IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, MERZ PHARMACEUTICALS GMBH, and ADAMAS PHARMACEUTICALS, INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 14-121-LPS
TEVA PHARMACEUTICALS USA, INC., WOCKHARDT USA LLC, WOCKHARDT BIO AG, WOCKHARDT LTD., SUN PHARMA GLOBAL FZE, and SUN PHARMACEUTICAL INDUSTRIES, LTD.,	:	
Defendants.	:	

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 14-200-LPS
APOTEX CORP., APOTEX INC., ZYDUS PHARMACEUTICALS (USA), INC., CADILA HEALTHCARE LTD. (d/b/a/ ZYDUS CADILA), PAR PHARMACEUTICAL, INC., ANCHEN PHARMACEUTICALS, INC., and ACTAVIS LABORATORIES FL, INC.,	:	
Defendants.	:	

FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., MERZ PHARMA GMBH & CO. KGAA, MERZ PHARMACEUTICALS GMBH, and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMERIGEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS LTD., and MYLAN PHARMACEUTICALS INC., Defendants.	:	C.A. No. 14-508-LPS
FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. RANBAXY INC., RANBAXY LABORATORIES LIMITED, and TEVA PHARMACEUTICALS USA, INC., Defendants.	:	C.A. No. 14-686-LPS

FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., PAR PHARMACEUTICAL, INC., ANCHEN PHARMACEUTICALS, INC., AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN PHARMACEUTICALS LTD., Defendants.	:	C.A. No. 14-1058-LPS
FOREST LABORATORIES, LLC, FOREST LABORATORIES HOLDINGS, LTD., and ADAMAS PHARMACEUTICALS, INC., Plaintiffs, v. AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN PHARMACEUTICALS LTD., Defendants.	:	C.A. No. 14-1271-LPS

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MEMORANDUM OPINION

January 5, 2016
Wilmington, Delaware

STARK, U.S. District Judge:

Pending in this patent infringement action brought pursuant to the Hatch-Waxman Act are claim construction disputes between Plaintiffs – Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, Merz Pharmaceuticals GmbH, and Adamas Pharmaceuticals, Inc. – and the remaining Defendants – Teva Pharmaceuticals USA, Inc., Apotex Corp., and Apotex Inc.[1] There are eight patents-in-suit: U.S. Patent Nos. 8,168,209 ("'209 patent"), 8,173,708 ("'708 patent"), 8,283,379 ("'379 patent"), 8,329,752 ("'752 patent"), 8,362,085 ("'085 patent"), and 8,598,233 ("'233 patent") (collectively, the "Went patents"); as well as U.S. Patent Nos. 8,039,009 ("'009 patent") and 5,061,703 ("'703 patent") (collectively, the "patents-in-suit").

The patents-in-suit are all listed in the United States Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering Namenda XR®. (D.I. 1 at ¶ 29)[2] Namenda XR® is approved by the FDA for treatment of moderate to severe dementia of the Alzheimer's type. (*See* D.I. 93-1 Tab A at 1)

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[1]Other prior Defendants have been dismissed. (*See* C.A. No. 14-121 D.I. 56 at 3 (dismissing without prejudice claims and counterclaims relating to Wockhardt USA, LLC, Wockhardt Bio AG, and Wockhardt Ltd.); C.A. No. 14-121 D.I. 103 at 3 (same for Sun Pharma Global FZE and Sun Pharmaceuticals Industries, Ltd.); C.A. No. 14-200 D.I. 62 at 1, *id.* D.I. 83 at 3, *id.* D.I. 84 at 3, *id.* D.I. 169 at 3, C.A. 14-1058 D.I. 54 at 3, *id.* D.I. 55 at 3 (same for Anchen Pharmaceuticals, Inc., Actavis Pharmaceuticals FL, Inc., Par Pharmaceutical, Inc., Zydus Pharmaceuticals (USA), Inc., and Cadila Healthcare Ltd.); C.A. No. 14-508 D.I. 208 at 3, *id.* D.I. 221 at 4, *id.* D.I. 223 at 2, C.A. No. 14-1058 D.I. 166 at 4, C.A. No. 14-1271 D.I. 128 at 4 (same for Mylan Pharmaceuticals Inc., Amerigen Pharmaceuticals, Inc., Amerigen Pharmaceuticals Ltd., Amneal Pharmaceuticals LLC, and Amneal Pharmaceuticals of New York, LLC); C.A. No. 14-686 D.I. 87 at 3 (same for Ranbaxy Inc. and Sun Pharmaceutical Industries, Ltd. (formerly Ranbaxy Laboratories Limited)); C.A. No. 14-1058 D.I. 169 at 1 (same for Lupin Limited and Lupin Pharmaceuticals, Inc.))

[2]All docket citations hereinafter are to C.A. No. 14-121, unless otherwise specified.

Defendants have submitted Abbreviated New Drug Applications seeking approval to commercially manufacture and sell generic versions of Namenda XR® prior to expiration of the patents-in-suit. (D.I. 92 at 4)

The parties present claim construction disputes for each of the patents-in-suit other than the '703 patent. (*See* D.I. 92 at 3; D.I. 116 at Ex. A) Pursuant to the operative Scheduling Order (D.I. 61), as amended (*see* D.I. 95, 96, 110, 177), the parties submitted technology tutorials on May 14, 2015 (*see* D.I. 104, 106) and completed claim construction briefing on July 15, 2015 (D.I. 88, 92, 99, 100, 124, 125). The Court held a claim construction hearing on August 3, 2015. (*See* D.I. 158) ("Tr.")[3]

LEGAL STANDARDS

The ultimate question of the proper construction of a patent claim is a question of law. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "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) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[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

[3]Neither side sought to present live testimony at the claim construction hearing. (*See* D.I. 130)

question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. The patent 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." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

"[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. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, 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) (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004)) (internal quotation marks omitted).

In addition to the specification, a 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 (1996). The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d

at 1317. "[T]he 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, making the claim scope narrower than it would otherwise be." *Id.*

In some cases, "the district 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. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, "[t]he construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct

interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

CLAIM CONSTRUCTION RECORD

Plaintiffs have moved to strike (D.I. 135) the Reply Declaration of Richard F. Bergstrom ("Bergstrom's Reply Declaration") (D.I. 126) and the related portions of Defendants' reply claim construction brief (D.I. 124). Plaintiffs contend that Bergstrom's Reply Declaration and Defendants' reply brief "introduce new opinions and arguments not presented in Defendants' original submissions." (D.I. 135 at 1) Plaintiffs further argue that Bergstrom's Reply Declaration undermines the "objective" of a stipulation between the parties (adopted by the Court, *see* D.I. 96) to take expert depositions and file reply claim construction briefs that would address "expert witness issues only." (*See* D.I. 96 at 4; D.I. 135 at 1) Defendants counter that Plaintiffs presented new arguments in their Responsive Claim Construction Brief (D.I. 100) that Defendants "had no opportunity to respond to" until filing Defendants' reply brief (along with Bergstrom's Reply Declaration). (*See* D.I. 138 at 1) As an alternative to striking the challenged materials, Plaintiffs ask for "leave to file a short response to provide the Court with a complete record to decide the pending claim construction and alleged indefiniteness issues." (D.I. 135 at 5) ("Plaintiffs' Response") Defendants, "[i]n a further effort to ensure that the record before the Court is complete," do not oppose "the submission of the sur-reply brief that Plaintiffs submitted with their motion to strike." (D.I. 138 at 3)

It appears that both sides delayed in providing their full arguments to one another during the process leading to the claim construction hearing. Under the circumstances, the Court will deny Plaintiffs' motion to strike. Further, the Court will grant Plaintiffs leave to file Plaintiffs'

Response (which is hereby deemed filed).

The record for claim construction includes the original and reply declarations of Dr. Richard Bergstrom (D.I. 89, 90, 126), the declaration of Dr. James Polli (D.I. 102), and the declaration of Richard Moreton (D.I. 91). The Court overrules the parties' objections to deposition testimony and all motions to "strike" deposition testimony are denied. (*See, e.g.*, D.I. 138 at 5-6) (quoting Plaintiffs' counsel moving to "strike" deposition testimony of Dr. Bergstrom) Hence, the record includes all of the deposition testimony referred to or relied on in the parties' claim construction briefs. The claim construction tutorials (*see* D.I. 104, 106) are also part of the record.

While the Court has received and reviewed the foregoing extrinsic evidence, the Court did not rely on this extrinsic evidence in resolving the parties' claim construction disputes, except in connection with the disputes in which the Court expressly refers to extrinsic evidence in the discussion below.

PERSON OF ORDINARY SKILL IN THE ART

The parties do not agree on the identity of the person of ordinary skill in the art ("POSA"), from whose perspective the claims must be construed. Plaintiffs describe the POSA as someone who

> would have been capable of preparing routine pharmaceutical formulations and would have had either: (1) a Master's degree in biochemistry, chemistry, pharmaceutical sciences, pharmacy, or a related field, and two or more years of practical experience in those areas; or (2) a Bachelor's degree in biochemistry, chemistry, pharmaceutical sciences, pharmacy, or a related field, and three or more years of practical experience in those areas.

(D.I. 92 at 8) Plaintiffs continue: "In addition, a person of ordinary skill in the art . . . would

have had a basic understanding of, and practical experience preparing and/or designing, immediate release and modified release solid oral dosage formulations." (*Id.*)

Defendants state:

> The parties are in general agreement regarding the level of education and experience of a POSA relevant to the patents-in-suit. However, to clarify, Defendants believe that a pharmaceutical scientist with the appropriate level of education and experience working with pharmaceutical formulators and formulations would qualify as a POSA. To the extent Plaintiffs contend that a POSA must have direct experience in personally making pharmaceutical formulations, Defendants do not agree that this is necessary.

(D.I. 99 at 3)

Based on the record currently before the Court, the Court agrees with Plaintiffs' recitation of the level of ordinary skill in the art pertinent to the patents-in-suit. The Court will apply Plaintiffs' formulation in construing the disputed claim terms.

STIPULATED CONSTRUCTIONS

The parties have agreed to construe "entry . . . into a use environment," as this term is used in claims 1, 21, and 22 of the '009 patent, to mean "contact of a formulation with the gastric fluids of the patient to whom it is administered or with a fluid intended to simulate gastric fluid."

The parties have also agreed to construe "immediate release form of memantine," as this term is used in claim 1 of the '209 patent, claims 1, 6, 10, and 15 of the '708 patent, claim 1 of the '379 patent, claims 1 and 9 of the '752 patent, claims 1 and 7 of the '085 patent, and claim 1 of the '233 patent, to mean "the present commercially available 5 mg and 10 mg tablets (i.e., Namenda from Forest Laboratories, Inc. or formulations having substantially the same release profiles as Namenda)."

The Court will adopt the parties' agreed-upon constructions of these terms.

CONSTRUCTION OF DISPUTED TERMS

A. The '009 Patent

Claim 1 of the '009 patent contains two disputed terms and is representative of claims 21 and 22, which contain the same two disputed terms. Claim 1 recites the following, with emphasis added to disputed terms:

> A method for treating Alzheimer's disease comprising once daily administration of ***a modified release solid oral dosage form*** comprising 28 mg ±5% of memantine or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable polymeric carrier ***substantially contributing to the modification of the release*** of the memantine or pharmaceutically acceptable salt thereof, said dosage form sustaining release of the memantine or pharmaceutically acceptable salt thereof from about 4 hours to about 24 hours following entry of said form into a use environment, wherein said dosage form has a single phase dissolution rate of less than about 80% after passage of about 6 hours following said entry into said use environment.

1. "a modified release solid oral dosage form"[4]

Plaintiffs "a solid oral dosage form that sustains the release of the active ingredient over an extended period of time as compared to an immediate release dosage form"
Defendants "a single solid oral dosage form that sustains the release of the active ingredient over an extended period of time as compared to an immediate release dosage form"
Court "a solid oral dosage form that sustains the release of the active ingredient over an extended period of time as compared to an immediate release dosage form"

The parties dispute whether this term requires use of a single dosage unit (i.e., a single

[4]This disputed term appears in claims 1, 21, and 22 of the '009 patent.

tablet) or whether multiple dosage units could be used. (*See* D.I. 88 at 26-28; D.I. 100 at 24-28) The plain and ordinary meaning of the claim language does not require use of a single dosage unit. Multiple dosage units could comprise a single dosage form. Therefore, the Court disagrees with Defendants that adopting Plaintiffs' construction would "vitiate the 'once daily' limitation" in all of the claims containing this term. (*See* D.I. 88 at 26)

The Court declines to import from the specification into the claim term any of Defendants' proposed limitations. (*See* D.I. 88 at 27) "Even when the specification describes only a single embodiment, 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." *Liebel-Flarsheim*, 358 F.3d at 906. There is no clear intention in the specification to limit the claim scope in the manner Defendants suggest. Moreover, Defendants make no effort in their briefing to connect the language from their cited portions of the specification to their "single solid dosage form" requirement.

Further support for Plaintiffs' proposed construction is found in the file history of the '009 patent. Although Defendants cite portions of Responses to Office Actions that purport to distinguish the '009 patent from prior art that used multiple dosage units (*see* D.I. 88 at 27-28), these portions of the file history do not evidence a clear disavowal of claim scope that would require usage of a single dosage unit. On the contrary, as Plaintiffs argue, the cited file history shows that the applicants distinguished prior art based on the ***total amount*** of memantine or the administration of memantine at ***multiple times during the day***. (*See* D.I. 100 at 26-28)

2. "substantially contributing to the modification of the release"[5]

Plaintiffs Plain meaning; no construction necessary
Defendants Indefinite
Court "contributing a substantial amount to modifying the release of memantine, as opposed to having little or no impact on the modification of the release"

The parties' dispute regarding this term focuses on the word "substantially"; the parties dispute how much the "pharmaceutically acceptable polymeric carrier" must "contribut[e]" to the modification of the release of memantine. (*See* D.I. 88 at 29-30; D.I. 92 at 25-27) Plaintiffs view this term as so clear that it does not require any construction whatsoever, while Defendants see the term as wholly failing to "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014).

Plaintiffs cite portions of the specification and claims of the '009 patent that generally describe the release characteristics of memantine, but they do not cite any intrinsic evidence that connects the "polymeric carrier" to these general release characteristics. (*See* Tr. at 120 ("We know from the rest of the claim that the dosage form that we're talking about is going to sustain release from about 4 hours to about 24 hours. So this polymer has got to do some work."); Tr. at 121 ("The specification . . . tells us the modified release solid oral dosage forms permit the sustained release of the active ingredient over an extended period of time.")) Plaintiffs do not cite any intrinsic evidence that shows or explains ***how much*** any particular polymeric carrier

[5]This disputed term appears in claims 1, 21, and 22 of the '009 patent.

contributes to the modification of the release of memantine. In these circumstances, it is appropriate to consider the parties' experts' opinions in determining how a person of ordinary skill in the art would understand this term.

A patent is presumed valid, and indefiniteness must be proven by clear and convincing evidence. *See* 35 U.S.C. § 282 (2006); *see also Nautilus*, 134 S. Ct. at 2130; *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 2015 WL 3772402, at *7 (Fed. Cir. June 18, 2015) (applying clear and convincing standard to indefiniteness analysis). Thus, the Court may conclude that this term is indefinite only if the record contains clear and convincing evidence that "substantially" would not inform a POSA with "reasonable certainty" as to the claim's meaning. *See Nautilus*, 134 S. Ct at 2129. Defendants have not met this burden.

Instead, a POSA would know, with reasonable certainty, that "substantially" means something like the description Plaintiffs employ in their opening brief: "contributing a substantial amount to modifying the release of memantine, as opposed to having little or no impact on the modification of the release." (D.I. 92 at 25) This characterization is supported by testimony from both sides' experts. For example, when asked at his deposition what "substantially contributing" means, Plaintiffs' expert Dr. Polli stated that "the polymer is impacting the release. In particular, it's slowing it down." (D.I. 128-1 Tab C at 319) Dr. Polli went on to explain that this "would result in the formulation to be not immediate-release," describing "immediate-release forms" as "permit[ting] the release of most or all of the active ingredient over a short period of time, such as 60 minutes or less." (*Id.* at 319-20)

Testimony by Defendants' expert, Dr. Moreton, also supports the Court's construction. Dr. Moreton testified at his deposition that a person of ordinary skill in the art would be able to

identify polymers capable of creating "release profiles" in accordance with claim 1 of the '009 patent. (*See* D.I. 128-1 Tab E at 124) Significantly, Dr. Moreton admitted that a POSA would know which excipients (i.e., non-active ingredients) would be causing release modification, based, at least in part, on function categorizations for each of the excipients that are disclosed to the FDA in new drug applications. (*See id.* at 121) Thus, inclusion of the term "substantially" in these claims would not deprive a POSA of "reasonable certainty" of the meaning of the claims.

B. The Went Patents

The parties' disputes stretch across three representative claims from the Went patents: claim 1 of the '209 patent, claim 10 of the '708 patent, and claim 1 of the '233 patent. These claims are quoted below, with emphasis added to show the disputed terms. As noted below, the parties agree that constructions of certain disputed terms in the representative claims will be applied to constructions of similar terms in non-representative claims of the Went patents. For purposes of construing the disputed terms in the Went patents, there are no substantive differences among the specifications.

Claim 1 of the '209 patent recites the following:

> A solid pharmaceutical composition in a unit dosage form for once daily oral administration comprising an extended release formulation of 5 to 40 mg memantine or pharmaceutically acceptable salt thereof, wherein administration of a dose of the composition to a human subject provides a ***plasma memantine concentration profile***, as measured in a single-dose human PK study, characterized by a ***change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition***, wherein ***the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine***.

Claim 10 of the '708 patent recites the following:

> A method of administering memantine to a human subject in need thereof comprising:
>
> administering to said subject once daily a sustained release oral dosage form comprising 5 to 40 mg of memantine or a pharmaceutically acceptable salt thereof and a component that sustains release of said memantine or salt thereof,
>
> wherein said sustained release memantine provides a ***change in plasma concentration as a function of time (dC/dT) in a defined time period of 0 to 6 hours after administration*** as measured in a single dose human PK study ***that is less than about 50% of the dC/dT provided by the same quantity of an immediate release form of memantine in said defined time period***;
>
> and wherein the subject has a condition selected from the group consisting of Alzheimer's disease, dementia, Parkinson's disease, and neuropathic pain.

Claim 1 of the '233 patent recites the following:

> A solid pharmaceutical composition in a unit dosage form for once daily oral administration ***comprising an extended release formulation of 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof***, wherein administration of a dose of the composition to a human subject provides a mean plasma memantine concentration profile characterized by a change in memantine concentration as a function of time (dC/dT) that is less than 50% of the dC/dT provided by the same quantity of an immediate release form of memantine, determined in a time period between 0 hours to 6 hours after administration of memantine, and wherein dC/dT is measured in a single-dose human PK study.

1. "plasma memantine concentration profile"[6]

Plaintiffs Plain meaning; no construction necessary; or "plasma memantine concentration profile"
Defendants "mean plasma memantine concentration profile"
Court "plasma memantine concentration profile"

The parties dispute whether this term refers to ***any*** plasma memantine concentration profile or whether it refers to a ***mean*** plasma memantine concentration profile. The plain and ordinary meaning of this term, in light of the intrinsic evidence, does not require addition of the word "mean."

Defendants argue that a declaration filed by Dr. Gregory Went, co-inventor of the Went patents, during prosecution of the '209 patent, limited this term to "mean" plasma memantine concentration profiles. (*See* D.I. 99 at 8-9) However, Defendants cite no clear disavowal or disclaimer in the file history or any clear intention in the specification to limit the language of this term to cover ***only*** mean profiles. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366-67 (Fed. Cir. 2012) ("To constitute disclaimer, there must be a clear and unmistakable disclaimer."). The Declaration is not itself a disclaimer or disavowal.

Instead, as Plaintiffs note, Figures 1A, 1B, and 2D disclose non-mean plasma concentration profiles. (*See* D.I. 92 at 11) Defendants contend that these figures "merely illustrate" profiles generated by computer simulations. (*See* D.I. 99 at 9) Regardless of how the

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[6]This disputed term appears in claim 1 of the '209 patent.

profiles were generated, however, the important point is that the specification discloses non-mean profiles (i.e., profiles corresponding to individual (simulated) test subjects). The fact that these profiles are not created from measurements conducted in "a single-dose human PK study" is material to the analysis for other terms (discussed below) but does not affect the Court's construction of this term.

As Plaintiffs note, other claims in the Went patents specifically claim "mean" plasma memantine concentration profiles. (*See* D.I. 92 at 11) Thus, when the applicants wanted to limit this term to cover only mean plasma concentration profiles, they knew how to do so. *See In re Rambus Inc.*, 694 F.3d 42, 47 (Fed. Cir. 2012) ("To the extent Rambus wanted to limit the memory device to a single chip component, it could have expressly done so. It did not, and this Court will not do so here."); *see also id.* at 48 (applying doctrine of claim differentiation between patent and related patents to support broader construction of claim term). While the doctrine of claim differentiation is not always decisive, *see Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011), here it provides further, important support for the Court's conclusion.

2. "change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition"[7]

Plaintiffs Plain meaning; no construction necessary; or "change in plasma memantine concentration of the extended [sustained] release dosage form as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the extended [sustained] release dosage form"
Defendants Indefinite Alternatively, if the Court determines this term is amenable to construction: "change in mean plasma concentration of memantine as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the extended release composition, where the plasma concentration of the extended release and the immediate release memantine are measured in the same PK study conducted in human subjects"
Court Indefinite

The Court finds by clear and convincing evidence that this term is indefinite because it fails to "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus*, 134 S. Ct. at 2129. As indicated in the claims, memantine concentration must be observed "as measured in a single-dose human PK study." A person of ordinary skill in the art would not know, with reasonable certainty, which "human PK study" on which to rely when considering whether a formulation of memantine might infringe the Went patents. The intrinsic evidence of the Went patents provides no guidance, other than non-limiting examples,

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[7]This disputed term appears in claim 1 of the '209 patent. Similar terms appear in claims 1 and 6 of the '708 patent, claim 1 of the '752 patent, and claim 1 of the '085 patent. The parties agree that their respectively proposed constructions should apply to each of these similar terms. (*See* D.I. 116 Ex. A at 2) For the reasons discussed below, all of these claims are indefinite.

regarding which concentration profile (or set of profiles) should be used when assessing potential infringement.

The specifications of the Went patents do not disclose ***any*** human PK study. Rather, they disclose memantine concentration data generated from computer simulations. (*See, e.g.*, '209 patent at Figs. 1A, 2D) In arguing that simulated profiles in the specification are implementations of this term, Plaintiffs gloss over claim language reciting "as ***measured*** in a single-dose ***human*** PK study." (*See* D.I. 100 at 13-14; *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim."); *see also Cat Tech LLC v. TubeMaster, Inc.*, 528 F.3d 871, 885 (Fed. Cir. 2008) (rejecting claim construction that rendered claim limitation meaningless).) Simulated data is not actual measurements in humans. Instead, simulations are models of what could ***hypothetically*** be measured. (*See* Bergstrom Decl. D.I. 89 at ¶ 33) ("[N]o pharmacokineticist would rely solely on performance predictions from an *in silico* [simulated] model to determine the *in vivo* PK characteristics of a drug.")

The only ***actual*** human PK study disclosed in the intrinsic evidence was included in a declaration submitted by Dr. Went during prosecution of each of the Went patents. (*See* D.I. 88 at 4-5; D.I. 100 at 16) There is no proper basis to limit the "study" in the patents' claims (from which to measure dissolution profile between immediate and extended release) to just the single study included with Dr. Went's declaration, as Plaintiffs suggest must be done. (D.I. 100 at 16) More particularly, there is no disclaimer or disavowal. *See Thorner*, 669 F.3d at 1366-67 ("To constitute disclaimer, there must be a clear and unmistakable disclaimer.").

The plain and ordinary meaning of this term and the intrinsic evidence indicate that ***any***

human PK study could be used to generate the memantine concentration data. Moreover, the intrinsic evidence says nothing about ***how*** a human PK study should be conducted. Therefore, it is necessary to consider extrinsic evidence submitted by the parties to determine how a person of ordinary skill in the art would understand this term.[8]

As discussed in Defendants' opening brief, citing Dr. Bergstrom's expert opinions, measurements from human PK studies vary widely in terms of the concentration profiles they generate. (*See* D.I. 88 at 10-16; *see also* D.I. 89 at 31-32) For example, Dr. Bergstrom cites reports of "Tmax" values for immediate-release memantine that vary between 1.6 and 9.8 hours. (D.I. 89 at 31) For any given formulation of extended-release memantine, a potential infringer would not know with reasonable certainty whether it would be infringing, since it would be unclear what Tmax value, or range of Tmax values, or even which subset of immediate-release profiles, would be proper reference points for analyzing the "50% of the dC/dT" limitation.

Plaintiffs' expert, Dr. Polli, provides no persuasive response. Although Dr. Polli states that a "person of ordinary skill in the art would rely on their training and experience to determine the appropriate design [of a human PK study] to use in a given set of circumstances," this statement and the remainder of Dr. Polli's analysis do not refute Dr. Bergstrom's points about the variable results that will be produced by different studies (even by appropriately-designed studies). (*See* D.I. 102 at 26) The claims and intrinsic evidence do not limit this term to a particular profile or human PK study or even a particular set of parameters with which one of

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[8]As noted by Plaintiffs during oral argument (*see, e.g.*, Tr. at 45), the Federal Circuit in *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374 (Fed. Cir. 2015), reiterated that "general principles of claim construction apply" when analyzing a claim for indefiniteness. The Court is applying these principles here.

ordinary skill in the art could design a study.

"[T]he definiteness requirement must take into account the inherent limitations of language. Some modicum of uncertainty, the Court has recognized, is the price of ensuring the appropriate incentives for innovation." *Nautilus*, 134 S. Ct. at 2128 (internal citations and quotation marks omitted). The Court is not subjecting Plaintiffs to a standard of ***perfect*** clarity. "The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable." *Id.* at 2129. During prosecution of the Went patents, the patentees could have specified a particular profile or collection of profiles or parameters with respect to the "human PK study" limitation. Other drafting solutions may also have been available. But the Court must judge the claims that were issued. Those claims, the clear and convincing evidence establishes, are indefinite.

3. "change in plasma concentration as a function of time (dC/dT) in a defined time period of 0 to 6 hours after administration ... that is less than about 50% of the dC/dT provided by the same quantity of an immediate release form of memantine in said defined time period"[9]

Plaintiffs
Plain meaning; no construction necessary; or "change in plasma memantine concentration of the sustained [extended] release dosage form as a function of time (dC/dT) in a defined time period of 0 to 6 hours after administration . . . that is less than about 50% of the dC/dT provided by the same quantity of an immediate release form of memantine in said defined time period"

[9]This disputed term appears in claim 10 of the '708 patent. Similar terms appear in claim 15 of the '708 patent, claim 1 of the '379 patent, claim 9 of the '752 patent, claim 7 of the '085 patent, and claim 1 of the '233 patent. The parties agree that their respectively proposed constructions should apply to each of these similar terms. (*See* D.I. 116 Ex. A at 3) For the reasons discussed below, all of these claims are indefinite.

Defendants Indefinite Alternatively, if the Court determines this term is amenable to construction: "the dC/dT for the immediate release form of memantine is the mean plasma memantine concentration of the immediate release form of memantine at 6 hours after administration divided by 6 hours and the dC/dT for the sustained release memantine is mean plasma memantine concentration of the sustained release memantine at 6 hours after administration divided by 6 hours, where dC/dT of the sustained release memantine is less than approximately 50% of the dC/dT of an immediate release form of memantine comprising the same quantity of memantine as the sustained release memantine, and where the plasma concentration of the extended release and the immediate release memantine are measured in the same PK study conducted in human subjects"
Court Indefinite

Plaintiffs suggest that the intrinsic evidence relevant to this term may differ from the intrinsic evidence relevant to the preceding term. (*See* Tr. 107) The Court disagrees. For the same reasons discussed above, the "human PK study" limitation (which is present in all of the claims containing this term) does not give a POSA the required "reasonable certainty." Thus, the Court finds by clear and convincing evidence that this term is indefinite.

4. "the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine"[10]

Plaintiffs Plain meaning; no construction necessary; or "the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine"

[10]This disputed term appears in claim 1 of the '209 patent. Similar terms appear in claims 1 and 6 of the '708 patent, claim 1 of the '752 patent, and claim 1 of the '085 patent. The parties agree that their respectively proposed constructions should apply to each of these similar terms. (*See* D.I. 116 Ex. A at 3)

Defendants "the dC/dT for the immediate release formulation is the mean maximum plasma memantine concentration (Cmax) of the immediate release formulation divided by the Tmax of immediate release formulation and the dC/dT for the extended release formulation is mean plasma memantine concentration of the extended release formulation at time of Tmax of the immediate release formulation divided by the Tmax of the immediate release formulation"
Court "the dC/dT is measured between the time period of 0 to Tmax of the immediate release form of memantine"

Defendants state that "[t]he only real dispute between the parties' competing constructions is that Defendants' construction requires the use of ***mean*** plasma concentration values." (D.I. 99 at 12) Defendants add that "mean plasma concentration values should be used in the dC/dT calculation for the reasons explained above in connection with the term 'plasma memantine concentration profile.'" (D.I. 88 at 20) Because the Court declined to include the word "mean" in the Court's construction of "plasma memantine concentration profile," the Court will decline to include it for the construction of this term. Instead, the Court adopts Plaintiffs' proposed construction. (*See also* Tr. at 96-98) (Plaintiffs' counsel arguing, "we're looking at dC/dT over time so we need a profile to compare to over that time" instead of merely a "mean" value)

5. "comprising an extended release formulation of 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof"[11]

Plaintiffs Plain meaning; no construction necessary; or "comprising 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof, in an extended release formulation"

[11]This disputed term appears in claim 1 of the '233 patent.

Defendants "comprising 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof, in the extended release formulation component of the dosage form and not including any memantine in an immediate release formulation component that may be present in the same dosage form"
Court "comprising 22.5 mg to 33.75 mg memantine, or a pharmaceutically acceptable salt thereof, in an extended release formulation"

The Court agrees with Plaintiffs that nothing in claim 1 of the '233 patent or the intrinsic evidence for the '233 patent requires the additional language in Defendants' proposed construction. The plain and ordinary meaning of "memantine" in this term refers to both ***extended***- and ***immediate***-release types of memantine. The applicants knew how to distinguish between extended and immediate forms of memantine, as evidenced by the numerous references to both types of memantine in the specification of the '233 patent, but chose not to do so in this term. (*See, e.g.*, '233 patent at 2:36-38) ("The NMDAr antagonist is desirably provided in a controlled or extended release form, with or without an immediate release component . . . .") In addition, claim 10 of the '233 patent specifies that the "22.5 to 37.5 mg memantine or pharmaceutically acceptable salt thereof" must be "provided in an extended release dosage form," whereas claim 1 does not. "The general presumption that different terms have different meanings remains." *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1369 (Fed. Cir. 2012). Thus, the doctrine of claim differentiation is further evidence favoring the Court's construction.

The Court finds additional support for its construction in the numerous distinctions between a release "***form***" and individual release "***components***" found in the specification of the '233 patent, as cited in Plaintiffs' opening brief. (*See* D.I. 92 at 19-20) This is further evidence

that the "formulation" referred to in this term is not merely a "component" of a dosage form. Rather, the Court interprets the "formulation" to be the potential combination of various components, including (potentially) extended- and immediate-release versions of memantine.

VII. CONCLUSION

The Court construes the disputed terms as explained above. An appropriate Order follows.