UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

Merck Sharp & Dohme LLC, MSD International GmbH, MSD International Business GmbH, and AIC246 AG & Co. KG v. DUS Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited

Civil Action No. 24-10820 (KMW-SAK) · No. Civil Action No. 24-10820 (KMW-SAK) · Decided December 29, 2025

SUMMARY

The United States District Court for the District of New Jersey construes disputed terms in U.S. Reissued Patent No. RE 46,791, relating to letermovir and antiviral treatment of cytomegalovirus. The court adopts Plaintiffs' proposed constructions for terms concerning stereoisomeric forms, methods for treating, antivirally effective amounts, and enantiomeric excess, rejecting Defendants' indefiniteness and racemic-mixture arguments. The court reserves any remaining indefiniteness arguments concerning the amount of an antivirally effective compound for summary judgment or trial.

OPINION

FOR PUBLICATION IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY CAMDEN VICINAGE fe MERCK SHARP & DOHME LLC, MSD {| HONORABLE KAREN M. WILLIAMS INTERNATIONAL GMBH, MSD INTERNATIONAL BUSINESS GMBH, and AIC246 AG & CO. KG, Civil Action Plaintiffs and Counterclaim Defendants, No, 24-10820 (KMW-SAK) MEMORANDUM OPINION DUS PHARMACEUTICALS (USA) INC.! and ZYDUS LIFESCIENCES LIMITED, Defendants and Counterclaim Plaintiffs.

WILLIAMS, District Judge: This matter comes before the Court upon the application of Plaintiffs Merck Sharp & Dohme LLC, MSD International GmbH, MSD International Business GmbH, and AIC246 AG & Co. KG ("Plaintiffs") and Defendants Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited (collectively, "Defendants") for claim construction, pursuant to Local Patent Rule 4.5.

The Parties submitted their Joint Claim Construction and Prehearing Statement (Dkt. No. 58) and filed their opening briefs (Pls.' Opening Br., Dkt. No. 65; Defs.' Opening Br., Dkt. No. 66). After the Parties filed their responsive briefs (Pls." Resp. Br., Dkt. No. 81; Defs.' Resp. Br., Dkt. No. 80), they presented their arguments at a Markman hearing on December 4, 2025 (Dkt.

No. 97). Having considered the Parties' written submissions and oral arguments, the Court sets forth its construction of the disputed terms below. I. BACKGROUND a. Cytomegalovirus

(“CMY”) Prophylaxis with PREVYMIS® (letermovir) Cytomegalovirus (“CMV”) is a common virus that can cause serious complications, including death, to transplant patients with weakened or ineffective immune systems.

(See Pls,’ Opening Markman Br. at 3, Dkt. No. 65.) Prior to the development of PREVYMIS®, available CMV treatments had significant side effects and could not be used to prevent infection and associated disease in bone marrow transplant patients. (/d.) PREVYMIS® is the first and only FDA-approved drug for prophylaxis of CMV infection in bone marrow transplant patients.

(See id.; see also Declaration of Yi (Sunnie) Ning in Support of Plaintiffs’ Opening Claim Construction Brief (“Ning Decl.”), Exhibit 3 —- Excerpts from Prosecution History of U.S. Reissued Patent No. RE46,791, Dkt. No. 65-4 at 131.)

The active ingredient in PREVYMIS® (and Defendants’ proposed generic product) is letermovir. (See Ning Decl., Ex. 3, Dkt. No. 65-4 at 131.) b. The Patent-In-Suit The reissued °791 Patent (“RE °791 Patent”), titled “Substituted dihydroquinazolines,” claims a novel class of stereochemical compounds and their use in medicaments for the treatment of diseases, in particular as antiviral agents against CMVs.

(See Ning Decl., Exhibit 1 - RE *791 Patent, Dkt. No. 65-2.) Letermovir is a member of the claimed class of compounds, (/d.) The RE °791 Patent is a reissue of U.S. Patent No. 7,196,086, and claims priority to April 26, 2004. Ud.)

The RE ’791 Patent discloses that “[t]he present invention provides compounds” of the following formula (called “formula (1)””’): a uy oe (See Ning Decl., Ex, 1 - RE’791] Patent, Dkt. No, 65-2 at 1:32-47,) The patent teaches that those “compounds according to the invention may, depending on their structure, exist in stereoisomeric forms (enantiomers, diastereomers[3]),” and that the “[t]he invention [] relates to the enantiomers or diastereomers and respective mixture thereof.” Ud, at 2:34-38,) The RE ’791 Patent has 44 claims directed to its novel chemical compounds.

(See generally id.) Clatm | recites the genus of the claimed compounds. (/d.}) The chemical structure recited in claim | is the same “formula (1)” structure described in the specification. Ud.) Other patent claims are directed to chemical structures within the genus of claim 1. (See id.)

For example, dependent claim 27 recites a particular molecular structure without specifying the stereochemistry, while dependent claim 24 recites the (S)-enantiomer of that structure—ie., letermovir. (See td.) I. LEGAL STANDARD A patent infringement case involves two steps.

First, the court determines the meaning of the claims in the patent. Amgen Inc. v. Amneal Pharms. LLC, 945 F.3d 1368, 1375 (Ped. Cir. 2020). Second, the court compares the claims, as construed, to the allegedly infringing product. fd. Where, as here, the Parties dispute the meaning of the patent’s claims, the construction of those claims is matter of law for the Court to decide, Markman

v. Westview Instruments, Inc., 517 U.S. 370, 391 (1996); Bayer Healthcare LLC y. Baxalta Inc., 989 F.3d 964, 977 (Fed, Cir, 2021). “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 (Ped, Cir, 2005) (en banc) (quoting Innova/ Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d Ui11, 1115 (Fed.

Cur. 2004)). The Court must “begin with the words of the claims themselves,” giving them the meaning that “a person of ordinary skill in the art” (“POSA”) would give them. Allergan Sales, LLC v. Sandoz, Inc., 935 F.3d 1370, 1373 (Fed. Cir. 2019) (citation omitted), A POSA would interpret the words in the context of the rest of the patent document, including the specification which describes the invention. /d. at 1373 & n.6.

The prosecution history, i.e., proceedings before the U.S. Patent and Trademark Office that led to approval of the patent, can further illuminate the meaning of a term. Id. at 1373 & n.7. All the foregoing constitutes “intrinsic evidence,” ie., evidence from within the patent process itself. “The claims, of course, do not stand alone. Rather, they are part of ‘a fully integrated written instrument’” that consists principally of the “specification,” which concludes with the claims, Phillips, 415 F.3d at 1315 (quoting Markman, 52 F.3d at 978).

The Federal Circuit has said that ‘claims must be read in view of the specification,” of which they are a part. Markman, 52 F.3d at 979, For this reason, “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 1312-13 (quoting Vitronics Corp. v. Conceptronic, Inc., 90 E.3d 1576, 1582 (Fed.

Cir. 1996)). Therefore, after examining the claims, “it is always necessary to review the specification to determine whether the inventor has used any terms in a manner inconsistent with their ordinary meaning.” Vitronics Corp., 90 F.3d at 1582.

For claim construction purposes, the specification acts as a dictionary, which explains the invention and may define terms used in the claims. id. “{i]deally there should be no ‘ambiguity’ in claim language to one of ordinary skill in the art that would require resort to evidence outside the specification and prosecution history.” Markman v. Westview Instruments, Inc., 52 F.3d 967, 986 (Fed, Cir.

1995), aff’d, 517 U.S. 370 (1996). However, if there remains ambiguity, the Court may consult “extrinsic evidence,” □□□□ evidence outside the patent and prosecution history, such as “expert and inventor testimony, dictionaries, and learned treatises.” Phillips, 415 F.3d at 1317, Extrinsic evidence is generally “less significant than the intrinsic record in determining the legally operative meaning of disputed claim language.” CLR.

Bard, Inc. v. U.S. Surgical Corp,, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotations omitted). In addition, extrinsic evidence ordinarily should not contradict intimsic evidence. Phillips, 415 F.3d at 1322-23. Therefore, extrinsic evidence must be viewed within the context of intrinsic evidence, /d, at 1319. Ili, DISCUSSION The Parties have identified six (6) claim terms that require construction by the Court. a. Claim 1 Claim Claim Term Plaintiffs' Proposed Defendants' Construction Proposed RE'791 "A compound of the formula | "A compound of the Indefinite.

Patent, Claim i formula E qa □□ aoe | 10 ae. We, MA Aue, i " x ae, Claim I which exists in a stereoisomeric form or a mixture of stereoisomeric forms." The core of the dispute with respect to claim 1 is whether the compound is limited to racemic forms or whether it may exist in a mixture of stereoisomeric forms. Defendants argue that because neither hashed nor wedged bonds are depicted in the compound, the "plain bonds" depict only racemates.

(Defs.' Opening Markman Br. at 8-11, Dkt. No. 66.) Plaintiffs argue that the use of plain bonds within the RE '791 Patent is consistent with International Union of Pure and Applied Chemistry ("TUPAC") standards, which state that "[i]f no stereochemical information [Z¢., hashed or solid wedges] is present in the diagram, it represents a molecular entity with unknown configuration," (IUPAC Graphical Representation of Stereochemical Configuration, Dkt.

No. 65- 3; Davies Decl. ff] 42-50, Dkt. No. 65-13.) As Plaintiffs correctly note, the specification within the RE'791 Patent expressly teaches that: "The compounds according to the invention may, depending on their structure, exist in stereoisomeric forms (enantiomers, diastereomers), The invention therefore relates to the enantiomers or diastereomers and respective mixtures thereof." (RE °791 Patent, Dkt.

No, 65-2.) As a general rule, "the claims of ja] patent will not be read restrictively unless the patentee has demonstrated a clear intention fo limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" Liebel-Flarsheitm Co. y. Medrad, Inc., 358 F.3d 898, 906 (Fed. Cir. 2004) (quoting Teleflex, Inc. v Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed, Cir.

2002)). "[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. Here, Defendants ask the Court to interpret the depictions of "plain bonds" as being limited to racemic mixtures.

The Court notes that nowhere in the patent do Plaintiffs demonstrate a "clear intention" to limit the scope of the claim to racemic mixtures. See Liebel-Flarsheim Co., 358 F.3d at 906, To the contrary, the specification unambiguously states that the compounds exist "in stereoisomeric forms (enantiomers, diastereomers) and respective mixtures thereof," (RE °791 Patent, Dkt.

No. 65-2.) "A claim construction that 'excludes the preferred embodiment is rarely, if ever correct.'" SynQor Inc. v. Artesyn Techs,, Inc., 709 F.3d 1365, 1378-79 (Fed. Cir. 2013).

Considering the words of the specification, the commonly accepted meaning of plain bonds according to TUPAC, and the usage of plain bonds throughout the RE ’791 Patent, the Court construes Claim 1 to mean its plain and ordinary meaning, which is consistent with Plaintiffs’ proposed construction.

Accordingly, the Court adopts Plaintiffs’ construction as the articulation of the term’s plain meaning, b. Claims 29 and 30 Claim Claim Term Plaintiffs’ Proposed Defendants’ Construction Proposed Construction RE ’79] “compound is of the formula | “A compound of the Indefinite. Patent, ¢ “ formula Claims 29 Ct. and 30 □□ ry SY, xo Te Sy Wwe. 7 8s x, LOR “S ues » LN, which exists in a stereoisomeric form or a mixture of stereoisomeric forms.” The Parties’ arguments as to Claim | of the RE 791] Patent apply to Claims 29 and 30 and are briefed together.

(See Pls.’ Opening Markman Br. at 7-12, Dkt. No. 65; Defs.’ Opening Markinan Br. at 6-14, Dkt. No. 66.) Again, the Court adopts Plaintiffs’ construction, finding that a POSA would understand the plain and ordinary meaning of the disputed claim ferm to mean the compound “exists in a stereoisomeric form or a mixture of stereoisomeric forms,” as expressly stated in the specification, (See RE *791 Patent, Dkt.

No. 65-2.) Moreover, Plaintiffs’ use of plain bonds to depict an “unknown configuration” is consistent within the RE *791 Patent and with IUPAC standards. (QUPAC Graphical Representation of Stereochemical Configuration, Dkt. No. 65-3; Davies Decl. f¥ 42-50, Dkt. No. 65-13.) Furthermore, while Defendants are correct that plain bonds can in some circumstances depict racemic mixtures, IUPAC standards dictate that to do so the plain bonds must be clearly labelled racemic.

(Dkt. No. 65-3.) This is precisely why the Court interprets the plain bonds depicted in Example 14 only as depicting racemic mixtures—because only those plain bonds are labelled as racemic. (See RE ’791 Patent, Dkt. No. 65-2.) Defendants ask the Court to extrapolate the clear labelling of plain bonds in Example 14 as racemic to define the use of plain bonds throughout the patent, but to do so would be to impermissibly limit the scope of Plaintiffs’ claims.

See Liebel-Flarsheim Co., 358 F.3d at 906. Here, the specification expressly states that the compound “exists in a stereoisomeric form or a mixture of stereoisomeric forms.” (RE *791 Patent, Dkt. No, 65-2,) The specification is “the single best guide”—usually “dispositive” the meaning of a disputed term in claim construction analysis, See Phillips, 415 F.3d at 1315, TUPAC standards further support both the general use of plain bonds in the patent as depicting unknown configuration and Plaintiffs’ limited use of plain bonds in Example 14 only to indicate a racemic mixture when clearly labelled as such.

The Court finds that a POSA would understand Claims 29 and 30 to mean their plain and ordinary meaning, which is consistent with Plaintiffs’ proposed construction. Accordingly, the Court adopts

Plaintiffs' construction as the articulation of the term's plain meaning, c. Claims 21, 26, 27, 32 Claim Claim Term Plaintiffs' Proposed Defendants' Proposed Construction Construction RE '791 "the compound: "A compound of the "a racemic mixture of Patent,. formula letermovir Claims 21, and its corresponding Ho ge 2 (us _ 26,27,32 | J. J Rie sus x AA 2 Ch, enantiomer (i.e., 50:50 | Lt on he ek muxture Tr Os DN, of (48)- {8-Fluoro-2-[4- TI |G methoxyphenyl)-f- which exists in a pipetazinyl]-3-[2- stereoisomeric form methoxy-5- or or a mixture of (triflucromethylpheny!]- 3,4- stereoisomeric dihydro-4- forms." quinazoliny]} acetic acid and (4R)- {8- Fluoro-2-[4- "said compound is: (3-methoxyphenyl)-1- piperazinyl]-3-[2- ak □ □ methoxy-5- Oh (trifluoromethyl)pheny!]- A 3,4- Pe dihydro-4- Cr » quinazoliny] } acetic acid)" Again, Defendants argue that these claims do not depict stereochemistry that may exist in stereoisomeric forms (enantiomers, diastereomers) and respective mixtures thereof, but are limited to racemic compounds.

(Defs.' Opening Markman Br. at 14-15, Dkt. No. 66.) Defendants seek a construction limiting these claims to racemic mixtures, (/d.) As previously stated, the Court will not read into the claim a limitation on its scope to racemic mixtures. See Liebel-Flarsheim. Co., 358 F.3d at 906.

The specification is clear that the compound "exists in a stereoisomeric form or a mixture of stereoisomeric forms." (RE '791 Patent, Dkt. No. 65-2); see Phillips, 415 F.3d at 1312- 13. The Court finds that a POSA would understand Claims 21, 26, 27, and 32 to mean their plain and ordinary meaning, which is consistent with Plaintiffs' proposed construction.

Accordingly, the Court adopts Plaintiffs' construction as the articulation of the term's plain meaning. d, Claims 18 and 21 — "method for treating" Claim Claim Term Plaintiffs' Proposed Defendants' Construction Proposed '791 "method for treating" "Method for "a medical care Patent, prophylactic or given after a Claims 18 & curative treatment." disease or injury 21 has already occurred, with a goal of curing or managing the existing illness.

(Treating is different from prophylaxis; prophylaxis is directed to preventing a disease or condition from occurring in the first place.' This dispute centers around whether the word "treating" is limited to curative treatments or includes treating patients to prevent a disease or condition from ever occurring. Plaintiffs argue that the word "treating" refers both to preventative treatments—prophylactic and curative—and is not limited to treating or curing diseases that presently exist/after they have occurred, (Pls.' Opening Markman Br. at 17-21.)

Plaintiffs point to the specification, which states that the compounds of the invention are intended to be used for prophylactic treatment. (Davies Decl. 61, Dkt. No. 65-13.) For example, the specification states that "[t]he invention relates to... use for preparing medicaments for the treatment and/or prophylaxis of diseases, in particular for use as antiviral agents, in particular against [CMVs]." (RE '791 Patent, Dkt.

No, 65-2.) Plaintiffs further cite to the prosecution history to support their position, as the specific claims cover PREV YMIS® (letermovir)—-a drug indicated solely for the prophylactic treatment of human CMY, (See RE ’791 File History, Dkt. No. 65-4.) Plaintiffs argue that one of the references in the prosecution history further supports their position that “treating” can meclude “prophylactic treatment” because it expressly states: “In addition to treatments for existing conditions, the present invention also provides methods for prophylactic treatments to prevent the onset of viral mfection in patients undergoing, for example, organ transplants.” Ud. at 36.)

10 Plaintiffs further contend that the extrinsic evidence Defendants rely on further supports Plaintiffs’ position, as multiple medical dictionaries—inciuding those cited by Defendants—define “treating” as including both prophylactic treatment and curative treatment. (See Pls.’ Opening Markman Br, at 19-21.) Defendants argue that “treating” does not include prophylactic treatment and is limited to curing/remedying presently existing conditions.

(Defs.’ Opening Markman Br. at 24-29, Dkt. No. 66.) Defendants argue that because the specification refers to “treatment and/or prophylaxis of diseases,” those are distinct concepts. (id. at 24.) Defendants also contend that because the patent uses examples of curatively treating active diseases, the use of the word “treating” in the patent is limited fo curing active diseases rather than prevention. (/d. at 25-26.)

Defendants further contend that extrinsic evidence from a variety of dictionaries, including Webster’s International and medical dictionaries, define treatment and prophylaxis differently. (id, at 26-29,) The Court finds, however, that the dictionaries cited by Defendants de_not limit the definitions of “treating” to Defendants’ construction, but as Plaintiffs point out, include alternate definitions and usages that support Plaintiffs’ construction..

As previously noted, “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 at 1315.

Here, the specification states “the invention relates to substituted dihydroquinazolines and to processes for their preparation and also to their use for preparing medicaments for the treatment and/or prophylaxis of diseases... one object of the present invention is therefore to provide novel compounds having the same or improved antiviral effect for the treatment of viral infective diseases in humans and animals.” (RE *791 Patent, Dkt.

No. 65- 2 (emphasis added).} This specification strongly supports Plaintiffs’ construction that the invention ll claims a method for treating to prevent disease. Moreover, nothing in the patent expressly limits the use of the invention to curative treatments and does not disclaim preventative treatment in any way, See Liebel-Flarsheun Co., 358 B.3d at 906. Furthermore, the prosecution

history demonstrates that the claims at issue cover PREVYMIS®, which is indicated solely for prophylactic use.

(See RE ’791 File History, Dkt. No. 65-4.) To the extent Defendants perceive any ambiguity with this claim, the extrinsic evidence further supports that “treatment” can include prophylactic or preventative treatment.

In light of the specification, prosecution history, and extrinsic evidence, the Court finds that a POSA would understand the term “method for treating” in Claims 18 and 21 to mean its plain and ordinary meaning—preventative and curative treatment—which is consistent with Plaintiffs’ proposed construction, Accordingly, the Court adopts Plaintiffs’ construction as the articulation of the term’s plain meaning. e. Claims 18 and 21 — “an antivirally effective amount” Claim Claim Term Plaintiffs’ Proposed Defendants’ Construction Proposed Construction RE °*791 “an antivirally effective “An amount that Indefinite.

Patent, amount” provides in vitro Claims 18 & or in vivo antiviral 21 or effect or activity.” “an antiviral effective amount” Defendants argue that this disputed claim term is indefinite. Defendants assert that if the Court adopts Plaintiffs’ proposed constructions for the preceding terms, the “antiviral effect amount” for prophylactic treatment is excessively broad because “a POSA would not know with reasonable certainty the boundaries of an antiviral effective amount is because different 12 stereoisomers or different ratios of a given stereoisomeric mixture could have a different antiviral effective amount.” (Defs.’ Opening Markman Brief at 30-31, Dkt.

No. 66.) Plaintiffs argue that the specification of the patent describes the antiviral effect in terms of in vitro and i vivo data, stating that: “[tlhe in vitro effect of the compounds of the invention can be shown in the following assays: Antic HCMV (Anti-HumanCytomegalovirus) Cytopathogenicity Tests.” (RE ’791 Patent at 117:14-17, Dkt. No. 65-2.) Jt further provides “[rJepresentative in vitro data for the effects of the compounds of the invention.” (/d. at 117:50-63.)

The prosecution history further cites i# vitro data as demonstrating antiviral effect/activity, including an acknowledgement _ by the Examiner that in vitro data in the patent “demonstrate[es] the activity of Applicant’s compound of working example 15 to inhibit the cytopathic effect of HCMV” and concludes that “(s]uch teachings support the finding that [the compound]... possesses anti-viral activity against HCMV.” (See RE’791 File History at MRKOO001411, Dkt.

No. 65-4.) With respect to in vivo data, the specification separately teaches that “[t]he suitability of the compounds of the invention for the treatment of HCMY can be shown in the following animal [i.e., in vive] model: HCMV Xenopraft Gelfoam® model.” (RE ’791 Patent at 117:64-67, Dkt. No. 65-2.) Plaintiffs de not rely on extrinsic evidence for the construction of this claim,

though they note that courts have repeatedly found the term “effective amount” are not indefinite for purposes of claim construction.

(See Pls.” Responsive Markman Br. at 26 & n.20, Dkt. No. 81.) Plaintiffs ask the Court to adopt their proposed construction with respect to the meaning of the term ‘‘an antiviral effective amount,” and reserve Defendants’ indefiniteness challenges as to what amount is antivirally effective in different circumstances to the summary judgment or trial stage of the litigation.

Ud. at 25.) 13 Courts have repeatedly found that the term “effective amount” is not indefinite, See Geneva Pharms., Inc. v. GlaxoSmithKline PLC, 349 F.3d 1373, 1383-84 (Fed. Cir. 2003) (holding “effective amount’ is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite”); see also Intmunomedics, Inc. vy. Roger Williams Med.

Ctr, No. 15- 4526, 2017 WL 788122, at *6 (D.N.J. Feb. 28, 2017) (“effective amount” not indefinite); Wyeth v. Abbott Lab’ys, No, 09-4850, 2011 WL 5873373, at *8 (D.N.J. Nov. 22, 2011) (same), Similarly, here, the Court finds that, based on the specification, in vivo and in vitro data, and prosecution history, a POSA would understand that an amount that provides an antiviral effect would fall within the scope of the claims.

Moreover, the patent teaches a POSA how to arrive at an antiviral effect amount. Furthermore, while the intrinsic evidence alone demonstrates that these claims mean their plain and ordinary meaning—which is consistent with Plaintiffs’ proposed construction—the extrinsic evidence of other courts faced with a similar question further supports that the claim term “an antiviral effective amount” is not ambiguous.

See Geneva Pharms, 349 F.3d at 1383-84; Lnmmunomedics, Inc., 2017 WL 788122, at *6; Wreth, 2011 WL 5873373, at *8. Accordingly, the Court adopts Plaintiffs’ construction as the articulation of the term’s plain meaning.

The Court reserves any remaining indefiniteness arguments as to the “amount” this term refers to for the summary judgment or trial stage of the htigation. f. Claims 41 and 42 — “having an enantiomeric excess of more than 90%” Claim Claim Term Plaintiffs’ Proposed Defendants’ Construction Proposed Construction RE’791 “having an “Within the limits of | Indefinite.

Patent, enantiomeric excess of detection, Claims 41 & | more than 90%” having more than 95% 42 of one enantiomer and less than 5% of the second enantiomer, such that 14 excess is more than 90% (i.2., 95% - 5%).” Finally, Defendants dispute the claim term, “having an enantiomeric excess of more than 90%.” Defendants argue that the term is indefinite because the upper boundary is unclear because it contains no express language regarding the upper limit.

(Defs.’ Opening Markman Br. at 21-22, Dkt. No. 66.) Defendants further argue that the patent prosecution history does not disclaim that the excess is “within the limits of detection,” so the

claim should not be read to describe an excess “within the limits of detection.” Ud. at 22-23.)

Because the patent does not describe any method for determining what the limits of detection are or set an upper boundary, Defendants argue that the claim is indefinite, Ud. at 23-24.) Plaintiffs argue that the term has a plain and ordinary meaning that a POSA would understand. (See Pls.’ Opening Markman Br. at 24, Dkt. No. 65.) Contrary to Defendants’ assertions, Plaintiff argue that the upper boundary is the limit of detection of the instruments used for measurement. (/d, at 25.)

Plaintiffs posit that the alternative is nonsensicai because any measurement must necessarily be “‘within the limits of detection,” Ud.) Turning to extrinsic evidence, Plaintiff argues that “enantiomeric excess” is a term of art with a well-understood meaning to a skilled artisan. Ud. at 24 (citing Davies Decl. ¢ 75.) IUPAC recommendations provide standardized rules and guidelines in the chemical arts and define the term “enantiomeric excess.” Ud.)

In layman’s terms, it “is the percentage that one enantiomer is present in excess of the other, ie, the percentage of the major enantiomer minus the percentage of the minor enantiomer.” Ud, at 25 (citing Davies Decl. □ 75.)) “{A] patentee need not define his invention with mathematical precision in order to comply with the definiteness requirement.” See Sonix Tech, Co. v. Publ’ns Int'l, Ltd., 844 F.3d 1370, 1377 15 (Fed.

Cir, 2017); see also Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374, 1382 (Ped. Cir. 2015) (“The degree of precision necessary for adequate claims is a function of the nature of the subject matter.”), Here, the term “enantiomeric excess” is a term of art with a meaning that would be understood by a skilled artisan according to its IUPAC definition.

The claim is specific as to the excess it recites, Ze., 90%. Thus, the Court finds that a POSA would understand “having an enantiomeric excess of more than 90%” to mean its plain and ordinary meaning—that with the limits of detection, having more than 95% of one enantiomer and less than 5% of the second enantiomer, such that the “enantiomeric excess” is greater than 90%—which is consistent with Plaintiffs’ proposed construction.

Accordingly, the Court adopts Plamtiffs’ construction as the articulation of the term’s plain meaning. IV. CONCLUSION For all the foregoing reasons, the Court will construe the disputed claim terms in the RE °791 Patent as indicated, The Court adopts Plaintiffs’ proposed construction of each disputed claim term as the articulation of the respective term’s plain meaning.

An appropriate Order shall follow. Dated: olay D9) PIs oD. UNITED STATES DISTRICT JUDGE 16