NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JANSSEN PRODUCTS, L.P., *et al.*, Plaintiffs, v. **EVENUS PHARMACEUTICALS LABORATORIES INC., *et al.*,** Defendants.	Civil Action No. 20-9369 (ZNQ) (LHG) **CLAIM CONSTRUCTION OPINION**

QURAISHI, District Judge

In this claim construction Opinion, the Court construes a single disputed claim term in a patent that is directed to trabectedin anti-tumor drug products. The parties submitted the following briefs: Opening Brief ("Def. Op. Br.," ECF No. 149) filed by Defendants Natco Pharma Ltd., Sun Pharmaceutical Industries, Ltd., and Sun Pharmaceutical Industries Inc. (collectively, "Defendants"), Opening Brief ("Plf. Op. Br.," ECF No. 150) filed by Plaintiffs Janssen Products, L.P. and Pharma Mar, S.A. (collectively, "Plaintiffs"); Defendants' Responding Brief ("Def. Resp. Br.," ECF No. 170), and Plaintiffs' Responsive Brief ("Plf. Resp. Br.," ECF No. 171). After reviewing the parties' submissions and conducting a *Markman* hearing on January 4, 2022, the Court construes the disputed term as set forth herein.

I. PROCEDURAL HISTORY

Plaintiffs bring this patent infringement suit against Defendants[1] for infringement of United

[1] The original Complaint names additional defendants that have not sought a claim construction from the Court in this matter: eVenus Pharmaceuticals Laboratories Inc. and Jiangsu Hengrui Medicine Co. Ltd. (*See* ECF No. 1.) The Amended Complaint adds a third defendant that also has not sought a claim construction: Fresenius Kabi USA, LLC. (*See* ECF No. 32.)

States Patent Nos. 8,895,557 ("the '557 Patent") and 7,420,051 ("the '051 Patent," together, the "patents in suit") based on the filing of two Abbreviated New Drug Applications ("ANDAs") with the U.S. Food & Drug Administration ("FDA") seeking to market a generic version of Yondelis® trabectedin 1 mg/vial product before expiration of the patents in suit. *See generally* Amended Complaint (ECF No. 132). The parties ask the Court to construe one claim term from the '557 patent: "single active anti-tumor compound."

II. FACTUAL BACKGROUND

Trabectedin is a member of the ecteinascidin family of compounds, used to treat certain types of soft tissue cancer. *See* Plf. Op. Br. at 1;[2] Transcript of January 4, 2022 Markman Hearing ("Markman Tr.") at 12:7–9 (ECF No. 190). It is also referred to as "ET-743." Markman Tr. at 12:1–3; '557 Patent, col. 1 lines 44–67. From a formulations perspective, ET-743 is a challenging compound insofar as it has limited aqueous solubility and, once dissolved, it has poor stability in solution. '557 Patent, col. 2 lines 27–30. As part of a drug product, ET-743 is therefore sold as a sterile, lyophilized composition that must be reconstituted prior to its administration by injection. *Id*. col. 2, lines 51–61; Markman Tr. at 13:6–9, 43:14–15. Prior art lyophilized compositions included ET-743, a phosphate buffer, and mannitol as a bulking agent. '557 Patent, col. 2, lines 51–55. One downside of these compositions was that they needed to be stored at -20°C to prevent decomposition. *Id*. col. 3, lines 7–11. Another downside was that the freeze-drying process and subsequent storage tended to hydrolyze the ET-743 into an impurity, identified as "ET-701." *Id*. col. 3, lines 12–34. To address these problems, the inventors developed an ET-743 formulation that included a disaccharide. *Id.*

[2] For clarity, the Court notes that it cites to the parties' submissions by their internal page numbering rather than the pagination imposed by the CM/ECF system.

As set forth above, Defendants filed Abbreviated New Drug Applications with the FDA that sought approval to market a generic version of Yondelis. Plaintiffs responded by filing this patent infringement suit. In accordance with this district's Local Patent Rules, the parties exchanged proposals for how to construe the claim terms of the patents in suit, and later exchanged evidence supporting their respective proposed constructions. They then filed a Joint Claim Construction and Prehearing Statement. (ECF No. 134.) Their joint statement indicates that the parties have agreed to construe the claim term "a Pictet-Spengler reaction" of the '051 Patent to mean "an organic reaction used to convert a β-arylethylamine and a carbonyl compound to a tetrahydroisoquinoline using an acid catalyst." *Id*. at 2. Plaintiffs and three of the five defendants named in this case have been unable to agree on an interpretation of the limitation "single active anti-tumor compound" that is recited in claims 1 and 22 of the '557 Patent. They therefore seek this Court's construction.

III. LEGAL STANDARD

A patent infringement case involves two steps: construing the claims and determining whether the accused product infringes the claims. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996); *Hormone Research Found., Inc. v. Genentech, Inc.*, 904 F.2d 1558, 1562 (Fed. Cir. 1990), *cert. dismissed*, 499 U.S. 955 (1991).

Claim construction is primarily a question of law. *See Teva Pharm. U.S.A., Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–26 (2015). It begins with the claim language. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004); *Markman*, 52 F.3d at 980. Claim language is generally "given [its] ordinary and customary meaning." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims

themselves . . . to define the scope of the patented invention."); *see also Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001) ("In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point [] out and distinctly claim[] the subject matter which the patentee regards as his invention.'") (quoting 35 U.S.C. § 112). Ordinary meaning is determined by "a person of ordinary skill in the art in question at the time of the invention."[3] *Phillips v. AHW Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (collecting cases); *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 (Fed. Cir. 2003). However, if a patentee has used the claim language in some manner other than its ordinary meaning, as indicated by the balance of intrinsic evidence, such as the specification, then that meaning controls. *See, e.g.*, *Phillips*, 415 F.3d at 1226; *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1366 (Fed. Cir. 2001); *Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1344 (Fed. Cir. 2002) ("It is thus necessary to review [intrinsic evidence] to determine whether the patentee has assigned any special meaning to claim terms.").

Because "there is no magic formula or catechism" for determining ordinary meaning, nor a "rigid algorithm" or "specific sequence," *Phillips*, 415 F.3d at 1324, a court must read claims in context. *See Medrad Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum."); *see also DeMarini Sports, Inc. v. Worth*, 239 F.3d 1314, 1324 (Fed. Cir. 2001). To this end, a court must consider "the written description and prosecution history," *Medrad*, 401 F.3d at 1319, "the specification," *Phillips*, 415 F.3d at 1313, which is "always highly relevant to the claim construction analysis," *Vitronics*, 90 F.3d at 1582, because it "may reveal whether the patentee has used a term in a way different from

[3] The parties disagree on the proper definition of a person of ordinary skill in the art, but conceded at oral argument that the Court need not decide that issue for the purposes of claim construction. *See* Markman Tr., at 31:6–25.

its plain meaning," *Brookhill-Wilk*, 334 F.3d at 1298, and "the surrounding words of the claim." *ACTV, Inc. v. Walt Disney Co.*, 346 F.3d 1082, 1088 (Fed. Cir. 2003).

Even "[o]ther claims of the patent in question, both asserted and unasserted, can [] be valuable sources of enlightenment as to the meaning of a claim term." *Vitronics*, 90 F.3d at 1582. In short, the "entire patent" matters, *Phillips*, 415 F.3d at 1313; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998), and "[t]he construction that stays true to the claim language" while "most naturally align[ing] 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).

In addition to "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," a court may also consider "extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Innova*, 381 F.3d at 1116; *see also Gemstar-TV Guide Int'l, Inc. v. Int'l Trade Comm'n,* 383 F.3d 1352, 1364 (Fed. Cir. 2004).

IV. DISCUSSION

The '557 Patent includes two independent claims, claims 1 and 22, that each employ the disputed phrase. Claim 1 recites:

> 1. A lyophilized anti-tumor composition comprising ***a single active anti-tumor compound*** and a disaccharide selected from sucrose, lactose, and a combination thereof, wherein the antitumor compound is ET-743 and wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C for 3 months.

'557 Patent, col. 27, lines 58–65 (emphasis added). Claim 22, below, differs from claim 1 only in the storage temperature stated at the end of the claim.

> 22. A lyophilized anti-tumor composition comprising ***a single active anti-tumor compound*** and a disaccharide selected from sucrose, lactose, and a combination thereof, wherein the antitumor compound is ET-743 and wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 25°C for 3 months.

'557 Patent, col. 28, line 64–col. 29, line 4 (emphasis added). No other claims use the disputed phrase.

The parties offer competing constructions as illustrated in the table below.

Claim Term	Plaintiffs' Proposal	Defendants' Proposal
"a single active anti-tumor compound"	plain and ordinary meaning (no construction needed) or "a single compound providing the anti-tumor activity of the composition"	"single compound possessing anti-tumor properties"

Plaintiffs first argue that no construction is needed because the plain and ordinary meaning of "single active anti-tumor compound" is plain on its face and readily understood by a person of ordinary skill in the art ("POSA"). Plf. Op. Br. at 6–7; Plf. Resp. Br. at 1. In the alternative, should the Court perceive a need to construe the term further, Plaintiffs propose an interpretation that they believe to be consistent with its plain and ordinary meaning: "a single compound providing the anti-tumor activity of the composition." Plf. Op. Br. at 6.

Plaintiffs begin by noting that a single compound, ET-743, is identified in the claims as "*the* anti-tumor compound." Plf. Op. Br. at 7 (emphasis added). They contend this makes two things clear. First, ET-743 is the sole active anti-tumor compound in the claimed compositions. Second, any other compound recited in the claims should not be considered an active anti-tumor compound. *Id*. Plaintiffs insist this interpretation is consistent with usage in this field because a POSA would recognize an "active compound" as the "active ingredient" or "active pharmaceutical

ingredient," which is the component of the formulation providing pharmaceutical activity. *Id*. at 7–8. Moreover, the claims acknowledge that related impurities are present in the formulation, and that they are undesirable because they set a 2% limit on the conversion of ET-743 to ET-701. *Id*. at 8.

For support from the patent's specification, Plaintiffs cite the fact that all of the examples are describe compositions with ET-743 as the sole active compound. *Id*. at 8, 10. Similarly, a primary object of the invention is disclosed as "to provide a new stable ET-743 formulation" "to avoid the formation of impurities." *Id*. at 9. Plaintiffs also highlight portions of the specification characterizing ET-701 as the "main impurity" (implying that there are other impurities) and characterizing "ET-745 and other impurities" as substances whose presence is to be reduced, rather than active compounds in their own right. *Id*. at 9–11.

Plaintiffs also contend the prosecution history favors plain and ordinary meaning. They argue that the patent applicants clearly narrowed the scope of their claims to cover compositions consisting of ETA-743 as the single active ingredient when their previous claims were rejected based on anticipation/obviousness in view of prior art that disclosed a similar formulation for another antitumor drug, kahalide F, in possible combination with ET-743. Plf. Op. Br. 11–12.

Plaintiffs object to Defendants' proposed construction because they believe it contradicts the intrinsic evidence, would read out the preferred embodiment, and would be inconsistent with representations that Defendants have already made to the FDA. *Id*. at 12–18. Plaintiffs also contend that Defendants' construction would impermissibly read "active" out of the claims. Plf. Resp. Br. at 5.

Unsurprisingly, Defendants do not agree. They insist the plain language of the claims supports their competing construction. They argue that a POSA would understand that the plain

meaning of "active tumor compound" is a "compound possessing anti-tumor properties," as they propose. Def. Op. Br. at 8. This is because the anti-tumor properties of a compound are what make it "active" against tumors. *Id*. Therefore, the claims require a lyophilized composition of certain compounds, and "one (and only one) of those compounds can possess anti-tumor properties." *Id*. Defendants accuse Plaintiffs of attempting to improperly rewrite the claims by importing functional language. *Id*. at 8–9.

Defendants also contend that the specification favors their construction. It uses "single" consistently to distinguish the invention from compounds that have more than one active tumor compound. *Id*. at 10. Likewise, the specification acknowledges that other ET compounds, like ET-745 and ET-770, are known to have anti-tumor properties. *Id*. at 11. Defendants highlight that ET-745 and ET-770 are listed by the specification among "preferred"[4] compounds of the invention. *Id*. at 11. Likewise, the specification incorporates two references that recognize that many ET compounds, including ET-745 and ET-770, have anti-tumor activity. *Id*.

Finally, according to Defendants, the prosecution history also favors their construction. They point to the same claim amendments and arguments identified by Plaintiffs and argue that the applicants clearly excluded compositions containing more than one active anti-tumor compound from their claims.

[4] Defendants' Opening Brief asserts that ET-745 and ET-770 are identified by the '557 Patent among the more highly favored "particularly preferred" compounds of the invention. Def. Op. Br. at 11. In support of this statement, the Brief cites to a passage of the Patent from column 7, line 39 to column 8, line 59. Prior to the *Markman* hearing, the Court observed that the passage instead identifies compounds that are merely "preferred." At the hearing, the Court questioned Defendants' counsel, who responded that the description in their brief may have been a misstatement and that "preferred" was the correct designation. Markman Tr. 50:22–51:18. Plaintiffs' counsel noted their confusion as well. *Id*. at 81:23–82:8. Given Defendants' express modification of their briefed assertion at oral argument, the Court considers their position to be that the compounds are merely "preferred." This is consistent with Defendants' Responsive Brief. *See* Def. Resp. Br. at 9.

The parties' briefing both point to extrinsic evidence that they say supports their respective claim constructions. At oral argument, however, counsel agreed that the Court did not need to resort to extrinsic evidence to construe the claim term in dispute.

1. The Claim Language

Absent lexicography or disclaimer, neither of which the parties argue here, the general rule is that a claim term is to be given its ordinary and customary meaning, *i.e.*, the one that a person of ordinary skill in the art would ascribe to it at the time of the invention.[5] *Phillips*, 415 F.3d at 1312–3; *Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). To discern this meaning, the Court begins by considering the language of the claims themselves.

> 1. A lyophilized anti-tumor composition comprising ***a single active anti-tumor compound*** and a disaccharide selected from sucrose, lactose, and a combination thereof, wherein the antitumor compound is ET-743 and wherein the disaccharide is present in a sufficient amount to inhibit conversion of the ET-743 into ET-701, such that the ET-743 composition comprises less than 2% ET-701 after storage of the ET-743 composition at 5°C for 3 months.

Claim 1 covers compositions "comprising a single active anti-tumor compound and a disaccharide . . . ." Ordinarily, "comprising" as a transitional phrase represents open claim language that would not exclude additional unrecited elements. The claim later specifies, however, that the antitumor compound "is ET-743," effectively limiting the universe of claimed anti-tumor compounds to ET-743. In other words, it excludes other antitumor compounds from the scope of the "single active anti-tumor compound." The fact that the claim excludes ET-701 as an active is clear because ET-701 is instead specified in the claim as a compound whose formation is to be kept to no more than 2% upon storage at the stated condition.

[5] Consistent with the stipulation and order entered in this case, Defendants are not arguing at this stage of the litigation that the term is indefinite, but reserve their right to do so at a later time. Def. Resp. Br. at 3 n. 2; (ECF No. 114).

The remaining claims offer no guidance. As already noted, claim 22 differs from claim 1 only with respect to the storage condition. The other twenty-four dependent claims are silent regarding the disputed claim term.

2. The Specification

The Court has carefully reviewed the specification of the '557 Patent. It does not use the phrase "single active anti-tumor compound" outside of its independent claims. One constituent phrase, "active compound" does appear three times, in adjacent sentences.

> When the *active compound* is ET-743, the ratio (w/w) of ET-743 to bulking agent is typically from about 1:100 to about 1:1500, preferably from about 1:200 to about 1:800, more preferably from about 1:250 to about 1:600, and even more preferably about 1:400.
>
> The lyophilised material is usually presented in a vial which contains a specified amount of ecteinascidin or *active compound*. When the *active compound* is ET-743, active amounts are illustrated by 250 μg and 1 mg.

'557 patent, col. 10, lines 56–65 (emphases added). The term "anti-tumor" is not used outside the claims either, although the related term "antitumoral" does appear thusly: "[i]n view of the potential of ET-743 formulations as *antitumoral* agents, there is a need to provide a formulation that can solve problems that conventional formulations and manufacturing methodologies do not address or do not completely solve." *Id*. at col. 3, lines 55–59.

As Defendants point out, the Background of the Invention section lists several exemplary ecteinascidin compounds, including ET-743, as well as ET-745 and ET-770. '557 Patent col. 1, lines 30–37. ET-743 is called out, however, as a "particularly preferred" compound for use in the invention. *Id*. at col. 8, lines 61–62. Moreover, formulations using ET-743 are the only ones for which the specification describes possible treatment uses. *Id*. at col. 11, lines 28–43. It is also the only active ingredient used in the examples of the '557 patent. *Id*. at col. 14, line 40–col. 27, line

55. From these statements, the specification appears to be consistent with the claims with respect to the special recognition afforded ET-743.

In contrast, ET-701 is absent from the list of exemplary ecteinascidin compounds identified in the Background of Invention section. '557 Patent col. 1, lines 30–37. Instead, consistent with the claims, the specification calls ET-701 out as the main impurity that is produced when ET-743 is lyophilized and stored. *Id*. at col. 3, lines 12–34. It also includes two statements that the Court finds worthy of noting. The first is set out in the Details of Invention section.

> When embodiments of this invention are to provide ET-743 formulations that are substantially free of other ecteineascidins such as ET-701, or at least with a content of ET-701 as low as possible, then ET-701 is regarded as an impurity whose presence in the formulation is to be at least reduced.

Id. at col. 5, lines 11–15 (emphases added). This paragraph makes clear, again, that ET-701 is an undesired impurity. It is especially telling because this language is consistent with the claims' language setting limits on ET-701.

In a second paragraph of interest, the specification suggests its view of ET-745 in the exemplified formulations.

> Embodiments of formulations according to this invention were tested after storage under a plurality of storage conditions . . . *Total impurities, including ET-701, ET-745, and other impurities* did not exceed 1.66% after 9 months of storage at 25°C/60% RH.

Id. at col. 27, lines 37–47. This language confirms that, in the context of the invention, ET-745, like ET-701, is viewed as an impurity. In short, the Court concludes that while the specification may broadly contemplate other ET compounds as an active ingredient for the formulations of the invention, the specification more specifically supports the plain and ordinary meaning of the claim, under which ET-743 is the sole active anti-tumor compound. On the whole, and for the purposes

of claim construction, the Court finds that the specification does support giving "a single active anti-tumor compound" its plain and ordinary meaning of "a single active anti-tumor compound."

In comparison, Defendants' proposed construction of "single compound possessing anti-tumor properties" finds only meager support in the specification. Beyond bald assertions that a POSA would read the disputed phrase this way, Defendants offer little explanation for why the word "active" requires clarification or why the active compound should be re-defined by the fact that it "possesses" the quality of antineoplastic activity. Moreover, the notion that the active compound "possesses" activity appears only once in the specification, in the Background of the Invention. *See* Def. Op. Br. at 11 (quoting '557 Patent at 2:10).

Plaintiffs' alternative construction, "a single compound providing the anti-tumor activity of the composition" fares no better. In summary fashion, Plaintiffs review the specification in general, then conclude without reference to the specification for their proposed language, that a "POSA reading the specification of the patent would have understood, consistent with claims 1 and 22, that 'a single active anti-tumor compound" means that ET-743 is the single anti-tumor compound providing anti-tumor activity to the composition." Plf. Op. Br. at 10 (citing Declaration of Cory Berkland, Ph.D.).

In short, the Court finds that the specification favors assigning the plain and ordinary meaning to the phrase "a single active anti-tumor compound."

3. The Prosecution History

Other than to observe that it is consistent with the other intrinsic evidence, the Court does not examine the prosecution history in depth because the parties are essentially in agreement that during the prosecution of the application that led to the '557 patent, the applicants excluded from their claims any composition containing more than one active anti-tumor compound. Def. Op. Br. at 15; Plf. Op. Br. at 11 ("Applicants made clear that the amendment was meant to exclude from

the scope of the claim lyophilized compositions that included combinations of anti-tumor drugs."); Def. Resp. Br. at 12; Plf. Resp. Br. at 13.

4. Claim Construction vs. Infringement

The crux of the parties' dispute appears to be at what point a compound with anti-tumor activity that is present in an accused product transitions from being an impurity to being a second active ingredient. *See* Plf. Op. Br. at 12 ("Natco seeks to rewrite the claims to create a noninfringement argument."); Def. Op. Br. at 11 ("Because Plaintiffs' construction seeks to cover a lyophilized composition containing two or more of ET-743, ET-745, and ET-770, each of which possesses anti-tumor properties, such a construction should be rejected."); Def. Resp. Br. at 11 ("In fact, Plaintiffs' construction appears to allow any amount of a second active anti-tumor compound as long as Plaintiffs also call that second active anti-tumor compound an 'impurity.'"); Plf. Resp. Br. at 1 ("Natco's claim construction disregards the intrinsic evidence and has a single litigation-inspired purpose—to read out the word 'active' from the claim in an attempt to capture known, impossible impurities of ET-743 as alleged second, third and fourth 'active anti-tumor compounds.' This is a meritless bid for noninfringement.") This is not an issue of claim construction. It is an infringement issue that would be premature for the Court to address at this stage of the proceedings. *See Chemours Co. v. Daikin Indus. Ltd.*, Civ. No. 17-1612, 2022 WL 605357, at *9 n.9 (D. Del. Jan. 13, 2022) (*quoting PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1355 (Fed. Cir. 1998)(a district court may not "under the rubric of claim construction, give a claim whatever additional precision or specificity necessary to facilitate a comparison between the claim and the accused product" . . . "determining whether the construed claim construction reads on the accused product is for the finder of fact.")) (interior quotation marks omitted); *Dow Chemical Co. v. NOVA Chemicals Corp. (Canada)*, 629 F. Supp. 2d 397, 408 (D. Del. 2009) (rejecting the defendant's argument as a premature request to address an infringement issue); *Eisai*

Co., Ltd. v. Glenmark Pharm., Ltd., Civ. No. 13-1279, 2015 WL 1228958, at *8 n.8 (D. Del. Mar. 17, 2015) (setting aside infringement questions raised in the context of claim construction for later determination by the factfinder); *Bayer AG v. Sony Electronics, Inc.*, 229 F. Supp. 2d 332, 334 (D. Del 2002) (declining to address factual infringement questions during the Court's legal claim construction process).

For this reason, the Court concludes its claim construction of "a single active anti-tumor compound" by giving its ordinary meaning of "a single active anti-tumor compound" and declines to proceed into what it perceives as an advisory infringement analysis.[6]

On a related point, the Court recognizes that Defendants criticize Plaintiffs' first position, "plain and ordinary, i.e., no construction," as "insincere because it fails to resolve an important dispute concerning the scope of the claims." Def. Op. Br. at 7 (citing *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). The Court notes that this does not prohibit its conclusion. As a first matter, *O2 Micro* is inapposite here because in that case the concerns raised by the court of appeals stemmed from the trial court's improper shift of the burden of claim construction to a jury, whereas this matter will be tried as a bench trial. *See O2 Micro*, 521 F.3d at 1360 ("When the parties raise an actual dispute regarding the proper scope of these claims, the court, not the jury, must resolve this dispute.") As a second and more practical matter, the Court is not assigning "no construction" to the disputed phrase; it is electing to proceed with the language of the claims which it finds to be sufficiently clear.

[6] Insofar as the Court has reached its conclusion based on the intrinsic evidence, its analysis can end without proceeding to the extrinsic evidence. *Vitronics*, 90 F.3d at 1584. Moreover, as set forth above, the parties agreed at the *Markman* hearing that the Court did not need to resort to extrinsic evident to construe the disputed phrase.

V. CONCLUSION

For the foregoing reasons, the Court will construe the disputed and stipulated terms of the patents in suit in accordance with the table below. An appropriate Order will follow.

TERM	COURT'S CONSTRUCTION
"a single active anti-tumor compound"	"a single active anti-tumor compound" (*i.e.*, plain meaning)
"a Pictet-Spengler reaction" (stipulated)	"an organic reaction used to convert a β-arylethylamine and a carbonyl compound to a tetrahydroisoquinoline using an acid catalyst"

DATED: April 7, 2022

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE