

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

PAR PHARMACEUTICAL, INC., PAR))	
STERILE PRODUCTS, LLC, and ENDO))	
PAR INNOVATION COMPANY, LLC,))	
)	
Plaintiffs,))	
)	
v.))	Civil Action No. 17-944-JFB-SRF
)	
HOSPIRA, INC.,))	UNSEALED 5/7/2019
)	
Defendant.))	

REPORT AND RECOMMENDATION

I. INTRODUCTION

In this patent infringement action filed by plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (“Par”) against defendant Hospira, Inc. (“Hospira”), Par alleges infringement of United States Patent Nos. 9,119,876 (“the ’876 patent”) and 9,295,657 (“the ’657 patent”) (together, the “patents-in-suit”). (D.I. 1) Presently before the court is the matter of claim construction.¹ This decision sets forth the court’s recommendations of constructions for the disputed claim terms discussed in the briefing and at the *Markman* hearing held on March 27, 2019.

II. BACKGROUND

The patents-in-suit, entitled “Epinephrine Formulations,” claim priority to U.S. Patent Application No. 14/657,990 (“the ’990 application”) and have an effective filing date of March 13, 2015. The ’657 patent is a continuation of the ’876 patent, and it shares the same inventors and specification. (D.I. 151, Exs. 1 & 2) The patents-in-suit are directed to a specific

¹ The briefing associated with claim construction can be found at D.I. 151, D.I. 152, D.I. 160, and D.I. 161.

epinephrine formulation with improved stability, as evidenced by the limited amounts of certain impurities after eighteen months of storage. In pharmaceutical compositions, epinephrine acts to improve breathing, stimulate the heart, raise dropping blood pressure, reverse hives, and reduce swelling of the face, lips, and throat. ('876 patent, col. 1:15-19) Epinephrine is used as an emergency treatment for Type 1 allergic reactions, among other conditions. (*Id.*, col. 1:20-29)

On July 13, 2017, Par filed suit against Hospira, alleging that Hospira's ANDA product infringes the patents-in-suit, as embodied by Par's Adrenalin® product. (D.I. 1) In 2012, the Food and Drug Administration ("FDA") approved the Adrenalin® epinephrine injection formulation of Par's predecessor, JHP Pharmaceuticals ("JHP"). However, the FDA asked JHP to investigate improvements to the formulation and process to reduce the levels of impurities in the Adrenalin® product. Subsequent testing revealed the presence of Impurity A, Impurity B, and Unknown C. The inventors developed a procedure using gradient Hydrophobic Interaction Liquid Chromatography ("HILIC")² to isolate Impurity A, Impurity B, and Unknown C. ('876 patent, col. 16:38-20:61, Figs. 1-4)

III. LEGAL STANDARD

Construing the claims of a patent presents a question of law, although subsidiary fact finding is sometimes necessary. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837-38 (2015) (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here

² Chromatographic analysis is used to identify impurities in drug products by separating the individual molecular components of the drug product, which elute at different points in time. (D.I. 152, Ex. D at 70:2-10)

is no magic formula or catechism for conducting claim construction.” *Id.* at 1324. Instead, the court may attach the appropriate weight to appropriate sources “in light of the statutes and policies that inform patent law.” *Id.*

The words of the claims “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1312-13 (internal citations and quotation marks omitted). “[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted); *see also Eon Corp. IP Holdings v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016). Claim terms are typically used consistently throughout the patent, and “usage of a term in one claim can often illuminate the meaning of the same term in other claims.” *Phillips*, 415 F.3d at 1314 (observing that “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . .”).

Other intrinsic evidence, including the patent specification, “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptor, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316 (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or

expressions of manifest exclusion or restriction.” *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff’d*, 481 F.3d 1371 (Fed. Cir. 2007). The specification “is not a substitute for, nor can it be used to rewrite, the chosen claim language.” *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman*, 52 F.3d at 980. The prosecution history, which is also “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

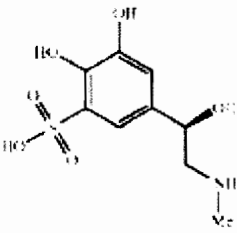
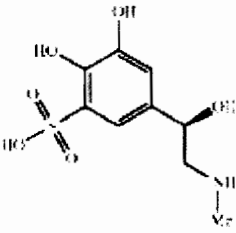
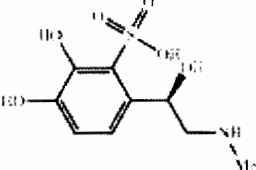
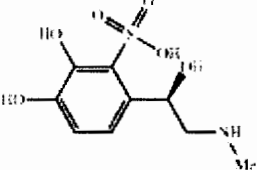
A court also may rely on “extrinsic evidence,” which “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and testimony [are] generated at the time of and for the purpose of

litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.*

(“[C]onclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court.”). Overall, while extrinsic evidence may be useful to the court, it is less reliable than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19.

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007).

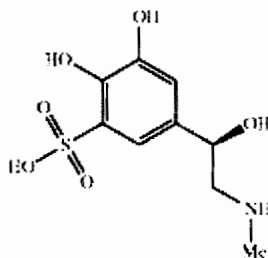
IV. CONSTRUCTION of “IMPURITY A,” “IMPURITY B,” and “UNKNOWN C” (’876 patent, claims 12-13 & 16-18; ’657 patent, claims 12-13 & 16-18)

Term	Par	Hospira	Court
Impurity A	A compound with the following structure (at ’876 patent at 16:41-55): 	Indefinite	A compound with the following structure (at ’876 patent at 16:41-55): 
Impurity B	A compound with the following structure (at ’876 patent at 16:56-67): 	Indefinite	A compound with the following structure (at ’876 patent at 16:56-67): 

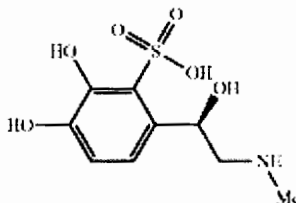
Unknown C	A compound characterized by an elution peak λ_{\max} of about 380 nm using HILIC (Hydrophilic Interaction Liquid Chromatography) separation of mixtures according to the conditions described in Tables 1-8 of the '876 patent at 17:12-19:37 and the '657 patent at 17:23-19:45.	Indefinite	A compound characterized by an elution peak λ_{\max} of about 380 nm using HILIC (Hydrophilic Interaction Liquid Chromatography) separation of mixtures according to the conditions described in Tables 1-8 of the '876 patent at 17:12-19:37 and the '657 patent at 17:23-19:45.
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I recommend that the court adopt Par's proposed constructions, which track the description of Impurity A, Impurity B, and Unknown C provided in the specification:

In some embodiments, Impurity A may be a compound with the following structure:



In some embodiments, Impurity B may be a compound with the following structure:



In some embodiments, Unknown C may be characterized by a λ_{\max} of about 380 nm. In some embodiments, Unknown C may be characterized by its elution peak using HILIC . . . , which differs from one substance to another. In some embodiments, Unknown C may be characterized using an isocratic HILIC separation of mixtures according to the conditions described in Tables 1-3. . . . In some embodiments, Unknown C may be characterized using a gradient HILIC method. An Epinephrine HILIC Impurities Marker Solution (EpiHILIC IMS) which comprises Unknown C may be analyzed using the conditions listed in Table 7 and 8.

('876 patent, col. 16:41-17:9, col. 18:66-19:3)

The parties agree that the challenged claim terms are generic designations which have no plain and ordinary meaning. (D.I. 152 at 7-9; D.I. 160 at 3) Par's expert, Dr. Christian Schoeneich, explains that the terms Impurity A, Impurity B, and Unknown C are arbitrary terms with no conventional definition, which are used as placeholders in the context of the patents-in-suit. (D.I. 152, Ex. B at ¶ 242; Ex. G at 212:13-213:6) Hospira's expert, Dr. Rodolfo Pinal, states that such terms are used by persons of ordinary skill in the art "as short-hand designations by those in the field who have identified through routine testing the existence of some impurity in a formulation but who have yet to characterize that impurity." (D.I. 152, Ex. A at ¶ 183) This is consistent with the testimony of Dr. Michael Bergren, an inventor of the patents-in-suit, who testified that arbitrary designations such as Impurity A, Impurity B, and Unknown C are commonly used when the location of an impurity's elution is specifically recognized in response to a given test prior to the identification of its chemical structure. (D.I. 152, Ex. D at 69:16-70:18)

When a claim term does not have a plain and ordinary meaning, the court must construe the term in accordance with "the remaining intrinsic evidence, including the written description, to aid in [its] construction of that term." *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 711 F.3d 1348, 1361 (Fed. Cir. 2013). In the present case, the specification identifies the distinct chemical structures of Impurity A and Impurity B. ('876 patent, col. 16:41-67) The specification also distinguishes Impurity A, Impurity B, and Unknown C based on their retention time in liquid chromatography. (*Id.*, Figs. 1-4) Moreover, the specification provides the experimental conditions for running isocratic and gradient HILIC to characterize Impurity A, Impurity B, and Unknown C. (*Id.*, col. 17:10-19:37) The guidance provided by the specification is sufficient to allow a person of ordinary skill in the art to determine whether the disputed

impurities are present in an epinephrine formulation. *See Astellas Pharma Inc. v. Actavis Elizabeth LLC*, C.A. No. 16-905-JFB-CJB, 2018 WL 4776372, at *7-8 (D. Del. June 18, 2018) (construing the terms “ α -form crystal” and “ β -form crystal” according to the description in the specification); *Celgene Corp. v. Natco Pharma Ltd.*, 2014 WL 2196941, at *4 (D.N.J. May 27, 2014) (construing the generic term “Form A” to have “all of the characteristics assigned to Form A in the specification.”).

I recommend that the court reject Hospira’s proposal to find Impurity A, Impurity B, and Unknown C indefinite. Hospira contends that the disputed terms are indefinite because the specification does not restrict the scope of the terms to the examples identified in the specification, nor does it provide guidance as to what else might fall within the scope of the terms. (D.I. 152 at 9-10) According to Hospira, the intrinsic record does not establish a clear intention to limit the claim scope through lexicography or disclaimer and, consequently, adopting Par’s construction would amount to improperly importing a limitation from the specification into the claims. (*Id.* at 10-14)

Lexicography and disclaimer do not apply to the circumstances presently before the court. Pursuant to Federal Circuit precedent, the inventor’s lexicography governs when the specification reveals a special definition given to a claim term by the patentee that differs from the meaning the claim term would otherwise possess. *Akami Techs., Inc. v. Limelight Networks, Inc.*, 805 F.3d 1368, 1375 (Fed. Cir. 2015) (quoting *Phillips*, 415 F.3d at 1316). As previously discussed, the parties in the present case agree that Impurity A, Impurity B, and Unknown C have no plain and ordinary meaning. (D.I. 152 at 7-9; D.I. 160 at 3) Instead of providing an alternative definition for a commonly-understood term, the specification of the patents-in-suit provides guidance as to the meaning of the disputed terms which otherwise have no precise

meaning to a person of ordinary skill in the art. Similarly, disclaimer of claim scope is not applicable where the disputed terms have no ordinary meaning. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014) (concluding there was no basis in the specification or prosecution history “to narrow the plain and ordinary meaning of the term datalink to one type of datalink—a cable.”).

For the reasons previously stated, the terms Impurity A, Impurity B, and Unknown C are not indefinite in the context of the patents-in-suit because the specification informs a person of ordinary skill in the art of the meaning of the terms. The fact that the specification discloses a single example of the challenged impurities, accompanied by the non-limiting phrases “may be” “[i]n some embodiments,” is not sufficient to render the terms indefinite. (’876 patent, col. 16:41-17:10) For example, in *Reckitt Benckiser Pharmaceuticals Inc. v. Watson Laboratories, Inc.*, the court rejected the argument that the claim limitation “optimized absorption” was indefinite where the specification described “only a single example of ‘optimized absorption’: absorption bioequivalent to the Suboxone® tablet.” C.A. No. 13-1674-RGA, 2016 WL 3186659, at *7 n.7 (D. Del. June 3, 2016). The court held the defendants failed to establish that the patent provided insufficient guidance to persons of skill in the art as to the meaning of “optimized absorption” based on the single example in the specification. *Id.*

Hospira’s arguments fail to acknowledge the “distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim.” *Phillips*, 415 F.3d at 1323. When the intrinsic evidence provides a single description of a claim term, that description informs the meaning of the claim term even if the description contains non-limiting language. *See Masimo Corp. v. Mallinckrodt Inc.*, 18 F. App’x 852, 855 (Fed. Cir. 2001) (adopting construction limiting “adaptive signal processor” to an adaptive noise

canceler, despite non-limiting language in the specification that “[t]he adaptive signal processor *may* comprise an adaptive noise canceler.”). When a person of ordinary skill in the art would rely on a single example in the specification to determine the meaning and scope of a claim term, the Federal Circuit has held that it is “entirely appropriate to limit the term . . . to the sole portion of the specification that adequately discloses” the term, even if the specification provides that the single example is non-limiting. *Meds. Co. v. Mylan Inc.*, 853 F.3d 1296, 1309 (Fed. Cir. 2017) (noting that the example in the specification provided “a clear objective standard by which to measure the scope of the term.”). The specifications of the patents-in-suit identify the chemical structures of Impurity A and Impurity B, as well as the chromatographic measurements of Unknown C, which is sufficient to provide a person of ordinary skill in the art with an objective standard. *See* Manual for Patent Examining Procedure (“MPEP”) § 2173.05(t) (chemical structures “should not be considered indefinite nor speculative in the absence of evidence that the assigned formula is in error.”); *see also Silvergate Pharm. Inc. v. Bionpharma Inc.*, C.A. No. 16-876-MSG, 2018 WL 1610513, at *8 (D. Del. Apr. 3, 2018) (construing “mannitol” to signify its chemical structure in accordance with the understanding of a person of ordinary skill in the art).

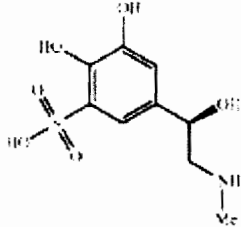
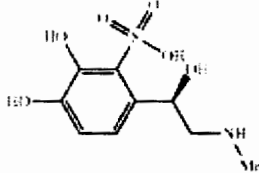
The cases relied upon by Hospira are distinguishable from the circumstances presently before the court. In *Kao Corp. v. Unilever United States, Inc.*, the court held that non-limiting language in the specification that a “kerotic plug remover . . . may take a form of a poultice” precluded a narrow construction limiting the challenged term to a liquid formulation. 334 F. Supp. 2d 527, 545 (D. Del. 2004). However, the intrinsic record did not support limiting the term to liquid formulations despite the examples in the specification because the plaintiffs submitted data for dry formulations during prosecution. *Id.* Unlike the circumstances in *Kao*

Corp., the intrinsic record before the court does not contain affirmative evidence supporting a broader construction of the disputed claim terms.

In *Interval Licensing LLC v. AOL, Inc.*, the Federal Circuit refused to limit the claim scope to a single example to overcome a finding of indefiniteness regarding the phrase “unobtrusive manner” because the disputed term was “facially subjective.” 766 F.3d 1364, 1373-74 (Fed. Cir. 2014) (“With this lone example, a skilled artisan is still left to wonder what other forms of display are unobtrusive and non-distracting.”). In contrast, the chemical structures associated with Impurities A and B in the specifications of the patents-in-suit provide an objective measure for a person of ordinary skill in the art to determine the scope of the limitations. The same is true of the chromatographic measurements of Unknown C. In this regard, the placeholder terms “Impurity A,” “Impurity B,” and “Unknown C” are defined in objective terms which avoid the “unpredictable vagaries of any one person’s opinion” confronting the court in *Interval Licensing*. *Id.* at 1374.

V. CONCLUSION

For the reasons set forth above, I recommend that the court construe disputed terms as follows:

Claim Term	Recommended Construction
Impurity A	A compound with the following structure (at '876 patent at 16:41-55): 
Impurity B	A compound with the following structure (at '876 patent at 16:56-67): 
Unknown C	A compound characterized by an elution peak λ_{\max} of about 380 nm using HILIC (Hydrophilic Interaction Liquid Chromatography) separation of mixtures according to the conditions described in Tables 1-8 of the '876 patent at 17:12-19:37 and the '657 patent at 17:23-19:45.

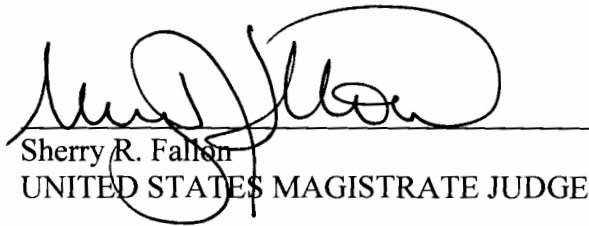
This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The objections and responses to the objections are limited to ten (10) pages each. The failure of a party to object to legal conclusions may result in the loss of the right to de novo review in the District Court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

Given that the court has relied upon material that technically remains under seal, the court is releasing this Report and Recommendation under seal, pending review by the parties. In

the unlikely event that the parties believe that certain material in this Report and Recommendation should be redacted, the parties should jointly submit a proposed redacted version by no later than **May 7, 2019**, for review by the court, along with a motion supported by a declaration that includes a clear, factually detailed explanation as to why disclosure of any proposed redacted material would “work a clearly defined and serious injury to the party seeking closure.” *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994) (internal quotation marks and citation omitted). The court will subsequently issue a publicly available version of its Report and Recommendation.

The parties are directed to the court’s Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court’s website, <http://www.ded.uscourts.gov>.

Dated: April 30, 2019



Sherry R. Fallon
UNITED STATES MAGISTRATE JUDGE