentee's presentation included the following slide. (*Id.* at 5).



Key Inventive Points

- Pimavanserin tartrate can surprisingly be granulated (without use of large amounts of excipients, i.e. only water) to achieve:
  a) novel granulated pimavanserin having a high bulk density of 0.4 to 0.6 g/ml of the granulated drug alone;
  b) a particle size distribution of 180 to 340 µm of the granulated drug alone
- Using the novel granulated pimavanserin tartrate, with 0.4 to 0.6 g/ml bulk density and 180 to 340 µm particle size distribution, the inventive blended pimavanserin compositions have significantly lower weight percentage of excipients as compared to prior art
- Contrast to well-understood formulation art that requires significant amounts of excipients with the active during granulation to achieve a higher density granulation formulation, thus requiring a very large volume of composition to deliver 34 mg of pimavanserin
- The final formulation also includes excipient (e.g., microcrystalline cellulose having high bulk density as in the novel granulated pimavanserin

[4] It is undisputed that the '185 patent's prosecution history applies equally to the '480 and '891 patents. (*See* D.I. 145 at 55:19–25); *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation.").

The patentee also provided the following table, which shows that the bulk density of the API used in the '330 Application is lower than the pimavanserin granulation of the claimed invention. (*Id.* at 6).

	Pimavanserin granulation (as e.g., instantly claimed)	Native API (e.g., as used in prior art)
Bulk density (g/ml) according to USP <616>	0.508 (n=4)	0.294 (n=2)

The patentee explained, "[T]he '330 Application starts with non-granulated pimavanserin with low density, in contrast to the claimed novel granulated pimavanserin." (*Id.*). The patentee further explained, "Achieving the claimed pimavanserin bulk density and particle size, without other excipients, was unpredictable and unexpected." (*Id.* at 9). These statements tend to show that the bulk density reported in the above table was the bulk density of the granulated pimavanserin tartrate alone.

Plaintiff argues that a POSA reading this presentation would understand that the claimed pimavanserin tartrate granulation allows minimal excipients, as compared to the significant amount of excipients used in the prior art. (D.I. 145 at 24:18–25:3). I disagree. Throughout this presentation, the patentee distinguishes the '330 Application by asserting that the claimed invention achieves the claimed high bulk density of the pimavanserin tartrate alone. The patentee is able to achieve this high bulk density of the API alone because it granulates the API alone. (*See, e.g.*, '480 patent, 10:55–59 (describing the "finding that pimavanserin could be successfully wet granulated achieving the targeted imp[ro]ved physical properties (e.g. bulk density) without the addition of a binder" as "surprising"). The high bulk density then allows fewer excipients to be added to the blended pimavanserin composition, which in turn results in a formulation that provides 34 mg of the drug in one small capsule. (D.I. 125-8, Ex. H, at 4 ("Discovered a formulation that could provide large amount (34 mg) of pimavanserin in a small

volume (e.g., size 3 or 4 capsule)."); *id.* at 5 ("Using the novel granulated pimavanserin tartrate, with 0.4 to 0.6 g/ml bulk density and 180 to 340 μm particle size distribution, the inventive blended pimavanserin compositions have significantly lower weight percentage of excipients as compared to prior art.")).

The patentee made the same arguments in its written office action response. The patentee explained that its "instant claimed invention" is "a small capsule having a high bulk density of 0.4 to 0.6 g/mL pimavanserin (drug alone) that eases swallowing while delivering a full 34 mg of drug." (D.I. 125-5, Ex. E, at 4). The patentee again distinguished the '330 Application, arguing, "Example 9 (and Table 8) of the '330 Application, which is representative, includes low-density pimavanserin, and requires ~80% w/w of the excipients mannitol, starch, povidone, and magnesium stearate to achieve a bulk density of 0.56 []g/mL of *a formulation of pimavanserin (and not pimavanserin alone)*." (*Id.* at 5). The patentee argued that the examiner failed to establish a prima facie case of obviousness because "there is no finding that one of skill in the art would have been motivated . . . to obtain the high density of pimavanserin alone." (*Id.* at 6; *see also id.* at 4–5 ("[T]here was no reasonable expectation at the time of the instant invention that obtaining such high bulk density of pimavanserin itself, to obtain a capsule that includes 34 mg of the drug, was achievable.")).[5]

[5] The patentee made similar arguments during the prosecution of the '480 patent—a continuation of the '185 patent. (*See, e.g.*, D.I. 125-10, Ex. J, at 5 (describing the claimed invention as "a small capsule having a high bulk density of 0.4 to 0.6 g/mL pimavanserin (drug alone)"); *id.* ("[T]here was no reasonable expectation at the time of the instant invention that obtaining such high bulk density of pimavanserin itself, to obtain a capsule that includes 34 mg of the drug, was achievable."); D.I. 125-14, Ex. N, at 2 (examiner's summary of applicant-initiated interview) ("Applicant argues that the claimed compound has a higher bulk density which allows for more of the drug to be granulated and fit into a smaller space, while the drug of the prior art requires other ingredients in the granulation which increases the space required."); D.I. 125-15, Ex. O, at 5 ("Pimavanserin tartrate *itself* can surprisingly be granulated (without use of large amounts of

Again, the patentee clearly states that the claimed invention achieves the claimed high bulk density of the pimavanserin tartrate alone, while the prior art achieved the same bulk density using excipients. Yet, Plaintiff argues that some of the patentee's statements are ambiguous. For example, Plaintiff argues that it is unclear whether the references to the granulated "drug" alone refer to the granulated pimavanserin itself or the granulated pimavanserin in the presence of excipients. (D.I. 137 at 48; D.I. 145 at 45:13–25). But viewing these statements in context, it is clear that the references to the granulated "drug" alone refer to the granulated pimavanserin itself. The patentee describes the "instant claimed invention" as "a small capsule having a high bulk density of 0.4 to 0.6 g/mL pimavanserin (drug alone) that eases swallowing while delivering a full 34 mg of drug." (D.I. 125-5, Ex. E, at 4). The reference to "34 mg of drug" is clearly referring to the pimavanserin alone. (D.I. 145 at 46:1–5). Thus, a POSA would understand that the reference to "pimavanserin (drug alone)" also refers to the pimavanserin alone.

While there are statements in the prosecution history that by themselves do not rise to the level of clear and unmistakable disclaimer,[6] I find that there is clear and unmistakable disclaimer when considering the prosecution history as a whole. *See Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999) ("[I]t is the totality of the prosecution history that must be

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excipients/binders, i.e. only water) to achieve: a *novel* granulated pimavanserin tartrate having a high bulk density of 0.4 to 0.6 g/ml of the granulated drug alone.")).

[6] For example, the first bullet point on the "Key Inventive Points" slide provides, "Pimavanserin tartrate can surprisingly be granulated (without use of large amounts of excipients, i.e. only water)." (D.I. 125-8, Ex. H, at 5). I agree with Plaintiff that this isolated statement is ambiguous. Plaintiff argues: "If only water was to be used during granulation, the previous phrase would have been 'without any excipients' and not 'without use of large amounts of excipients.'" (D.I. 137 at 48; *see* D.I. 145 at 69:19–70:3). On the other hand, this statement, which is about how surprising the result is, suggests not a modest change—less excipients—but a large change, that is, "only water." Thus, the bullet point by itself is ambiguous.

assessed, not the individual segments of the presentation made to the Patent and Trademark Office by the applicant . . . ."). Throughout the prosecution history, the patentee makes clear that the claimed granules having the required bulk density are granules of the API alone. (*See, e.g.*, D.I. 125-5, Ex. E, at 4 ("high bulk density of . . . pimavanserin (drug alone)"); *id.* at 5 ("high bulk density of pimavanserin itself"); *id.* at 6 ("high density of pimavanserin alone"); D.I. 125-8, Ex. H, at 5 ("high bulk density of . . . the granulated drug alone"); D.I. 125-10, Ex. J, at 5 ("high bulk density of . . . pimavanserin (drug alone)"); *id.* ("high bulk density of pimavanserin itself")). Further, the patentee distinguishes the prior art on this basis. (*See, e.g.*, D.I. 125-5, Ex. E, at 5). This disavowal in claim scope is unequivocal and unambiguous.[7]

Defendants' construction is also supported by the claim language. Claim 1 of the '480 patent, for example, recites: "40 mg granulated pimavanserin tartrate wherein the bulk density of the granulated pimavanserin tartrate is 0.4 to 0.6 g/ml as determined by USP<616>, method 1." It is undisputed that "40 mg granulated pimavanserin tartrate" refers to the amount of API in the claimed "blended pimavanserin composition." (D.I. 137 at 11; D.I. 145 at 13:1–4, 56:13–15).

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[7] Plaintiff argues that the examiner's stated reasons for allowance for the patents "reflect an understanding that the claimed inventions are concerned with fitting the total daily dose of 40 mg pimavanserin tartrate into a smaller size 3 or 4 capsule and not towards any particular process for granulation or select embodiment." (D.I. 137 at 13). For example, in the notice of allowance for the '185 patent, the examiner states, "The instantly claimed, granulated pimavanserin formulation allows for minimal excipients, and compaction into smaller dosage forms to ease delivery by oral delivery." (D.I. 125-7, Ex. G, at 6). This statement is consistent with the patentee's disclaimer. The patentee discovered that by granulating the pimavanserin tartrate alone, the need for excipients in the final formulation was reduced, thereby allowing a greater amount of pimavanserin to fit into a smaller volume. Regardless, statements by the examiner cannot erase a patentee's clear and unmistakable disclaimer. *See Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1325 (Fed. Cir. 2015) ("[T]he interested public has the right to rely on the inventor's statements made during prosecution, without attempting to decipher whether the examiner relied on them, or how much weight they were given."); *Comput. Docking Station Corp. v. Dell, Inc.*, 519 F.3d 1366, 1377 (Fed. Cir. 2008) ("[T]he examiner's citation of the single connection limitation in the reasons for allowability does not erase the applicants' clear disavowal of laptops.").

Thus, the claimed bulk density of "the granulated pimavanserin tartrate" is the bulk density of the API alone, measured using the claimed method. Plaintiff's expert and Defendants' expert agree that USP<616>, method 1 measures the bulk density of the solid material being tested. (*See* D.I. 138, Ex. 5, ¶ 44; *id.*, Ex. 8, ¶ 58). For example, if a POSA is testing a mixture (e.g., pimavanserin and excipients), the resulting measurement will be the bulk density of the mixture, not the bulk density of the individual components. (*See* D.I. 145 at 157:14–16).

Plaintiff's expert Dr. Klibanov states, "[A] POSA would have understood that any bulk density measurement performed on pimavanserin granulations, including pimavanserin and other ingredients, could be used to determine with a certain degree of confidence the bulk density of the pimavanserin." (D.I. 138, Ex. 8, ¶ 58). Dr. Klibanov further states, "[A] POSA would have been aware of analytical methods to determine the attributes of components, including image analysis of sieve fractions and microscopic techniques." (*Id.*). But this is not what the claims require. The claims require determining the bulk density of the API alone using USP<616>, method 1, not measuring the bulk density of a mixture of API and excipients and then using "analytical methods" to determine the bulk density of the API alone. A POSA would understand that in order to measure the bulk density of the pimavanserin tartrate alone using USP<616>, method 1—as required by the claims—the pimavanserin tartrate must be granulated alone. (*See id.*, Ex. 5, ¶¶ 44–45).

Defendants' construction is further supported by the specification. The only detailed description of the "Granulation" process in the specification describes granulating pimavanserin tartrate alone. (*See* '480 patent, 20:20–45; *see also id.*, 15:8–10 ("[I]t was surprisingly found that a 100% pimavanserin high-shear granulation was possible by using only small water

quantities . . . .");[8] 16:25–30 ("One embodiment of the compositions described herein includes pimavanserin tartrate granulation without binder, dried, and thereafter blended with less than 60% w/w microcrystalline cellulose such as Avicel PH302 or equivalent microcrystalline cellulose, and about 1% w/w magnesium stearate.")). Although the specification contains other embodiments that permit granulation with excipients, this does not change the result. (*See id.*, 17:36–51). As discussed above, Plaintiff disavowed that subject matter during prosecution of the relevant patents. *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1095 (Fed. Cir. 2013) ("[W]hen the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent, the doctrine of prosecution history disclaimer narrows the meaning of the claim consistent with the scope of the claim surrendered.").[9]

I therefore adopt Defendants' proposed construction.

2. "the granulated pimavanserin tartrate" (claims 1, 5, 12, 14, and 15 of the '480 patent; claim 1 of the '891 patent)

a. *Plaintiff's proposed construction*: The term "the granulated pimavanserin tartrate" refers to the term "40 mg granulated pimavanserin tartrate" which is recited in the same claim or in a parent claim.

b. *Defendants' proposed construction*: "the pimavanserin tartrate that has been granulated alone"

c. *Court's construction*: The term "the granulated pimavanserin tartrate" refers to the term "40 mg granulated pimavanserin tartrate" which is recited in the same claim or in a parent claim.

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[8] The sentence goes on, but the remainder of the sentence does not make much sense.

[9] Plaintiff also argues that because claim 13 of the '891 patent recites granulation "without addition of a binder," the independent claim must include a binder or other excipient. (D.I. 137 at 62). This argument, however, does not change the result here because there is prosecution history disclaimer. *Biogen Idec*, 713 F.3d at 1097 ("Our cases make clear, however, that where found, prosecution history disclaimer can overcome the presumption of claim differentiation.").

3. **"the granulated pimavanserin" (claim 1 of the '185 patent; claim 20 of the '480 patent)**

   a. *Plaintiff's proposed construction*: The term "the granulated pimavanserin" refers to the term "40 mg granulated pimavanserin tartrate" which is recited in the same claim or in a parent claim.

   b. *Defendants' proposed construction*: "the pimavanserin that has been granulated alone"

   c. *Court's construction*: The term "the granulated pimavanserin" refers to the term "40 mg granulated pimavanserin tartrate" which is recited in the same claim or in a parent claim.

Terms 2 and 3 both have antecedent basis in the term "40 mg granulated pimavanserin tartrate." For term 3 specifically, the only "granulated pimavanserin" recited in claim 1 of the '185 patent and claim 14 of the '480 patent is the "40 mg granulated pimavanserin tartrate." Thus, a POSA would clearly understand that the term "the granulated pimavanserin" in claim 1 of the '185 patent and claim 20 of the '480 patent refers to the term "40 mg granulated pimavanserin tartrate" in claim 1 of the '185 patent and claim 14 of the '480 patent, respectively.

4. **"granulated pimavanserin or a pharmaceutically acceptable salt thereof" (claim 8 of the '891 patent)**

   a. *Plaintiff's proposed construction*: "granulation resulting from an act or process in which particles, including pimavanserin or a pharmaceutically acceptable salt thereof, are made to adhere to form larger, multiparticle entities"

   b. *Defendants' proposed construction*: "pimavanserin or a pharmaceutically acceptable salt granulated alone"

   c. *Court's construction*: "pimavanserin or a pharmaceutically acceptable salt granulated alone"

The parties' constructions for this term mirror their constructions for "40 mg granulated pimavanserin tartrate." Thus, for the reasons discussed above, I adopt Defendants' construction.

The above constructions are so ordered.