IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACADIA PHARMACEUTICALS INC., Plaintiffs, v. AUROBINDO PHARMA LIMITED, et al., Defendants.	C. A. No. 22-cv-1387-GBW **CONSOLIDATED**

MEMORANDUM OPINION

Before the Court is Acadia Pharmaceutics Inc. ("Acadia") and Aurobindo Pharma Limited, et al.'s ("Defendants,") joint request for construction of claims 1 and 4 of U.S. Patent No. 11,452,721 (the "'721 patent"). D.I. 39. The Court has reviewed the parties' briefing, *id.*, and construes the claims at issue as set forth below.

I. LEGAL STANDARDS

"'[T]he 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) (citation omitted); *Aventis Pharms. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1363, 1373 (Fed. Cir. 2013) (same). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. The Court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.* The ultimate question of the proper construction of a patent is a question of law, although "subsidiary factfinding is sometimes necessary." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 326–27 (2015); *see Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) ("the construction of a patent . . . is exclusively within the province of the court.").

"The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1313); *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1358 (Fed. Cir. 2016) (similar). The "'only two exceptions to this general rule'" are (1) when a patentee defines a term or (2) disavowal of "'the full scope of a claim term either in the specification or during prosecution.'" *Thorner*, 669 F.3d at 1365 (citation omitted).

The Court "'first look[s] to, and primarily rel[ies] on, the intrinsic evidence,'" which includes the claims, written description, and prosecution history and "'is usually dispositive.'" *Personalized Media Commc'ns, LLC v. Apple Inc.*, 952 F.3d 1336, 1340 (Fed. Cir. 2020) (citation omitted). "[T]he specification ' . . . is the single best guide to the meaning of a disputed term.'" *Akzo Nobel Coatings, Inc. v. Dow Chem. Co.*, 811 F.3d 1334, 1340 (Fed. Cir. 2016) (citation omitted). "'[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess.' When the patentee acts as its own lexicographer, that definition governs." *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019) (quoting *Phillips*, 415 F.3d at 1316). However, "'[the Court] do[es] not read limitations from the embodiments in the specification into the claims.'" *MasterMine Software, Inc. v. Microsoft Corp.*, 874 F.3d 1307, 1310 (Fed. Cir. 2017) (citation omitted)). The "written description . . . is not a substitute for, nor can it be used to rewrite, the chosen claim language." *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

The Court "should also consider the patent's prosecution history, if it is in evidence." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370; *Cont'l Cirs.*, 915 F.3d at 796 (same). The prosecution history may "'demonstrat[e] how the

inventor understood the invention and whether the inventor limited the invention in the course of prosecution . . . ." *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1377 (Fed. Cir. 2021) (quoting *Phillips*, 415 F.3d at 1317).

The Court may "need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period." *Teva*, 574 U.S. at 331. "Extrinsic evidence consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317 (same). Extrinsic evidence may be useful, but it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Cont'l Cirs.*, 915 F.3d at 799 (internal quotation marks and citations omitted). However, "[p]atent documents are written for persons familiar with the relevant field . . . . Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention." *Verve, LLC v. Crane Cams, Inc.*, 311 F.3d 1116, 1119 (Fed. Cir. 2002); *see Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 899 (2014) (explaining that patents are addressed "to those skilled in the relevant art").

II. DISPUTED TERMS

The following terms are in dispute. The Court finds that the terms require no further construction, and gives each term it's plain and ordinary meaning, as set forth below for the following reasons:

Term No.	Claim Term	Plaintiffs' Construction	Defendant's Construction	Court's Construction
1	A blended pimavanserin composition comprising:	A mixture of pharmaceutical ingredients including	A mixture containing pimavanserin or its salt made up of at	Plain and ordinary meaning; an extra-granular component is not

	granules comprising 40 mg pimavanserin tartrate and optionally one or more pharmaceutically acceptable excipients; and one or more blending excipients '721 patent, claim 1	pimavanserin or a pharmaceutically acceptable salt thereof and one or more excipients mixed together, including but not limited to: multiparticle entities, including but not limited to, (1) 40 mg pimavanserin tartrate granulated alone or (2) 40 mg pimavanserin tartrate granulated with one or more pharmaceutically acceptable excipients; and one or more blending excipients	least two components, including one component that is "granules comprising 40 mg pimavanserin tartrate," and at least one additional extra-granular component of blending excipient(s)	required.
2	A blended pimavanserin composition comprising: granules comprising 40 mg pimavanserin tartrate and one or more pharmaceutically acceptable excipients '721 patent, claim 4	A mixture of pharmaceutical ingredients including pimavanserin or a pharmaceutically acceptable salt thereof and one or more excipients mixed together, including but not limited to: multiparticle entities, including but not limited to, 40 mg pimavanserin tartrate granulated with	A mixture of at least two components, including one component that is 40 mg of pimavanserin tartrate that has been granulated alone, and at least one additional extra-granular component of excipient or excipients	Plain and ordinary meaning; an extra-granular component is not required.

		one or more pharmaceutically acceptable excipients		
	"Granules comprising 40 mg pimavanserin tartrate" '721 patent, claims 1 and 4 "Granules comprising 40 mg pimavanserin tartrate and optionally one or more pharmaceutically acceptable excipients" '721 patent, claim 1 "Granules comprising 40 mg pimavanserin tartrate and one or more pharmaceutically acceptable excipients" '721 patent, claim 4	Claim 1: "multiparticle entities, including but not limited to, (1) 40 mg pimavanserin tartrate granulated alone or (2) 40 mg pimavanserin tartrate granulated with one or more pharmaceutically acceptable excipients" Claim 4: "multiparticle entities, including but not limited to, 40 mg pimavanserin tartrate granulated with one or more pharmaceutically acceptable excipients"	40 mg pimavanserin tartrate that has been granulated alone	Plain and ordinary meaning; the scope of the term granule includes granules granulated with pimavanserin and excipients

III. DISCUSSION

Essentially, the parties raise two disputes. *See* D.I. 39. First, the parties dispute whether the claimed "granule" must contain pimavanserin (and only pimavanserin) or whether the

granule can contain pimavanserin along with other chemical compounds. Second, the parties dispute whether the claimed "blended pimavanserin composition" may consist solely of granules, or whether the composition must contain both a granular and an extra-granular component. The Court addresses each in turn, concluding that the "granule" need not be limited to pimavanserin granulated alone and that the "blended pimavanserin composition" need not possess an extra-granular component.

A. Claims 1 and 4 of the '721 Patent Do Not Require that Pimavanserin be Granulated Alone.

The parties dispute whether the "granule" claimed in claims 1 and 4 of the '721 patent must consist of solely pimavanserin.

Claim 1 recites:

1. 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:

> granules comprising 40 mg pimavanserin tartrate and optionally one or more pharmaceutically acceptable excipients;
>
> and one or more blending excipients; wherein the bulk density of the granules is >0.4 g/ml as determined by USP<616>, method 1.

Claim 4 recites:

4. A pharmaceutically acceptable capsule for orally delivering 34 mg of pimavanserin to a patient, wherein the capsule has a capsule shell with a capsule shell size 3 or 4, that encapsulates a blended pimavanserin composition comprising:

> granules comprising 40 mg pimavanserin tartrate and one or more pharmaceutically acceptable excipients; and
>
> wherein the bulk density of the granules is >0.4 g/ml as determined by USP<616>, method 1.

In support for its position, Defendants direct the Court to Judge Andrew's ruling in a previous dispute between the parties, C.A. No. 20-985-RGA, D.I. 152 or "*Acadia I.*" There, Judge Andrews construed the terms of U.S Patent Nos. 10,849,891 ("the '891 patent") and

10,646,480 ("the '480 patent") (the "predecessor patents") and found that Acadia had made a "clear and unmistakable disclaimer" that precluded them from claiming "pimavanserin tartrate granulated with excipients." *Id.* at 8.

Defendants contend that Judge Andrew's ruling in *Acadia I* is dispositive of the issue in the instant case because the '721 patent claims priority to the predecessor patents. D.I. 39 at 37. Further, Defendants argue that the predecessor patents share a "substantively identical" specification and written description with the '721 patent. *Id.* Thus, because "each patent is directed to granulated pimavanserin of a specific bulk density in order to fit into a specific size capsule for a specific reason," Defendants claim that the scope of the '721 patent is equivalent to that of the predecessor patents. *Id.* Accordingly, Defendants contend that any disclaimer arising from the predecessor patents applies equally to the '721 patent.

Conversely, Acadia argues that *Acadia I* is not dispositive because the scope of the '721 patent is greater than that of the predecessor patents. *Id.* at 44. When a patentee disclaims claim scope in a predecessor patent, that disclaimer binds the patentee's subsequent patents only if the subsequent patent has the same, or immaterially different, claim limitations as its predecessor. *See Saunders Grp. v. Comfortrac, Inc.*, 492 F.3d 1326, 1333 (Fed. Cir. 2007) ("When the purported disclaimers are directed to specific claim terms that have been omitted or materially altered in subsequent applications . . . those disclaimers do not apply."). Accordingly, Acadia argues that any disclaimer it made with respect to its predecessor patents does not bind it with respect to the '721 patent.

The Court finds that, with respect to claim 1 and claim 4 of the '721 patent, Acadia did not clearly disavow granules containing both pimavanserin and excipients because the '721 patent has greater claim scope than the predecessor patents.

First, the Court starts with the language of the claims. Claim 1 of the '721 patent expressly contemplates pimavanserin granulated with other ingredients because the claim states that the "granule" consists of pimavanserin and "optionally one or more pharmaceutically acceptable excipients." This is unlike the '480 and '891 patents, which expressly claimed only pimavanserin. *Compare* '721 patent claim 1 ("granules comprising 40 mg pimavanserin tartrate and optionally one or more pharmaceutically acceptable excipients") *with* '480 patent claim 1 ("40 mg granulated pimavanserin tartrate") *and* '891 patent claim 1 ("granulated pimavanserin or a pharmaceutically acceptable salt thereof."). Moreover, the '721 patent claims granules with a "bulk density" of ">0.4 g/ml as determined by USP<616>, method 1" whereas the predecessor patents claimed "granulated pimavanserin tartrate" of a certain bulk density. Claim 1. In *Acadia I*, Judge Andrews explained that—because USP<616>, method 1 measures the bulk density of the solid material being tested—the bulk density of the granulated pimavanserin recited in the predecessor patents could be measured using that method only if the granulated pimavanserin was granulated alone. *Acadia I* at 9-10. The '721 patent, however, merely recites a certain bulk density for the granule. '721 patent claim 1. Thus, because the claims of the '721 patent recite measuring the entire granule, there is no need to use "analytical methods" to separate the bulk density of the pimavanserin from the excipients—as would be required to calculate the bulk density of the granulated pimavanserin in the predecessor patents if the pimavanserin were granulated with excipients. *See Acadia I* at 9-10.

Further, claim 11 (which depends on claim 1) recites "the pharmaceutically acceptable capsule of claim 1, wherein the granules comprise a pharmaceutically acceptable excipient which is a binder." '721 patent. Defendants' proposed construction would exclude this claim. D.I. 39 at 30. This further distinguishes the '721 patent from the predecessor patents because the

predecessor patents did not include dependent claims reciting specific formulations for the claimed granules. *See* '891 patent; '480 patent.

Next, the Court considers the specification, and finds that it also shows Acadia did not clearly disavow granules containing both pimavanserin and excipients. For example, the specification states that "granules" are "multiparticle entities" consisting of "primary powder particles" that were "made to adhere [together]," and that "[g]ranules may for example be formed collecting particles together by creating mechanical bonds between them, e.g., by compression or by using a binder." '721 patent at 4:43-46, 4:47-50. The specification then explains that "a 'binder' is an excipient holding the ingredients together, and forming granules or tablets with required mechanical strength, and may give volume to the formulation." *Id.* at 3:63-66. Thus, the specification contemplates that a "binder" may be paired with "pimavenserin" to form a "granule." *See id.*

The Court is further unconvinced by Defendants' argument that the prosecution history of the '721 patent evinces that its scope is equivalent to that of the predecessor patents. *See* D.I. 39 at 37. During prosecution of the patent application that led to the '721 patent, the patent examiner rejected the pending claims, which contained the presently disputed claim term, for non-statutory obviousness type double patenting over claims of the then-issued '185, '480, and '891 patents. *See id.* Acadia subsequently filed terminal disclaimers over the '185, '480, and '891 patents. *See id.* Defendants argue that this disclaimer establishes that the scope of the '721 patent is the same as that of the predecessor patents. *See id.*

However, the doctrine of prosecution disclaimer generally does not apply when the claim term in the descendant patent uses different language. *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1078 (Fed.Cir.2005) ("[T]he prosecution of one claim term in a parent

application will generally not limit different claim language in a continuation application."); *ResQNet.com, Inc. v. Lansa, Inc.*, 346 F.3d 1374, 1383 (Fed.Cir.2003) ("Although a parent patent's prosecution history may inform the claim construction of its descendant, the [parent] patent's prosecution history is irrelevant to the meaning of this limitation because the two patents do not share the same claim language.") Further, "the filing of a terminal disclaimer" "raises neither presumption nor estoppel on the merits of the rejection," because the filing "simply serves the statutory function of removing the rejection of double patenting." *Ventana Med. Sys. v. Biogenex Labs.*, 473 F.3d 1173, 1184 n. 4 (Fed. Cir. 2006). In *Acadia I*, Judge Andrews explained that "[t]hroughout the prosecution history [of the predecessor patents], the patentee makes clear that the claimed granules having the required bulk density are granules of the [pimavanserin] alone." *Acadia I* at 9. In contrast, the claims of the '721 patent make clear that the "claimed granules" differ in scope from that of the predecessor patent because the '721 claims either allow (claim 1) or require (claim 4) the granulation of pimavanserin with a separate ingredient. '721 patent claim 1 ("granules comprising 40 mg pimavanserin tartrate and optionally one or more pharmaceutically acceptable excipients"; '721 patent claim 4 ("granules comprising 40 mg pimavanserin tartrate and one or more pharmaceutically acceptable excipients.")

B. Claims 1 and 4 of the '721 Patent Do Not Require an Extra-Granular Component.

The parties also dispute whether "a blended pimavanserin composition" must contain both a "granular" and an "extra-granular" component. The Court finds that the composition is not required to contain an "extra-granular" component.

Defendants argue that a "blended composition" implies that there must be a mixture of two (2) things. Thus, because one of those things is granular, the other must not be granular. Conversely, Acadia argues that a "blended composition" is a "mixture of pharmaceutical ingredients" including at least "one or more excipients." The Court agrees with Acadia that the claims do not specifically require an extra-granular component.

The Court starts with the language of the claims. Claim 1 of the '721 patent states that a "blended pimavanserin composition" comprises granules and "at least one or more blending excipients." Claim 4 of the '721 patent, however, omits the "blending excipients" requirement. Accordingly, construing a "blended composition" to always include a blending excipient, or other extra-granular component, would improperly import a limitation and erase the differences between the two (2) claims. Instead, claim 4 makes clear that the pharmaceutical excipient already present in the granule is sufficient to make a "blended composition." '721 patent.

The specification further supports that a "blended composition" need not contain an extra-granular component. The specification explains that the term "blending" "refers to the mixing of pharmaceutical ingredients to form a mixture of the ingredients." '721 patent at 4:59-64. Further, the specification includes examples of excipients being mixed with pimavanserin prior to or during granulation. *See id.* at 3:63-66 ("Optionally suitable binders and/or disintegrants may be included in the blending of the pimavanserin granulation."). While the specification also describes a mixing process that occurs after granulation, nowhere does the specification explicitly state that extra-granular excipients are mandatory. *See id.* at 20:60-21:15 (describing a process by which the pimavanserin is granulated, the granules are dried, and then the dried granules are diluted and blended).

The Court's finding that the granules may contain more than just pimavanserin also supports a finding that the blended mixture is not required to include an extra-granular component. If the Court had found the opposite—that granules must consist solely of pimavanserin—it would support a finding that there must be an extra-granular component, since a mixture requires two (2) components. However, because the Court has found that the granules may themselves be a mixture of multiple components, it stands to reason that a blended composition can consist of these multi-component granules.

For the reasons stated above, the Court finds that a "blended composition" is not required to contain an extra-granular component. Beyond that finding, the Court finds that the plain and ordinary meaning of the term is sufficient and declines to construe the term further.

V. CONCLUSION

The Court will construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

Date: December 13, 2023