IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEWRON PHARMACEUTICALS S.p.A., ZAMBON S.p.A., MDD US OPERATIONS, LLC, Plaintiffs, v. AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA INC., MSN LABORATORIES PRIVATE LIMITED, OPTIMUS PHARMA PVT LTD, PRINSTON PHARMACEUTICAL, INC., RK PHARMA INC., ZENARA PHARMA PRIVATE LIMITED, Defendants.	C.A. No. 21-843-GBW

MEMORANDUM OPINION

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GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE

In this action filed by Plaintiffs Newron Pharmaceuticals S.p.A., Zambon S.p.A., and MDD US Operations, LLC (together, "Plaintiffs") against Defendants MSN Laboratories Private Limited, RK Pharma Inc., Prinston Pharmaceutical, Inc., and Prinston Pharmaceutical, Inc., and Zenara Pharma Private Limited (together, "Defendants"), Plaintiffs allege infringement of U.S. Patent No. 8,076,515 ("the '515 patent"), U.S. Patent No. 8,278,485 ("the '485 patent"), and U.S. Patent No. 8,283,380 ("the '380 patent"). Before the Court is the issue of claim construction of multiple terms in these patents. The Court has considered the parties' joint claim construction brief, the accompanying appendix and declarations, the parties' supplemental submissions as requested by the Court, and argument at the claim construction hearing (the "Hearing"). *See* D.I. 120, 133, 134, 180, 181, 198, 199.

I. LEGAL STANDARDS

A. Claim Construction

"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); *see also Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989) ("A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention"). "[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 fact-finding is sometimes necessary. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996)).

"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. Ent. Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1312–13). A person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at at 1313.

"When construing claim terms, the court first looks to, and primarily rely on, the intrinsic evidence, including the claims themselves, the specification, and the prosecution history of the patent, which is usually dispositive." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1276 (Fed. Cir. 2013). "Other claims of the patent in question, both asserted and unasserted, can . . . be valuable" in discerning the meaning of a disputed claim term because "claim terms are normally used consistently throughout the patent," and so, "the usage of a term in one claim can often illuminate the meaning of the same term in other claims." *Phillips*, 415 F.3d at 1314. In addition, "[d]ifferences among claims can also be a useful guide[.]" *Id.* For example, "the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15.

In addition to the claim, the Court should analyze the specification, which "is always highly relevant to the claim construction analysis ... [as] it is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. "Even when the specification describes only

a single embodiment, [however,] the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)). And, the specification "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*, 52 F.3d at 980. The prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution[.]" *Phillips*, 415 F.3d at 1317.

In some cases, the Court "will 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*, 135 S. Ct. at 841. 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. Overall, while extrinsic evidence may be useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (internal quotation marks and citations omitted).

B. Indefiniteness

Section 112 of Title 35 imposes a definiteness requirement on patent claims. 35 U.S.C. § 112(b) (requiring that the claims "particularly point[ ] out and distinctly claim[ ] the subject matter which the inventor ... regards as the invention"). "The primary purpose of the definiteness

requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, e.g., competitors of the patent owner, can determine whether or not they infringe." *All Dental Prodx, LLC v. Advantage Dental Prods., Inc.*, 309 F.3d 774, 779–80 (Fed. Cir. 2002).

"A patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). To determine indefiniteness, courts examine "the patent record—the claims, specification, and prosecution history—to ascertain if they convey to one of skill in the art with reasonable certainty the scope of the invention claimed." *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). Like claim construction, definiteness is a question of law, but the Court must sometimes render factual findings based on extrinsic evidence to resolve the ultimate issue of definiteness. *See, e.g., Sonix Tech. Co. v. Publications Int'l, Ltd.*, 844 F.3d 1370, 1376 (Fed. Cir. 2017); *see also Teva*, 135 S. Ct. at 842-43. "Any fact critical to a holding on indefiniteness ... must be proven by the challenger by clear and convincing evidence." *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003); *see also Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

II. AGREED-UPON TERMS

The parties agreed upon the construction of four claim terms as follows:

Claim Term	Agreed-Upon Construction
"an effective amount" ('515 patent, claim 40)	"an amount sufficient to treat the selected CNS disorder"

"classified as" ('515 patent, claim 44)	Plain and ordinary meaning, "with an understanding that Defendants may argue that the terms are indefinite in the factual context of an infringement analysis" (D.I. 181)
"are known to interact with" ('515 patent, claim 44)	Plain and ordinary meaning, "with an understanding that Defendants may argue that the terms are indefinite in the factual context of an infringement analysis" (D.I. 181)
"are known to have HERG channel blocking properties" ('515 patent, claim 44)	Plain and ordinary meaning, "with an understanding that Defendants may argue that the terms are indefinite in the factual context of an infringement analysis" (D.I. 181)

D.I. 180 at 3. The Court will adopt these agreed-upon constructions and will grant Defendants leave to renew their indefiniteness arguments.

III. DISPUTED TERMS

A. "stable dose of levodopa"

Claim Term	Plaintiffs' Construction	Defendants' Construction	The Court's Construction
"stable dose of levodopa" ('380 patent, claims 1-2)	"a dose of levodopa that is neither increased nor decreased"	Not amenable to construction; indefinite	"a dose of levodopa that is neither increased nor decreased"

While Plaintiffs maintain that "stable dose of levodopa" can be understood according to its plain and ordinary meaning, which according to Plaintiffs is "a dose of levodopa that is neither increased nor decreased", Defendants contend that "stable dose" is indefinite as it "provides no indication of the length of time and frequency during that time" so as to inform a skilled artisan

with reasonable certainty what "unchanging dose of levodopa should be administered before it can be considered to be 'stable.'" D.I. 133 at 7-9.

Starting with the claims, claim 1 of the '380 patent recites:

> 1. In a method of treating idiopathic Parkinson's disease in a patient receiving a stable dose of levodopa, the improvement comprising:
> concurrently administering safinamide, or a pharmaceutically acceptable salt thereof, on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day,
> while maintaining the patient on a stable dose of levodopa.

'380 patent at cl. 1. Claim 2 of the '380 patent recites:

> 2. A method of treating idiopathic Parkinson's Disease comprising:
> administering a therapeutically effective stable dose of levodopa; and
> concurrently administering safinamide, or a pharmaceutically acceptable salt thereof, on an oral dosage schedule of about 0.5 mg/kg/day to about 5 mg/kg/day.

'380 patent at cl. 2. In claim 1, which the parties agree is written in *Jepson*[1] format (D.I. 133 at 5, 10), the prior art methods of treating idiopathic Parkinson's Disease ("PD") used a "stable dose of levodopa". The inventors improved upon the prior art by adding safinamide to the patient's treatment regimen "while maintaining the patient on a stable dose of levodopa." That the method of treatment involves "maintaining" a patient on that "stable dose" suggests that the "stable dose" does not increase or decrease. Further, given claim 1's *Jepson* format, explaining that treating a patient with a "stable dose of levodopa" was accomplished in the prior art, the claim language suggests that a skilled artisan would understand how to treat PD with levodopa, including how to recognize when a patient is receiving a stable levodopa dose.

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[1] *See Dow Chem. Co. v. Sumitomo Chem. Co.*, 257 F.3d 1364, 1368 (Fed. Cir. 2001) (explaining that when a claim "is written in *Jepson* format, ... the claim first describes the scope of the prior art and then claims an improvement over the prior art.").

Claim 2 recites, in non-*Jepson* format, a method of treatment that involves concurrent administration of safinamide and a "stable dose of levodopa." That the method of treatment involves "administering a therapeutically effective stable dose" implies that that once the "stable dose" is "therapeutically effective," that dose stays the same.

Turning to the specification, while the term "stable dose of levodopa" is not used, the specification describes a clinical trial that studied the effect of safinamide on PD symptoms in a "de novo" group and "single DA group", the latter of which "were treated with one single dopamine agonist at stable doses for at least four weeks prior to the screening visit." '380 patent at 20:25-36; 50-60. The specification describes that the single DA group fared better than the de novo group "when safinamide was added to a stabilized dose of a variety of dopamine agonists" (as adjunctive therapy) as compared to when safinamide was administered alone (as monotherapy). *Id.* at 3:5-9; *see also id.* at 23:51-55 (describing favorable results for "patients under stable dopamine agonist treatment"). Thus, these descriptions suggest that "stable doses" and "stabilized dose[s]" are unchanged doses.

The prosecution history further supports understanding "stable dose of levodopa" as a dose that is unchanged. In the Notice of Allowance, the Examiner's explained: "By 'stable dose,' Applicant provides support for this term whereby the dose of L-DOPA is neither increased nor decreased to treat a patient with Parkinson's Disease . . . thereby rendering it distinguishable from the art." D.I. 120-24, Ex. W at JA717. The prosecution history is also consistent with the four-week time period identified in the specification as the applicant submitted materials describing a clinical study in which patients went through a four-week "levodopa stabilization phase". *See, e.g.*, D.I. 120-18, Ex. Q at JA427; D.I. 134-13, Ex. JJ at JA760; D.I. 120-22, Ex. U at JA507 ("In addition, to guard against changes in drugs confounding the results of the clinical trial, patients

must be on stable doses of these medications for at least 4 weeks prior to entry into the study, and the drug and the dosage must be maintained at a constant level throughout the course of the study, if possible.").

Accordingly, in light of the intrinsic record which suggests that a "stable dose" is one that is unchanged, the Court will construe "stable dose of levodopa" to mean "a dose of levodopa that is neither increased nor decreased."

Defendants do not provide an alternate construction. Instead, they contend that the term "stable dose of levodopa" is indefinite, arguing that "[t]he intrinsic evidence fails to provide reasonable certainty as to the required period of time (i.e., days, weeks, months, etc.) and a frequency of administration during that period of time (q.d., b.i.d., t.i.d., etc.) for a 'dose of levodopa' to become 'stable.'" D.I. 133 at 10. According to Defendants, without any measurement scale to determine what constitutes a "stable dose", "stable dose of levodopa" fails to provide objective boundaries to a person having ordinary skill in the art. *Id.* at 38.

Descriptive words and terms of degree do not render a claim indefinite if there is adequate objective guidance regarding the boundaries of the claim. *See Niazi Licensing Corp. v. St. Jude Med.*, 30 F.4th 1339, 1347 (Fed. Cir. 2022); *see also Guangdong Alison Hi-Tech v. ITC*, 936 F.3d 1353, 1359 (Fed. Cir. 2019) ("[A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.") (internal quotation marks omitted). In some circumstances, a person of ordinary skill can ascertain an invention's boundaries from exemplary designs or specific examples offering an "objective anchor" for comparison. *Niazi*, 30 F.4th at 1348 (internal quotation marks omitted).

Here, the intrinsic record provides adequate reference points such that the Court cannot conclude "stable dose of levodopa" is indefinite. The specification and prosecution history disclose

a data point of four weeks as constituting being on a "stable dose." '380 patent at 20:25-36; 20:50-60; 23:51-55; *see also* D.I. 120-18, Ex. Q at JA427; D.I. 134-13, Ex. JJ at JA760; D.I. 120-22, Ex. U at JA507. While Defendants argue that the specification provides conflicting temporal guidance because it discloses that in the prior art, patients were administered levodopa for 5-7 years, '380 patent at 1:28-33, the specification does not state that the levodopa dosage remained stable for that 5-7 year time-period. Rather, the specification explains that patients treated with levodopa began to exhibit motor fluctuations after that time period. '380 patent at 1:28-33. Accordingly, the specification's four-week period provides an objective anchor from which a skilled artisan can determine the scope of the claim.

Defendants further contend that the specification's disclosures are inapposite because they relate to a stable dose of a dopamine agonist, which "would be unhelpful to [a person of ordinary skill in the art] deciphering the meaning of a 'stable dose of levodopa.'" D.I. 133 at 10-22. But Defendants do not support their assertion with any evidence as to what a person of ordinary skill in the art would understand about the claims' scope—even after the Court invited Defendants to do so.[2] Thus, "Defendants' attorney argument falls far short of meeting their burden to prove, by clear and convincing evidence," that the '380 patent fails to reasonably inform a person of ordinary skill in the art about the scope of the invention. *Dasso Int'l, Inc. v. MOSO N. Am., Inc.*, No. 17-01574-RGA, 2019 WL 2135855, at *2 (D. Del. May 16, 2019); *see also MiiCs & Partners Am., Inc. v. Toshiba Corp.*, No. 14-803-RGA, 2016 WL 4573103, at *10 & n.23 (D. Del. Aug. 31, 2016). The Court declines to find "stable dose of levodopa" to be indefinite.

[2] *See* October 7, 2022 Oral Order.

B. "maintaining"

Claim Term	Plaintiffs' Construction	Defendants' Construction	The Court's Construction
"maintaining" ('380 patent, claim 1)	Plain and ordinary meaning, which is "keeping"	Not amenable to construction; indefinite	Plain and ordinary meaning, which is "keeping"

While Plaintiffs argue that "maintaining" can be understood according to its plain and ordinary meaning, which is "keeping", Defendants contend the term is indefinite. D.I. 133 at 23-29.

The intrinsic record supports construing "maintaining" as "keeping". Starting with the claims, claim 1 (as discussed *supra*) describes the prior art method of treating a PD patient who is "receiving a stable dose of levodopa", the concurrent administration of safinamide to that patient, and explains that safinamide should be given "while maintaining the patient" on the stable dose of levodopa. '380 patent at cl. 1. "[M]aintaining" appears to refer back to the prior art method, requiring the patient to be "maintained" or kept on that same stable dose of levodopa. Indeed, dependent claim 5[3] reflects this concept, requiring that the patient receiving a stable dose of levodopa in claim 1 be administered safinamide for at least 12 weeks. '380 patent at cl. 5. A skilled artisan would understand that the patient treated according to claim 5's method was being "maintain[ed]" on the stable levodopa dose for those 12 weeks as well.

Turning to the specification, it uses "maintaining" in other contexts to mean "keeping." For example, the specification describes that "[o]ther symptoms of PD include poor balance, due to

[3] Claim 5 recites: "The method of claim 1 or claim 2, wherein safinamide, or pharmaceutically acceptable salt thereof, is administered for at least 12 weeks."

the impairment or loss of the reflexes that adjust posture in order to maintain balance." '380 patent at 10:47-49. It discusses adding buffers to a formulation in "amounts sufficient to maintain the pH" within a specified range, and explains ways a composition's fluidity "can be maintained." *Id.* at 17: 35-40.

During prosecution, the applicant distinguished the prior art by arguing that it did not teach that the levodopa dose given to patients could "be maintained without reduction when further agents are added to the treatment regimen." D.I. 120-21, Ex. T at JA482. Additionally, the applicant added the clause "while maintaining the patient on a stable dose of levodopa" to replace "without reducing the patient's dose of concurrently administered levodopa" in response to an examiner interview so as to "align more precisely with written description support in the specification." D.I. 120-23, Ex. V at JA710-711.

Thus, the intrinsic record suggests that "maintaining" can be understood according to its plain and ordinary meaning, which is "keeping". The Court will adopt that construction.

Defendants do not contest this construction,[4] but argue that "maintaining" suffers not only from the same indefiniteness as "stable dose of levodopa", but it also introduces "additional indefiniteness: for how long after safinamide is added to the patient's treatment regimen must the 'stable dose' be maintained, and what is the significance of a change in the patient's levodopa dose after that time?" D.I. 133 at 25. But for the reasons identified above, including that Defendants' do not support their indefiniteness arguments with any evidence as to what a person of ordinary skill in the art would understand about the claims' scope, Defendants have not met their burden and the Court does not find "maintaining" to be indefinite.

[4] D.I. 133 at 25.

C. "a therapeutically effective stable dose of levodopa"

Claim Term	Plaintiffs' Construction	Defendants' Construction	The Court's Construction
"a therapeutically effective stable dose of levodopa" ('380 patent, claim 2)	"a dose of levodopa sufficient to treat idiopathic Parkinson's disease that is neither increased nor decreased"	Not amenable to construction; indefinite	"a dose of levodopa sufficient to treat idiopathic Parkinson's disease that is neither increased nor decreased"

Plaintiffs propose construing "a therapeutically effective stable dose of levodopa" as "a dose of levodopa sufficient to treat idiopathic Parkinson's disease that is neither increased nor decreased", while Defendants contend that this term is indefinite. D.I. 133 at 30-33.

Plaintiffs' construction is supported by the intrinsic record. Starting with the claims, claim 2 of the '380 patent recites (as described above) a method of treating idiopathic PD and explains that to accomplish such treatment, a "therapeutically effective stable dose of levodopa" is administered concurrently with safinamide. '380 patent at cl. 2. The specification describes treatment kits that "include a therapeutically effective dose of an agent for treating or at least partially alleviating the symptoms of Parkinson's Disease (e.g., levodopa plus carbidopa (SINEMET®), levodopa plus controlled release carbidopa (SINEMET®-CR), levodopa plus benserazide (MADOPAR®), levodopa plus controlled release benserazide (MADOPAR®-HBS), [and other Parkinson's agents] and safinamide (or a safinamide derivative). . . ." '380 patent at 5:54-60. And the prosecution history explains that a "therapeutically effective" dose refers to a "clinically-relevant" dose—that is, a dose that is effective to treat PD. D.I. 120-13, Ex. L at JA357; *see also* D.I. 120-18, Ex. Q at JA405 ("safinamide can be added to a stable and therapeutically effective L-dopa regimen, providing additional symptomatic benefit").

Thus, the claims read in light of the specification and prosecution history suggest that the stable levodopa dose be of an unchanging amount sufficient to achieve the desired goal of treating PD. Accordingly, the Court will construe "a therapeutically effective stable dose of levodopa" to mean "a dose of levodopa sufficient to treat idiopathic Parkinson's disease that is neither increased nor decreased."

Defendants argue indefiniteness by incorporating their previous arguments as to "stable dose of levodopa" and "maintaining." D.I. 133 at 32-33. For the reasons identified above, including that Defendants' do not support their assertions with any evidence as to what a person of ordinary skill in the art would understand about the claims' scope, Defendants have not met their burden and the Court does not find "a therapeutically effective stable dose of levodopa" to be indefinite.

D. "high purity . . ."

Claim Term	Plaintiffs' Construction	Defendants' Construction	The Court's Construction
"high purity safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof"/ "high purity safinamide or ralfinamide salt with a pharmaceutically acceptable acid"/ "high purity safinamide or a pharmaceutically acceptable acid salt thereof" ('515 patent, claims 32-35, 40-44; '485 patent, claim 37)	"safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof that has lower than 0.03% (by weight) of impurity IIa7 or impurity IIb8 or their pharmaceutically acceptable acid salts"	Not amenable to construction; indefinite	"safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof that has lower than 0.03% (by weight) of impurity IIa7 or impurity IIb8 or their pharmaceutically acceptable acid salts" and not indefinite

The parties principally dispute the meaning of the phrase "high purity" in disputed terms of the '515 and '485 patents. While Plaintiffs argue that "high purity" refers to safinamide and ralfinamide preparations with lower than 0.03% by weight of impurities, D.I. 133 at 34, Defendants contend that "high purity" refers to the "overall chemical purity of a safinamide preparation," resulting in a term that is ambiguous and thus, indefinite. *Id.* at 42.

Starting with the claims, claim 32 of the '515 patent recites:

> 32. High purity safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof with a content of the respective impurity (S)-2-[3-(3-fluorobenzyl)-4-(3-fluorobenzyloxy)-benzylamino]propanamide (IIa) or (S)-2-[3-(2-fluorobenzyl)-4-(2-fluorobenzyloxy)-benzylamino]propanamide (IIb) [graphic omitted] or their pharmaceutically acceptable acid salts, which is lower than 0.03% (by weight).

'515 patent at cl. 32. Defendants argue that "Plaintiffs' construction would render half of the claim language that starts with 'with a content' completely superfluous" because "high purity" modifies "safinamide" whereas "lower than 0.03%" refers "to a required level of an impurity," meaning that "'[h]igh purity' does not modify "a content of impurity IIa," D.I. 133 at 39. But that claim language can be read to reflect the inventors' discovery disclosing a new process for keeping specific toxic impurities below 0.03% by weight in large scale preparations of safinamide and ralfinamide. *See, e.g.*, '515 patent at 1:60-2:27; 7:1-3, 7:11-22, 7:57-8:7.

The specification supports this reading. It consistently uses the phrases "high purity", "highly pure," and "high purity degree" to specify safinamide or ralfinamide preparations that have less than 0.03% by weight of impurities IIa and IIb and their salts; not to refer to an overall chemical purity level:

> Moreover, another object of this invention is to provide pharmaceutical formulations comprising safinamide or ralfinamide or a salt thereof with a pharmaceutically acceptable acid, preferably methanesulfonic acid, as the active agents wherein the content of the respective dibenzyl derivatives (IIa) and (IIb) or the salt thereof with

> a pharmaceutically acceptable acid, e.g. methanesulfonic acid, is lower than 0.03%, preferably lower than 0.01% (by weight) with respect to the above said active agents. These new pharmaceutical formulations were neither suggested nor achievable by applying the pharmaco-toxicological knowledge regarding safinamide and ralfinamide nor by using these active agents prepared according to the methods available in the state of the art.
>
> Therefore, said pharmaceutical formulations comprising safinamide or ralfinamide or the salts thereof with a pharmaceutically acceptable acid, preferably methanesulfonic acid, having the above said high purity degree constitute a further object of this invention.

Id. at 7:57-8:8; *see also id.* at 7:50-56 ("high purity degree" safinamide or ralfinamide has a content of impurities IIa or IIb or the salts thereof "lower than 0.03%, preferably lower than 0.01% by weight"), *id.* at 8:50-60 ("high purity safinamide" has a content of impurity IIa or a salt thereof "lower than 0.03%, preferably lower than 0.01% by weight"), *id.* at 9:1-12 ("high purity ralfinamide" has a content impurities IIb or a salt there of "lower than 0.03%, preferably lower than 0.01% by weight"); *see also id.* at Abstract ("A process for obtaining therapeutically active 2-[4-(3- and 2-(fluorobenzyloxy)benzylamino]propanamides and their salts with pharmaceutically acceptable acids with high purity degree, in particular, with a content of dibenzyl derivatives impurities lower than 0.03%, preferably lower than 0.01% by weight."). The specification also includes multiple examples relating to the chemical synthesis of safinamide or ralfinamide of a "High Purity Degree." In those examples, the purity information related is the content of impurity IIa or IIb by weight. *See id.* at Examples 2, 3, 6, 7, 8, 9. In view of these citations, Defendants' assertion that "[n]othing in the specification could possibly lead a POSA to believe that 'high purity' refers only to a low level of a specific impurity, such as IIa or IIb" is not persuasive. D.I. 133 at 40.

Defendants, after pointing out that there is "no definition of 'high purity'" in the specification, turn to expert testimony to elucidate that term's meaning. *Id.* But that effort divorces claim construction from the intrinsic record, and cannot be squared in view of the Federal Circuit's guidance that "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 (quotation marks omitted)). Indeed, Defendants' view that "high purity" refers to a "'high' (but undefined) level of an overall chemical purity of a safinamide preparation," rather than to any particular impurity, obtains considerably less support in the specification. D.I. 133 at 40.

Defendants also argue that, when applying Plaintiffs' construction to certain unasserted claims of the '515 patent, claim 29 takes on the same scope as claim 12. D.I. 133 at 47-48. Claim 29 recites:

> The process as in claim 12 wherein safinamide or ralfinamide or their pharmaceutically acceptable acid salts, have a content of the respective impurity (S)-2-3-(3-fluo robenzyl)-4-(3-fluorobenzyloxy)-benzylaminopropana mide (IIa) or (S)-2-3-(2-fluorobenzyl)-4-(2-fluorobenzy loxy)-benzylaminopropanarnide (IIb) [graphic omitted] or their pharmaceutically acceptable acid salts, which is lower than 0.03% (by weight).

Claim 12 recites:

> The process as in claim 8 wherein the 4-(3-fluoroben Zyloxy)benzaldehyde or 4-(2-fluorobenzyloxy)benzalde hyde of formula (IVa) or (IVb) employed as the starting material to obtain the Schiff base intermediate of formula (VIa) or (VIb) contains less than 0.03% (by weight), of the respective impurities 3-(3-fluorobenzyl)-4-(3-fluorobenzy loxy)benzaldehyde (Va) or 3-(2-fluorobenzyl)-4-(2-fluo robenzyloxy)benzaldehyde (Vb) [graphic omitted]

According to Defendants, the "'only additional limitation in claim 29 is that the impurities IIa and IIb are limited to less than 0.03% by weight. If 'high purity' were defined as the limitation of these two specific impurities, this additional element in dependent claim 29 would not provide any further limitation." D.I. 133 at 48. But "claim differentiation is a guide, not a rigid rule, and does not alter a construction otherwise compelled by the intrinsic record." *Ultravision Techs., LLC v. Govision, LLC*, No. 2022-1098, 2023 WL 2182285, at *4 (Fed. Cir. Feb. 23, 2023) (internal quotation marks and citations omitted). Here, the intrinsic record indicates that the scope the patentee ascribed to "high purity" is safinamide or ralfinamide preparations that have less than 0.03% by weight of impurities IIa and IIb and their salts. That the patentee also decided to claim with greater particularity that safinamide or ralfinamide impurities are less than 0.03% by weight in claim 29 "does not overcome that conclusion in these circumstances." *Ultravision*, 2023 WL 2182285, at *4.

Accordingly, the Court will construe the "high purity" terms to mean "safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof that has lower than 0.03% (by weight) of impurity IIa7 or impurity IIb8 or their pharmaceutically acceptable acid salts."

Defendants argue that, under Defendants' proposed construction, the "high purity" terms are indefinite. D.I. 133 at 37-38. Defendants do not argue indefiniteness under Plaintiffs' construction. As the Court has declined to adopt Defendants' proposed construction, the Court concludes the "high purity" terms are not indefinite.

IV. CONCLUSION

The Court will adopt the parties' agreed-upon constructions and construe the disputed claim terms as described above. The Court will issue an Order consistent with this Memorandum Opinion.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEWRON PHARMACEUTICALS S.p.A., ZAMBON S.p.A., MDD US OPERATIONS, LLC, Plaintiffs, v. AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA INC., MSN LABORATORIES PRIVATE LIMITED, OPTIMUS PHARMA PVT LTD, PRINSTON PHARMACEUTICAL, INC., RK PHARMA INC., ZENARA PHARMA PRIVATE LIMITED, Defendants.	C.A. No. 21-843-GBW

ORDER

At Wilmington this 14th day of April, 2023:

For the reasons set forth in the Memorandum Opinion issued this day, IT IS HEREBY ORDERED that the Court construes the following claim terms of U.S. Patent No. 8,076,515 ("the '515 patent"), U.S. Patent No. 8,278,485 ("the '485 patent"), and U.S. Patent No. 8,283,380 ("the '380 patent") as follows:

Claim Term	**Court's Construction**
Agreed-Upon Constructions	
"an effective amount" ('515 patent, claim 40)	"an amount sufficient to treat the selected CNS disorder"
"classified as" ('515 patent, claim 44)	Plain and ordinary meaning, with leave to renew indefiniteness

Claim Term	Court's Construction
"are known to interact with" ('515 patent, claim 44)	Plain and ordinary meaning, with leave to renew indefiniteness
"are known to have HERG channel blocking properties" ('515 patent, claim 44)	Plain and ordinary meaning, with leave to renew indefiniteness
Disputed Constructions	
"stable dose of levodopa" ('380 patent, claims 1-2)	"a dose of levodopa that is neither increased nor decreased"
"maintaining" ('380 patent, claim 1)	Plain and ordinary meaning, which is "keeping"
"a therapeutically effective stable dose of levodopa" ('380 patent, claim 2)	"a dose of levodopa sufficient to treat idiopathic Parkinson's disease that is neither increased nor decreased"
"high purity safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof"/"high purity safinamide or ralfinamide salt with a pharmaceutically acceptable acid"/"high purity safinamide or a pharmaceutically acceptable acid salt thereof" ('515 patent, claims 32-35, 40-44; '485 patent, claim 37)	"safinamide or ralfinamide or a pharmaceutically acceptable acid salt thereof that has lower than 0.03% (by weight) of impurity IIa7 or impurity IIb8 or their pharmaceutically acceptable acid salts" and not indefinite

GREGORY B. WILLIAMS
UNITED STATES DISTRICT JUDGE