UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GLYCOBIOSCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case Nos. 12-1901, 15-592 (RDM)**
	)	
INNOCUTIS HOLDINGS, LLC, et al.,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM OPINION REGARDING CLAIM CONSTRUCTION

Plaintiff Glycobiosciences, Inc. filed this patent infringement suit against Defendants Innocutis Holdings, LLC and Dara Biosciences, Inc., *see* Dkt. 1, alleging that Defendants indirectly or contributorily infringed U.S. Patent No. 6,387,407 ("the '407 patent") by importing, selling, or offering to sell Defendants' BIONECT product, *see* Dkt. 23 ¶¶ 18, 25, 32, 38.[1] Plaintiff subsequently filed a second infringement action asserting the '407 patent against Defendant Fidia Farmaceutici, S.p.A ("Fidia"), the manufacturer of BIONECT. *See* No. 15-592, Dkt. 1. Given the overlap in the complaints, the Court consolidated the cases. *See* June 10, 2015, Minute Order.

"A determination of [patent] infringement involves a two-step analysis. First, the claim must be properly construed to determine its scope and meaning. Second, the claim as properly construed must be compared to the accused device or process." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1320 (Fed. Cir. 2003) (internal quotation marks omitted). The matter

[1] Citations to docket entries are to the docket in Civil Action No. 12-1901. The '407 patent appears in the record at Dkt. 48-9.

before the Court pertains to the first step of this analysis: claim construction. *See* Dkts. 48, 49, 62, 63, 70, 72. The parties have asked the Court to construe two disputed terms in claim 1 of the '407 patent: "nonionic polymer" and "weight average molecular weight from *about* 650,000 to *about* 800,000." *See* '407 patent, col.16:21-36 (emphases added).

For the reasons given below, and upon consideration of the '407 patent, its prosecution history, the parties' briefs and expert declarations, and the argument and testimony at the June 10, 2015, claim construction hearing, the Court concludes as follows:

(1) "*Nonionic polymer*" means a polymer composed of macromolecules that do not contain ionic bonds, ions, or functional groups that would ionize in aqueous solution under conditions applicable to the production of pharmaceutical products.

(2) The use of the word "*about*" in the phrase "*[w]eight average molecular weight from about 650,000 to about 800,000*" is not subject to a precise numerical definition. The meaning of the term, moreover, turns on both (a) consideration of fair notice to those skilled in the art regarding the scope of the claimed invention and (b) consideration of how variations in molecular weight affect the performance and characteristics of the claimed invention. Considering the first factor, the Court concludes that the word "about" cannot admit of variations even approaching the ± 10% figure that Plaintiff attributes to the term. The Court accordingly recognizes a maximum possible variation in the claimed range.

The Court, however, reserves judgment as to whether the meaning of "about" can be affixed with greater precision based on the second factor. As explained below, the parties have yet to present the Court with sufficient evidence to permit it to assess how small variations in molecular weight might affect the functionality of the claimed invention. Thus, for present purposes, the Court merely concludes that any variation in molecular weight even approaching

± 10% plainly falls beyond the scope of claim 1. In the face of uncertainty regarding the effect of small changes in molecular weight on the performance and characteristics of the invention, Defendants' proposed range of variation of no more than ± 2% might have merit, while a somewhat wider range might be appropriate if Plaintiff can show that such a variation would have no functional affect on the invention.

I. BACKGROUND

The only patent presently asserted in this litigation is Plaintiff's '407 patent, which issued on May 14, 2002.[2] *See* Dkt. 23-1. That patent is directed to a topical—or "transdermal"—drug delivery process. *See* '407 patent, col. 1:10-15. As explained in the patent's specification, the claimed process involves the application of a water-based gel that may contain a therapeutic drug to the skin; the drug is released slowly over time as the gel penetrates the tissues beneath the skin's outer layer. *See id.* col. 1:10–15, col. 2:52–64; col. 3:29–46. The gel contains a blend of two polymer components: (1) "a negatively charged polymer material" called "hyaluronate sodium salt," and (2) an unspecified "nonionic polymer." *Id.* col. 16:26–31.

The '407 patent's only independent claim, claim 1, recites:

> A process for the use of a composition as a medical device, for drug delivery, the application of a diagnostic agent, or the prevention of post operative adhesions, said process comprises topically administering to a mammal an aqueous based gelled composition containing a polymer matrix composed of a negatively charged polymer material blended with a *nonionic polymer*;

[2] As summarized in the Court's June 10, 2015 Memorandum Opinion, Dkt. 64, the '407 patent expired for failure to pay maintenance fees and was subsequently reinstated by the Patent and Trademark Office, at which point Plaintiff amended its complaint to add infringement contentions based on that patent. The file history of the '407 patent, including the cited administrative documents, may be viewed at http://portal.uspto.gov/pair/PublicPair (select "Patent Number" option and enter "6,387,407").

> wherein the negatively charged polymer material is hyaluronate sodium salt; and
>
> wherein the hyaluronate sodium salt has *a weight average molecular weight from about 650,000 to about 800,000,* a sulphated ash content below about 15%, a protein content below about 5%[,] and purity of at least 98%.

Id. col. 16:22–36 (emphases added). The parties ask the Court to resolve the meaning of two disputed claim terms: "nonionic polymer" and "weight average molecular weight from about 650,000 to about 800,000." Dkt. 61 at 1–2.

To set the stage for the parties' dispute, it is necessary to review some basic chemistry. A "polymer" is "[a] macromolecule formed by the chemical union of five or more identical combining units called monomers." *Hawley's Condensed Chemical Dictionary* 1013 (15th ed. 2007) ("*Hawley's Dictionary*"); *see also* Dkt. 42-1 at 3 (Kolbert (I) Decl. ¶ 10); Transcript of Claim Construction Hearing at 82–83 ("*Markman* Hearing"). The monomers are connected together in long, bead-like chains that are often made up of thousands of monomers. *See Hawley's Dictionary* at 1013; *see also* Transcript of Technology Hearing ("Tech. Hearing") at 24. The physical characteristics of a polymer are often dependent on the length of these chains. Dkt. 42-1 at 3 (Kolbert Decl. (I) ¶ 10).

Because the number of monomers in a polymer can vary, and this variation may affect the characteristics of the polymer, it can be important to specify its size, or "molecular weight." Dkt. 63-7 at 2 (Ex. F).[3] As with other polymers, "many of the biological functions of [hyaluronic acid] are dependent on molecular size," Dkt. 63-8 at 2 (Ex. G),[4] which explains

[3] David C. Armstrong & Michael R. Johns, *Culture Conditions Affect the Molecular Weight Properties of Hyaluronic Acid Produced by* Streptococcus Zooepidemicus, 63 Applied & Envtl. Microbiology 2759 (1997).

[4] Esteban Marcellin et al., *Insight into Hyaluronic Acid Molecular Weight Control*, 98 Applied Microbiology & Biotech. 6947 (2014).

why—as here—"the molecular weight of [hyaluronic acid] is a primary criterion in patents describing [hyaluronic acid] production," Dkt. 63-7 at 2 (Ex. F at 2759). Generally speaking, changes in the molecular weight of hyaluronic acid affect its viscosity—its ability to flow. *Markman* Hearing at 67.

There are several ways to calculate molecular weight, *see* Dkt. 63-12 at 2–3 (Ex. K),[5] which is measured in Daltons—a unit of mass equal to one-twelfth "the mass of a free carbon 12 atom, at rest and in its ground state." Nat'l Institute of Standards & Tech., NIST Special Publ'n No. 330, *The International System of Units* (SI) 34 (Barry N. Taylor & Ambler Thompson eds., 2008).[6] The parties do not dispute, however, that "weight average molecular weight," measured in Daltons, is the relevant measure with respect to the construction of claim 1 of the '407 patent. *See* Dkt. 61 at 2. The "weight average molecular weight" of a polymer is calculated in a manner that accounts for variation in size between the individual molecules in a sample. *See* Dkt. 63-12 at 3 (Ex. K). It is a method of calculating the weight of a polymer "by taking all the different-sized molecules in the mix that makes up [the polymer] and calculating their average weight while giving heavier molecules a weight-related bonus when doing so." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 836 (2015).

Polymers, like other molecules, contain chemical bonds. The monomers in a polymer are linked together by "covalent" bonds, *Markman* Hearing at 81–82, that is, bonds in which electrons are shared between two atoms, *Hawley's Dictionary* at 342. Polymers may also contain "ionic" bonds, which are bonds created by "the force of attraction between oppositely

[5] Polymer Science Learning Center, Dep't of Polymer Science, The Univ. of S. Miss., *Calculating Molecular Weights* (2005).

[6] *Available at* http://physics.nist.gov/Pubs/SP330/sp330.pdf.

charged" ions. Dkt. 63-3 at 6 (Ex. B).[7] An ion is "[a]n atom or radical that has lost or gained one or more electrons and has thus acquired an electric charge." *Hawley's Dictionary* at 697. In short, an atom that loses an electron has more protons than electrons, and accordingly becomes a positively charged ion, which is called a cation. Dkt. 63-3 at 6 (Ex. B at 11); *see also* T.R. Dickson, *Introduction to Chemistry* 254 (8th ed. 2000) (Dickson, *Intro to Chemistry*). An atom that gains an electron has more electrons than protons, and thus becomes a negatively charged ion, which is called an anion. Dkt. 63-3 at 6 (Ex. B at 11); Dickson, *Intro to Chemistry,* at 254. An ionic bond occurs when one molecule transfers an electron to another molecule, forming oppositely charged ions that are attracted to each other. *See Hawley's Dictionary* at 697; Dkt. 63-3 at 6 (Ex. B at 11). By contrast, the bonded molecules in a covalent bond share, rather than transfer, electrons between them. *See Hawley's Dictionary* at 342. Covalent bonding occurs between molecules that are not ionized; they do not depend on the loss or gain of an electron to form a bond. *See* Dickson, *Intro to Chemistry* at 258–59. Rather, "[t]he result of [a covalent bond] is that both atoms attain a stable electronic configuration by mutual possession of electrons." *Id.* at 259.

Hyaluronic acid, a polymer used to prepare the gel composition described in the '407 patent, is derived from "various tissue sources including umbilical cords, skin, vitreous humour, synovial fluid, tumors, haemolytic streptocci pigskin, rooster combs, and the walls of veins and arteries." '407 patent col. 4:33–35. It can also be "synthesized artificially and by recombinant technology." *Id.* col. 4:36–37. It is soluble in water and able to form a gel matrix to which drugs that are dissolved or disbursed in water may be added. *Id.* col. 4:23; *id.* col. 5:56–57.

[7] Francis A. Carey, *Chapter 1: Chemical Bonding, Atoms, Electrons, and Orbitals, Organic Chemistry* 11 (McGraw-Hill 4th ed. 2000).

Of particular relevance here, the parties agree that "hyaluronate sodium salt"—the salt form of hyaluronic acid—contains ionic bonds. *See* Dkt. 70 at 9; Dkt. 72 at 11. The parties also agree that hyaluronic acid itself does not contain ionic bonds before it is in solution. *See* Dkt. 70 at 9; Dkt. 72 at 11; *Markman* Hearing at 39. Hyaluronic acid does, however, contain ionizable "carboxyl" or "-COOH" acid functional groups that consist of carbon, oxygen, and hydrogen atoms. Dkt. 70 at 8; Tech. Hearing at 27–29. As relevant here, when hyaluronic acid is placed into an aqueous solution containing sodium hydroxide, a process known as neutralization, the carboxyl groups lose hydrogen ions (protons), leaving oxygen atoms from the carboxyl group negatively charged. Tech. Hearing at 27–29; *see also* Michael Munowitz, *Principles of Chemistry* 284 (1st ed. 2000) (explaining carboxylic acid functional groups); *Hawley's Dictionary* at 1054 (defining "proton"). The negatively charged oxygen ions then form ionic bonds with the positively charged sodium ions from the ionized sodium hydroxide, forming hyaluronate sodium salt (and water). Tech. Hearing at 27–29. To summarize, hyaluronic acid does not contain *ionic bonds*, but when placed in an aqueous solution, hyaluronic acid *ionizes*—it dissociates into *ions* that are then attracted to oppositely charged ions, resulting in ionic bonds. As relevant here, those bonds are formed with sodium cations, creating hyaluronate sodium salt.

The '407 patent claims a process for the use of "an aqueous based gelled composition containing a polymer matrix composed of" hyaluronate sodium salt "blended with a nonionic polymer." Col. 16:25–31. The hyaluronate sodium salt, moreover, must have a weight average molecular weight of between "about 650,000 to about 800,000" Daltons. *Id.* col. 16:32-34.

On February 20, 2015, the parties filed their opening claim construction briefs addressing the meaning of (1) "nonionic polymer" and (2) "a weight average molecular weight from about 650,000 to about 800,000." *See* Dkts. 48, 49. Pursuant to the Court's May 1, 2015, Minute

Order, the parties subsequently filed a Joint Claim Construction Statement to identify the disputed terms and proposed constructions. *See* Dkt. 61. They then filed responsive claim construction briefs on May 20, 2015. *See* Dkts. 62, 63. On May 29, 2015, the parties presented a technology tutorial to the Court, and, on June 10, 2015, the Court held a claim construction—or "*Markman*"—hearing. At the hearing, Defendants offered the testimony of their expert, Dr. Jason Burdick. Plaintiff offered no expert testimony at the hearing.

At the claim construction hearing, Plaintiff conceded that dependent claim 2 is indefinite because it does not contain any limitation that is narrower than independent claim 1. *Markman* Hearing at 24–25. At the hearing, Plaintiff also conceded that dependent claim 3 "may be redundant" and failed to identify any way in which the subject matter covered by that claim differs from the subject matter covered by independent claim 1. *Markman* Hearing at 24. The Court, accordingly, does not address claims 2 or 3 in this order. In addition, on the same day as the *Markman* hearing, the Court consolidated Plaintiff's infringement action against Innocutis Holdings, LLC and Dara Biosciences, Inc., No. 12-cv-1901, with its later-filed action against Fidia, No. 15-cv-0592. The parties agree that the Court's ruling on claim construction will bind Fidia, as well as the previously named Defendants. Dkt. 69 at 2 (Defendants); *Markman* Hearing at 25–26 (Plaintiff).

After the hearing, Plaintiff filed a motion to strike portions of Defendants' claim construction submissions, or for alternative relief. *See* Dkt. 66. The Court denied the motion for failure to comply with Local Civil Rule 7(m) and directed the parties jointly to propose a schedule for the submission of reply briefs addressing any remaining claim construction disputes. *See* June 22, 2015, Minute Order; *see also* Dkt. 68 (Joint Stipulation); June 23, 2015,

Minute Order. Plaintiff filed its reply on June 30, 3015, *see* Dkt. 70, and Defendants filed their reply on July 8, 2015, *see* Dkt. 72.

The construction of the disputed terms of the claim, accordingly, is now ripe for decision.

II. DISCUSSION

"'[T]he construction of a patent, including terms of art within its claim,' is not for a jury but 'exclusively' for 'the court' to determine . . . even where the construction of a term of art has 'evidentiary underpinnings.'" *Teva*, 135 S. Ct. at 835 (quoting *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 390 (1996)). In this limited respect, the construction of a patent is "much the same task as the judge would [conduct] in construing other written instruments, such as deeds, contracts, or tariffs." *Id.* at 837. "[T]he ultimate issue of the proper construction of a claim should be treated as a question of law," but "subsidiary factfinding is sometimes necessary." *Id.* at 838.

In construing a patent, the court considers both intrinsic and extrinsic evidence. The first category, intrinsic evidence, includes the claim language itself, the specification, and the prosecution history of the patent. "[T]he claims are 'of primary importance'" because they "'ascertain precisely what it is that is patented.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876)). When the court construes the language of a claim, words are given "the ordinary and customary 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." *Id.* at 1313. In turn, "the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent . . . ." *Id.* This context includes the patent specification, which is the statutorily required "written

description of the invention, and of the manner and process of making and using it" in "full, clear, concise, and exact terms," such that "any person skilled in the art" could make and use the invention. 35 U.S.C. § 112(a). Other than the language of the claim itself, the specification "'is the single best guide to the meaning of a disputed term,'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)), although the court must be careful not to import limitations from the specification into the claim that are not already included in the latter, *id.* at 1323.

The prosecution history of a patent "provides evidence of how the [Patent and Trademark Office] and the inventor understood the patent," and thus supplies further intrinsic evidence of the meaning of disputed terms. *Id.* at 1317. Moreover, "where the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender." *Omega*, 334 F.3d at 1324. Because the prosecution history "often lacks the clarity of the specification," it is often "less useful for claim construction purposes." *Phillips*, 415 F.3d at 1317.

The second category of evidence, extrinsic evidence, includes "'all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.'" *Id.* (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370 (1996)). Such evidence is "less significant than the intrinsic record" but can nonetheless "shed useful light on the" meaning of the disputed terms. *Id.* (internal quotation marks omitted). For example, dictionaries, treatises, and expert testimony can help "to provide background on the technology at issue, to explain how an invention works, 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.* at 1318. In construing a patent, the court must remain cognizant of the fact that, for a variety of reasons, "extrinsic evidence in general [is viewed] as less reliable than the patent and its prosecution history in determining how to read claim terms," *id.* at 1318–19, but it may admit and use such evidence for the purpose of "help[ing] [to] educate the court regarding the field of the invention and . . . help[ing] the court [to] determine what a person of ordinary skill in the art would understand claim terms to mean," *id.* at 1319.

A. Meaning of "Nonionic Polymer"

The first claim term disputed by the parties is the meaning of "nonionic polymer." Defendants posit that the phrase refers to "polymers such as hydroxyethyl cellulose that do not contain ionizable groups, such as a carboxylic group, and does not refer to polymers such as hyaluronic acid, that do contain ionizable or ionized groups." Dkt. 61 at 2.

Plaintiff's position is more difficult to pin down. Plaintiff initially took the position that "nonionic polymer" means "a polymer that has no charge attached to it in the actual gel composition [as distinguished from a starting ingredient]." *See* Dkt. 61 at 2. It then disavowed this position in its responsive claim construction brief and at the *Markman* hearing, arguing instead that "nonionic polymer" means "a polymer that does not contain ionic bonds." Dkt. 63 at 2; *Markman* Hearing at 7–8. After Defendants disputed this and offered supporting testimony from their expert, Dr. Burdick, Plaintiff again changed course and stated in its post-hearing brief that its "'revised' proposed claim construction . . . turned out to be erroneous," Dkt. 70 at 9 n.10, and that its "original proposed claim construction . . . [was] correct," *id.* at 9. But, in referring to the "correct," "original" proposed construction, Plaintiff cited an expert declaration describing

the "proposed original definition" as "a polymer that does not contain ionic bonds . . . ." *Id.* (citing Dkt. 70-8 ¶ 13). That, however, was the essence of the revised definition, which Plaintiff purported to disavow. It is thus unclear whether the Plaintiff's current position is that the definition of "nonionic polymer" is (1) "a polymer that has no charge attached to it in the actual gel composition [as distinguished from a starting ingredient]," Dkt. 61 at 2; or (2) "a polymer that does not contain ionic bonds," Dkt. 63 at 2. In light of this confusion, the Court considers all three proposed definitions—the one proffered by Defendants and the two proposed by the Plaintiff. The definition ultimately adopted by the Court combines elements of Defendants' proposed definition and Plaintiff's second proposed definition.

As a starting point, the parties agree that neither the claims, the specification, nor anything included in the prosecution history of the '407 patent expressly defines the meaning of "nonionic polymer." *See Markman* Hearing at 8, 32. Nor is there any dispute that the term "nonionic polymer" stands in contrast with the phrase "negatively charged polymer material," or that the "negatively charged polymer material" is "hyaluronate sodium salt"—that is, the salt formed when hyaluronic acid is placed in an aqueous solution containing sodium hydroxide. *See Markman* Hearing at 7, 34; Tech. Hearing at 27–29. The parties also agree that hyaluronic acid does not contain ionic bonds, but that hyaluronate sodium salt does. Dkt. 70 at 9; Dkt. 72 at 9. And finally, the parties agree that a polymer that contains ionic bonds is an ionic polymer. Dkt. 70 at 9; Dkt. 72 at 9.

This common ground, however, does little to resolve the interpretive dispute. The parties disagree about whether all polymers that lack existing ionic bonds are nonionic. *See* Dkt. 70 at 9; Dkt. 72 at 9. At the *Markman* hearing, Plaintiff relied exclusively on the definitions of "ionic bond" and "covalent bonds" and on a single passage in the patent specification to argue that a

nonionic polymer is one that does not contain ionic bonds. *Markman* Hearing at 7–8. The fact that "ionic bonds" involve the transfer of electrons, while "covalent bonds" involve the sharing of electrons, Dkt. 63-4 at 2–4 (Ex. C at 11–13), however, is not disputed and, in any event, does little to elucidate whether the term "nonionic polymer" in claim 1 is limited to polymers that contain no existing ionic bonds, or whether it means one that has no charge attached to it in the actual gel composition, or one that does not contain ionizable groups. Indeed, the passage that Plaintiff identified from the patent specification, if anything, supports Defendants' position. That passage notes that "hyaluronic acid possesses a negative charge at neutral pH" and is "soluble in water." '407 patent, col. 4:22–24. Although far from clear, the implication is that—as Defendants contend—the relevant inquiry is whether the polymer is ionizable when neutralized in an aqueous solution.

Plaintiff initially relied on a different passage from the specification to support its first proposed definition of a nonionic polymer as one "that has no charge attached to it in the gel composition." Dkt. 49 at 10. That passage states that "the polymers used in the formulation are of two basic types: those which have a strong negative charge, and those which are non-ionic or have no charge attached to them." '407 patent col. 3:7-10. This intrinsic evidence, however, is of little help in elucidating the meaning of "nonionic polymer." If anything, it suggests that the definition of "nonionic" cannot be limited to polymers that have no charge attached because "non-ionic" and "no charge attached" are listed as alternatives. Moreover, this proposed definition introduces unnecessary confusion about the meaning of "charge attached." Plaintiff asserts that one can "neutralize the charge on" an ionic polymer and that "the polymer with a neutralized charge would be considered [to be a] polymer having no charge attached to it." Dkt 49 at 10. This contention, however, is belied by the passage of the specification discussed above,

which states that "hyaluronic acid possesses a negative charge *at neutral pH*." '407 patent col. 4:22–23 (emphasis added). That is, under the terminology of the specification, when hyaluronic acid is neutralized—for example, when it is in salt form and thus contains ionic bonds—it has a "negative charge." Although "neutralized" in the sense that compounds containing ions held together by ionic bonds "are overall electrically neutral because . . . [there are] as many positive charges as negative charges," Dickson, *Intro to Chemistry* at 2557, the patent specification would still consider the polymer to have a "charge." For these reasons, the Court rejects Plaintiff's first proposed definition.

Defendants also find little support for their position in the language of the patent. They correctly note that Plaintiff's focus on the state of the polymer "in the actual gel composition," Dkt. 61 at 2, is difficult to reconcile with the language of the claim. That language provides that the "nonionic polymer" is blended with the "negatively charged polymer material," '407 patent col. 16:27–28, and thus suggests that the "nonionic polymer" can be identified as such before it is blended in the "actual gel composition." Thus, not surprisingly, Plaintiff revised its "proposed definition" at the *Markman* hearing, and conceded that the meaning of "nonionic polymer" would not vary based on whether the polymer has already been blended in the gel composition. *Markman* Hearing at 8.

The remainder of Defendants' textual argument, however, is less convincing. In an effort to rebut Plaintiff's contention that a "nonionic polymer" is simply a polymer that lacks ionic bonds, Defendants point to language in the specification asserting that "[e]xemplary . . . compounds that may be used as a source of" the ionic polymer used in the matrix—that is, the negatively charged material—include "mucopolysaccharides." '407 patent col. 4:8–10. Noting that hyaluronic acid is a mucopolysaccharide, *see id.* col. 4:18, and that it contains no

ionic bonds, they then argue that the definition of "nonionic polymer" cannot turn on whether the polymer contains existing ionic bonds, Dkt. 72 at 9–10. Similarly, Defendants argue that hyaluronic acid does not contain ionic bonds and that a definition of "nonionic polymer" that turns on whether the polymer has existing ionic bonds would improperly encompass hyaluronic acid. *Id.* The problem with these arguments is that the quoted language from the specification says only that the mucopolysaccharide is the "source" of the negatively charged polymer. '407 patent col. 4:7–11. And, while hyaluronic acid does not contain ionic bonds, when it is neutralized it forms hyaluronate sodium salt, which does contain ionic bonds; thus, it is indeed a "source" of the ionic polymer. Moreover, claim 1 identifies "hyaluronate sodium salt," rather than hyaluronic acid, as the ionic polymer material. '407 patent col. 16:30–31. Thus, the fact that hyaluronic acid itself does not contain ionic bonds says little about the definition of "nonionic" in the context of the '407 patent.

Plaintiff's effort at a similar syllogism also fails. Plaintiff notes that the patent specification asserts that hydroxyethyl cellulose—or "HEC"—is a "preferred nonionic polymer[]" to use in the matrix. Dkt. 70 at 8. It then argues that HEC contains "a hydroxyl group," which Plaintiff contends is "ionizable." Dkt. 70 at 7–8. From this, Plaintiff would have the Court conclude that Defendants' test, which asks whether the polymer contains an ionizable group, cannot be squared with the patent specification. In response, Defendants offer an expert declaration, which the Court finds credible, explaining that hydroxyl groups that are covalently bonded to a carbon atom to produce an alcohol, like those contained in HEC, do not participate in ionic bonding except under extreme conditions that are inapplicable to pharmaceutical products. Dkt. 72 at 10 (citing Dkt. 72-3, Burdick (III) Decl. ¶¶ 8–10).

Carboxyl groups, in contrast, do participate in ionic bonding. *Id.* This, then, raises a further question regarding the '407 patent's specification of "preferred nonionic polymers," which, in addition to HEC, includes carboxymethylcellulose sodium. '407 patent col. 2:61–62. Following Plaintiff's reasoning, one might reasonably argue that the identification of a polymer that contains an ionizable group as a "preferred nonionic polymer" shows that the relevant test cannot be whether the polymer contains an ionizable group. At the *Markman* hearing, however, the Court asked a related question about claim 5 of the patent, which provides that the nonionic polymer would be selected from, among other polymers, carboxymethylcellulose sodium, *id.* col. 16:47–49. As with the specification, this language would seem to suggest that Defendant's proposed definition of "nonionic polymer" could include polymers containing ionizable carboxyl groups. Counsel for Plaintiff, however, explained that the inclusion of carboxymethylcellulose sodium in claim 5 was a mistake and that, accordingly, Plaintiff was not asserting claim 5 in the litigation. *Markman* Hearing at 79. That concession would seem to apply to the specification of the preferred nonionic polymers as well, and, indeed, Plaintiff has not relied in any way on the reference to carboxymethylcellulose sodium in the specification.

Given the absence of any conclusive intrinsic evidence, the Court turns to the extrinsic evidence. Although not relied upon by either party, a number of lay dictionary definitions provide helpful guidance. According to the Oxford English Dictionary, "non-ionic" means "not dissociating into ions in aqueous solution." OED Online (Sept. 2015).[8] Similarly, the Random House Kerneman Webster's College Dictionary defines "nonionic" to mean "not ionizing in

[8] http://www.oed.com/view/Entry/127976?redirectedFrom=non-ionic& (last visited Nov. 11, 2015).

aqueous solution." K Dictionaries Online (2010).[9] Other dictionaries define the term more generally to mean "not ionic: nonpolar," Webster's Third New International Dictionary, Unabridged Dictionary (May 2015), or "not ionic; especially: not dependent on a surface-active anion for effect," Webster's Third New International Dictionary, Collegiate Dictionary (May 2015).

These lay definitions are consistent with the testimony of Defendants' expert, Dr. Burdick. In his third declaration, he explained that "[o]ne of ordinary skill in the art would never refer to a polymer such as hyaluronic acid as ever being non-ionic," because "once placed in an aqueous solution, the polymer would possess a charge." Dkt. 72-3 at 3 (Ex. 3 ¶ 11). In support of this understanding, Dr. Burdick points to a publication by the International Union of Pure and Applied Chemistry ("IUPAC"). *See* Dkt. 72-3 at 9–16 (Ex. A).[10] According to IUPAC, an "ionic polymer" is a "[p]olymer composed of macromolecules containing ionic or ionizable groups, or both, irrespective of their nature, content, and location." *Id*. at 13. IUPAC also states that "ion-containing polymer" is a synonym for "ionic polymer." *Id.* The meaning of "nonionic polymer," it follows, would merely be the flip side of these definitions.

The Court finds that this extrinsic evidence is convincing. Accordingly, based on this evidence and the available intrinsic evidence, the Court concludes that, as used in the '407 patent, "nonionic polymer" means "a polymer composed of macromolecules that do not contain

[9] http://www.kdictionaries-online.com/DictionaryPage.aspx?ApplicationCode=18&DictionaryEntry=nonionic&SearchMode=Entry&TranLangs=18 (last visited Nov. 11, 2015).

[10] Hess et al., Polymer Div. Comm'n on Macromolecular Nomenclature & Subcomm. on Macromolecular Terminology, *Terminology of Polymers Containing Ionizable or Ionic Groups and of Polymers Containing Ions*, Pure Applied Chemistry 2067 (2006).

ionic bonds, ions, or functional groups that would ionize in aqueous solution under conditions applicable to the production of pharmaceutical products."

B. The Meaning of "About 650,000 to About 800,000" Daltons

The second disputed claim term relates to the weight of the hyaluronate sodium salt used in the gel composition. As recited in claim 1, "the hyaluronate sodium salt has a weight average molecular weight from *about* 650,000 to *about* 800,000" Daltons. '407 patent col. 16:32-33 (emphases added). The dispute turns on the meaning of the word "about."

1. *At What Point In the Process Is the Molecular Weight Determined?*

As an initial matter, Defendants argue that the relevant measurement is the weight average molecular weight of the hyaluronate sodium salt *before* it is blended with the "nonionic polymer." Dkt. 48 at 7. For at least two reasons, the Court agrees. First, claim 1 specifies that there are two distinct components of the claimed composition: (1) hyaluronate sodium salt of the specified weight and purity, and (2) a nonionic polymer with which the hyaluronate sodium salt is blended. The plain language of the claim makes clear that the weight limitation applies only to the first of those components—the hyaluronate sodium salt. *See* '407 patent col. 16:29–32. Second, in discussing the negatively charged polymer "used to form the matrix of this invention," the specification explains that "the polymers must be sterilizable and be stable during sterilization so that the polymer *does not lose molecular weight once formulated* into the final transdermal delivery form." *Id.* col. 4:3–6 (emphasis added). It also states that "the negative[ly] charged polymer may be blended and stirred in water until it is dissolved. . . . [T]he molecular weight of the polymer *must not be significantly changed* during processing and as such mild process conditions are required." *Id.* col. 5:38–44 (emphasis added). The plain import of these statements is that the molecular weight of the negatively charged polymer—that is, the

hyaluronate sodium salt—is assessed before blending and that the specified weight of the hyaluronate sodium salt is its weight at that stage of the process. Had the patentees intended for the weight specification to apply to the entire composition, they could easily have said so, as they did in a parent application of the '407 patent. *See* Dkt. 48-2 at 24 ('750 application, Ex. B at col. 22:24–25) (including claim "wherein the negative charged polymer is present in amounts of about 0.1% to about 2.0% by weight of the entire composition").

Plaintiff asserted at the *Markman* hearing that the timing of the measurement of the weight of the hyaluronate sodium salt is a "nonissue" because its weight is "not supposed to change during the making of the product." *Markman* Hearing at 18–19. But, as discussed above, the patent includes specifications premised on the possibility that the weight of the hyaluronate sodium salt might, in fact, change—at least modestly—during formulation. Plaintiff further stated that it was "satisfied to measure [the weight] after [blending] because that's when you can buy it—that's when you can get the accused product commercially and test it." *Id.* at 19. The relevant question at this stage of the proceedings, however, is not one of the convenience of testing the accused product, but of the meaning of claim 1 to a person of ordinary skill in the art. The Court finds that the claim describes the weight average molecular weight of the hyaluronate sodium salt prior to blending with the nonionic polymer for the reasons above. How to assess whether the allegedly infringing product contains hyaluronate sodium salt with the claimed weight average molecular weight may be determined at a later stage in the proceeding.

Finally, the Court notes that it is the weight of hyaluronate sodium salt—and not hyaluronic acid—that is relevant under the terms of claim 1. Although the parties, at times, seem to refer to the polymers interchangeably, the patent does not, and it is the language of the claim that controls.

2. *What Does "About" Mean In The Relevant Context?*

The lion's share of the parties' briefing focuses on the meaning of the term "about," which appears twice in the weight limitation in claim 1: the hyaluronate sodium salt must have "a weight average molecular weight from *about* 650,000 to *about* 800,000." '407 patent col. 16:32–34 (emphases added). The parties agree that nothing contained in the claims, specification, or prosecution history expressly defines the term "about." *See generally* Dkt. 48 at 12–15; Dkt. 49 at 10–12. The term, moreover, lacks any fixed meaning in patent law. *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995). Although the Federal Circuit has opined that "about" ordinarily means "approximately," *Merck & Co. v. Teva Pharm. USA*, 395 F.3d 1364, 1369 (Fed. Cir. 2005), in the present context that does not answer the question of how much variation is covered by the terms of the claim. That is, the Court must still determine how close is close enough.

A number of factors can guide the Court in making that determination. First, and foremost, the patent must "afford clear notice of what is claimed, thereby appris[ing] the public of what is still open to them." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2123 (2014) (quotation marks and citation omitted). Thus, if a patentee intends to give a term a meaning that differs from its ordinary usage, it is incumbent on the patentee to speak with "sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck*, 395 F.3d at 1370. Second, the entire point of using a word like "about" is that it eschews precision; if the patentees intended to claim a precise weight range, they would have specified that precise weight range. *See, e.g.*, *id.* at 1372; *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996); *W.L. Gore & Assoc., Inc. v.*

Garlock, Inc., 842 F.2d 1275, 1280 (Fed. Cir. 1988).[11] As the Federal Circuit has observed, "[i]t is usually incorrect to read numerical precision into a claim from which it is absent." *Modine*, 75 F.3d at 1551. Third, where the term "about" is used to modify a specified range, the range itself will often inform the meaning of the term "about." *See Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995). It is improbable, for example, that the addition of the word "about" to a specified range would have the effect of doubling the range. *Id.* Fourth, the term "about" "must be interpreted in its technological and stylistic context." *Pall Corp.*, 66 F.3d at 1217. Finally, as with all other material terms, the prosecution history can shed light on the scope of the relevant claim. *See, e.g.*, *Teva*, 135 S. Ct. at 841; *Phillips*, 415 F.3d at 1317.

Applying these considerations, the Court turns to the competing interpretations offered by the parties.

a. Polydispersity

Defendants' first proposed interpretation of the meaning of the word "about" turns on the concept of "polydispersity." They argue that the use of "about" in the weight limitation "might" be understood by a person of ordinary skill in the art to refer to the degree of variation inherent in the calculation of a polymer's average molecular weight—that is, that "the term 'about' . . . mean[s] that there is a distribution of polymer chain lengths" within the measured sample, known in the field as the polydispersity of the sample. *See* Dkt. 48 at 12. The calculation of a polymer's weight average molecular weight is a mechanism of averaging the weight of polymer chains of varying molecular weights into one numerical figure. In Defendants' view, "about" in

[11] *Modine Manufacturing Co. v. U.S. International Trade Commission* was abrogated on other grounds by *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), but subsequently reinstated by *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739–40 (2002).

claim 1 merely refers to the "distribution of polymer chain lengths, but" does not mean that the molecular weight "is outside of the stated range." *Id.* Under this view, Defendants submit that the Court should construe "about 650,000 to about 800,000" to mean a weight average molecular weight falling within the exact range of 650,000 to 800,000. *See id.*

The Court rejects this construction of the claim. If one thing is clear, it is that "about" does not mean "exactly." *See Merck*, 395 F.3d at 1370. Such a construction would be contrary to common usage and would fail to provide notice of the scope of the claim to those "reasonably skilled in the art." *Id.* It would also deprive a modifier that appears twice in the claim—"*about* 650,000 to *about* 800,000"—of any meaning, *see id*. at 1372, and would disregard repeated admonitions from the Federal Circuit that "[t]he use of the word 'about[]' avoids a strict numerical boundary to the specified parameter," *Pall Corp.*, 66 F.3d at 1217; *see also Cent. Admixture Pharmacy Servs., Inc. v. Advanced Cardiac Sols., P.C.*, 482 F.3d 1347, 1355 (Fed. Cir. 2007); *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326 (Fed. Cir. 2007). There is nothing on the face of the patent that would "justify such a counterintuitive definition." *Merck*, 395 F.3d at 1369–70.

Other intrinsic evidence also supports a construction that would give the word "about" its ordinary meaning, which, at its core, conveys a degree of variance outside the expressly delimited range. In construing the meaning of a claim term, courts can, and should, look to other claims in the same patent, whether asserted or not. *See Phillips*, 415 F.3d at 1314. Here, the terms of claim 4 shed light on the meaning of claim 1. Although claim 1 defines the hyaluronate sodium salt as having "a weight average molecular weight from *about* 650,000 to *about* 800,000," '407 patent col. 16:33–34 (emphases added), claim 4 omits the term "about" and covers only hyaluronate sodium salt having "a weight average molecular weight between

700,000 and 775,000," *id.* col. 16:46. "When a limitation is included in several claims but is stated in terms of apparently different scope, there is a presumption that a difference in scope is intended and is real." *Modine*, 75 F.3d at 1551. Defendants have not provided any evidence to rebut this inference or that otherwise demonstrates that the word "about" should be deprived of its ordinary meaning—and, indeed, of any meaning at all.

b. Degree of Variance

It remains, then, for the Court to consider the degree of variance in weight average molecular weight captured in claim 1 through the use of the modifier "about." Even assuming that some variance is appropriate, the parties argue for vastly different constructions of the patent. According to the Defendants, even if "about" invites some degree of variance, any such variance cannot reasonably exceed ± 2%. Backed by expert testimony, they explain that the procedures used to calculate the molecular weight of hyaluronic acid are "very accurate" and that "those skilled in the art," as a result, "do not really consider experimental error or imprecision for these procedures." Dkt. 48-7 at 7 (Burdick (I) Decl., Ex. G ¶ 29). But, in any event, as confirmed by a brochure from "one of the major manufacturers of" the system used in measuring weight average molecular weight, the system performs within a 1.5% margin of error. *Id.* (Ex. G ¶ 30). Thus, at most, one skilled in the art would "assign a range of imprecision" of "less than 2%." *Id.* (Ex. G. ¶ 29).

In stark contrast, Plaintiff argues that use of the word "about" contemplates a variance as large as ± 20%. Dkt. 49 at 11. According to Plaintiff, what matters most in construing the word "about" is the function of the invention; the word "about" expands coverage of the claim to those variations in weight average molecular weight that do not affect functionality. Dkt. 63 at 11, 13; *Markman* Hearing at 11. Plaintiff adds, moreover, that hyaluronic acid is typically offered for

sale with average molecular weights that fall within bands or ranges, *Markman* Hearing at 13 (citing Dkt. 42-1 at 4 (Ex. 1 ¶ 16)), and that the scientific literature refers to weight average molecular weight bands or ranges as well, Dkt. 63 at 10–11 (citing Dkt. 63-8 at 3 (Ex. G at 6948)). One such range is the "low to moderate weight average molecular weight" range from about 500,000 to 2,000,000 Daltons. *Id.* According to Plaintiff, hyaluronic acid "within this range [will likely] have the same physical and biological properties." *Id.* at 11. Similarly, Plaintiff's expert notes that the "low" average molecular weight range extends from 10,000 to 1,000,000 Daltons and argues that "a customer purchasing" hyaluronic acid in this range "could not reject the product if the average molecular weight was slightly less than 10,000 or slightly greater than one million." Dkt. 42-1 at 4–5 (Ex. 1 ¶¶ 16–18). Although unable to provide a precise limit, Plaintiff's expert estimates that, even without use of the word "about," one skilled in the art would understand a range of 650,000 to 800,000 Daltons to contemplate a variance of ± 10% and asserts that use of the word "about" twice in the stated range would convey a far more expansive range—extending "from 552,500 to 920,000 [if ± 15% is applicable]" to "520,000 to 960,000 [if ± 20% is applicable]." *Id.* at 6 (Ex. 1 ¶¶ 22–23). Finally, in its post-*Markman* hearing brief, Plaintiff suggests that it is premature to define the permissible range, since the parties will need discovery and further factual development to assess how variations in molecular weight affect the functionality of the invention. Dkt. 70 at 7–8.

As an initial matter, for the same reason that the Court cannot accept Defendants' contention that "about" means "exactly," the Court cannot accept Plaintiff's contention that, even without the modifier "about," one skilled in the art would understand the range of 650,000 to 800,000 to encompass a ± 10% variance. *See* Dkt. 49 at 11. The purpose of the word "about" is to admit of some variance, and, as with Defendants' argument, Plaintiff's contention would

deprive the word "about" of independent meaning.

The Court is also unconvinced by Plaintiff's contention that an additional ± 10% variance is justified to reflect the use of the word "about" in claim 1. Plaintiff's expert Dr. Andrew Kolbert contends that those skilled in the art would understand "about" to admit of up to an additional 10% variance but, as Defendants note and as Plaintiff conceded at the claim construction hearing, Dr. Kolbert provides no evidentiary support for his conclusion. *See* Markman Hearing at 12; Dkt. 62 at 6. Application of a ± 10% margin, moreover, is contrary to the intrinsic evidence. The word "about" is not freestanding, but modifies the range from 650,000 to 800,000. That range already captures an inexactitude and a sense of the magnitude of acceptable differences. The 150,000-Dalton difference between the endpoints of the range is about 20%—more specifically, 23% of the lower limit and 19% of the upper limit. Reading the word "about" to justify a 10% variance at either end of the range, as Plaintiff proposes, would almost double the size of the range from 150,000 Daltons to 295,000 Daltons. Indeed, even a ± 5% variance would extend the range from 150,000 Daltons to 222,500 Daltons—an expansion of almost 50%. Given this context, the Court rejects a construction of the word "about" that would permit a variance even approaching the ± 10% figure proposed by Plaintiff. "About" denotes a degree of numerical imprecision; it does not, however, encompass a fundamental shift in the scope of the claim.

Plaintiff's proposed construction is also difficult to reconcile with the Federal Circuit's decision in *Eiselstein v. Frank*, 52 F.3d 1035. There, the Federal Circuit considered the scope of a claim limitation regarding the percentage of nickel in an alloy. *Id.* at 1040. It construed the meaning of the claim in an initial, or "grandparent," application in order to determine whether a later application was sufficiently disclosed so that the earlier application established the patent's

filing date. *Id.* The grandparent application claimed a range that the court construed as "'about' 45–55%" nickel. *Id.* The later application claimed an alloy with "about 50 to about 60%" nickel. *Id.* The Federal Circuit concluded that the later claim was not adequately disclosed by the grandparent application based on a comparison to the variance within the expressly stated range. As the court explained:

> Whatever the term "about" means in this context, it is clear that it does not extend 55% to encompass 60%. Moreover, the 10% range of 45–55%, even if it is an approximate "about" 45–55%, is not the same as a very different 10% range, *viz.*, 50–60%. The limits of these ranges vary from each other by about 10%, which is comparable to the extent of the variation within each range. Eiselstein has therefore not persuaded us that the Board clearly erred in finding that the grandparent application did not provide an adequate written description of the invention comprising 50–60% nickel.

Id. Applying the same type of analysis here, the Court concludes that Plaintiff's proposed variance of up to ± 10%—and also its more general contention that the claim should be construed as a whole to permit a variance of ± 15% to ± 20%—is much too large.

Other intrinsic evidence bolsters this conclusion. Dependent claim 4 of the patent, for example, provides that the "negatively charged polymer material has a weight average molecular weight between 700,000 and 775,000." '407 patent col. 16:44–46. The specification explains that this range is a preferred embodiment of the invention for "excellent matrix formation." *Id.* col. 5:6–9. The range covered by claim 4 corresponds to a span of slightly more than 10%; that is, the upper limit of 775,000 is roughly 111% of the lower limit of 700,000. Thus, where a range as large as 11% was contemplated, the inventor specified the range and did not merely rely on the word "about" to do the work of the range.

The prosecution history points in a similar direction. The '407 patent was granted from Application No. 09/280,841 ("the '841 application"), which was a continuation-in-part of Application No. 08/536,750 ("the '750 application"). Dkt. 48-9 at 2. As Defendants note, the

specification of the ’750 application stated that “[p]articularly preferred polymers have mean average molecular weights below about 800,000 and preferably molecular weights between about 500,000 to 800,000 have been found acceptable to form useable polymer matrixes.” Dkt. 48-2 at 6 (Ex. B at col. 4:21–24). The inventor, however, modified this language in the ’841 application in relevant part by substituting “650,000” for the previous low end of the range of “500,000.” Dkt. 48-3 (Ex. C, ’841 application at 29). According to Defendants, Plaintiff thereby disclaimed or surrendered the subject matter between “about 500,000” and “about 650,000,” and thus cannot now reclaim the surrendered subject matter through an expansive understanding of the word “about.” Dkt. 48 at 14.

Whether treated as a relinquishment of the subject matter or simply as more intrinsic evidence of the meaning of the claim, the Court agrees that this history informs the construction of the patent. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 736–37 (2002) (“A patentee who narrows a claim as a condition for obtaining a patent disavows his claim to the broader subject matter, whether the amendment was made to avoid the prior art or to comply with § 112.”); *id.* at 739 (placing “the burden on the patentee to show that an amendment was not for purposes of patentability”). The Federal Circuit addressed a similar issue in *Modine*, 75 F.3d 1545. In that case, the patent applicant replaced a range of “about 0.015–0.070” inches with a range with an upper limit of “about 0.040” inches in a subsequent application for the same invention. *Id.* at 1552. Against this backdrop, the Federal Circuit held that “the replacement of 0.070 with 0.040 in the text require[d] the conclusion that the applicant limited the invention described in the refiled application to . . . diameters of up to about 0.040 inch[es].” *Id.*

The same is true here. The refiled ’841 application did not include any reference to an embodiment in which the negatively charged polymer weighed “between about 500,000,” which

was the original lower limit, and "about 650,000," which was the final lower limit. *See generally* Dkt. 48-3 (Ex. C, '841 application); '407 patent. Although Defendants at one point argue that this demonstrates a disavowal of the entire range from 500,000 to 650,000 Daltons, Dkt. 72 at 7, that overstates the point, since it fails to account for whatever flexibility the word "about" affords. The more general point, however, is well taken. The fact that the inventors elected not to include the range from "about 500,000" to "about 650,000" in their operative application supports the conclusion that the word "about"—which appeared in the '841 application and in the '407 patent—should not be construed in a manner that would simply recapture the relinquished portion of the range. This prosecution history does not suggest that the inventors disavowed a molecular weight of 649,999 Daltons, which is undoubtedly "about" 650,000 Daltons. But it does support the conclusion that the word "about" cannot reasonably be construed to permit anything like a ± 10% variance, which would extend the claim to cover molecular weights close to the midpoint of the disavowed range.

Plaintiff responds that prior art referenced in the '407 patent covered the molecular weight range of 50,000 to 8,000,000, and that there is accordingly no basis to believe that the '407 patent relinquished, disclaimed, or abandoned molecular weight ranges below "about 650,000." Dkt. 70 at 6–7. In other words, the amendment deleting "about 500,000" cannot have been necessitated by prior art because the '407 patent itself references prior art covering that range. *Modine*, however, held that the patent-in-suit was limited by amendment even though prior art did not render it "necessary" for the inventor to make the amendment. 75 F.3d at 1552. As the Federal Circuit explained, because the "change [to the patent application] was conspicuous and unambiguous," the "interested public [was] entitled to rely on it in interpreting the claim." *Id.* Here, Plaintiff offers no basis to distinguish this result. As in *Modine*, the

interested public is entitled to notice regarding the scope of the claim and is entitled to rely on the prosecution history to understand the nature of the invention ultimately claimed.

Finally, Plaintiff's extrinsic evidence is also unpersuasive. Plaintiff's expert, Dr. Kolbert, submitted a declaration opining that persons of ordinary skill in the art would understand that an average molecular weight range encompasses a "variance of at least ± 10%," and that adding the term "about" before each of the end points in the range would indicate "that the range is even broader, and would encompass ± 15% to ± 20%." Dkt. 42-1 at 6 (Ex. 1 ¶ 22). As explained above, the notion that a specified range incorporates a variance of "at least ± 10%" even without a modifier like "about" cannot be reconciled with basic rules of construction. But, even putting that aside, Dr. Kolbert's assertions are not supported by any evidence or any means of validation. Such "conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court." *Phillips*, 415 F.3d at 1318. In addition, Dr. Kolbert was not subject to cross-examination because he did not testify at the *Markman* hearing, and Plaintiff was unable to offer any further explication for his conclusions at the hearing or in its subsequently filed brief. *Markman* Hearing at 12; Dkt. 70. The Court, accordingly, declines to credit Dr. Kolbert's conclusory and untested opinion. *See id.*

Defendants' alternative construction of the disputed claim language is closer to the mark, but it also poses difficulties. Unlike Plaintiff's expert, Defendants' expert, Dr. Jason Burdick, testified at the *Markman* hearing. Both there and in his declarations, he explained that "about" is not commonly used by persons of ordinary skill in the art; that it might refer to polydispersity, which is discussed above, or to experimental error; and that, if he had to quantify the experimental error that might occur in the relevant context, he would use a figure of less than 2%. *Markman* Hearing at 61–62; Dkt. 48-7 at 6–7 (Ex. G ¶¶ 21–29); Dkt. 62-1 at 6–7 (Burdick

(II) Decl., Ex. H ¶ 16). To support this figure, Dr. Burdick submitted a brochure from a major manufacturer of the technology most commonly used to measure weight average molecular weight, in which the manufacturer advertised a "relative standard deviation"—a measurement of performance precision—of "<1.5%." Dkt. 48-7 at 7 (Ex. G ¶ 30 (quoting Dkt. 48-10 at 2 (Ex. 3))).

The Court concludes that this testimony is credible and that the margin of experimental error is less than 2%. Plaintiff's *post hoc* attempts to call into question Dr. Burdick's credentials after conceding at the *Markman* hearing that Defendants had "[a]bsolutely" established them are without merit. *Compare Markman* Hearing at 57 *with* Dkt. 70 at 5–6. *See also Teva*, 135 S. Ct. at 850 ("[T]rial courts have a special competence in judging witness credibility and weighing the evidence . . . ."). Plaintiff, moreover, seemingly concedes that manufacturing tolerances in the industry are limited to "slight[]" variations. Dkt. 42-1 at 5 (Ex. 1 ¶ 18).

At least at this time, however, the Court declines to adopt Defendants' proposed ± 2% test for two reasons. First, adopting an exact ± 2% limit would, once again, defeat the purpose of using the term "about," which serves to "avoid[] a strict numerical boundary to the specified parameter." *Pall Corp.*, 66 F.3d at 1217; *see also W.L. Gore*, 842 F.2d at 1280 ("'[A]bout' is not subject to such a precise construction . . . ."). Second, and more importantly, Defendants' test fails to address the relevant functional considerations, which can illuminate the meaning of the word "about." The concept of "close enough" means one thing for horseshoes or hand grenades but something very different when it comes to sewing or surgery. Likewise, as the Federal Circuit has observed, the meaning of the word "about" will often turn on its technological context. *Modine*, 75 F.3d at 1554 ("Although it is rarely feasible to attach a precise limit to 'about,' the usage can usually be understood in light of the technology embodied in the

invention."); *Pall Corp.*, 66 F.3d at 1217 ("[T]he word 'about' does not have a universal meaning in patent claims, and . . . the meaning depends on the technological facts of the particular case.").

Here, neither party has presented evidence that establishes the extent to which variations from the range of 650,000 to 800,000 Daltons are likely to affect the performance or characteristics of the claimed invention. Plaintiff argues that the scientific "literature identifies low to moderate weight-average molecular weight" hyaluronic acid "as being in the range of about 500,000 to about 2,000,000 Daltons, and argues that hyaluronic acid "within this range [will likely] have the same physical and biological properties." Dkt. 63 at 10–11. The article Plaintiff cites, however, does not go that far. It recognizes that "many of the biological functions of" hyaluronic acid "are dependent on molecular size," Dkt. 63-8 at 2 (Ex. G at 6947), and that "[s]maller molecules of" hyaluronic acid "lack the rheological properties found in very high" molecular weight hyaluronic acid, *id.* at 3 (Ex. G at 6948). The article also addresses how hyaluronic acid within specified ranges can be used in treatment. *See id.* But those general assertions do not remotely establish that variations of the magnitude suggested by Plaintiff will not affect the qualities or performance of the claimed invention. Plaintiff also points to a passage of the specification which states that polymers with "molecular weights above *about* 800,000 form solid gels in solution and are unable to serve as part of a transdermal delivery system." '407 patent col. 4:1–3 (emphasis added). Although this passage suggests that a functional definition of "about" might be appropriate, it itself uses the word "about" and does not clarify what degree of variation such a definition would encompass, particularly at the lower end of the range. *See also Cent. Admixture*, 482 F.3d at 1356 (considering evidence regarding functionality in construing the meaning of the term "about" preceding the range); *Pall Corp.*, 66 F.3d at 1218

(same).

Defendants, in turn, acknowledge that variations in molecular weight can affect the properties of hyaluronic acid, but have not identified a range that those skilled in the art would consider functionally immaterial or insignificant. At the *Markman* hearing, the Court asked Dr. Burdick "how the properties of hyaluronic acid may vary based on its molecular weight, in particular as" those properties relate "to the functionality of the" invention. *Markman* Hearing at 73. In response, Dr. Burdick testified that the molecular weight of the polymer is "important" to functionality, but he could not define a range in which variations would not affect how the product performs. *Id.* at 73–74. He explained that the range "can be very narrow," and would depend on "how a cell" might interact with hyaluronic acid. *Id.* at 74. Ultimately, however, he simply testified that he could not define such a range and that it "would be very hard to do" so. *Id.*

c. Preliminary Construction

Absent more conclusive evidence regarding the effect of variations in molecular weight beyond the 650,000 to 800,000 range, the Court cannot reach definitive conclusions regarding the meaning of the word "about" as it is used in claim 1. The Court does, however, reach the following conclusions. The meaning of the word "about" is determined by context, including (1) the scope of the range that it modifies, (2) other ranges and terms that appear in the patent claims and specification, (3) the range of measurement error acceptable to those skilled in the art, (4) the evolution of the relevant range through the course of the prosecution history, and (5) how changes in molecular weight might affect the quality and performance of the invention.

Here, as explained above, the intrinsic evidence shows that the word "about" cannot admit of variations even close to ± 10%. Because this conclusion is based, in large part, on the

language of the patent itself, fair notice to the public requires that the word "about" be construed in a manner that forecloses variations of that magnitude, regardless of functionality. *See Markman*, 517 U.S. at 373 ("It has long been understood that a patent must describe the exact scope of an invention and its manufacture to 'secure to [the patentee] all to which he is entitled, [and] to apprise the public of what is still open to them.'" (citation omitted)). That is, even if the evidence ultimately shows that variations of ± 10% or more from the 650,000 to 800,000 range do not affect the performance of hyaluronate sodium salt in the invention, the word "about" still cannot be construed to permit variations approaching ± 10%. Consideration of function, however, may further illuminate the permissible degree of variation below that point. To the extent that there is uncertainty regarding the effect of even small variations, Defendants may well be right that any variation of greater than ± 2% falls outside of the claim. But, if Plaintiff can show that larger variations make no difference to performance, the word "about" might reasonably be construed to permit variations of, for example, twice that amount.

Given the lack of evidence regarding functionality, the Court cannot provide a more precise or definitive definition of the word "about" on the present record. The parties are free to present any additional evidence on functionality on the schedule currently set for summary judgment briefing. To the extent that evidence is disputed, the parties may request a further hearing before the Court.

III. CONCLUSION

For the foregoing reasons, the Court adopts the following constructions: "nonionic polymer" means "a polymer composed of macromolecules that do not contain ionic bonds, ions, or functional groups that would ionize in aqueous solution under conditions applicable to the production of pharmaceutical products." As explained above, the meaning of "weight average

molecular weight from about 650,000 to about 800,000" is inherently less precise, but does not encompass variations in the specified range of an amount even approaching ± 10%. Consideration of how the changes in molecular weight might affect the performance and characteristics of the invention, moreover, may be used to further clarify the meaning of "about," as that term is used in claim 1.

It is **SO ORDERED.**

/s/ Randolph D. Moss
RANDOLPH D. MOSS
United States District Judge

Date: November 25, 2015