IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,	§	
	§	
Plaintiff,	§	
	§	
v.	§	CIVIL ACTION NO. 2:20-CV-00337-JRG
	§	
DAIICHI SANKYO CO., LTD.,	§	
	§	
Defendant,	§	
	§	
ASTRAZENECA PHARMACEUTICALS LP, and ASTRAZENECA UK LTD	§	
	§	
Intervenor-Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is the opening claim construction brief of Plaintiff Seagen Inc. ("Plaintiff") (Dkt. No. 121), the response of Defendant Daiichi Sankyo Co., Ltd. and Intervenor-Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca UK Ltd. (collectively, the "Defendants") (Dkt. No. 130, filed on July 30, 2021), and the reply of Plaintiff (Dkt. No. 135, filed on August 6, 2021). The Court held a claim construction hearing on August 27, 2021 (*see* Dkt. No. 149). Having considered the arguments and evidence presented by the parties at the hearing and in their claim construction briefing, the Court issues this Claim Construction Order.

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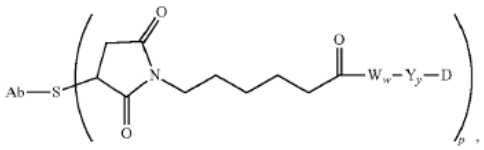
I. BACKGROUND

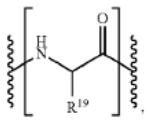
Plaintiff brings suit alleging infringement of U.S. Patent No. 10,808,039 ("the '039 Patent"). The '039 Patent is entitled "Monomethylvaline Compounds Capable of Conjugation to Ligands." The application leading to the '039 Patent was filed on July 10, 2019 and issued on October 20, 2020, and it is a continuation application of a series of patent applications and patents that ultimately claims priority to a provisional patent application filed on November 6, 2003.

The '039 Patent relates to a particular type of molecule known as an antibody-drug conjugate ("ADC"). '039 Patent at 1:58-2:3. The disclosed ADC enables the delivery of chemotherapeutic drugs directly to cancer cells by linking them to antibodies. *See id.* at 1:58-3:14. As described generally in the specification and in claim 1, an ADC composes primary components that interact together, including (1) an antibody (Ab) connected to (2) a drug moiety (D) via (3) a linker (A-W-Y). The parties dispute the meaning of terms within claims 1 and 2 of the '039 Patent. Claim 1 is the sole independent claim in the '039 Patent and is reproduced below:

1. An antibody-drug conjugate having the formula:



or a pharmaceutically acceptable salt thereof, wherein:
Ab is an antibody,
S is sulfur,
each —W_w— unit is a tetrapeptide; wherein each —W— unit is independently an Amino Acid unit having the formula denoted below in the square bracket:



wherein R^{19} is hydrogen or benzyl,

Y is a Spacer unit,
y is 0, 1 or 2,
D is a drug moiety, and
p ranges from 1 to about 20,

wherein the S is a sulfur atom on a cysteine residue of the antibody, and
wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate.

The Abstract of the '039 Patent is reproduced below:

> Auristatin peptides, including MeVal-Val-Dil-Dap-Norephedrine (MMAE) and MeVal-Val-Dil-Dap-Phe (MMAF), were prepared and attached to Ligands through various linkers, including maleimidocaproyl-val-cit-PAB. The resulting ligand drug conjugates were active in vitro and in vivo.

II. LEGAL PRINCIPLES

A. Claim Construction

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips*, 415 F.3d 1303 at 1312 (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004)). The Court first examines a patent's intrinsic evidence to define the patented invention's scope. *Id.* at 1313–14; *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001). Intrinsic evidence includes the claims themselves, the specification and the prosecution history. *Phillips*, 415 F.3d at 1312–13; *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 861 (Fed. Cir. 2004). The general rule—subject to certain specific exceptions discussed *infra*—is that each claim term is construed according to its ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the patent. *Phillips*, 415 F.3d at 1312–13; *Alloc, Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003); *see also Azure Networks, LLC v. CSR PLC*, 771 F.3d 1336, 1347 (Fed. Cir. 2014) ("There is a heavy presumption that claim terms carry their accustomed meaning in the relevant community at the relevant time.").

"The claim construction inquiry. . . begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). "[I]n all aspects of claim construction, 'the name of the game is the claim.'" *Apple Inc. v.*

Motorola, Inc., 757 F.3d 1286, 1298 (Fed. Cir. 2014) (quoting *In re Hiniker Co.*, 150 F.3d 1362, 1369 (Fed. Cir. 1998)). First, a term's context in the asserted claim can be instructive. *Phillips*, 415 F.3d at 1314. Other asserted or unasserted claims can also aid in determining the claim's meaning, because claim terms are typically used consistently throughout the patent. *Id.* Differences among the claim terms can also assist in understanding a term's meaning. *Id*. For example, when a dependent claim adds a limitation to an independent claim, it is presumed that the independent claim does not include the limitation. *Id*. at 1314–15.

"[C]laims 'must be read in view of the specification, of which they are a part.' " *Id*. (quoting *Markman v. Westview Instruments, Inc*., 52 F.3d 967, 979 (Fed. Cir. 1995)). "[T]he 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.'" *Id*. (quoting *Vitronics Corp. v. Conceptronic, Inc*., 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex, Inc. v. Ficosa N. Am. Corp*., 299 F.3d 1313, 1325 (Fed. Cir. 2002). In the specification, a patentee may define his own terms, give a claim term a different meaning than it would otherwise possess, or disclaim or disavow some claim scope. *Phillips*, 415 F.3d at 1316. Although the Court generally presumes terms possess their ordinary meaning, this presumption can be overcome by statements of clear disclaimer. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc*., 242 F.3d 1337, 1343–44 (Fed. Cir. 2001). This presumption does not arise when the patentee acts as his own lexicographer. *See Irdeto Access, Inc. v. EchoStar Satellite Corp*., 383 F.3d 1295, 1301 (Fed. Cir. 2004).

"Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims." *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1187 (Fed. Cir.

1998) (quoting *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see also Phillips*, 415 F.3d at 1323. "[I]t is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004).

The prosecution history is another tool to supply the proper context for claim construction because, like the specification, the prosecution history provides evidence of how the U.S. Patent and Trademark Office ("PTO") and the inventor understood the patent. *Phillips*, 415 F.3d at 1317. However, "because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Id.* at 1318; *see also Athletic Alternatives, Inc. v. Prince Mfg.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (ambiguous prosecution history may be "unhelpful as an interpretive resource").

Although extrinsic evidence is useful, it is "less significant than the intrinsic record in determining the legally operative meaning of claim language." *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard, Inc.*, 388 F.3d at 862) (internal quotation marks omitted). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *Id.* at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition are not useful. *Id.* Generally, extrinsic evidence

is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id*.

B. Departing from the Ordinary Meaning of a Claim Term

There are "only two exceptions to [the] general rule" that claim terms are construed according to their plain and ordinary meaning: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of the claim term either in the specification or during prosecution." *Golden Bridge Tech., Inc. v. Apple Inc.*, 758 F.3d 1362, 1365 (Fed. Cir. 2014) (quoting *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012)); *see also GE Lighting Solutions, LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014) ("[T]he specification and prosecution history only compel departure from the plain meaning in two instances: lexicography and disavowal."). "The standards for finding lexicography or disavowal are 'exacting.' " *GE Lighting Solutions*, 750 F.3d at 1309.

To act as his own lexicographer, the patentee must "clearly set forth a definition of the disputed claim term," and "clearly express an intent to define the term." *Id.* (quoting *Thorner*, 669 F.3d at 1365); *see also Renishaw*, 158 F.3d at 1249. The patentee's lexicography must appear "with reasonable clarity, deliberateness, and precision." *Renishaw*, 158 F.3d at 1249.

To disavow or disclaim the full scope of a claim term, the patentee's statements in the specification or prosecution history must amount to a "clear and unmistakable" surrender. *Cordis Corp. v. Boston Sci. Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009); *see also Thorner*, 669 F.3d at 1366 ("The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope."). "Where an applicant's statements are amenable

to multiple reasonable interpretations, they cannot be deemed clear and unmistakable." *3M Innovative Props. Co. v. Tredegar Corp.*, 725 F.3d 1315, 1326 (Fed. Cir. 2013).

C. Definiteness Under 35 U.S.C. § 112, ¶ 2 (pre-AIA)/§ 112(b) (AIA)

Patent claims must particularly point out and distinctly claim the subject matter regarded as the invention. 35 U.S.C. § 112, ¶ 2. A claim, when viewed in light of the intrinsic evidence, must "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 910 (2014). If it does not, the claim fails § 112, ¶ 2 and is therefore invalid as indefinite. *Id.* at 901. Whether a claim is indefinite is determined from the perspective of one of ordinary skill in the art as of the time the application for the patent was filed. *Id.* at 911. As it is a challenge to the validity of a patent, the failure of any claim in suit to comply with § 112 must be shown by clear and convincing evidence. *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360, 1365 (Fed. Cir. 2017). "[I]ndefiniteness is a question of law and in effect part of claim construction." *ePlus, Inc. v. Lawson Software, Inc.*, 700 F.3d 509, 517 (Fed. Cir. 2012).

"When a 'word of degree' is used, the court must determine whether the patent provides 'some standard for measuring that degree.'" *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374, 1378 (Fed. Cir. 2015). "'Reasonable certainty' does not require 'absolute or mathematical precision.'" *BASF*, 875 F.3d at 1365, quoting *Biosig*, 783 F.3d at 1381. Likewise, when a subjective term is used in a claim, the "court must determine whether the patent's specification supplies some standard for measuring the scope of the [term]." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1351 (Fed. Cir. 2005). The standard "must provide objective boundaries for those of skill in the art." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014).

III. CONSTRUCTION OF DISPUTED TERMS

The parties' positions and the Court's analysis as to the disputed terms within the claims of the Asserted Patent are presented below.

"D is a drug moiety"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Plain meaning/no construction is necessary. Alternatively: "D is a drug portion."	"a drug of the dolastatin/auristatin-type having a nitrogen atom that can form a bond with the Spacer unit when y=1 or 2, or with the C-terminal carboxyl group of an Amino Acid unit when y=0"

(1) The Parties' Positions

Plaintiff argues that the term is readily understood and does not need construction. *See, e.g.*, Dkt. No. 121, Plaintiff's Opening Claim Construction Brief, at 8–11. Plaintiff argues that, to the extent helpful for jurors, the "moiety" term could be construed as "portion." *Id.* at 8. Plaintiff argues that Defendants' construction adds limitations that do not appear in the claim and do not comport with the plain meaning of the term. *Id.* In particular, Defendants' construction limits the term to drugs "of the dolastatin/auristatin-type" and to drug-linkages involving a "nitrogen atom." *Id.* Plaintiff argues that Defendants' construction contradicts the intrinsic evidence. *Id.* at 9–10. Plaintiff argues that the extrinsic evidence confirms the plain meaning of the term (as proposed by Plaintiff). *Id.* at 11.

Defendants argue that the term was given a specific definition in the specification, and thus lexicography governs. *See, e.g.*, Dkt. No. 130, Defendants' Responsive Claim Construction Brief, at 7–14. Defendants argue that several paragraphs in Section 9.4 of the specification on the drug moiety term evidences lexicographic intent. *Id.* at 8–11. Defendants further argue that Plaintiff's technical expert confirmed in testimony that a definition of the drug moiety could be found in this

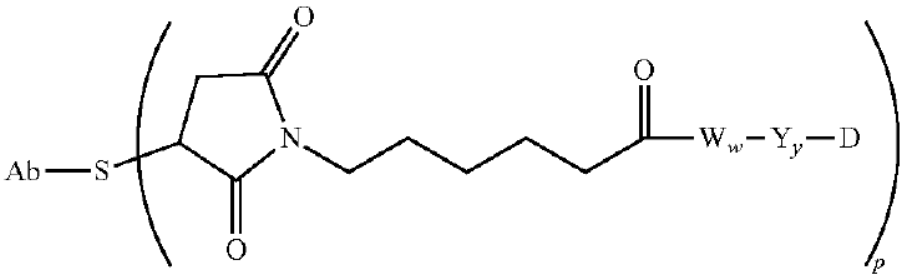
section. *Id.* at 11–12. Defendants argue that Plaintiff's intrinsic and extrinsic evidence citations do not override the lexicographical definition. *Id.* at 12–13.

In its Reply, Plaintiff argues that the term needs no construction. *See, e.g.*, Dkt. No. 135, Plaintiff's Reply Claim Construction Brief, at 1–4. Plaintiff argues that there is no clear intent to redefine the term, and the references to a particular type of drug is merely an embodiment. *Id.* Plaintiff argues that its expert did not agree to the construction offered by Defendants. *Id.* at 3.

(2) Analysis

The parties dispute whether the term has its plain and ordinary meaning. In particular, the parties dispute whether a different meaning to the term is warranted based on the specification and an alleged lexicographical definition.

Claim 1 requires an antibody-drug conjugate (ADC) having the following formula:



Claim 1 specifies that "D is a drug moiety." The claims, by themselves, do not specify or require that the drug be limited to a dolastatin/auristatin-type drug, or that it has a nitrogen atom that can form a bond to a spacer unit.

The patent is entitled "Monomethylvaline Compounds Capable of Conjugation to Ligands," which appears to be a reference to dolastatin/auristatin-type drugs. The Abstract of the '039 Patent mentions "auristatin peptides." The background section of the patent teaches that antibody-drug conjugates (ADCs) can be delivered with particular agents or drugs (*e.g.*, a drug

moiety) to kill or inhibit tumor cells for cancer treatment. '039 Patent, 2:43–49. The background section provides many different examples of drugs that can be used, including dolastatin type drugs and auristatin type drugs. *See id.* at 2:43–4:20. The background specification teaches that "there is a clear need in the art for dolastatin/auristatin derivates having significantly lower toxicity yet useful therapeutic efficiency." *Id.* at 4:23–27. The Summary of the Invention section and Section 9.2 (the Compounds of the Invention section) likewise are directed to dolastatin/auristatin type drug moieties. *See id.* at 6:31–67, 7:43–57; 44:57–45:25). Most of the specification is directed to dolastatin/auristatin type drugs. While the specification provides numerous examples of drugs that are not limited to a dolastatin/auristatin-type drug (*see id.* at 31:39–33:31), Defendants dispute that these are drugs in relation to a drug moiety as opposed to general chemotherapeutic agents in addition to the claimed drug. Overall, it is clear that a primary embodiment of the patent is dolastatin/auristatin-type drugs, but it is not clear that the invention is necessarily limited to such drugs.

The specification discusses the Drug Unit (Moiety) in Section 9.4 and provides a description of the drug moiety with the following language:

> **The drug moiety (D)** of the antibody drug conjugates (ADC) are of the dolastatin/auristatin type (U.S. Pat. Nos. 5,635,483; 5,780,588) which have been shown to interfere with microtubule dynamics, GTP hydrolysis, and nuclear and cellular division (Woyke et al. (2001) Antimicrob. Agents and Chemother. 45(12):3580-3584) and have anti-cancer (U.S. Pat. No. 5,663,149) and antifungal activity (Pettit et al. (1998) Antimicrob. Agents Chemother. 42:2961-2965)
>
> D is a Drug unit (moiety) having a nitrogen atom that can form a bond with the Spacer unit when y=1 or 2, with the C-terminal carboxyl group of an Amino Acid unit when y=0, with the carboxyl group of a Stretcher unit when w and y=0, and with the carboxyl group of a Drug unit when a, w, and y=0. **It is to be understood that the terms "drug unit" and "drug moiety" are synonymous and used interchangeably herein.**

'039 Patent, 71:20–37 (emphasis added). The specification states that a "drug unit" is synonymous with "drug moiety." *Id.* at 71:36–37. Defendants allege this section is a lexicographical definition of the term, while Plaintiff argues that it is not a lexicographical definition.

On balance, the Court is not persuaded by Defendants' arguments. In particular, the Court is not convinced that the section on drug moiety in section 9.4 of the specification is a lexicographical definition as opposed to a non-limiting embodiment. The patent specification provides a separate section for express definitions in Section 9.1, entitled "Definitions and Abbreviations," which provides many definitions of various terms. *See* '039 Patent, 21:55–44:53. In general, each paragraph in Section 9.1 provides a term and then defines it by using language such as the phrase "refers" to, "as used herein," or "means," or even "is" in some instances. Section 9.1 is clear that it is providing lexicographical definitions. In contrast, the language in Section 9.4 for "drug moiety" is more exemplary in format as opposed to definitional statements. On balance, the Court finds that the paragraphs in Section 9.4 relating to Defendants' proposed limitations are not definitional. While the specification mentions that a "drug moiety" is synonymous with "drug unit," such a comparison does not necessarily mean the other sentences contain lexicographical definitions. Further, the Court rejects Defendants' arguments relating to the testimony of Plaintiff's expert and finds that at no point did Plaintiff's expert agree that the drug moiety of claim 1 is limited to dolastatin/auristatin drugs.

Overall, Defendants' arguments and citations to the intrinsic evidence are not persuasive. First, the claim language does not require the limitations proposed by Defendants. Claim 1 simply requires D as a drug moiety. Nothing in the claim requires the drug to be a particular type of drug or have a nitrogen atom that bonds with the spacer unit. Had the patentee wanted to limit the claims to a particular drug or have particular limitations, it could have easily done so. Indeed, the

patentee did claim dolastatin/auristatin type drugs in prior related patents to the '039 Patent (*see* Plaintiff's Exhibits 27, 28 (U.S. Patent Nos. 7,994,135 and 8,703,714, respectively)), evidencing the fact that patentee did not intend to limit the broad drug moiety term in claim 1 of the '039 Patent. Overall, the fact that the claim does not limit the type of drug is highly persuasive. Second, the prosecution history supports Plaintiff's construction. There is no disavowal or disclaimer in the prosecution history, and no evidence that the Examiner considered the meaning of the drug moiety D to be important. In particular, the Examiner applied prior art drugs that were not limited to non-dolastatin/auristatin-type drugs. *See* November 6, 2019 Office Action on the '039 Patent at 4 (Examiner finding that D could be the drug moiety "doxorubicin"). In other words, the Examiner did not understand the drug moiety to be limited to dolastatin/auristatin-type drugs or have the limitations proposed by Defendants. Third, as discussed in more detail above, the Court finds that there is no lexicography, disavowal or disclaimer in the specification to require the limitations suggested by Defendants. While there are certainly embodiments within the patent that reference a drug having a nitrogen atom for bonding or being of a dolastatin/auristatin-type drug, at no point do they rise to the level of a disclaimer, disavowal, or lexicographical definition. Defendants' relied upon portions of the specification do not otherwise equate or limit the "drug" term to the limitations proposed by the Defendants. At best, they are non-limiting embodiments that should not be imported into the claims. The Federal Circuit has consistently held that "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova/Pure Water,* 381 F.3d at 1117. Even where a patent describes only a single embodiment, absent a "clear intention to limit the claim scope," it is improper to limit the scope of otherwise broad claim language by resorting to a patent's specification. *Id.*; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir.

2004) (citing numerous cases rejecting the contention that the claims of the patent must be construed as being limited to the single embodiment disclosed and stating that claims are to be given their broadest meaning unless there is a clear disclaimer or disavowal); *Comark Commc'ns, Inc. v. Harris Corp.,* 156 F.3d 1182, 1187 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims."); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) ("even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction."); *Phillips*, 415 F.3d at 1323.

Defendants admit that they do not disagree about the ordinary meaning of "drug moiety" outside the context of the specification. *See* Defendants' Responsive Brief at 7. The Court finds that a plain and ordinary meaning construction for this disputed term is consistent with the intrinsic record. The Court finds that one of ordinary skill in the art, based upon the specification and the claims, would understand the disputed term to have its plain and ordinary meaning. Outside the context of the specification, the "moiety" term is widely understood to people of skill in the art. *See* McGraw-Hill Dictionary of Scientific and Technical Terms, 6th Ed., Ex. 11 of Plaintiff's Opening Brief ("moiety: a part or portion of a molecule, generally complex, having a characteristic chemical or pharmacological property."); *see also* Trail Declaration ¶¶ 24–25. The use of the "drug moiety" term in the claims and in the specification is consistent with the plain meaning of the term. Nevertheless, while a plain meaning approach might be appropriate, the Court finds that a construction as to this term would be helpful to resolve the dispute between the parties. The patent specification equates "drug moiety" with "drug unit" in Section 9.4 and repeatedly uses

"drug unit" throughout the specification. The Court finds that the specification equates "drug moiety" to "drug unit," which is consistent with the plain meaning of the term.

Because this resolves the dispute between the parties, the Court finds that no other terms within the disputed phrase requires further construction. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims.") (*citing U.S. Surgical*, 103 F.3d at 1568).

The Court hereby construes the phrase "**D is a drug moiety**" to mean **"D is a drug unit."**

"Y is a spacer unit"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Plain meaning/no construction is necessary. Alternatively: "Y is a unit that links the amino acid unit to a drug."	"one or more atoms that links W_w to a nitrogen atom of D, the drug moiety"

(1) The Parties' Positions

Plaintiff argues that the term is readily understood and does not need construction. *See, e.g.*, Dkt. No. 121, Plaintiff's Opening Claim Construction Brief, at 5–7. Plaintiff argues that the term "Y is a Spacer unit" refers to the part of an ADC that links an amino acid unit to a drug unit. *Id.* at 5. Plaintiff argues that "spacer unit" is a commonly understood term within the field of ADCs and it does not require construction. *Id.* Plaintiff argues that Defendants' construction adds limitations that do not appears in the claim and do not comport with the plain meaning of the term.

Id. Plaintiff argue that Defendants' construction contradicts the intrinsic evidence. *Id.* at 6. Plaintiff argues that extrinsic evidence confirms the plain meaning of the term (as proposed by Plaintiff). *Id.* at 7.

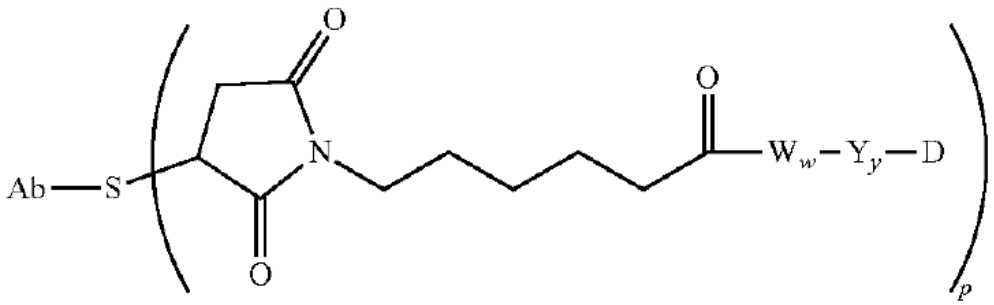
Defendants argue that its proposed construction provides a structural limitation to the component in view of the claim language and the specification's disclosure. *See, e.g.*, Dkt. No. 130, Defendants' Responsive Claim Construction Brief, at 14–17. Defendants argue that their construction is warranted by the disclosures within the specification showing that a spacer unit is linked to a nitrogen atom on the drug unit. *Id.* at 14. Defendants argue that Plaintiff's relied upon specification citations are not persuasive. *Id.* at 15. Defendants argue that Plaintiff's construction does not limit the structure of the spacer unit in any meaningful way. *Id.* at 16.

In its Reply, Plaintiff argues that the term needs no construction. *See, e.g.*, Dkt. No. 135, Plaintiff's Reply Claim Construction Brief, at 4–6. Plaintiff argues that Defendants' arguments fail for the same reason the arguments to the "drug moiety" term fail. *Id.* at 4. Plaintiff argues that Defendants' construction excludes embodiments from the specification. *Id.* at 4-5. Plaintiff also argues that the mere fact the term includes functional language does not automatically convert it into a means-plus-function limitation. *Id.* at 5.

(2) Analysis

The parties dispute whether the term has its plain and ordinary meaning. The dispute between the parties is whether the term is limited to an embodiment in the specification, and in particular, whether the spacer unit must connect to a nitrogen atom of D.

Claim 1 requires an antibody-drug conjugate (ADC) having the following formula:



Claim 1 specifies that "Y is a Spacer unit" and "y is 0, 1, or 2." Claim 2 specifies that Y is a "self-immolative spacer." The claims, by themselves, do not specify or require that the spacer unit is linked to a nitrogen atom of D.

Section 9.3.3 of the patent specification discusses the "Spacer Unit (Y)." The specification is clear that the spacer unit (Y), when present, "links an Amino Acid unit to the Drug moiety when an Amino Acid unit is present." '039 Patent, 68:14–16. Alternatively, the spacer unit "links the Stretcher unit to the Drug moiety when the Amino Acid unit is absent." *Id.* at 63:16–17. The spacer unit also "links the Stretcher unit to the Drug moiety when the Amino Acid unit is absent." *Id.* at 68:18-19. The specification teaches that a "spacer unit" is one component within a linker unit and that a "linker unit" or "link" means a "chemical moiety comprising a covalent bond or a chain of atoms that covalently attaches an antibody to a drug moiety." *Id.* at 40:9–11; 63:16–35. While the parties disagree as to the effects of these disclosures, there are examples in the specification that show a spacer unit connected to groups on a drug that do not contain a nitrogen atom (relied upon by Plaintiff), as well as examples that show it connected to a nitrogen atom (relied upon by Defendants).

On balance, the Court is not persuaded by Defendants' arguments, and rejects Defendants' arguments and citations to the intrinsic evidence. First, the claim language does not require the

limitations proposed by the Defendants. Nothing in the claim requires the spacer unit to link the amino acid to a nitrogen atom of D. Second, the fact that the definition/construction uses the word "links" (which is functional) does not necessarily make the term a means-plus-function limitation and does not require the structural nitrogen component proposed by Defendants—the Court rejects Defendants' arguments to the contrary. Indeed, Defendants' own construction provides functional linking language as the definition of the term, and to the extent Defendants criticize Plaintiff's construction for providing functional language, Defendants' own construction is likewise problematic. The fact that a limitation may include functional language in its construction is not improper and does not necessarily convert the term into a means-plus-function limitation. *See, e.g., Nevro Corp. v. Boston Scientific Corp.*, 955 F. 3d 35, 39 (Fed. Cir. 2020) (rejecting an indefiniteness argument and finding that "'paresthesia-free' is a functional term, defined by what it does rather than what it is…[b]ut that does not inherently render it indefinite."); *see also Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1008 (Fed. Cir. 2018) ("the mere fact that the disputed limitations incorporate functional language does not automatically convert the words into means for performing such functions"), *citing Greenberg v. Ethicon Endo-Surgery, Inc.*, 91 F. 3d 1580, 1583 (Fed. Cir. 1996). Third, the Court finds that there is no lexicography, disavowal or disclaimer in the specification to require the limitations suggested by Defendants. Defendants' relied upon portions of the specification do not otherwise equate or limit the "spacer unit" term to the limitations proposed by the Defendants. At best, they are non-limiting embodiments that should not be imported into the claims. The Federal Circuit has consistently held that "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova/Pure Water,* 381 F.3d at 1117. Even where a patent describes only a single embodiment, absent a "clear intention to limit the claim scope," it is improper to limit the

scope of otherwise broad claim language by resorting to a patent's specification. *Id.*; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (citing numerous cases rejecting the contention that the claims of the patent must be construed as being limited to the single embodiment disclosed and stating that claims are to be given their broadest meaning unless there is a clear disclaimer or disavowal); *Comark Commc'ns, Inc. v. Harris Corp.,* 156 F.3d 1182, 1187 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims."); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) ("even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction."); *Phillips*, 415 F.3d at 1323.

On balance, while a plain meaning approach might be appropriate, the Court finds that a construction as to this term is necessary to resolve the dispute between the parties. The specification clearly states that the spacer unit "links an amino acid unit to the drug moiety when an amino acid unit is present." '039 Patent, 68:14–16. The specification could not be clearer as to what is meant by the "spacer unit" term. Consistent with the specification and the claim, the Court finds that Y links an amino acid unit to the drug unit. The Court finds that while the spacer unit may link the amino acid (W) to the drug (D) by a nitrogen atom, it is not required to do so and is not a proper limitation as to the "spacer unit" term itself. Further, the Court rejects Defendants' arguments for the same reasons that it rejects Defendants' arguments on the separate "drug moiety" term.

The Court hereby construes the phrase "**Y is a spacer unit**" to mean **"Y is a unit that links the amino acid (W) unit to the drug (D)."**

"wherein Y is a self-immolative spacer"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Plain meaning/no construction is necessary. Alternatively: "wherein Y is a spacer that degrades to release the drug after cleavage of the amino acid unit."	"wherein the drug moiety is released from Y without a separate hydrolysis step"

(1) The Parties' Positions

Plaintiff argues that the term is readily understood and does not need construction. *See, e.g.*, Dkt. No. 121, Plaintiff's Opening Claim Construction Brief, at 21–22. Plaintiff argues that the term refers to part of an ADC that degrades after cleavage of the amino acid unit to release the drug. *Id.* at 21. Plaintiff argues that Defendants' construction conflicts with the plain meaning of the term and narrows it to units that release the drug "without a separate hydrolysis step." *Id.* at 21. Plaintiff argue that Defendants' construction contradicts the intrinsic evidence and excludes embodiments. *Id.* at 21–22. Plaintiff argues that Defendants' construction is an impermissible limitation to an embodiment. *Id.* at 22. Plaintiff argues that extrinsic evidence confirms its construction. *Id.* at 22.

Defendants argue that the specification provides a specific meaning to the term. *See, e.g.*, Dkt. No. 130, Defendants' Responsive Claim Construction Brief, at 17–20. In particular, Defendants argue that the specification distinguishes a non self-immolative spacer unit to a self-immolative spacer unit, and by contrast, the self-immolative spacer unit can release the drug moiety without the need for a separate hydrolysis step. *Id.* Defendants argue that its construction

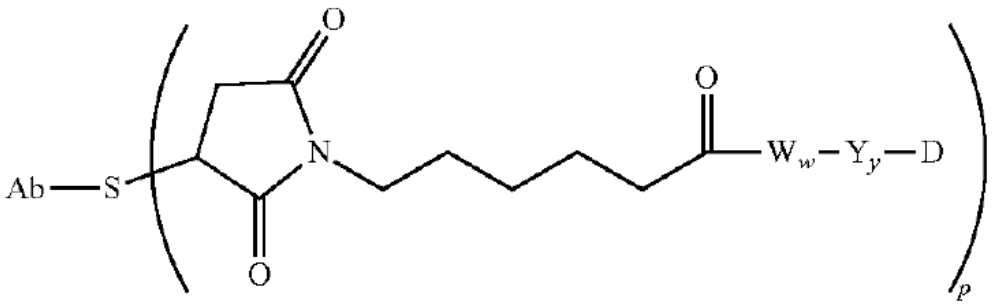
does not exclude any embodiments and is consistent with the specification. *Id.* at 20. Defendants argue that Plaintiff's construction is not supported by the intrinsic evidence and does nothing to differentiate a non self-immolative spacer unit to a self-immolative spacer unit. *Id.*

In its Reply, Plaintiff argues that Defendants' construction conflicts with the plain meaning of the term. *See, e.g.*, Dkt. No. 135, Plaintiff's Reply Claim Construction Brief, at 6–7. Plaintiff argues that one of skill in the art would understand the term to refer to the part of the ADC that degrades after cleavage of the amino acid unit to release the drug. *Id.* Plaintiff argues that Defendants' construction would exclude embodiments from the specification. *Id.*

(2) Analysis

The parties dispute whether the term has its plain and ordinary meaning. In particular, the parties dispute the effect and/or requirement of a separate hydrolysis step.

Claim 1 requires an antibody-drug conjugate (ADC) having the following formula:



Claim 1 specifies that "Y is a Spacer unit," and claim 2 specifies that Y is a "self-immolative spacer." The claims, by themselves, do not specify or require that the spacer unit undergo or not undergo a separate hydrolysis step to release the drug.

The specification notes that spacer units of the invention are of two general types: self-immolative and non self-immolative. '039 Patent at 68:20–21. A non self-immolative spacer

unit is one in which part or all of the spacer unit remains bound to the drug moiety after cleavage. *Id.* at 68:21–24. The specification provides various examples of a non self-immolative spacer unit, and in one embodiment, an independent hydrolysis reaction takes place within the target cell, cleaving the glycine-drug moiety bond and liberating the drug. *Id.* at 68:21–36. The specification also describes a self-immolative spacer unit as one that can release a drug moiety without the need for a separate hydrolysis step. *Id.* at 68:48–50. The specification provides multiple examples of self-immolative spacers that could be used in the context of the invention, which Plaintiff asserts can be used with a hydrolysis step. *Id.* at Figs. 21–23, 30–32; *see also* 21:5–13, 21:26–34, 68:48–70:17, 142:42–47, 147:52–57. Relevant to the parties' dispute, FIG. 20 describes reactions relating to a non self-immolative spacer, while FIG. 21 describes reactions relating to a self-immolative spacer. In particular, FIG. 20 mentions a first cleavage step followed by a separate hydrolysis step, while FIG. 21 shows a first cleavage step followed by a 1,6-elimination step.

On balance, the Court is not persuaded by Defendants' arguments to the specification. The Court is not convinced that the reference to "without the need for a separate hydrolysis step" in the specification is a limiting statement for the term, much less a lexicographical definition. The specification is clear that the relation of a hydrolysis reaction to the meaning of an immolative spacer is just an embodiment. *See* '039 Patent, 68:32–35; 68:48–51. In particular, the specification teaches that in one embodiment, an independent hydrolysis reaction takes place within the target cell for a non self-immolative spacer unit. *Id.* at 68:32–35. Likewise, the absence of a hydrolysis reaction is mentioned in reference to an embodiment of the self-immolative spacer unit. *Id.* at 68:48–51. On balance, the Court finds that the relation of a hydrolysis reaction to these terms is in the context of an embodiment of the specification and is not a limiting definitional statement or disclaimer. In other words, whether or not a hydrolysis step is used for a self-immolative spacer

or a non self-immolative spacer is not a definitional meaning to the term. The fact that a self-immolative spacer can release the drug without hydrolysis does not necessarily require the absence of a hydrolysis reaction.

Defendants' arguments and citations to the intrinsic evidence are not persuasive. First, the claim language does not require the limitations proposed by the Defendants. Nothing in the claim mentions a separate hydrolysis step. Second, the Court finds that there is no lexicography, disavowal or disclaimer in the specification to require the limitations suggested by Defendants. As described above, Defendants' relied on portion of the specification does not otherwise equate or limit the "self-immolative spacer" term to the limitations proposed by the Defendants. At best, it is a non-limiting embodiment that should not be imported into the claims. The Federal Circuit has consistently held that "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova/Pure Water,* 381 F.3d at 1117. Even where a patent describes only a single embodiment, absent a "clear intention to limit the claim scope," it is improper to limit the scope of otherwise broad claim language by resorting to a patent's specification. *Id*.; *see also Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (citing numerous cases rejecting the contention that the claims of the patent must be construed as being limited to the single embodiment disclosed and stating that claims are to be given their broadest meaning unless there is a clear disclaimer or disavowal); *Comark Commc'ns, Inc. v. Harris Corp.,* 156 F.3d 1182, 1187 (Fed. Cir. 1988) ("Although the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims."); *Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254 (Fed. Cir. 2011) ("even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee

has demonstrated a clear intention to limit the claim scope using words of expressions of manifest exclusion or restriction."); *Phillips*, 415 F.3d at 1323.

The Court finds that one of ordinary skill in the art, based on the specification and the claims, would understand the disputed term to have its plain and ordinary meaning. Nevertheless, to resolve the dispute between the parties, on balance, the Court finds that a construction as to the term is necessary and helpful. Plaintiff contends that the plain and ordinary meaning of the term is a spacer that degrades to release the drug after cleavage of the amino acid unit, and such a drug could be released through a hydrolysis step. Plaintiff provides evidence that the "self-immolative spacer" is a well understood term. For example, extrinsic evidence relied upon by Plaintiff describes a self-immolative spacer as one that decomposes and spontaneously releases the free drug following cleavage. Further, Plaintiff relies upon publications by Defendants that teach a self-immolative spacer can be hydrolyzed, resulting in the release of the drug. While extrinsic evidence may not be used to contradict an express definition or clear teaching in a patent, the Court finds that it may be used to confirm a construction that is consistent with the intrinsic evidence. The Court finds that such extrinsic evidence is helpful, and supports Plaintiff's position that hydrolysis may be used in conjunction with a self-immolative spacer. Further, the extrinsic evidence supports Plaintiff's construction that the spacer degrades to release the drug after cleavage. During the claim construction hearing, Plaintiff proposed the word "spontaneously" to be included in front of the term "degrades" in its proposed construction to help with the parties' dispute. The Court finds that the "spontaneous" word is supported in the extrinsic evidence and the specification. On balance, the Court finds that Plaintiff's construction provides an accurate understanding of the term based on the intrinsic record and the extrinsic record, differentiates a

self-immolative spacer from a non self-immolative spacer, and helps to resolve the dispute between the parties.

The Court hereby construes the phrase "**wherein Y is a self-immolative spacer**" in claim 2 to mean **"wherein Y is a spacer that spontaneously degrades to release the drug at a time after cleavage of the amino acid unit."**

"p ranges from 1 to about 20"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Plain meaning/no construction is necessary. A person of ordinary skill in the art would understand with reasonable certainty the scope of what is claimed. Alternatively: "The drug to antibody ratio ranges from 1 to about 20." The drug to antibody ratio, p, does not need to be an integer.	"p" must be an integer

(1) The Parties' Positions

Plaintiff argues that the term is readily understood and does not need construction. *See, e.g.*, Dkt. No. 121, Plaintiff's Opening Claim Construction Brief, at 12–13. Plaintiff argues that "p" is the "drug to antibody ratio of an ADC, and as commonly understood it refers to the average number of drug molecules per antibody. *Id.* at 12. Plaintiff argues that because it refers to an average, the ratio will often be a non-integer value. *Id.* Plaintiff argues that Defendants' construction does not comport with the plain meaning of the term. *Id.* Plaintiff argues that Defendants' construction contradicts the intrinsic evidence. *Id.* at 12–13. Plaintiff argues that extrinsic evidence confirms the plain meaning of the term (as proposed by Plaintiff). *Id.* at 13.

Defendants argue that the term must be an integer (whole number) because it is not possible to connect fractions of atoms to a molecule. *See, e.g.*, Dkt. No. 130, Defendants' Responsive Claim Construction Brief, at 24. Defendants argue that the specification's use of "p" as an average

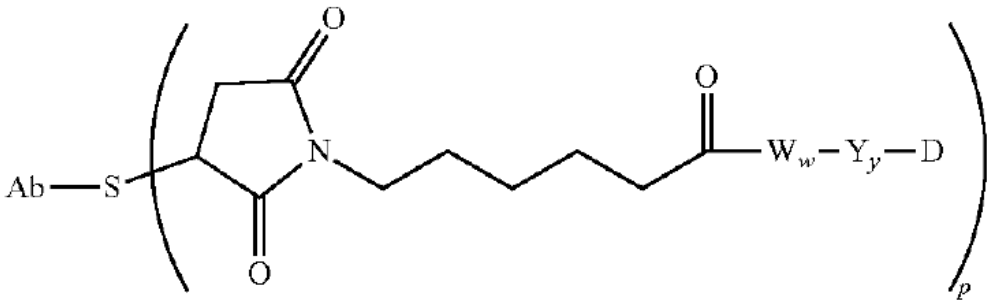
is in relation to a composition containing several ADCs, but claim 1 only requires a single ADC. *Id.* Because claim 1 requires a single ADC, it must have a p value that is an integer. *Id.* Defendants argue that the Plaintiff's expert confirms Defendants' construction and the use of the term "about" does not preclude "p" from being an integer. *Id.* at 24-25.

In its Reply, Plaintiff argues that this term needs no construction. *See, e.g.*, Dkt. No. 135, Plaintiff's Reply Claim Construction Brief, at 7–8. Plaintiff argues that the specification specifically defines the term to be the average number of drug molecules per antibody in a molecule, which is consistent with the understanding in the art. *Id.* at 7. Because it is an average, the ratio will often be a non-integer value. *Id.* Plaintiff argues that "a" in the claim can be applied to "one or more," including multiple ADC molecules. *Id.* at 8.

(2) Analysis

The parties dispute whether the term has its plain and ordinary meaning. In particular, the dispute is whether "p" must be an integer (*i.e.*, a whole number).

Claim 1 requires an antibody-drug conjugate having the following formula:



Claim 1 specifies that y is "0, 1, or 2", and that "p ranges from 1 to about 20." Dependent claim 3 specifies that "y is 1," dependent claim 4 specifies that "p is about 3 to about 8," and dependent claim 5 specifies that "p is about 8."

The patent specification provides meaning for the term "p:"

> **The drug loading is represented by p, the average number of drug molecules per antibody in a molecule** (e.g., of Formula Ia, Ia' and Ic). Drug loading may range from 1 to 20 drugs (D) per Ligand (e.g., Ab or mAb). Compositions of Formula Ia and Formula Ia' include collections of antibodies conjugated with a range of drugs, from 1 to 20. The average number of drugs per antibody in preparation of conjugation reactions may be characterized by conventional means such as mass spectroscopy, ELISA assay, and HPLC. The quantitative distribution of Ligand-Drug-Conjugates in terms of p may also be determined. In some instances, separation, purification, and characterization of homogeneous Ligand-Drug-conjugates where p is a certain value from Ligand-Drug-Conjugates with other drug loadings may be achieved by means such as reverse phase HPLC or electrophoresis.
>
> * * * * * *
>
> **The drug loading is represented by p, the average number of drugs per antibody in a molecule** of Formula I. Drug loading may range from 1 to 20 drugs (D) per antibody (Ab or mAb). Compositions of ADC of Formula I include collections of antibodies conjugated with a range of drugs, from 1 to 20. The average number of drugs per antibody in preparations of ADC from conjugation reactions may be characterized by conventional means such as UV/visible spectroscopy, mass spectrometry, ELISA assay, and HPLC. The quantitative distribution of ADC in terms of p may also be determined. In some instances, separation, purification, and characterization of homogeneous ADC where p is a certain value from ADC with other drug loadings may be achieved by means such as reverse phase HPLC or electrophoresis.
>
> **For some antibody drug conjugates, p may be limited by the number of attachment sites on the antibody.** For example, where the attachment is a cysteine thiol, as in the exemplary embodiments above, an antibody may have only one or several cysteine thiol groups, or may have only one or several sufficiently reactive thiol groups through which a linker may be attached.

'039 Patent, 51:33–48; 61:43–65 (emphasis added). The patent specification is clear that "p" is the average number of drugs per antibody in a molecule. *See id.* Further, the specification teaches that the drug to antibody ratio (drug loading) may be controlled in different manners:

> The loading (drug/antibody ratio) of an ADC may be controlled in several different manners, including: (i) limiting the molar excess of drug-linker intermediate or linker reagent relative to antibody, (ii) limiting the conjugation reaction time or temperature, and (iii) partial or limiting reductive conditions for cysteine thiol modification.

'039 Patent, 62:52–58.

The patent specification repeatedly provides examples of non-integer p values. For example, Figures 7–10 illustrate non-integer p values, such as 3.3, 3.7, 3.8, 3.9, 4.1, and 4.8 drug/AB ratios. *See also* '039 Patent, 19:63–20:19. FIG. 23 is describing m as being an integer ranging from 0-4, n is 0 or 1, and p ranges from 1 to about 20. *Id.* at 69:21-23. FIG. 36 illustrates a methodology for making drug-linker-ligand conjugates having "about 2 to about 4 drugs per antibody." *Id.* at 152:45–47. Various tables are illustrated showing the drug/antibody ratio as being a non-integer. *Id.* at 153:19–154:12.

On balance, the Court finds that the term "p" is the drug to antibody ratio and does not need to be an integer. The specification defines "p" as being the average number of drug molecules per antibody. '039 Patent, 51:33–48; 61:43–65. Because it is an average, it is quite possible—if not likely—that the ratio may be a non-integer value. Further, as referenced above, the specification has numerous examples of p having a non-integer value. At no point does the specification require p to be an integer. Further, the specification repeatedly references the "integer" of m or y, but never discusses an integer of "p" and merely provides ranges for "p." *See id.* at 63:18–64:3; 69:21– 23. Likewise, consistent with the specification, claim 1 specifies that y is 0, 1, or 2 (*i.e.*, an integer) but p ranges from 1 to about 20 (*i.e.*, does not have to be an integer). The Court finds that the different treatment in the intrinsic record—both in the specification and the claims—between y and p confirms that p need not be an integer.

This finding is confirmed by the extrinsic evidence. For example, various publications (including those by Defendants' scientists) relied upon by Plaintiff demonstrate that a drug to antibody ratio need not be an integer. While extrinsic evidence may not be used to contradict an

express definition or clear teaching in a patent, the Court finds that it may be used to confirm a construction based on the intrinsic evidence.

The Court is not persuaded by Defendants' arguments and rejects Defendants' construction. Defendants provide no good reason why the specification should be ignored. At best, Defendants argue that Plaintiff's construction is an attempt to change the plain text of the claim. In effect, Defendants argue that because the claim recites "an" ADC, it is limited to a single ADC (and not a population of ADC molecules) and it is not possible to connect fractions of atoms to a single molecule. The Court disagrees with Defendants' arguments, at least with respect to the meaning of the "p" term. While an individual ADC molecule may have a p value that is an integer, in the context of the specification and the claims—and a definition of the p term—the Court finds that one of skill in the art would understand that the p value of claim 1 may be a non-integer (*e.g.*, an average number of drug molecules per antibody).

On balance, the Court finds that a construction as to this term is necessary to resolve the dispute between the parties. Consistent with the intrinsic record, the Court finds that "p" is the drug to antibody ratio and that it need not be an integer. Because this resolves the dispute between the parties, the Court finds that no other terms within the disputed phrase requires further construction.

The Court hereby construes the phrase "**p ranges from 1 to about 20**" to mean **"p, the drug to antibody ratio, ranges from 1 to about 20 and does not need to be an integer."**

"wherein the S is a sulfur atom on a cysteine residue of the antibody"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Plain meaning/no construction is necessary. A person of ordinary skill in the art would understand with reasonable certainty the scope of what is claimed. Alternatively: "wherein S is a sulfur atom on a cysteine amino acid in the antibody."	Indefinite (the claim does not provide reasonable certainty at least regarding how the POSA would understand the scope of "a sulfur atom on a cysteine residue of the antibody" given that "p ranges from 1 to about 20") Alternatively, each of the p [parenthetical drug linker unit structure] are attached to a single sulfur atom.

(1) The Parties' Positions

Plaintiff argues that the term is readily understood and does not need construction. *See, e.g.*, Dkt. No. 121, Plaintiff's Opening Claim Construction Brief, at 14–18. Plaintiff argues that the term refers to the way that each drug-linker unit is attached to the antibody. *Id.* at 14. Plaintiff argues that a person of skill in the art would understand that this formula and the accompanying text describe attachment of each drug-linker unit to its own "cysteine residue" in the antibody, and that each individual cysteine residue would have a "sulfur atom" (denoted as an "S") available for creating the bond between the antibody and drug-linker unit. *Id.* Plaintiff argue that Defendants' construction requires every drug-linker unit "p" must bond with a single sulfur atom. *Id.* at 15. Plaintiff argues that Defendants' construction contradicts the intrinsic evidence. *Id.* at 15–16. Plaintiff argues that extrinsic evidence confirms Plaintiff's construction. *Id.* at 16–17. Plaintiff argues that Defendants have failed to meet its burden that the term is indefinite. *Id.* at 17–18.

Defendants argue that there is a difference in the claim language and the specification, and that Defendants' construction is true to the claim language while Plaintiff's construction is an attempt to rewrite the claim based on the specification. *See, e.g.*, Dkt. No. 130, Defendants' Responsive Claim Construction Brief, at 26–28. Defendants argue that by the claim placing the

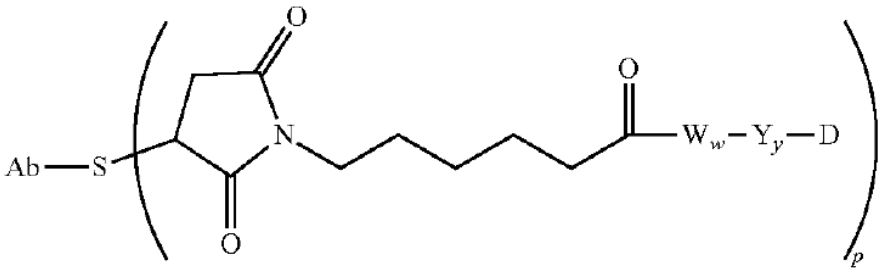
parenthesis between the S and linker-drug unit, the claim makes clear that each of the linker-drug units are connected to the same, single sulfur atom. *Id.* at 27. By contrast, the specification (column 70) places the parenthesis between Ab and the S, indicating that each linker-drug unit is connected to a different S, and then are connected to the same antibody. *Id.* Because sulfur is only able to form a bond with a single p unit, it cannot form a bond with up to 20 p units, and thus the claim language as written is indefinite. *Id.* Plaintiff argues that the Court should not re-write the claim to fix any indefinite issues. *Id.* at 28.

In its Reply, Plaintiff argues that the term is straightforward and does not need construction. *See, e.g.*, Dkt. No. 135, Plaintiff's Reply Claim Construction Brief, at 8–9. Plaintiff argues that it refers to the way each drug-linker unit is attached to the antibody, with each such unit being attached to its own cysteine residue in the antibody through a sulfur atom within the cysteine residue. *Id.* at 8. Plaintiff argues that Defendants' construction is nonsensical, and would require all drug-linker units to be attached to a single sulfur atom on a single cysteine. *Id.* Plaintiff argues that the significance of the parenthesis in a chemical structure is determined from the viewpoint of a skilled artisan. *Id.* Plaintiff argues that Defendants fail to provide any expert testimony on why the term is indefinite, and cannot meet its high burden to establish indefiniteness. *Id.* at 9. Plaintiff also argues that Defendants' own publications provide a similar diagram as found in claim 1. *Id.* at 9-10.

(2) Analysis

The parties dispute whether the term has its plain and ordinary meaning or is indefinite. In particular, the parties dispute whether all of the claimed parenthetical structure has to bond with a single sulfur atom or whether there can be multiple sulfur atoms, with each sulfur bonded to a separate claimed parenthetical structure.

Claim 1 requires an antibody-drug conjugate having the following formula:



Claim 1 specifies that Ab is an antibody, and that "S is a sulfur atom on a cysteine residue of the antibody." The formula within the parenthetical structure (Aa-Ww-Yy) is a drug linker unit, which is used to attach the drug (D) to the antibody (Ab). '039 Patent, 63:17–30. The "A" is a Stretcher Unit, which links a ligand unit (antibody) to an amino acid unit (W). *Id.* at 63:40–41. The "Y" is Spacer Unit that links the amino acid unit (W) to the drug moiety (D). *Id.* at 68:14–16. The parties dispute whether all of the parenthetical structures (up to 20 p units) are connected to a single sulfur atom or whether they can be connected to different sulfur atoms. The claim clearly requires the parenthetical structure to be attached to a sulfur atom. Based on the claim language itself, it is unclear whether the claim requires all of the parenthetical structures to be attached to a single sulfur atom or whether the parenthetical structures may be attached to different sulfur atoms.

The patent specification provides many different examples of a Stretcher Unit (A). The specification explains that each drug-linker unit is attached to its own sulfur atom. *See* '039 Patent, 63:54–56 ("the stretcher unit forms a bond with a sulfur atom of the ligand unit"); 64:53–55 ("the stretcher unit is linked to the ligand unit via a disulfide bond between a sulfur atom of the ligand unit and a sulfur atom of the stretcher unit"). In other words, the specification teaches that the linker forms a bond with a functional group, including sulfur, on the ligand (i.e., the antibody). *See id.* at 63:40–64:3. As discussed above in relation to the "p" term, the patent specification is

clear that "p" is the average number of drugs per antibody in a molecule. *Id.* at 61:43–65. The specification is clear that for some ADCs, "p may be limited by the number of attachment sites on the antibody." *Id.* at 61:59–60. "For example, where the attachment is a cysteine thiol, as in the exemplary embodiments above, an antibody may have only one or several cysteine thiol groups, or may have only one or several sufficiently reactive thiol groups through which a linker may be attached." *Id.* at 61:60–65. Thus, the patent teaches that the number of drug-linkers that can be attached is limited by the number of sufficiently reactive cysteine groups. *See id.* The specification teaches that each linker-drug unit is connected to a different sulfur atom. *Id.* at 50:57 (figure); 61:1-62:39 (figures); 70:23-27 (figure). At no point does the specification provide an example or suggest that more than one drug-linker can be attached to a single sulfur atom on a single cysteine. Based on the specification, it is clear that each of the parenthetical structures is attached to a different sulfur atom.

The Court is not persuaded by Defendants' arguments and rejects Defendants' construction. Defendants provide no good reason why the specification should be ignored. Nowhere does the specification suggest that more than one drug-linker can be attached to a single sulfur atom on a single cysteine. Defendants' sole argument is that the claim language trumps the specification, even if it renders an indefinite or non-sensical result, and even if it is contrary to the specification. In particular, Defendants argue that the specification provides an exemplary structure with the S inside the parenthetical (*see* 70:23–27), while the claim illustrates an S outside of the parenthetical. Based on this placement of the parenthesis, Defendants argue that every drug-linker unit must be attached to a single sulfur atom. In effect, Defendants argue that the claim language controls and must be given effect without regards to the intrinsic or extrinsic evidence, relying on *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004). The Court

rejects such an argument. First, while the claim is clear that the parenthetical attaches to a sulfur atom, in contrast to the *Chef America* case, the claim is susceptible to more than one reasonable interpretation as to how the parenthetical structure attaches to the sulfur, and thus it is appropriate and necessary to rely on the specification. As discussed above, the specification is clear and is in contrast to Defendants' proposed construction, which is nonsensical and chemically impossible. Second, Defendants do not look to what one of ordinary skill in the art would understand the term to mean and instead relies solely on attorney argument for its interpretation. Defendants do not provide any expert testimony for its position, nor does it provide any evidence of what one of skill in the art would understand the claim to require. In contrast, Plaintiff provides expert testimony that one of skill in the art would understand this claimed structure to allow the parenthetical structure to be attached to multiple sulfur atoms. Plaintiff's expert testimony is not rebutted by any expert. The Court finds that one of skill in the art would understand claim 1 to not require all parenthetical drug linker units to attach to a single sulfur atom, in contrast to Defendants' construction.

This finding is confirmed by the extrinsic evidence, which is relied upon by Plaintiff's expert. For example, various publications demonstrate that drug-linkers can attach to multiple sulfur-containing cysteine residues. Other extrinsic evidence (*see, e.g.*, Plaintiff's Ex. 18, a publication by scientists of Defendants) relied upon by Plaintiff provides a similar diagram as found in claim 1, where sulfur appears outside the parenthesis to illustrate a drug-linker unit. While extrinsic evidence may not be used to contradict an express definition or clear teaching in a patent, the Court finds that they may be used to confirm a construction based on the intrinsic evidence.

Lastly, this finding is supported by the Court's separate analysis and conclusions regarding the "p" term, which the Court finds that "p" is the drug to antibody ratio and does not need to be

an integer. In other words, because the "p" term does not need to be an integer, the Court finds that the claim—as a whole—does not require all of the parenthetical "p" units to be attached to a single sulfur atom.

The last issue is that of indefiniteness. Defendants argue the term is indefinite because the claim allegedly requires attachment of up to 20 drug linker units to a single sulfur atom, but sulfur is only able to bond with a single p unit. In short, Defendants argue that such a construction results in a chemical impossibility, thereby rendering the claim indefinite. The Court rejects Defendants' arguments, in part for at least the reasons discussed above. First, Defendants' construction is divorced from the teachings of the specification that clearly contradict Defendants' position. At no point does the specification provide an example or suggest that more than one drug-linker can be attached to a single sulfur atom on a single cysteine. Second, indefiniteness is viewed from the eyes of one of skill in the art. Defendants do not rely on any expert testimony for its indefinite positions. While this is not controlling, it is relevant. Plaintiff's expert testifies that one of skill in the art would understand the claimed formula, in connection with intrinsic evidence as well as extrinsic evidence, to mean that each individual cysteine residue would have a sulfur atom available for creating a bond between the antibody and the drug-linker unit. Such testimony is unrebutted. On balance, the Court does not find that any potential difference in the patent specification as compared to the claim renders the term indefinite. The Court finds that one of skill in the art would be able to reasonably determine what is meant by the disputed term, particularly with the Court's construction. Overall, the Court finds that there is no dispute that one of ordinary skill in the art would understand with "reasonable certainty" the scope of the invention and the bounds of the claim. Accordingly, pursuant to the Supreme Court's holding in *Nautilus*, the Court rejects Defendants' arguments that the claim when "read in light of the specification

delineating the patent, and the prosecution history, fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." The Court finds that Defendants have failed to prove by clear and convincing evidence that the term is indefinite; accordingly, the Court rejects Defendants' indefiniteness arguments.

On balance, while a plain and ordinary meaning approach may be applicable, the Court finds that a construction as to this term is necessary to resolve the dispute between the parties. Consistent with the intrinsic record, the Court finds that each of the parenthetical drug linker units need not be bonded to a single sulfur atom but can be bonded to multiple sulfur atoms. Plaintiff has provided dictionary definitions of the terms "cysteine" and "residue," which are not disagreed to by Defendants. Based on these dictionary definitions, the ordinary meaning of "cysteine" is "a sulfur-containing amino acid," and the ordinary meaning of "residue" is "the portion of a molecule that remains after it has lost some of its components, such as an amino acid residue." Further, both parties agree that a sulfur atom on a cysteine residue of an antibody is able to form a bond with only a single "drug-linker." (*See* Defendants' Responsive Claim Construction Brief at 28). Consistent with the intrinsic record, and the plain meaning of these terms, the Court finds that Plaintiff's construction is most appropriate as to this term.

The Court hereby construes the phrase "**wherein the S is a sulfur atom on a cysteine residue of the antibody**" to mean **"wherein S is a sulfur atom on a cysteine amino acid in the antibody."**

"wherein the drug moiety is intracellularly cleaved …"

Plaintiff's Proposed Construction	**Defendants' Proposed Construction**
Plain meaning/no construction is necessary. Alternatively: "wherein the drug is separated within a cell from the antibody of the antibody drug conjugate or a metabolite of the antibody-drug conjugate."	"wherein the free drug moiety dissociates from the antibody as a result of a metabolic process or reaction inside a cell in a patient that breaks the covalent attachment, of an antibody-drug conjugate or an intracellular metabolite of an antibody-drug conjugate, between the drug moiety (D) and the antibody (Ab)"

(1) The Parties' Positions

Plaintiff argues that the term is readily understood and does not need construction. *See, e.g.*, Dkt. No. 121, Plaintiff's Opening Claim Construction Brief, at 19–20. Plaintiff argues that the words "intracellularly" and "cleaved" are commonly understood. *Id.* at 19. Based on the plain meaning of the term, Plaintiff argues that "intracellularly cleaved" simply means "separated within a cell." *Id.* Plaintiff argues that Defendants' construction is based on a complicated discussion of the term within the specification that introduces additional terms that are not necessary to an understanding of the term. *Id.* at 19-20. Plaintiff argues that Defendants change the specification's teaching regarding the phrase and applies the "covalent bond" to the wrong location and is thus contrary to the claims and intrinsic evidence. *Id.* at 20.

Defendants argue that the term is expressly defined in the specification, which should control over any supposed plain meaning to the term. *See, e.g.*, Dkt. No. 130, Defendants' Responsive Claim Construction Brief, at 21. Defendants argue the issue for the Court is how to modify the grammar of the specification's definition to match the context of the claim. *Id.* at 22. Defendants argue that the concept of "free drug dissociation" needs to be in the construction, no matter how the language in the specification is modified. *Id.*

In its Reply, Plaintiff argues that the term does not need construction. *See, e.g.*, Dkt. No. 135, Plaintiff's Reply Claim Construction Brief, at 10. Plaintiff argues, in the alternative, that the Court may adopt the exact language in the specification related to the term. *Id.* Plaintiff argues that a primary issue between the parties is regarding the "free drug" dissociation, but if the Court adopts the language from the specification verbatim, that issue should be resolved. *Id.*

(2) Analysis

Claim 1 requires a "drug moiety" D, "wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate." The parties dispute whether the term has its plain and ordinary meaning. In particular, the parties dispute the phrase "intracellularly cleaved," and whether a limiting construction should be applied to that phrase based on language from the specification.

The specification provides an express definition for the "intracellular metabolite" term and the "intracellularly cleaved" term:

> The term "**intracellular metabolite**" refers to a compound resulting from a metabolic process or reaction inside a cell on an antibody drug conjugate (ADC). The metabolic process or reaction may be an enzymatic process such as proteolytic cleavage of a peptide linker of the ADC, or hydrolysis of a functional group such as a hydrazone, ester, or amide. Intracellular metabolites include, but are not limited to, antibodies and free drug which have undergone intracellular cleavage after entry, diffusion, uptake or transport into a cell.
>
> The terms "**intracellularly cleaved**" and "**intracellular cleavage**" refer to a metabolic process or reaction inside a cell on an Drug-Ligand Conjugate, a Drug-Linker-Ligand Conjugate, an antibody drug conjugate (ADC) or the like whereby the covalent attachment, e.g., the linker, between the drug moiety (D) and the antibody (Ab) is broken, resulting in the free drug dissociated from the antibody inside the cell. The cleaved moieties of the Drug-Ligand Conjugate, a Drug-Linker-Ligand Conjugate or ADC are thus intracellular metabolites.

'039 Patent, 29:37–47; 29:48–57 (emphasis added). Both of the parties point to and rely on this portion of the specification relating to the definition of the "intracellularly cleaved" term. Plaintiff

argues for a simple plain and ordinary meaning construction for the "intracellularly cleaved" term ("separated within a cell"), but in the alternative recognizes that the more complicated definition in the specification could be used. In contrast, Defendants argue that the specification definition is a lexicographical definition, but then rewrites the language in the specification in an attempt to make it more focused on the parties' dispute.

It is well recognized that a patentee may set out a definition of a term and act as his own lexicographer. *See, e.g., Phillips*, 415 F.3d at 1316 (if a special definition is provided to a claim term by the patentee, the inventor's lexicography governs). On balance, the Court finds that the patentee acted as a lexicographer for the "intracellularly cleaved" term, and the definition within the specification should govern. The Court notes that the specification uses quotation marks around the word "intracellularly cleaved," which is a strong indicator of lexicography. *See Sinorgchem C.. v. ITC*, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (quotation marks are a strong indicator that what follows is a definition). Likewise, the specification uses the term "refer to" after the disputed term, which is another indicator of lexicography. The fact that there is or may be a common meaning to the term (such as "separated within a cell") does not change the fact that the patentee attempted to act as a lexicographer. On balance, the Court finds that the patentee acted as a lexicographer for the "intracellularly cleaved" term in the '039 Patent, and such a definition is controlling.

Despite a finding of lexicography, two primary issues relating to lexicography remain: (1) if, and how, the language in the specification should be modified to make it more clear for claim 1, and (2) whether adoption of the lexicographical definition for "intracellularly cleaved" resolves the disputes between the parties.

Both parties rely on the lexicographical definition for "intracellularly cleaved." Plaintiff suggests that the express language from the specification can be utilized, without any rearrangement or modification of the definition. Defendants suggest that its construction is accurate because it captures the key components within the lexicographical definition and appropriately addresses cleavage in relationship to the parties' dispute around "free drug" dissociation. The Court finds that Defendants' modifications to the definition provided in the specification are not warranted or appropriate. Defendants' modification rearranges key terms in the definition that appear to provide a different meaning to the phrase as a whole. The Court finds that a construction that is most consistent with the specification's definition is appropriate, as any modification or rearrangement of the lexicographical definition may intentionally or unintentionally alter the scope of the term.

The claim language simply requires that the "drug moiety is intracellularly cleaved…from the antibody." The claim itself does not have an express requirement on the meaning of "free drug," how the free drug moiety dissociates, and whether the free drug dissociates as a result of a separate step. However, the claim expressly requires "intracellularly cleaved," and the specification defines that term. The Court finds that a construction that is true to the definition provided in the specification for the cleavage term will resolve any dispute between the parties as to this term.

It is undisputed that claim 1 refers to an antibody drug conjugate (ADC), and the "intracellularly cleaved" definition refers to other molecules besides an ADC. Consistent with the lexicographical definition and the scope of claim 1, the Court finds that it is helpful to remove the references to other drug conjugates besides an ADC (in particular the drug-ligand conjugate and the drug-linker-ligand conjugate), while keeping the rest of the definition intact and unchanged.

During the claim construction hearing, the Court proposed such changes and Plaintiff was acceptable to such changes to the specification definition. Further, such changes are consistent with Defendants' proposed construction. For the above reasons, and as defined expressly in the specification, the Court finds that the term "intracellularly cleaved" means "a metabolic process or reaction inside a cell on an antibody drug conjugate (ADC) whereby the covalent attachment, e.g., the linker, between the drug moiety (D) and the antibody (Ab) is broken, resulting in the free drug dissociated from the antibody inside the cell." The Court finds that this construction resolves the disputes between the parties as to the disputed term.

The Court is not convinced that the rest of the disputed phrase needs construction. The parties' dispute focuses on the "intracellularly cleaved" term, and neither party provides a construction for the other embedded terms, such as "intracellular metabolite." Because the Court's finding resolves the dispute between the parties, the Court finds that no other terms—besides the "intracellularly cleaved" term—within the disputed phrase requires further construction. *See U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997) ("Claim construction is a matter of resolution of disputed meanings and technical scope, to clarify and when necessary to explain what the patentee covered by the claims, for use in the determination of infringement. It is not an obligatory exercise in redundancy."); *see also O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008) ("[D]istrict courts are not (and should not be) required to construe every limitation present in a patent's asserted claims.") (*citing U.S. Surgical*, 103 F.3d at 1568).

The Court hereby construes the term "**intracellularly cleaved**" within the phrase **"wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate"** to mean "**a**

metabolic process or reaction inside a cell on an antibody drug conjugate (ADC) whereby the covalent attachment, e.g., the linker, between the drug moiety (D) and the antibody (Ab) is broken, resulting in the free drug dissociated from the antibody inside the cell," with the rest of the phrase having its plain and ordinary meaning.

IV. CONCLUSION

The Court adopts the above constructions set forth in this opinion for the disputed terms of the patent-in-suit. The parties are ordered that they may not refer, directly or indirectly, to each other's claim construction positions in the presence of the jury. Likewise, the parties are ordered to refrain from mentioning any portion of this opinion, other than the actual definitions adopted by the Court, in the presence of the jury. Any reference to claim construction proceedings is limited to informing the jury of the definitions adopted by the Court.

Within thirty (30) days of the issuance of this Memorandum Opinion and Order, the parties are hereby **ORDERED**, in good faith, to meet and confer regarding another effort to mediate this case with the mediator agreed upon by the parties. As a part of such mediation, each party shall appear by counsel and by at least one corporate officer possessing sufficient authority and control to unilaterally make binding decisions for the corporation adequate to address any good faith offer or counteroffer of settlement that might arise during such mediation. Failure to do so shall be deemed by the Court as a failure to mediate in good faith and may subject that party to such sanctions as the Court deems appropriate.

So ORDERED and SIGNED this 14th day of September, 2021.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE