

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

INTEGRA LIFESCIENCES CORP.,)	
INTEGRA LIFESCIENCES SALES LLC,)	
CONFLUENT SURGICAL, INC., and)	
INCEPT LLC,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 15-819-LPS-CJB
)	
HYPERBRANCH MEDICAL)	
TECHNOLOGY, INC.,)	
)	
Defendant.)	

REPORT AND RECOMMENDATION

In this action filed by Plaintiffs Integra LifeSciences Corp. (“Integra”), Integra LifeSciences Sales LLC (“Integra Sales”), Confluent Surgical, Inc. (“Confluent”) and Incept LLC (“Incept”) (collectively, “Plaintiffs”) against Defendant HyperBranch Medical Technology, Inc. (“HyperBranch” or “Defendant”), Plaintiffs allege infringement of United States Patent Nos. 6,566,406 (the “406 patent”), 7,009,034 (the “034 patent”), 7,332,566 (the “566 patent”), 7,592,418 (the “418 patent”), 8,003,705 (the “3705 patent”) and 8,535,705 (the “5705 patent”) (collectively, the “patents-in-suit” or “asserted patents”). Presently before the Court is the matter of claim construction. The Court recommends that the District Court find that the two terms discussed in this Report and Recommendation are indefinite.¹

I. BACKGROUND

¹ The parties submitted 18 terms or sets of terms for claim construction. (D.I. 248 at 2) The parties grouped the 18 terms/term sets into seven groups for purposes of the *Markman* hearing. (*Id.* at 1-2) This Report and Recommendation addresses the second group of terms. On July 27, 2017, the Court issued a Report and Recommendation regarding claim construction for the first group of terms (which included 8 terms/term sets), (D.I. 307), and the Court will address the remaining groups in separate, forthcoming Report and Recommendations.

The Court incorporates by reference herein the factual and procedural background regarding this case and the patents-in-suit set out in the Court’s July 27, 2017 Report and Recommendation regarding claim construction. (D.I. 307 at 2-5)

II. STANDARD OF REVIEW

The Court also incorporates by reference herein the discussion of general principles of claim construction, as well as the legal standard relating to the definiteness requirement, which were set out in its July 27, 2017 Report and Recommendation. (*Id.* at 5-7, 30-32)

III. DISCUSSION

The Court takes up the two disputed terms addressed herein in the order in which the parties addressed them at the *Markman* hearing.

A. “molecular weight”

The term “molecular weight” appears in claims 1, 12 and 23 of the '406 patent. The use of the disputed term in claim 1 is representative:

1. A method for preparing a biocompatible crosslinked polymer hydrogel, comprising:
providing a biocompatible small molecule crosslinker with a *molecular weight* of 2000 or less . . . providing a synthetic biocompatible functional polymer with a *molecular weight* of at least about 7 times more than the crosslinker . . . combining the crosslinker and functional polymer to react the crosslinker functional groups with the functional polymer functional groups to form a hydrogel . . .

('406 patent, col. 30:29-49 (emphasis added)) Defendant contends that the term is indefinite under 35 U.S.C. § 112. (D.I. 231 at 2-5) In response, Plaintiffs assert that the term is not indefinite (or that such an argument is premature at this time), and that it should be construed to mean “[t]he mass of a molecule which is often expressed in Daltons or g/mol[.]” (D.I. 230 at

18)²

The claims refer to the molecular weight of a small molecule crosslinker and a functional polymer. Polymers are large molecules made up of many repeat units, formed by joining (in a process known as polymerization) small molecules called monomers. (D.I. 232 at ¶ 28) In the polymerization process, the monomers randomly react with one another, resulting in a polymer product that includes a mix of individual polymer molecules with small, medium and long chains (with the non-uniformity of the chain lengths of polymer products referred to as “polydispersity”). (*Id.* at ¶ 29; *see also* D.I. 159 at 125)

It is undisputed here that, when determining the molecular weight of a polymer, different statistical measures could be used, such as number-average molecular weight (“Mn”) or weight-average molecular weight (“Mw”). (D.I. 232 at ¶¶ 31, 33, 34; *see also* D.I. 10, ex. 13 at ¶ 381 (Plaintiffs’ expert Dr. Jimmy W. Mays explaining that “I understand that the term ‘molecular weight’ when referring to polymers may be one of several types, such as ‘number average molecular weight’ or ‘weight average molecular weight’”)) Mn refers to the arithmetic mean, or the total mass of all molecules in the sample divided by the total number of molecules, whereas Mw is calculated differently, and encompasses the different mass contributions of the different chains of molecules making up a polymer product. (D.I. 232 at ¶ 31) It is also undisputed here

² With respect to Plaintiffs’ argument that it would be premature to resolve the definiteness issue now, (D.I. 230 at 18; *see also* Tr. at 129-30), Plaintiffs do not specifically identify how additional time would better advance the record with respect to the issue. The parties’ experts have presented dueling opinions as to the question, (*see, e.g.*, D.I. 10, ex. 13 at ¶¶ 381-84; D.I. 232 at ¶¶ 27-39; D.I. 242, ex. 14 at ¶¶ 44-47), the parties have fully joined the issue, (*see, e.g.*, D.I. 241 at 4-6 (Plaintiffs articulating their response to Defendant’s indefiniteness position in the event “the Court desires to address this potentially dispositive [issue] at this time”)), and they have had a full, fair opportunity to litigate it. The Court therefore agrees with Defendant that the issue is “ripe” for consideration. (Tr. at 54-55)

that these different measures are generated using different calculations and can yield different numerical values for a given polymer. (*Id.* at ¶¶ 32, 39); *see also* *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015) (explaining that the term “molecular weight” could refer to, *inter alia*, Mw or Mn and that “each of these measures is calculated in a different way and would typically yield a different result for a given polymer sample”). Defendant argues that the intrinsic evidence does not indicate which measure of molecular weight should be used, and that this renders the term indefinite, because a polymer might simultaneously satisfy and not satisfy the claim limitations reciting “molecular weight” depending upon which measure is used to determine claim scope. (D.I. 231 at 3-4; D.I. 243 at 4-5)

Defendant relies heavily on the decision of the United States Court of Appeals for the Federal Circuit in *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335 (Fed. Cir. 2015) (“*Teva II*”) in support of its argument, a case that analyzed indefiniteness with respect to the same term (albeit one found in different patents than the one at issue here). In *Teva II*, the claim at issue recited a method of manufacturing a product called copolymer-1 “having a *molecular weight* of about 5 to 9 kilodaltons.” 789 F.3d at 1338 (certain emphasis omitted). The *Teva II* Court explained that there were three different relevant measures of molecular weight including Mn and Mw (as well as a third measure, Mp, or peak average molecular weight), with each measure being calculated differently and yielding different values for a given polymer sample. *Id.* The district court had agreed with the patentee’s position that the record compelled a conclusion that “molecular weight” meant Mp in the context of the claimed invention. *Id.* at 1338-39.

In reaching its conclusion, the district court had credited the plaintiff’s expert’s testimony

that Example 1 in the specification of the asserted patent (which corresponded to Figure 1 in the specification) described an analytical method utilizing a chromatogram and calibration curve, from which M_p is the only type of average molecular weight that could be obtained. *Id.* at 1338. While experts testified that M_n and M_w could also be obtained from the chromatogram and calibration curve, the district court noted that doing so would require additional data manipulation and calculations that were not described in the specification; for this reason, the district court credited the plaintiff's expert's opinion that Example 1 implied the use of M_p . *Id.* The district court also rejected the defendant's argument that Figure 1 did not disclose M_p because the peaks of the depicted curves did not match the molecular weight values reported in the legend. Instead, the district court accepted the plaintiff's expert's explanation that a person of ordinary skill in the art ("POSITA") would understand that a shift in the peak of the curves could occur when transferring data from a chromatogram. *Id.* at 1338-39. The district court also relied on the patentee's statement during prosecution of a later related patent (to the effect that "average molecular weight" meant M_p) in reaching its conclusion that the term was not indefinite. *Id.* at 1339.

On appeal, the Federal Circuit reversed the district court's conclusion as to definiteness. *Id.* The Supreme Court of the United States then vacated that decision and remanded for the Federal Circuit to review the district court's subsidiary fact findings for clear error. *Id.* at 1339-40.

On remand, the *Teva II* Court again considered whether the claim was indefinite for its inclusion of the term "molecular weight," looking to the intrinsic record (i.e., the claims, specification and prosecution history) to "ascertain if [it] convey[s] to one of skill in the art with

reasonable certainty” the measure of molecular weight to be used. *Id.* at 1341. Ultimately, the *Teva II* Court again reversed the district court on this question.

The Court prefaced its holding by differentiating between fact finding and legal analysis with respect to this issue. On the one hand, it explained that “[t]he meaning one of skill in the art would attribute to the term molecular weight in light of its use in the claims, the disclosure in the specification, and the discussion of this term in the prosecution history is a question of law.” *Id.* at 1342. Even if an expert offers an opinion regarding a term’s meaning in the context of a patent, that does not “transform [the issue] into a factual matter[,]” the Court noted, since “[d]etermining the meaning or significance to ascribe to the legal writings which constitute the intrinsic record is legal analysis.” *Id.* Put another way, a party may not “transform legal analysis about the meaning or significance of the intrinsic evidence into a factual question simply by having an expert testify on it.” *Id.* On the other hand, factual issues are those regarding “[u]nderstandings that lie outside the patent documents about the meaning of terms to one of skill in the art or the science or state of the knowledge of one of skill in the art[.]” *Id.*; *see also id.* (noting that the “Supreme Court made clear that the factual components [relating to the meaning of a term] include ‘the background science or the meaning of a term in the relevant art during the relevant time period’”) (quoting *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015)).

Turning next to the intrinsic evidence with respect to the meaning of “molecular weight,” the *Teva II* Court noted that neither the claim at issue nor the patent specification indicated which measure of molecular weight should be utilized. *Id.* at 1341. And nowhere did the patent set out an express definition of “molecular weight.” *Id.* The *Teva II* Court then found that the district

court did not clearly err in: (1) determining that a POSITA could read M_p from a chromatogram and that alternate readings of M_w or M_n would require further calculations; (2) crediting the plaintiff's expert's testimony that Figure 1 was created by transforming data from a chromatogram to the curves shown in Figure 1; and (3) accepting the expert's opinion that the POSITA would understand that the process of transforming such data could cause the peaks of the curves to slightly shift, such that a POSITA would understand that the listed molecular weights fall approximately at the peaks (i.e., M_p). *Id.* at 1342. However, the *Teva II* Court emphasized that the district court's acceptance of these findings of fact did not create a *presumption* regarding the meaning of the claim term in the art generally or in the context of the patent—that “[e]ven accepting as correct the district court’s factual determinations [in this regard], these facts do not resolve the ambiguity in the [] claim about the intended molecular weight measure.” *Id.*

The *Teva II* Court then focused on relevant prosecution history. *Id.* at 1342-43. During prosecution of two later patents in the same family as the asserted patent (patents that shared nearly identical specifications, and included the same Example 1 and Figure 1), the patentees made statements about the meaning of “molecular weight” that the *Teva II* Court found to be “legally relevant to the meaning one of skill in the art would attribute to the identical term in the [asserted] patent.” *Id.* at 1343. The examiner had rejected the claims of these later patents as indefinite on the basis that the term “average molecular weight was meaningless without [the patent] specifying whether M_p , M_n , or M_w should be used.” *Id.* (internal citation omitted).

With respect to the first of the two latter patents, the applicant overcame the rejection by arguing that the term “molecular weight” was not indefinite because the POSITA “could

understand that kilodalton units implies” a measure of Mw. *Id.* (internal quotation marks and citation omitted). Mw, of course, is a different measure than that advanced by the plaintiff’s expert in the district court proceedings (i.e., Mp). In the district court proceeding, the district court heard testimony to the effect that this prosecution history statement was scientifically wrong, because each type of “molecular weight” could indeed be expressed in kilodaltons. *Id.* The *Teva II* Court, in turn, agreed that this fact finding was not clearly erroneous. *Id.* at 1343-44. But it explained that regardless, a POSITA reviewing this statement in the prosecution history would understand that the applicants had there defined the term “molecular weight” to be Mw, in order to obtain their claims. *Id.* at 1344.

As to the second of the two later patents, during prosecution, the applicants overcame a nearly identical indefiniteness rejection with respect to the term “molecular weight.” They did so by asserting that the POSITA, upon reviewing the patent specification, would understand the measure of molecular weight to be Mp. *Id.*

In light of this intrinsic record, the *Teva II* Court reversed the district court’s conclusion that the claim was definite. *Id.* at 1345. It summarized its holding as follows:

[I]t is undisputed that “molecular weight” or average molecular weight can be ascertained by any of three possible measures: Mp, Mn, and Mw. The claims do not indicate which measure to use. The specification never defines molecular weight or even mentions Mp, Mw, or Mn. And the term “average molecular weight” does not have a plain meaning to one of skill in the art. . . . During prosecution of the related [] patents, which with respect to molecular weight have identical specifications, examiners twice rejected the term “molecular weight” as indefinite for failing to disclose which measure of molecular weight to use (Mp, Mn, or Mw). And the patentee in one instance stated that it was Mw and in the other stated it was Mp. . . . We hold that claim 1 is invalid for indefiniteness by clear and convincing evidence because read in

light of the specification and the prosecution history, the patentee has failed to inform with *reasonable certainty* those skilled in the art about the scope of the invention. On this record, there is not reasonable certainty that molecular weight should be measured using *M_p*.

Id. at 1344-45 (emphasis in original).

With the Federal Circuit's holding in *Teva II* firmly in mind, the Court now turns to the record before it here. Plaintiffs claim that "molecular weight" is a well-known term of art that should be accorded its plain meaning consistent with its use in the patent—i.e., "the mass of a molecule which is often expressed in units of Daltons or g/mol." (D.I. 230 at 18) The problem with this proposal, however, is that by simply providing the *units* for a molecular weight, Plaintiffs' construction does not address the issue of *which measure* of "molecular weight" is encompassed by the claims (e.g., *M_n* or *M_w*), because both measures use Daltons or g/mol as their unit of measurement. (D.I. 231 at 4; D.I. 243 at 4-5; D.I. 232 at ¶ 39)

Indeed, it is clear from this record that one must know which measure of molecular weight applies in the context of the patent to ascertain the appropriate claim scope. Thus, the question for the Court is whether the intrinsic record conveys to the POSITA with reasonable certainty the particular measure of "molecular weight" that must be used here (*M_n* or *M_w*). *See Teva II*, 789 F.3d at 1341; *see also* (D.I. 241 at 4; Tr. at 116 (Defendant's counsel framing the issue as whether "the intrinsic record give[s] somebody of ordinary skill in the art guidance as to the singular method that should be used to calculate molecular weight for a polymer"))).

Here, as in *Teva II*, the claims do not specify the type of "molecular weight" that should be utilized, nor otherwise define the term. (D.I. 231 at 3; D.I. 243 at 5) And so the term in the claims could be referring to, at minimum, either *M_n* or *M_w*. (D.I. 232 at ¶ 34) Nor does the '406

patent specification (nor the specifications of any of the other patents-in-suit) set out the measure of “molecular weight” that should be used (just as the specification at issue in *Teva II* did not). (See, e.g., '406 patent, cols. 3:40-41 (referring to a small molecule precursor that “is a polymer and is of a molecular weight of less than 1000 Daltons”), 15:50-51 (referring to a “tetrafunctional polyethylene glycol (molecular weight 2000 Da)”), 16:13-14 (referring to “low molecular weight multi-branched oligoesters, with molecular weights below 1000”); '034 patent, col. 6:5-15 (discussing a macromolecule that is a “functional polymer” and that, when reacted with a crosslinker, “is preferably at least five to fifty times greater in molecular weight than the small molecule crosslinker and is preferably less than about 60,000 Da”); '3705 patent, col. 6:57-60 (“A low molecular weight amine is a molecule having at least two primary amine groups and a molecular weight of less than 1000.”); see also D.I. 232 at ¶ 35) Without any indication in the intrinsic record regarding which measure of molecular weight to use, Defendant asserts that the facts here are “precisely analogous to *Teva II*” and that the term “molecular weight” therefore renders the claims indefinite. (D.I. 243 at 5; see also D.I. 231 at 3-4)

In response, Plaintiffs assert that the POSITA considering the specifications of the asserted patents would understand “with reasonable certainty that when dealing with polymers the value of the molecular weight is the value of the [Mn].” (D.I. 241 at 5) They rely on the opinion of their expert, Dr. Mays, in support of this argument. (*Id.* (citing D.I. 233, ex. 3 at ¶¶ 381-84; D.I. 242, ex. 14 at ¶¶ 45-47)) Dr. Mays, in turn, sets out nine steps that the POSITA would take in order to reach this conclusion, which the Court describes below:

1. Dr. Mays turned to the '3705 patent to understand the claimed molecular weight of the '406 patent, since the patents are related and are in the same patent family (the '3705 patent is a

continuation-in-part of the '406 patent). (D.I. 10, ex. 13 at ¶ 382)³

2. Dr. Mays located the reference to “Low Molecular Weight Amine Precursors” in the '3705 patent specification and asserts that it “describes to one of skill in the art low molecular weight amine precursors and hydrogels with reference to the characterization used by the Aldrich Catalog of 2002[.]” (*Id.* at ¶ 383)

3. More specifically, following a header entitled “Low Molecular Weight Amine Precursors and Hydrogels[.]” the '3705 patent specification states: “Some embodiments are directed to the use of low molecular weight amines having at least two primary amines and a molecular weight of less than about 1000. Examples of such low molecular weight amines are dilysine, trilysine, tetralysine, and Tris. *Following the nomenclature set forth in the Aldrich Catalog of 2002*, other such examples are ornithine, spermine, spermidine, urea” ('3705 patent, cols. 9:61-10:1 (emphasis added))

4. According to Dr. Mays, that paragraph would prompt the POSITA to then look to the “Aldrich Catalog of 2002 to gain an understanding of how the Aldrich Catalog of 2002 describes the low molecular weight amines of the '3705 patent, and accordingly, the '406 patent.” (D.I. 10, ex. 13 at ¶ 384) Upon learning that Aldrich Chemical did not actually issue an “Aldrich Catalog of 2002,” Dr. Mays claims that the POSITA would next turn to the Aldrich Catalog issued in 2000-2001 (entitled “Aldrich Handbook of Fine Chemicals and Laboratory Equipment” and hereinafter referred to as “Aldrich Catalog”). (*Id.*)

5. Dr. Mays did so, explaining that: “I have obtained the Aldrich Catalog from 2000-2001 and have reviewed the characterization of low molecular weight amine precursors used to make a hydrogel.” (*Id.*)

6. Dr. Mays noted that the Aldrich Catalog “describes low molecular weight amine precursors in terms of [Mn], though reference is also made where indicated to [Mw].” (*Id.* (citing *id.*, ex. N at 1371))

³ The application for the '406 patent was filed on December 3, 1999, and that patent issued on May 20, 2003. ('406 patent) The application for the '3705 patent was filed on May 29, 2008, and that patent issued on August 23, 2011. ('3705 patent)

7. Dr. Mays next “reviewed the characterization of polyethylene glycol polymers which can be functionalized to be crosslinked by low molecular weight amine precursors, as this is a species of functional polymer taught by the '3705 patent and the '406 patent.” (*Id.*)

8. Dr. Mays observed that “[s]uch PEG-based polymers are described in the Aldrich [Catalog] (Exhibit N, page 1363) only in terms of [Mn].” (*Id.*)

9. Finally, Dr. Mays concludes that, based on his review of the '406 patent, the '3705 patent, and the Aldrich Catalog, the POSITA “would understand the molecular weight referred to in the claims of the '406 patent to be [Mn], as the crosslinker and the functional polymer are intended to be reacted together and their molecular weights are to be compared and so would be understood to be of the same type.” (*Id.*; see also Plaintiffs’ Claim Construction Presentation, Slide 41 (noting that the claims at issue use the same “molecular weight” to describe both the crosslinker and functional polymer, with claim 12 of the '406 patent reciting, for example, a functional polymer having “a molecular weight at least about 7 times more than the small molecule crosslinker”))

Defendant retorts that “Dr. Mays’ 9-step path does not provide reasonable certainty that Mn should be used[,]” instead asserting that it is “almost inconceivable . . . that somebody would sit down [with the issue presented here—whether the intrinsic record conveys with reasonable certainty what measure of molecular weight must be utilized] and follow this path that is outlined by Dr. Mays.” (Defendant’s Claim Construction Presentation, Slide 86; Tr. at 118) To that end, Defendant’s expert Dr. Anthony Lowman “disagree[d] that [the POSITA] would follow the convoluted approach to the claims outlined by Dr. Mays to look to a selective disclosure in a piece of extrinsic evidence in order to choose [Mn]. Rather, after examining the intrinsic record, [the POSITA] would be left with no understanding as to which molecular weight measure was to be used in the claims.” (D.I. 232 at ¶ 37) For the reasons discussed below, the Court agrees with

Defendant's position, and concludes that by clear and convincing evidence, Defendant has demonstrated that there is no reasonable certainty as to which measure of molecular weight should be utilized.

As previously noted, the intrinsic record alone does not specifically indicate which type of molecular weight measure should be used here. Thus, the next question is whether the intrinsic record would, in fact, have referred the POSITA to the Aldrich Catalog in order to determine what measure of molecular weight the patentees intended be used to assess the '406 patent's claim scope. As noted above, Dr. Mays relies on the '3705 patent specification's reference to the Aldrich Catalog in order to make this link.⁴

But when one hones in on the relevant portion of the '3705 patent specification, one sees that it does *not* expressly direct the reader to the Aldrich Catalog of 2002 “to determine the *molecular weight* measure to be used for determining whether a polymer does or does not meet the molecular weight cutoff of the claims.” (*Id.* at ¶ 38 (emphasis in original); *see also* Tr. at 120) Instead, the specification lists examples of some low molecular weight amines

⁴ Defendant suggests that part of the “inconceivability” of Dr. Mays’ path is his assertion that the POSITA would begin by looking to the disclosure of the '3705 patent at all (a patent that is a continuation-in-part of the '406 patent, with an application that was filed five years after the '406 patent had issued). (*See* Defendant’s Claim Construction Presentation, Slide 86; Tr. at 119, 123, 131) And, indeed, the '3705 patent’s disclosure does seem pretty far afield. But Defendant does not cite to any caselaw for the proposition that a POSITA *could never* look to the specification of such a later-issued, related patent for guidance in determining the meaning of a claim term found in an earlier-issued patent. *See, e.g., Visto Corp. v. Sproqit Techs., Inc.*, 445 F. Supp. 2d 1104, 1109-11 (N.D. Cal. 2006) (concluding that the specification for a later-issued, related patent could not be used to construe claims of earlier patents, but noting that “there may be narrow circumstances where a later patent may be looked to in construing an earlier subject patent even where it is not part of the subject patent’s prosecution history”). And so, for our purposes here, the Court will credit Dr. Mays’ assertion that a POSITA would in fact have turned to the '3705 patent in this way for guidance.

encompassed by certain embodiments, and then lists the names of some additional such amines “[f]ollowing the *nomenclature* set forth in the Aldrich Catalog of 2002[.]” (’3705 patent, col. 9:62-67 (emphasis added); *see also* D.I. 232 at ¶ 38 (identifying as a “flaw[]” in Dr. Mays’ 9-step approach that “the specification of the ’3705 patent merely directs that the Aldrich 2002 catalog is to be used for the *nomenclature* of ‘low molecular weight amines’”) (emphasis in original)) As Defendant’s counsel explained during the *Markman* hearing, “in chemistry there are different ways of naming things[—][y]ou have common names and what’s known as an IUPAC [or International Union of Pure and Applied Chemistry] name” and the specification’s reference to “[n]omenclature is [referring to] what these things are called.” (Tr. at 120) In other words, the ’3705 patent, on its face, was clearly making a statement here only as to (as Defendant’s counsel articulated) “what we’re going to call these [amines].” (*Id.*) The Court cannot see why the ’3705 patent’s bare reference to “nomenclature” would signal to a POSITA that she should turn to the Aldrich Catalog to assess how the *molecular weight* of the materials described in the ’406 patent should be measured. And Dr. Mays, in his report, never explains why this is so.

Moreover, even if the Court could accept Dr. Mays’ bare assertion in this regard, the next step of Dr. Mays’ path is unhelpful to Plaintiffs. Here, Dr. Mays attaches a two-page excerpt from the Aldrich Catalog to his declaration, and refers to a single page as describing “low molecular weight amine precursors[.]” (D.I. 10, ex. 13 at ¶ 384 (citing *id.*, ex. N at 1371)) Looking to that page of the catalog, it lists a few entries of “polyethylenimine” as “low molecular weight[;]” presumably, this is the content on the cited page that Dr. Mays is referring to. (*See* Defendant’s Claim Construction Presentation, Slide 86 (noting that “presumably” Dr. Mays’ 9-step path entails looking up “polyethylenimine” in the Aldrich Catalog)) As acknowledged by

Dr. Mays, however, the entries here list both the average Mn *and* the average Mw. (D.I. 10, ex. 13, ex. N at 1371; Tr. at 121; *see also id.* (Defendant’s counsel also asserting that, in addition to these citations, “[t]here are a number of other polymers [listed in the Aldrich Catalog] that are expressly recited in the patent that use [Mw] and not [Mn]”)) And so, even assuming a POSITA were to look to the Aldrich Catalog for more than “nomenclature” purposes, and were to try to use it to assess how the molecular weight measures for low molecular weight amine precursors in the '406 patent are to be measured, the cited page in the Aldrich Catalog would only *underscore* the uncertainty on that front.

Furthermore, Dr. Mays never explains *why* this single page from the Aldrich Catalog is representative of any and all low molecular weight amine materials listed in the catalog. In other words, the Court is left without an answer as to why the POSITA—on a quest to figure out which measure of molecular weight should be utilized to assess claim scope—would be compelled to turn to this single page and consult the entry for a single material (“polyethylenimine”). (See D.I. 232 at ¶ 37 (characterizing Dr. Mays’ approach as looking “to a selective disclosure”); Defendant’s Claim Construction Presentation, Slide 86 (noting that Dr. Mays’ 9-step process involves “look[ing] up *a single type* of low molecular weight amine material” (emphasis added)); Tr. at 120) Indeed, as far as the Court can tell, the examples of low molecular weight amine precursors that the '3705 patent specification goes on to list “[f]ollowing the nomenclature set forth in the Aldrich Catalog of 2002” do not even include polyethylenimine. ('3705 patent, cols. 9:66-10:16)⁵

⁵ Dr. Lowman notes that if a POSITA *did* want to evaluate the molecular weight of the low molecular weight polyethylenimine materials recited in the '3705 patent, she “would most likely look to the supplier of the specific polyethyleneimine material identified in that

Next, after consulting the polyethylenimine entries in the Aldrich Catalog and remaining at a loss about which molecular weight measure to use, Dr. Mays' 9-step path would have the POSITA turn to the Aldrich Catalog's listing of polyethylene glycol polymers. This is because, according to Dr. Mays, "this is a species of functional polymer taught by the '3705 patent and the '406 patent[,]'" and such a polymer can be functionalized to be crosslinked by low molecular weight amine precursors as required by, for example, claim 12 of the '406 patent. (D.I. 10, ex. 13 at ¶ 384) It is this step that leads Dr. Mays to conclude that the POSITA would understand the molecular weight referred to in the claims of the '406 patent to be M_n , since a measure of M_n is listed for this polymer (and the POSITA would purportedly understand the crosslinker to be measured in the same way). (*Id.*)

Yet here again, Dr. Mays' statement provides no explanation as to *why* this would be the POSITA's next step. Dr. Mays does not include a citation to where the patents purportedly teach polyethylene glycol polymers as a species of functional polymer. The Court notes that the '3705 patent does state that functional polymers such as "multifunctional poly(ethylene glycol) ('PEG') can be used[,]'" but it also lists several other functional polymers that may be used. (*See, e.g.*, '3705 patent, col. 9:51-60) Since we only have a short excerpt from the Aldrich Catalog, it is not clear if the other functional polymers called out by the '3705 patent are listed therein, and if so,

patent, which is 'LUPASOL polyethyleneimine.'" (D.I. 232 at ¶ 38 (citing '3705 patent, col. 38:39)) Dr. Lowman then explains that Lupasol is a BASF trade name, and "BASF identifies the molecular weight of these polyethyleneimine products by [Mw]." (*Id.* (citing *id.*, ex. 11)) This certainly seems to be a much less convoluted method of determining which measure of molecular weight the patentee intended (at least with respect to polyethyleneimine materials) than that laid out by Dr. Mays.

what measure of molecular weight is associated with them.⁶

In sum, the Court does not agree with Plaintiffs that the POSITA “can look to the specification of the patents-in-suit and see with reasonable certainty that when dealing with polymers the value of the molecular weight is the value of [Mn].” (D.I. 241 at 5)⁷ The claims and the specification of the '406 patent do not directly speak to this issue at all. Nor is the Court persuaded that the POSITA would follow Dr. Mays’ 9-step pathway to “Mn” in order to fill in the gap. That pathway relies in significant part on a single citation in the later-issued '3705

⁶ Defendant notes that the low molecular weight amine and the functional polymer that Dr. Mays relies upon in his analysis happen to be the two polymers that are found in the accused product. (Tr. at 120-21; *see also* D.I. 94 at 2 (“HyperBranch’s technology is based on a two component polyethyleneglycol (PEG) and polyethyleneimine (PEI) polymer platform[.]”)) To the extent that this is the reason why Dr. Mays suggested that a POSITA would look to these specific two materials over others referenced in the patent, it would appear to conflict with the axiom that claims are to be construed objectively “without reference to the accused device[.]” *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

⁷ This is in contrast to the facts of a recent case from this Court, *Purdue Pharma L.P. v. Amneal Pharms., LLC*, Civil Action Nos. 1:15-cv-01152-RGA-SRF, 1:16-cv-0025-RGA-SRF, 2017 WL 634939 (D. Del. Feb. 16, 2017). There, the Court rejected an argument by one of the two sets of defendants that a claim term including “molecular weight” was indefinite because the intrinsic evidence failed to identify which measure of molecular weight was required by the asserted claims. *Purdue Pharma*, 2017 WL 634939, at *5. The claims at issue recited “at least one polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 4,000,000.” *Id.* at *2. The specification of the asserted patent explained that “[p]olyethylene oxide is considered to have an approximate molecular weight of 4,000,000 when a 1% (by wt) aqueous solution of said polyethylene oxide using a Brookfield viscometer Model RVF, spindle No. 2, at 2 rpm, at 25° C. shows a viscosity range of 1650 to 5500 mPa s (cP).” U.S. Patent No. 8,808,741, cols. 7:64-8:1 (cited in *Purdue Pharma L.P.*, 2017 WL 634939, at *5). The Court explained that “[w]hile it seems clear to me that the intrinsic evidence indicates that the inventors were referring to [Mw]” the term was not indefinite regardless, where “[t]he specification defines polyethylene oxide (‘PEO’) as having a molecular weight of 4,000,000 by reference to a specific test performed on a specific instrument.” *Purdue Pharma L.P.*, 2017 WL 634939, at *5. The Court concluded that this constituted “an express definition of what the inventor considered to be a PEO having an approximate molecular weight of 4,000,000” that would allow the POSITA to “understand the scope of the invention.” *Id.*

patent to the Aldrich Catalog. And that very citation, on its face, does *not* direct anyone to consult the Aldrich Catalog for purposes of assessing measurements of *molecular weight*. Even if one did turn to the Aldrich Catalog for this purpose, the catalog does nothing to clearly indicate what measurement should be used; instead, it makes reference to different types of molecular weight measurements, a fact that would only solidify a POSITA's uncertainty. All of this, along with Dr. Mays' tendency to cherry-pick (without explanation) which portions of the Aldrich Catalog a POSITA would look to in the first place, renders the outcome here clear.⁸ See *Butamax Advanced Biofuels, LLC v. Gevo, Inc.*, 117 F. Supp. 3d 632, 641 (D. Del. 2015) (finding claim indefinite where various methods could have been used to make the calculation called for by the claim limitation at issue, and "[b]ased on the broad and ambiguous language of the specification, the court does not find commonsensible [the expert's] conclusory assertion that a [POSITA] would be directed by the specification to use the MegAlign program (and its online help manual

⁸ The Court views nearly all of these determinations as being legal determinations (for example, the question of whether the patent includes any definition of which measure of molecular weight should be used, or the question of what is meant by the patent's reference to following the "nomenclature" of the Aldrich Catalog), where in the main the Court is being asked to draw conclusions about what certain portions of the patent mean, or whether certain references in the patent would direct the POSITA to consult particular types of extrinsic evidence. Even to the extent that certain of these conclusions could be said to relate to an issue of fact, in those cases the Court has not credited Dr. Mays' expert opinion because that opinion often amounts to a bare assertion about what a POSITA would do, without any underlying factual explanation as to *why* a POSITA would take such action. Cf. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005) (noting that "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court"); *Sandvik Intellectual Prop. AB v. Kennametal, Inc.*, Civil Action File No. 2:10-CV-00654-TFM, 2012 WL 3027983, at *9 (W.D. Pa. Feb. 16, 2012) (explaining that in the context of assessing indefiniteness, "a court may consider or reject certain extrinsic evidence in resolving disputes en route to pronouncing the meaning of claim language or in rendering the claim indefinite in its role as construer of claims" and "[a]s in summary judgment . . . 'conclusory, unsupported assertions by experts are not useful to a court'" (citation omitted)).

not referred to in the specification)” to do so). The Court agrees with Defendant that this case is similar to *Teva II*, and that the conclusion reached here should be the same as the conclusion the Federal Circuit reached in that case.⁹

The Court therefore concludes that “molecular weight” is indefinite in the context of the claims of the '406 patent.

B. “small molecule”

This term is found in certain claims of the '406 patent, which recite a “biocompatible small molecule crosslinker” with a molecular weight of 2000 or less. ('406 patent, cols. 30:31-32, 31:3-16, 31-33) The specification of the '406 patent expressly defines a “small molecule” as “a molecule that is not a polymer and is typically of a molecular weight of less than 2000 Daltons, or else is a polymer and is of a molecular weight of less than 1000 Daltons[.]” (*Id.*, col. 3:38-41)

Defendant’s argument with respect to this term is derivative of its argument with respect to “molecular weight.” That is, Defendant asserts that “the intrinsic record does not specify a

⁹ Plaintiffs attempt to distinguish the facts of *Teva II* from the instant case. In doing so, they stress that in *Teva II*, it was the dueling statements made during the prosecution histories of related subsequent patents (regarding which measure of molecular weight should be used) that led to the Court’s finding of indefiniteness. (D.I. 241 at 5; Tr. at 125-26) It is true that the *Teva II* Court explained that it was the “entire record[,]” including these statements, that would have left the skilled artisan “still not [] reasonably certain” as to which type of molecular weight was intended. 789 F.3d at 1345. And here, it is also true that neither party points to any portion of the prosecution history as relevant to the issue. But *Teva II* is nevertheless on point in counseling that the skilled artisan must understand how to measure “molecular weight” in order to assess claim scope, and that the “patent record . . . [must] convey to one of skill in the art . . . the measure of molecular weight to be used.” *Id.* at 1341. A record that contains contradictory statements in the prosecution history on this score is not the only type of record that would fail to provide the requisite reasonable certainty. And, for the reasons set out above, the record here compels the same conclusion as that reached in *Teva II*.

single measure of ‘molecular weight’ to be used to determine whether a particular polymer is or is not of a ‘molecular weight of less than 1000.’” (D.I. 243 at 5-6; Tr. at 123-24; *see also* Plaintiffs’ Claim Construction Presentation, Slide 43 (noting the parties’ agreement that the dispute with respect to this term is resolved with the Court’s determination regarding “molecular weight”)) Defendant’s expert Dr. Lowman explains that “a polymer with a polydispersity of 1.1 could have a [Mw] molecular weight of 1,045 and a [Mn] molecular weight of 950” and it would therefore “both meet and not meet the definition of ‘small molecule’ at the same time.” (D.I. 232 at ¶ 45) For the same reasons as discussed above with respect to molecular weight, then, the term “small molecule” is indefinite.

IV. CONCLUSION

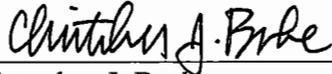
For the foregoing reasons, the Court recommends that the District Court find that:

1. “molecular weight” is indefinite
2. “small molecule” is indefinite

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 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 Henderson v. Carlson*, 812 F.2d 874, 878–79 (3d Cir. 1987); *Sincavage v. Barnhart*, 171 F. App’x 924, 925 n.1 (3d Cir. 2006).

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 District Court’s website, located at <http://www.ded.uscourts.gov>.

Dated: August 4, 2017



Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE