United States District Court
District of Massachusetts

MOMENTA PHARMACEUTICALS, INC., SANDOZ INC., Plaintiffs,	)	
v.	)	**Civil Action No. 11-11681-NMG**
AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC. Defendants.	)	
MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC., Plaintiffs,	)	
v.	)	**Civil Action No. 10-10279-NMG**
TEVA PHARMACEUTICALS USA, INC., Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

Plaintiffs Momenta Pharmaceuticals, Inc. ("Momenta") and Sandoz Inc. ("Sandoz") (collectively, and for simplicity, "Momenta") bring suit against Amphastar Pharmaceuticals, Inc. ("Amphastar"), International Medication Systems, Ltd. ("IMS"), Watson Pharmaceuticals, Inc. ("Watson") and Watson Pharma, Inc. ("Watson Pharma") (collectively, and for simplicity, "Amphastar") for infringement of U.S. Patent Nos. 7,575,886 and 7,790,466 and

declaratory judgment of infringement for those same patents. In a separate action, Momenta brings suit against Teva Pharmaceuticals USA, Inc. ("Teva") for infringement of those same patents.[1]

The Court held a joint Markman hearing in these two actions on May 4, 2012 at which counsel offered arguments in support of their proposed claim construction of disputed terms. The following is the Court's ruling with respect to those terms.

I. Background

In July, 2010, Momenta began to market the first generic enoxaparin sodium product in the United States. Enoxaparin is an anticoagulant used, inter alia, to prevent blood clots in the legs and other parts of the body. It is a kind of low molecular weight heparin ("LMWH") manufactured by cleaving raw heparin, which consists of sugar chains (saccharides) of various lengths and composition, into smaller sugar chains. Heparin is also an anticoagulent, but the therapeutic effects of LMWH are more lasting and predictable than heparin.

Momenta is the assignee of two patents, U.S. Patent No. 7,575,886 ("the '886 patent"), issued in August, 2009, and U.S. Patent No. 7,790,466 ("the '466 patent"), issued in September, 2010, which, Momenta contends, are directed at a set of

[1] Teva Pharmaceuticals Industries Ltd. was also named as a defendant in that complaint but was dismissed by stipulation of the parties on January 20, 2011.

manufacturing control processes that ensure that each batch of its generic product includes the individual sugar chains characteristic of enoxaparin. A particular batch of its enoxaparin will not be finalized and approved for sale until those processes confirm that the batch contains a certain percentage of the unique sugars.

Momenta filed the instant action against Amphastar, IMS, Watson and Watson Pharma on September 21, 2011, two days after Watson issued a press release announcing that the companies would launch Amphastar's newly FDA-approved generic enoxaparin product. Shortly thereafter, Momenta moved for a temporary restraining order and preliminary injunction to keep Amphastar from marketing its product, which Momenta alleges infringe its patents. The Court allowed the motion, entered a preliminary injunction and subsequently denied two motions to stay or dissolve that injunction filed by Amphastar. Amphastar appealed those rulings to the United States Court of Appeals for the Federal Circuit. On January 25, 2012, the Federal Circuit stayed the preliminary injunction pending appeal but has not yet entered a final decision on the merits.

Momenta filed its complaint against Teva in December, 2010 and moved for expedited discovery. Approximately ten months earlier, in February, 2010, Teva had announced its intention to sell a generic enoxaparin as soon as it obtained FDA approval.

Momenta alleges that Teva has infringed its patents by making material preparations to sell a generic enoxaparin product that has been manufactured using the methods in Momenta's patents. This Court denied the motion for expedited discovery in February, 2011.

II. Principles of Claim Construction

In analyzing a patent infringement action, a Court must 1) determine the meaning and scope of the patent claims asserted to be infringed and 2) compare the properly construed claims to the infringing device. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The first step, known as claim construction, is an issue of law for the court to decide. Id. at 979. The second step is determined by the finder of fact. Id.

The Court's responsibility in construing claims is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001). The meaning of the terms are initially discerned from three sources of intrinsic evidence: 1) the claims themselves, 2) the specification and 3) the prosecution history of the patent. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996).

The claims themselves define the scope of the patented

invention. See Philips, 415 F.3d at 1312. Claim terms are generally given their "ordinary and customary meaning", which is the meaning that a person skilled in the art would attribute to the claim term. See id. at 1312-13. Even if a particular term has an ordinary and customary meaning, however, a court may need to examine the patent as a whole to determine if that meaning controls. Id. at 1313 ("[A] person of ordinary skill in the art is deemed to read the claim term ... in the context of the entire patent...."); see also Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) (noting that a court cannot construe the ordinary meaning of a term "in a vacuum"). Ultimately, the correct construction will be one that "stays true to the claim language and most naturally aligns with the patent's description of the invention...." Id. at 1316 (citation omitted).

> The patent specification is
>
> the single best guide to the meaning of a disputed term [because it may reveal] a special definition given to a claim term that differs from the meaning it would otherwise possess [or contain] an intentional disclaimer, or disavowal, of claim scope by the inventor.

Phillips v. AWK Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The Court should also consult the prosecution history to see how the inventor and PTO understood the patent and to ensure the patentee does not argue in favor of an interpretation it has disclaimed. Id. at 1317.

In the rare event that analysis of the intrinsic evidence does not resolve an ambiguity in a disputed claim term, the Court may turn to extrinsic evidence, such as inventor and expert testimony, treatises and technical writings. Id. at 1314. Although extrinsic evidence may be helpful in construing claims, the intrinsic evidence is afforded the greatest weight in determining what a person of ordinary skill would have understood a claim to mean. Id. at 1324.

III. Analysis

Momenta contends that both Amphastar and Teva infringe over 30 claims of the '886 patent and 6 claims of the '466 patent. There are 19 disputed terms within the '886 Patent and 15 disputed terms within the '466 patent.

A. The '886 Patent

1. The Technology

The patented methods in the '886 patent involve the analysis of batches of enoxaparin based on the presence, or absence, of non-naturally occurring sugar that arises when enoxaparin is manufactured. At step 1 in the relevant independent claims, an enoxaparin sample is exhaustively digested using two or more heparin degrading enzymes. This step results in a mixture of short sugar chains ("sub-chains") of enoxaparin. At step 2, a separation method is used to separate the sub-chains from one another and to depict them at particular discrete locations

("peaks") in a visual output or chart.

Some digested sub-chains of enoxaparin include an individual sugar that is 1) non-naturally occurring, meaning that it has a structure that is not present in raw heparin, and 2) unique to enoxaparin because the structure results from the method used to make enoxaparin. It is now known, although it was not known at the time the patent was filed, that the non-naturally occurring structure is a 1,6-anhydro ring structure. The FDA requires that each production batch of a generic enoxaparin be evaluated to determine whether between 15% and 25% of the sugar chains therein include, at their reducing ends, a sugar containing the 1,6-anhydro ring structure. Thus, a commercial manufacturer of enoxaparin must be able to identify that structure and determine its quantity in a given batch to ensure that the batch is, in fact, enoxaparin that conforms to the requisite standards.

Importantly for claim construction purposes, the '886 patent does not expressly identify the 1,6-anhydro ring structure because, at the time the patent was issued, that information was unknown to the patentees. Instead, the patent identifies the structure indirectly as a "structural signature" which is "associated" with "the non-naturally occurring sugar" which is "associated" with "peak 9 of figure 1". Figure 1 is a visual output created using a separation technique known as capillary electrophoresis ("CE"). The patent also does not identify the

structure of the sugar associated with peak 9 of Figure 1.

Step 3 of the independent claims involves "making a determination" about the enoxaparin sample by comparing the information gathered to a "reference standard for enoxaparin" in order to, for example, decide whether to, at the same step or at Step 4, keep or discard the sample (Claim 3), assess the quality of the sample (Claim 6), assess the level of non-naturally occurring sugar in the sample (Claim 15) or select an appropriate batch (Claim 53).

Claim 53 is representative of the independent claims of the '866 patent which are allegedly infringed and encompasses most of the terms the parties contend require construction:

> 53. A method for analyzing an enoxaparin sample for the presence or amount of a non naturally occurring sugar associated with peak 9 of FIG. 1 that results from a method of making enoxaparin that included β-eliminative cleavage with a benzyl ester and depolymerization, comprising:
>
> [1] providing an enoxaparin sample that has been exhaustively digested with two or more heparin degrading enzymes;
>
> [2] using a separation method to determine, in the enoxaparin sample that has been contacted with two or more heparin degrading enzymes, the presence of a structural signature associated with the non naturally occurring sugar associated with peak 9 of FIG. 1 that results from a method of making enoxaparin that includes β-eliminative cleavage with a benzyl ester and depolymerization;
>
> [3] making a determination about the enoxaparin sample based upon a comparison of the determination of the presence of a structural signature associated with the non naturally occurring sugar associated with peak 9 to

a reference standard for enoxaparin; and

[4] selecting a batch of enoxaparin based upon a comparison of the determination of the presence of the structural signature associated with the non naturally occurring sugar associated with peak 9 of FIG. 1 to a reference standard for enoxaparin,

to thereby analyze the enoxaparin sample.

2. Disputed Claim Terms

a. "A Separation Method" and "Using a Separation Method to Determine, in the Enoxaparin Sample..."

As they did with respect to Momenta's motion for a preliminary injunction, Momenta and Amphastar dispute the appropriate construction of the term "a separation method". Momenta proposes a construction for both "a separation method" and "using a separation method to determine, in the enoxaparin sample...." Amphastar contends the term can only be understood in context and so proposes a construction only for the latter term.

The parties agree that the plain and ordinary meaning of the term "a separation method" would include all separation techniques, including capillary electrophoresis ("CE") and high performance liquid chromatography ("HPLC"). Momenta contends the ordinary meaning should control, whereas Amphastar contends that the context of the patent makes clear that the term has a more

limited meaning and refers only to CE.[2]

The Court preliminarily construed the term in Momenta's favor to include both CE and HPLC. On appeal, Amphastar has argued, inter alia, that construction was erroneous. The Federal Circuit has not yet decided the issue on the merits. At the Markman hearing and in its supporting memoranda, Amphastar supports its limited construction with essentially the same arguments it raised in opposition to the motion for preliminary injunction on essentially the same record. Amphastar adds that the separation method is being used to do something specific, i.e., to get to peak 9 of Fig. 1 (a CE Electrograph), and that one simply cannot arrive at peak 9 of Fig. 1 through use of a different separation method.

Although it is a contested issue, the Court discerns no reason to depart from its preliminary construction. Instead, for the reasons previously articulated, see Momenta Pharms., Inc. v. Amphastar Pharms., Inc., No. 11-11681, 2011 WL 5114475, at *5-8 (D. Mass. Oct. 28, 2011), the Court concludes it is inappropriate to depart from the plain and ordinary meaning of the term "a separation method". The Court continues to understand that the

[2] Confusingly, Teva contends that the plain and ordinary meaning of separation method should control, but also contends that it does not agree with Momenta's construction. Because Teva has submitted essentially no oral or written argument on the subject, however, the Court considers only the dispute between the Momenta and Amphastar.

pertinent structural signature corresponds to peak 9 but that a different separation method can be used to isolate and identify it.

The Court will therefore adopt Momenta's proposed construction of a "separation method", with a few minor modifications, and construe the term as follows:

> A method, e.g., capillary electrophoresis ("CE") or high performance liquid chromatography ("HPLC"), used to separate the components of a heterogeneous mixture based on the physical or chemical properties of those components.

The phrase "using a separation method to determine, in the enoxaparin sample..." incorporates that construction and is otherwise accorded its plain and ordinary meaning (the meaning of the claim term "sample" is discussed more fully below).

b. "Non Naturally Occurring Sugar"

The term "non naturally occurring sugar" appears in each independent claim of the '886 patent. The Court will construe it consistent with Momenta's proposed construction, "a sugar having a structure that does not normally exist in heparin in nature", which is how the term is defined in the specification, see 8:63-65, and to which Amphastar has withdrawn its objection.

c. "A Structural Signature"

Momenta and Amphastar dispute the appropriate construction of "a structural signature". Teva does not request a construction.

Momenta proposes that the term be defined to mean:

> A structural feature of enoxaparin, or information regarding a structural feature of enoxaparin, that is characteristic of enoxaparin and distinguishes it from other heparins.

Amphastar proposes that the term be defined as it is in the specification, see 6:59-7:1, to mean:

> Information regarding the identity and number the mono- and di-saccharide building blocks of a polysaccharide, information regarding the physiochemical properties such as overall charge (also referred to as the 'net charge' or 'total charge'), charge density, molecular size, charge to mass ratio and the presence of iduronic and/or glucuronic acid content as well as the relationships between the mono- and di-saccharide building blocks, and active sites associated with these building blocks, inter alia. The structural signature is something that uniquely identifies a specific non naturally occurring sugar at peak 9 of Fig. 1.

Momenta contends that the definition in the specification is non-limiting, bears no relationship to the context in which the term is used in the claims and would be unintelligible to a jury. Amphastar responds that Momenta's construction is overly broad and impermissibly disregards an explicit definition offered by the patentee.

The Court agrees that Momenta may not ignore the patentee's explicit definition of this term, see Sinorgchem Co., Shandong v. Int'l Trade Comm'n, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (noting that "the patentee must be bound by the express definition" offered in the specification), but concludes that the rather unwieldy definition offered in the specification should be

simplified. It will therefore define the term according to the first part of that definition and omit the latter part, which is exemplary and nonlimiting, to construe the term as "information regarding, e.g., the identity, number and physiochemical properties of the mono- and di-saccharide building blocks of a polysaccharide".

d. "A Structural Signature Associated with the Non Naturally Occurring Sugar Associated with Peak 9 of FIG. 1"

Momenta, Teva and Amphastar contest the meaning of the term "a structural signature associated with the non naturally occurring sugar associated with Peak 9 [of FIG. 1]", which appears in every independent claim of the '886 patent.[3] The crux of the dispute concerns whether the language "...associated with the non naturally occurring sugar associated with Peak 9 [of FIG. 1]" renders those terms indefinite.

Teva and Amphastar contend the terms are indefinite because the patent, and relevant art at the time the patent was filed, did not 1) identify the structure of the sugar associated with peak 9 of figure 1 or 2) provide enough information (such as the buffer, pH, type of capillary or voltage) to enable a person skilled in the art to replicate figure 1 in order to

[3] The parties also request the Court to construe a subset of that term, "the non naturally occurring sugar associated with Peak 9 of FIG. 1". The Court will construe only the longer term with the understanding that the meaning of the shorter term is contained therein.

experimentally determine that structure. All of those conditions, defendants assert, can impact the results of the CE chart, including the number and order of its peaks. Defendants add that it is now known that there are up to four non-naturally occurring sugars containing the 1,6-anhydro ring structure in a digested sample of enoxaparin and a skilled artisan would have no way to know which, if any, of those four sugars corresponds to peak 9 of Figure 1.

Plaintiffs respond that the term itself is readily capable of construction and that the defendants' indefiniteness argument is an affirmative defense more appropriately raised upon a motion for summary judgment. Construction of the claim term itself, plaintiffs state, merely involves 1) combining the definitions of "structural signature" with "non-naturally occurring sugar", discussed above, 2) adding the definition of "associated with", which means "having a relationship of some kind with" and 3) specifying that the association or relationship is with peak 9 of figure 1 of the patent.

The requirement that claims be definite is set out in the second paragraph of 35 U.S.C. § 112, which provides that claims must particularly point out and distinctly claim the subject matter which the applicant regards as his invention. The requirement essentially serves a public notice function and assures that patent claims will be "sufficiently precise to

permit a potential competitor to determine whether or not he is infringing." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1342 (Fed Cir. 2003) (internal quotation omitted).

Proof of indefiniteness of patent claims, sufficient to render a patent invalid, is met where an accused infringer shows by clear and convincing evidence that a skilled artisan could not discern the bounds of the claim "based upon the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249-50 (Fed. Cir. 2008). The bar is high: "a claim is not indefinite merely because its scope is not ascertainable from the face of the claims." Amgen, 314 F.3d at 1342. Instead, it must be "insolubly ambiguous" such that "reasonable efforts at claim construction prove futile." Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1375 (Fed. Cir. 2010). Indeed,

> Even if it is a formidable task to understand a claim, and the result not unanimously accepted, as long as the boundaries of a claim may be understood it is sufficiently clear to avoid invalidity for indefiniteness.

Invitogen Corp. v. Biocrest Mfg., L.P., 424 F.3d 1374, 1383 (Fed. Cir. 2005) (internal quotation omitted); see also Exxon Research & Eng'g Co. v. United States, 265 F.3d 1371, 1379 (Fed. Cir. 2001) ("Provided that the claims are enabled, and no undue experimentation is required, the fact that some experimentation

may be necessary to determine the scope of the claims does not render the claims indefinite.").

The Court agrees with plaintiffs that it is inappropriate to resolve the question of indefiniteness at this juncture. Although it is true that "the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction," Praxair, Inc. v. ATMI, Inc., 543 F.3d 1306, 1319 (Fed. Cir. 2008) (citation omitted), there are several reasons to defer rulings on indefiniteness until summary judgment, CSB-Syst. Int'l Inc. v. SAP Am., Inc., No. 10-2156, 2011 WL 3240838, at *17-18 (E.D. Pa. July 28, 2011). Those reasons include the fact that an allegedly infringing party must prove indefiniteness by "clear and convincing proof" to overcome the statutory presumption of validity and that

> unlike a Markman proceeding that gives meaning to patent claims, indefiniteness invalidates the claims entirely. As such, this dispositive effect is more appropriately tackled at summary judgment...

Id. at *18 (citing numerous instances in which courts elected to defer indefiniteness until summary judgment).

Those considerations especially apply here where the claim language itself is amenable to construction but is alleged to be indefinite as applied. Compare Am. Med. Systs., Inc. v. Biolitec, Inc., 666 F. Supp. 2d. 216, 223 (D. Mass. 2009) (construing a claim as indefinite where claim language itself was

subject to "multiple conflicting interpretations"); with Takeda Pharm. Co. v. Handa Pharms., LLC, 2012 WL 1243109, at *16 (N.D. Cal. Apr. 11, 2012) (deferring indefiniteness until summary judgment because whether a skilled artisan could determine relevant amounts without undue experimentation was a "largely factual" inquiry). The issue devolves into a "battle of the experts" over whether a skilled artisan could, or could not, identify the pertinent structural signature without undue experimentation. That issue needs to be resolved, and will be, at a later point upon a complete record.

The Court will therefore construe the terms without prejudice to the defendants' ability to challenge the validity of these claims for indefiniteness at the summary judgment stage. As the terms "structural signature" and "non-naturally occurring sugar" have been defined already, the remaining issue to resolve is the meaning of "associated with". Momenta offers the dictionary definition of "associated with" to claim it means "bears a relationship to". Both sets of defendants contend that dictionary definition is overly broad in the context of the patent: Teva contends "associated with" means "corresponds to" and Amphastar contends it means "found at". Their proposed constructions are aimed at the relationship between "the non-naturally occurring sugar" and "peak 9 of Fig. 1" rather than the relationship between "a structural signature" and "the non-

naturally occurring sugar".

Momenta's proposed construction appears warranted with respect to the association between "a structural signature" and "the non-naturally occurring sugar". The Court comprehends no reason from the patent itself or prosecution history to construe the claimed "association" otherwise than its dictionary definition and, indeed, neither Amphastar nor Teva disputes that proposed construction.

By contrast, the Court agrees with the defendants that there is ample evidence in the specification and prosecution history to construe the association between "the non-naturally occurring sugar" and "peak 9 [of Fig. 1]" more restrictively. See Fin Control Sys. Pty, Ltd. v. OAM, Inc., 265 F.3d 1311, 1318 (Fed. Cir. 2001) (instructing that "the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims"). In context, "the non-naturally occurring" does more than just "bear a relationship" to "peak 9 of Fig. 1". Rather, Peak 9 indicates that the pertinent non-naturally occurring sugar is present, i.e., their only association. The applicants essentially used peak 9 as a substitute for identifying the non-naturally occurring sugar that peak depicts. See '886 Patent, 9:5-14; 10:26-27; 27:25-28. Furthermore, during

prosecution, the applicants specifically changed "a" non-naturally occurring sugar to "the" non-naturally occurring sugar in the disputed claim steps, and added "associated with peak 9 of Fig. 1" to modify "the" non-naturally occurring sugar.

Thus, the phrase "bears a relationship to", which could refer to any number of different relationships, is overly broad when describing the relationship between "the non-naturally occurring sugar" and "peak 9". Nonetheless, such considerations do not apply for purposes of the relationship between "a structural signature" and "the non-naturally occurring sugar", and neither Teva nor Amphastar has addressed that relationship. Thus, the Court will construe the term "a structural signature associated with the non naturally occurring sugar associated with Peak 9 [of FIG. 1]" as "a structural signature which bears a relationship to the non-naturally occurring sugar which corresponds to Peak 9 [of Fig. 1]".

e. "Two or More Structural Signatures" and "The Structural Signatures of the Non-Naturally Occurring Sugars Are Associated with Peaks 9 and 10 of Fig. 1"

These two terms appear in claims 20 and 49. Claim 20 states:

> "wherein the level of *two or more structural signatures* associated with non-naturally occurring sugars that result from a method that includes β-eliminative cleavage with a benzyl ester and depolymerization are detected, and wherein *the structural signatures of the non naturally occurring sugars are associated with peaks 9 and 10 of FIG. 1.*"

First, the Court declines to construe separately the term "two or more structural signatures". It has already construed the meaning of "structural signature", and the meaning of "two or more" is entirely self-explanatory.

Second, for the reasons discussed in subheading (d) above, the term "the structural signatures of the non-naturally occurring sugars are associated with peaks 9 and 10 of Fig. 1" will be construed to mean "the structural signatures are associated with the non-naturally occurring sugars which correspond to peaks 9 and 10, respectively, of Fig. 1".

f. "A Reference Standard"

All of the independent claims of the '886 patent require a "comparison of the determination of the presence of a structural signature associated with the non naturally occurring sugar associated with peak 9 to a reference standard for enoxaparin". Momenta contends the term "a reference standard" means "a pre-selected value", whereas Teva contends it means "a highly purified and characterized physical substance to which enoxaparin is compared" and Amphastar contends it means "a standard physical sample of enoxaparin".

Teva and Amphastar state that the plain and ordinary meaning of the term "a reference standard" refers to a physical substance or sample and not a numerical value. Momenta concedes that is a possible definition but declare that it is not the definition

offered by the patent. The primary dispute is whether the patentee offered an alternative definition of the term which overrides the ordinary meaning and supports Momenta's construction. Phillips v. AWH Corp., 415 F.3d 1303, 1316 (Fed. Cir. 2005) ("[T]he specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs.").

Momenta emphasizes that, in seven different places in the specification, the term "a reference standard" is equated to a "pre-selected value" through use of the abbreviation "e.g.". See 6:15-16, 11:52-54, 14:42-44, 15:33-34, 16:12-13, 17:3-4, 18:20-21 ("the method ... includes comparing the results of the determination to preselected values, e.g., a reference standard."). Momenta argues that those instances reveal an "explicit" definition of the term which is controlling.

Teva and Amphastar respond that although the specification often equates "preselected values" to "a reference standard", this is not the sort of affirmative definition found elsewhere in the specification for other terms. See, e.g., 8:53-65 ("As used herein, 'non-natural sugars' refers to..."). They also contend that their respective constructions, which reflect the plain and ordinary meaning of the term as a physical substance, fit with how the term is used throughout the patent. Teva notes that

Claim 43, which requires comparison of an enoxaparin sample to a reference standard for enoxaparin, adds another limitation that requires determining if the sugar associated with peak 9 of Fig. 1 is "present in a preselected range." Claims 44 through 48, which all depend on Claim 43, provide different values for "pre-selected ranges". The additional limitation, Teva asserts, indicates there is a difference between "a reference standard" (i.e., a physical substance) and a "pre-selected range" of values (i.e., a quantitative specification). Teva and Amphastar also cite to a portion of the specification which explains that "the reference standard may be a previously characterized composition", as opposed to a "pre-selected value". See 34:50-56.

Generally,

> To act as its own lexicographer, a patentee must clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning. In other words, the patentee must clearly express an intent to redefine the term. This clear expression need not be in haec verba but may be inferred from clear limiting descriptions of the invention in the specification or prosecution history.

Aventis Pharma S.A. v. Hospira, Inc., No. 2011-1018, 2012 WL 1155716, at *3 (Fed. Cir. Apr. 9, 2012) (internal citation and quotation omitted).

Applying that standard, it appears that the specification adequately defines "a reference standard" as a "pre-selected value" for purposes of the disputed claims. In addition to the

seven instances in which "preselected values" are equated with "a reference standard" by use of "e.g.", a numerical construction appears generally consistent with how the term is used throughout the claims and the specification. Cf. Pfizer, Inc. v. Teva Pharms., USA, Inc., 429 F.3d 1364, 1374-75 (Fed. Cir. 2005) (concluding that "i.e." as used in the specification was not definitional where a different meaning of the term was also taught in the specification). For example, certain claims assign particular numerical values to a "reference standard", see, e.g., 65:40-48, or involve a determination of whether the level of the structural signature varies less than a particular numerical range from the reference standard, see, e.g., 67:22-34. As Momenta points out, the several instances in which the specification describes determining or creating a reference standard, see, e.g., 10:38-47; 11:57-12:8; 12:19-22; 34:50-66, are not necessarily inconsistent but rather refer to a reference standard as "information" developed in advance and then used, as a reference standard, in a subsequent procedure.

Thus, the Court will construe "a reference standard" to mean "pre-selected values".

g. "Exhaustively Digested"

The meaning of this term was disputed in the supporting memoranda but the parties, at the Markman hearing, agreed that it should be construed to mean "sugar chains of enoxaparin that have

been broken down as far as the two or more heparin degrading enzymes of the claim will permit".[4] The Court will construe it accordingly.

h. Terms re: "Sample"

The parties dispute the meaning of the claim term "an enoxaparin sample", "a sample" and "of the sample". First, the Court notes that the term "a sample" is never used in any claim. The term "an enoxaparin sample" is used in every independent claim of the patent, and the terms "the enoxaparin sample", "of the sample" or simply "the sample" are used to refer back to that same claim term. Accordingly, the Court will consider only the appropriate construction of the term "an enoxaparin sample".

Momenta contends that "sample" means "a composition that includes polysaccharides". That definition, Momenta asserts, is offered in the specification and is controlling. See 4:68-5:1 ("...analyzing a sample, e.g., a composition which includes a polysaccharide"); 6:57-58 ("The method includes analyzing a sample comprising a polysaccharide..."); 9:29-30 ("...analyzing a sample, e.g., a composition including a mixed population of polysaccharides..."); 11:59-63 ("...analyzing a sample, e.g., a

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[4] Although the parties did not agree on precise wording, the Court understands the particular definition to comport with the substance of their agreement. See Markman Hrg. Transcr. at 107-110. The parties may, however, submit a separate joint proposed construction for the Court's reconsideration if necessary.

sample including a composition including a mixed population of polysaccharides..."). Accordingly, "an enoxaparin sample" should be construed to mean "an enoxaparin composition" because adding "that includes polysaccharides" would be redundant. See 5:23-25 ("A polysaccharide according to the invention can be a mixed population of polysaccharides, e.g., a heparin, synthetic heparin, or LMWH preparation.").

Teva and Amphastar both respond that "sample" or "an enoxaparin sample" should be given its plain and customary meaning. The term is purportedly well-understood by a layperson and does not possess a more particular meaning in the context of the patent. Neither defendant has suggested what it understands the plain meaning of "an enoxaparin sample" to be, except that, when asked at the Markman hearing, defendant's counsel said it means simply "a sample of enoxaparin".

The Court determines that construction of the term "an enoxaparin sample" is warranted but that Momenta's proposed definition is too general. The patent reveals that a "sample" is "a composition that includes polysaccharides"; it also claims that the sample composition is a smaller, representative portion of something larger. See, e.g., 5:38-42 ("In some embodiments, the sample is derived from ... any commercially available preparation of polysaccharides ... including but not limited to enoxaparin (Lovenox™)...."). Otherwise, a "sample" could be

synonymous with a "batch" when it is apparent that an enoxaparin sample is a representative portion of a particular enoxaparin batch. See Crawford Decl. ¶¶ 46, 56 (explaining that if an enoxaparin sample possesses certain qualities, the batch from which it is derived is either selected for further testing or discarded). The Court will therefore construe "an enoxaparin sample" to mean "an enoxaparin composition which is derived from and representative of a particular batch of enoxaparin".

Certain other "sample" terms, including 1) "making a determination about the enoxaparin sample", 2) "a method for analyzing an enoxaparin sample", 3) "to thereby analyze the enoxaparin sample", 4) "to keep or discard the sample" and 5) "the quality of the sample", incorporate that definition and will not be separately construed. With respect to the first four, Momenta's proposed constructions simply combine its proposed construction of "enoxaparin sample" with common synonyms, or unsupported variations, of the remaining language in the terms. With respect to the fifth, "the quality of the sample", Amphastar unconvincingly contends that it means "any information about any attributes of the tested sample" and is therefore indefinite. The word "quality" is a commonly understood word that has more than one meaning, and one such meaning, i.e., "degree or grade of excellence", WEBSTER'S II NEW COLLEGE DICTIONARY 926 (3d ed. 2005), is clearly applicable in the

context of the patent.

I. Terms re: "Batch"

Momenta and Amphastar dispute the appropriate construction of the terms "selecting a batch" and "in a second batch of enoxaparin". Teva does not request a construction.

The terms "batch" and "batch of a drug" are both defined in the specification:

> As used herein, "batch" refers to a quantity of anything produced at one operation, e.g., a quantity of a compound produced all at one operation. A "batch of drug" is a quantity of a drug that was produced at one operation, e.g., in a single process.

See 8:27-31. The term "selecting a batch" appears in the fourth limitation of Claim 53 (quoted in full, supra) wherein a batch of enoxaparin is selected based upon a comparison of the "determination" of an exhaustively digested sample to a reference standard. Momenta claims the term means "choosing a quantity of enoxaparin that was produced in a single process for further testing or processing". The term "in a second batch of enoxaparin" appears in the fourth limitation of Claim 1: limitations one through three discuss the analysis of an exhaustively digested sample and limitation four involves "determining the presence of the structural signature associated with the non-naturally occurring sugar associated with peak 9 of Fig. 1 in a second batch of enoxaparin". Momenta contends the claim should be construed to mean "in a second quantity of

enoxaparin that was produced in a single process".

Amphastar argues that both "batch" terms render their respective claims indefinite insofar as they lack "antecedent basis" in the claims. Although that argument with respect to "selecting a batch" is not elaborated upon, it presumably concerns the fact that, in limitations one through three, Claim 53 discusses analysis of an enoxaparin sample but then, in the fourth limitation, jumps to selecting a batch of enoxaparin. With respect to "in a second batch of enoxaparin", Amphastar notes that there is no mention of a first batch and the claim does not include a step for testing the second batch in order to analyze the first batch.

A claim may be indefinite if a particular term does not have proper antecedent basis "where such basis is not otherwise present by implication or the meaning is not reasonably ascertainable." Halliburton Energy Servs., Inc. v. M-I LLC, 514 F.3d 1244, 1249 (Fed. Cir. 2008). If the claim can reasonably be understood by a person of ordinary skill when read in light of the specification, however, it is "not subject to invalidity upon departure from the protocol of 'antecedent basis.'" Energizer Holdings, Inc. v. Int'l Trade Comm'n, 435 F.3d 1366, 1370 (Fed. Cir. 2006).

Here, the meaning of both terms is readily ascertainable from the specification, which explains that the analysis methods

are to be used as quality-control techniques which increase batch-to-batch consistency, to select an appropriate batch of a drug as a result of determining the structural signature of one or more batches and, depending on the result of the analysis, to accept certain enoxaparin batches and reject others. See, e.g., 6:10-16; 61:52-54. The Court will therefore adopt Momenta's proposed constructions and construe the term "in a second batch of enoxaparin" to mean "in a second quantity of enoxaparin that was produced in a single process", and the term "selecting a batch" to mean "selecting a quantity of enoxaparin that was produced in a single process for further testing or processing".

j. "A Pre-Selected Range"

The parties agree that "a pre-selected range" requires no construction or can be construed according to its plain and ordinary meaning, and the Court concurs. Momenta offers a possible alternative construction, i.e., "one or more sets of values having an upper and lower bound that is identified in advance", but that construction is self-evident and thus unnecessary.

C. The '466 Patent

1. The Technology

Unlike the '886 patent, which involves analysis of individual component sugars of polysaccharides in an exhaustively digested sample, the '466 patent involves isolating and

categorizing the tetrasaccharides (four-sugar chains) in a non-exhausted enoxaparin preparation. Tetrasaccharides are the constituents of enoxaparin that result from the greatest number of cleavage reactions during the process of manufacturing enoxaparin. Consequently, they are among the oligosaccharides that are most affected by the unique way that enoxaparin is made and are highly characteristic of enoxaparin.

The '466 patent teaches that, to analyze and monitor the production of enoxaparin, one should first separate tetrasaccharides from chains of other lengths in a production batch and then separate the individual tetrasaccharide species from one another, according to the identity and sequence of their components, using SAX-HPLC or HPLC. Identifying and quantifying the relative amounts of various tetrasaccharide chains allows a manufacturer to determine whether a given batch of enoxaparin has a required characteristic of enoxaparin and can be used in the manufacturing process.

Claim 1 of the '466 patent is illustrative:

> 1. A method of analyzing an enoxaparin preparation, comprising:
>
> [a] providing an isolated tetrasaccharide fraction from a size fractioned enoxaparin preparation;
>
> [b] analyzing the tetrasaccharide fraction using strong anion exchange high performance liquid chromatography (HPLC) to determine if one or more chains shown in the following table is present or is present in amount identified in the following table:

[table provided which lists the particular structural sequences of 15 tetrasaccharides and includes various amounts under the headings "Range A", "Range B" and "Range C"]

and

[c] if one or more of said chains is present or is present in an amount identified in the table, processing said preparation, wherein processing includes one or more of selecting, accepting, processing into drug product, shipping, formulating, labeling, packaging or selling said preparation,

thus analyzing the enoxaparin preparation.

2. Disputed Terms

a. "Strong Anion Exchange High Performance Liquid Chromatography (HPLC)"

The second limitation of claim 1 states that the tetrasaccharide fraction will be analyzed using "strong anion exchange high performance liquid chromatography (HPLC)", i.e., "SAX-HPLC". Both SAX-HPLC and HPLC are analytical methods used to separate components of a mixture but HPLC separates those components according to their physical or chemical attributes while SAX-HPLC separates them based on the degree to which they are negatively charged. Claims 1 through 7 of the '466 patent require SAX-HPLC; Claim 8 requires HPLC.

In SAX-HPLC, tiny particles (beads) are placed in a column. A substance that has a strong positive charge ("an ion exchanger") is attached to the individual beads in the column. A liquid that includes the "analyte" (the mixture whose components

are to be separated) is then introduced into the column under pressure. The negatively charged components of the analyte adhere to the positively charged ion exchangers which are, in turn, attached to the beads in the column. Then a solution containing a low concentration of salt ("a buffer") is introduced into the column. This causes the least negatively charged species in the analyte to be released from the ion exchangers, i.e., to "elute", and to exit the column. The salt concentration in the buffer is then increased. As it is increased, progressively more negatively charged species elute separately, one after the other. Each component of the mixture that elutes at a separate point in time is depicted as a separate peak on an HPLC chromatogram. The position of the peak indicates how securely a component was bound and the area under the peak indicates how much of the component was present in the mixture.

The dispute over the construction of the term SAX-HPLC is essentially a disagreement over how much detail must be included in the definition. Momenta contends that it should be construed to mean

> A type of HPLC that is used for analyzing negatively charged analytes (things to be analyzed), including oligosaccharides, based on the relative strength of their negative charges,

whereas Teva contends (and Amphastar concurs) that it should be construed to mean

> A type of anion exchange HPLC, in which the stationary

> phase in the column is covalently bound to a quaternary ammonium ion or an equivalent functional group, the positive charge in the functional group on the stationary phase is present across the entire pH range, and high salt concentration is usually necessary to release the analyte.

Momenta's proposed construction is, of course, simpler, but Teva contends that, by defining the term simply according to its function and omitting the specific components and operating condition of SAX-HPLC, the definition encompasses other, distinct HPLC analytical methods such as weak anion exchange HPLC ("WAX-HPLC") and reverse phase ion pairing HPLC ("RP-IP HPLC"). At the Markman hearing, the experts of both parties confirmed that not only are there several different kinds of HPLC but there are also different kinds of anion exchange HPLC. They agreed that, as the plain meaning of the names would suggest, WAX-HPLC is distinct from SAX-HPLC. Teva's expert, Dr. Robert Linhardt ("Dr. Linhardt"), further testified, and Momenta's expert, Dr. Zachary Shriver ("Dr. Shriver"), did not dispute, that Momenta's proposed definition of SAX-HPLC is broad enough to include WAX-HPLC.

Clearly, a definition which encompasses an HPLC method which Momenta's own expert admits is distinct from the method claimed in the patent is overly broad. The Court will therefore adopt a more detailed definition in line with that proposed by Teva. Nonetheless, the Court finds certain portions of Teva's definition to be unduly limiting and will modify it accordingly.

Teva's definition requires that the "stationary phase" (the

beads) in the HPLC column be "covalently bound to a quarternary ammonium ion or an equivalent functional group" ion exchanger. The patent teaches, however, that

> ... beads suitable for [SAX-HPLC] include those with strongly basic (cationic) groups such as quarternary ammonium groups ..., tertiary sulfonium groups, quarternary phosphonium groups, or alkyl pyridinium groups.

24:14-18. Thus, a "quarternary ammonium ion" is just one example of a suitable ion exchanger. Although Teva's proposed definition also states that "an equivalent functional group" may be used, it is unclear how one would determine whether a different functional group is, or is not, "equivalent".

Furthermore, the ion exchanger is not held to the beads by a covalent bond in certain SAX-HPLC methods disclosed in the patent, namely, dynamic coated SAX-HPLC and what the patent refers to as CTA-SAX-HPLC, in which a molecule called cetyltrimethylammonium ("CTA") is non-covalently attached to the ion exchanger. Dr. Linhardt did not contest the fact that, with respect to those methods, the ion exchanger need not be covalently bound but instead was of the opinion that dynamic coating SAX-HPLC and CTA-SAX-HPLC are not subsets of SAX-HPLC, either as a general scientific matter or within the meaning of the patent. Dr. Shriver disagreed, testifying that dynamic coated SAX-HPLC is a subset of SAX-HPLC and that CTA-SAX-HPLC is a form of dynamic coating SAX-HPLC.

The Court agrees with Momenta that the patent itself treats dynamic coated SAX-HPLC and CTA-SAX-HPLC as kinds of SAX-HPLC. The patent specifically teaches that an enoxaparin preparation can be analyzed

> with HPLC, e.g., anion exchange HPLC such as strong anion exchange HPLC (SAX -HPLC), dynamic coated strong anion exchange HPLC,

7:29-32, and specifies that beads suitable for SAX-HPLC can be "a [CTA] coated C_8 or C_{18} substrate", 24:18-20. Although the specification employs CTA-SAX-HPLC for some analyses and SAX-HPLC for others, there is no indication that CTA-SAX-HPLC is anything but a derivative method appropriately within the scope of the claim term SAX-HPLC. Moreover, it is unclear whether, as Dr. Linhardt suggests, a person skilled in the art would necessarily understand those methods to be distinct from one another. On cross-examination of Dr. Linhardt, Momenta introduced a book that Dr. Linhardt co-edited in which an article uses the term CTA as a sub-category of SAX-HPLC. While Dr. Linhardt responded that he was not responsible for editing every chapter and focused on readability rather than substance, he also admitted that at least one of the authors of the subject article is an expert in separation sequencing of heparin and heparin sulfate saccharides.

Teva's definition also states that "high salt concentration is usually necessary to release the analyte". That information appears warranted because both experts agree that using high salt

concentrations is the dominant method of eluting an analyte. Dr. Linhardt testified that WAX-HPLC, by contrast, is generally eluted either with salt or by adjusting the pH. The patent also teaches that "[u]seful mobile phases include a salt", and Dr. Shriver testified that, while a high salt concentration is usually used, it is not necessary. The Court will therefore include this terminology but is convinced that, based on the patent itself and the testimony of both parties' experts, it is more appropriate to state that a high salt concentration is "usually employed", rather than "usually necessary".

Finally, although it lengthens the construction, the Court concludes that a definition which includes a general description of the function of SAX-HPLC (as proposed by Momenta) followed by specific operating conditions (as proposed by Teva) would be most understandable to a juror. Accordingly, the Court will construe the term to mean

> a type of anion exchange HPLC that is used for analyzing negatively charged analytes based on the relative strength of their negative charges. The stationary phase in the column is attached to positively charged functional groups, the positive charge in the functional groups on the stationary phase is present across the entire pH range, and a high salt concentration is usually employed to release the analyte.

b. "Whether a Tetrasaccharide Structure is Present" and "If Said Structures Are Present"

Claim 8 teaches a processing method which first involves "providing [an HPLC] determination of whether a tetrasaccharide

structure is present" in an enoxaparin preparation in a particular amount specified in a table. Then, "if said structures are present" in the specified amounts, the preparation is processed.

Amphastar and Momenta dispute the meaning of the terms "whether a tetrasaccharide structure is present" and "if said structures are present" (Teva does not request constructions). According to Momenta, 1) "whether a tetrasaccharide structure is present" means "determining if one or more of the identified tetrasaccharide structures is present in an undigested enoxaparin preparation" and 2) "if said structures are present" means "if one or more of the tetrasaccharides identified in the claim are present". Amphastar argues that both terms require an additional step of determining the structural sequences of the listed tetrasaccharides in order to determine if a tetrasaccharide structure in the table is present. Such a determination would have to be made through technology other than HPLC, though, because HPLC is not capable of identifying the individual saccharides in a tetrasaccharide, determining the structure of those individual saccharides or deciphering the order in which those individual saccharides are arrayed. Instead, it simply separates the tetrasaccharides chains in a preparation according their structural sequences. A visual output, or chromatogram, may be generated on the basis of that analysis which depicts, via

its peaks and the relative height of those peaks, the presence and relative amounts of the various tetrasaccharides.

Momenta responds that a separate "determining" step is not warranted because the claims reasonably assume that the person using the method has otherwise established a correlation between a particular peak on the chromatogram and the structural sequence of the tetrasaccharide which corresponds to that peak, or else will simply rely on the structural information provided in the table itself. The '466 patent, Momenta contends, specifically teaches that a combination of techniques may be used to determine the structural sequences of the tetrasaccharides associated with a particular peak: it explains that tetrasaccharides may be digested and analyzed using CE, MALDI-MS and NMR and that the "combination of data" generated by the use of those separate processes "allows determination of the structures" of the tetrasaccharides listed in the table. See 9:33-41. Thus, a person skilled in the art would understand that he or she should reproduce that table in advance and should then rely on the HPLC chromatogram to determine whether a particular tetrasaccharide structure is present and in what amount.

The Court agrees with Momenta. The patent discloses the pertinent structures and the peaks to which they correspond and teaches how to ascertain that correspondence. A person skilled in the art would understand from the patent that the correlation

between peaks and structure should be ascertained in advance so that he or she is able to determine the presence or amount of a particular tetrasaccharide structure by the HPLC chromatogram. Adopting a different procedure whereby a separate analytical technique is used each time a preparation is processed would be inefficient to say the least.

Thus, the Court will construe "whether a tetrasaccharide structure is present" to mean "whether one or more of the tetrasaccharide structures identified in the claim is present" and will construe "if said structures are present" to mean "if one or more of the tetrasaccharide structures identified in the claim is present".

d. "A Method Of Processing an Enoxaparin Preparation"

The preamble of Claim 8 describes "[a] method of processing an enoxaparin preparation" comprising the two limitations listed in the claim. Momenta contends that the term "[a] method of processing an enoxaparin preparation" means "a way of making enoxaparin drug substance or drug product", whereas Teva and Amphastar contend its plain and ordinary meaning should control.

The Court will adopt Momenta's proposed construction, in part. The specification provides that the term "'enoxaparin preparation' as used herein refers to both enoxaparin drug substance preparations and enoxaparin drug product preparations." 19:13-15. Thus, when read in light of the specification, a

person of skill in the art would understand "enoxaparin preparation" to mean "enoxaparin drug substance or drug product". Nonetheless, there is no reason to construe "a method of processing" as "a way of making" when the scope of "processing" is described differently in the second limitation of the claim itself:

> ...wherein processing includes one or more of selecting, accepting, processing into drug product, shipping, formulating, labeling, packaging or selling said preparation.

28:49-52.

Accordingly, the Court will construe "[a] method of processing an enoxaparin preparation" to mean "a method of processing enoxaparin drug substance or drug product."

e. "Providing an Isolated Tetrasaccharide Fraction"

The first limitation of Claim 1 involves "providing an isolated tetrasaccharide fraction from a size fractioned enoxaparin preparation". Momenta defines "providing an isolated tetrasaccharide fraction" to mean:

> providing the group of sugar chains in an undigested enoxaparin preparation that consist of four sugars separated from and substantially free of sugar chains of different lengths.

Amphastar defines it to mean:

> providing a preparation of tetrasaccharides that is substantially free of at least one and preferably all other size classes. Substantially free means that at least 70, 80, 90, 95, 99, 99.5, or 99.9%, or substantially all of the contaminating carbohydrate size

class have been removed.

Teva contends the plain and ordinary meaning of the term should control.

In the specification, an "isolated size fraction preparation" is defined as

> a preparation containing saccharides of a selected size class that is substantially free of saccharides of at least one and preferably all other size classes.

"Substantially free" is defined to mean "that at least 70, 80, 90, 95, 99, 99.5 or 99.9%, or substantially all, of a contaminating carbohydrate size class have been removed." See 21:4-12.

Amphastar's proposed definition tracks that definition and includes a definition of "substantially free", which is useful in understanding the meaning of the claim term. Momenta's proposed definition unnecessarily adds that tetrasaccharides include four sugars, does not define "substantially free" and, oddly, includes the fact that the claim is directed to analyzing an undigested enoxaparin preparation. The latter information was apparently included to distinguish this claim from the claims of the '886 patent which analyze exhaustively digested preparations. The Court declines, however, to incorporate such superfluous information merely to distinguish an entirely separate patent.

The Court will therefore adopt the following construction, which is in line with Amphastar's proposal but somewhat simpler:

providing a preparation containing tetrasaccharides which is substantially free of saccharides of different lengths, and substantially free means that at least 70% of different-length saccharides have been removed.

f. "Providing a High Performance Liquid Chromatography (HPLC) Determination"

This term appears in the first limitation of Claim 8. Teva and Amphastar both contend its plain and ordinary meaning should control. Momenta requests a construction ("using a particular method, HPLC, to make a determination") but does not offer any argument or support for why such a construction is necessary, and the Court is unable to discern one. Its proposed definition also seems to alter the meaning of the term somewhat by changing "providing" a determination to "using" a method to make a determination, and it is not clear why Momenta construes "providing" in the context of Claim 8 to mean "using" when it construes "providing" in the context of Claim 1 simply as "providing". Accordingly, the Court declines to construe the term as Momenta requests and instead accords the term its plain and ordinary meaning.

g. "Range A, Range B, Range C"

As discussed, Claims 1 and 8 involve determining if the tetrasaccharide structures listed in the table provided are present and/or are present in the amounts specified therein. The same table is provided in both claims, and it describes the upper

and lower amounts under the headings of Ranges A, B and C. These amounts are expressed as a percentage of the area under the HPLC curve.

Momenta defines the ranges as

> a percent area under an HPLC curve between and including the lower and upper bounds of the relevant range; and, in certain cases defined in the claim, the presence of a particular tetrasaccharide,

whereas Amphastar defines them as "the percent area under the curve as expressed in the table". Teva does not request a construction.

Momenta contends that the headings require clarification because, in two particular instances, the table states that the relevant range is "present or detectable" and, in two other instances, lists the low end of the range as "0.0". In both instances, Momenta asserts, the mere presence of the defined structure will satisfy the relevant claim limitation.

The Court agrees that clarification of the "present or detectable" value, which is not a numerical value for the percent area under the curve, is warranted, see, e.g., 10:33-35 ("The value need not be a numerical value but, e.g., can be merely an indication of whether the subject entity is present."), but will not elaborate upon the 0.0 lower range which is a numerical value. Presumably, if the percent area under the curve is 0.0, the tetrasaccharide in question simply is not "present" under the meaning of the final limitation of either claim.

Accordingly, the Court will construe the ranges to mean "the percent area under an HPLC curve between and including the lower and upper values listed; and, in two instances specified in the claim, presence or detectability."

h. "Maintaining the Process Based, At Least In Part, upon the Analysis"

The preamble to Claim 7 states that the claim is directed at "[a] method of analyzing a process of making an enoxaparin preparation". The first two limitations involve analyzing a tetrasaccharide fraction and the final limitation involves "maintaining the process based, at least in part, upon the analysis", a term which Teva states should be accorded its plain and ordinary meaning and Momenta contends should be construed to mean "continuing the same manufacturing process based, at least in part, on the results of the tetrasaccharide analysis". Amphastar does not request a construction.

Momenta contends that its proposed definition is necessary to clarify that the word "maintaining" refers to continuing in the same manufacturing process without change. That meaning is apparent from the written description, it argues, where the term "maintaining" the manufacturing process is used as a counterpoint to "altering" that process. See 14:66-15:3.

The Court agrees that clarifying the precise meaning of the word "maintaining" in this context is appropriate. It will therefore adopt Momenta's proposed construction in substance but,

beyond substituting "continuing" for "maintaining", will use clarifying language (for "the process" and "the analysis") only insofar as it appears within the claim itself. Thus, the term will be construed to mean "continuing the process of making an enoxaparin preparation based, at least in part, on the analysis of the tetrasaccharide fraction".

3. Agreed-upon Terms

The following terms are listed as disputed in the parties' joint statement but the parties agree that they may be ascribed their plain and ordinary meaning and need not be separately construed:

1) "If One or More [Said] Chains Are Present"
2) "A Method of Analyzing an Enoxaparin Preparation"
3) "Analyzing the Tetrasaccharide Fraction"
4) "Amount Identified [or Provided] in the Following Table"
5) "Processing Said Preparation, Wherein Processing Includes One or More of Selecting, Accepting, Processing into Drug Product, Shipping, Formulating, Labeling, Packaging or Selling Said Preparation"
6) "A Method of Analyzing a Process of Making an Enoxaparin Preparation"
7) "Thus Analyzing the Enoxaparin Preparation"

Because there is no dispute, those terms will incorporate,

where applicable, the definition of "enoxaparin preparation" (discussed in subheading C.2.d) but will otherwise be accorded their plain and ordinary meanings.

ORDER

In accordance with the foregoing, the disputed claim terms in the '886 patent are construed as follows:

1) "a separation method" means "A method, e.g., capillary electrophoresis ("CE") or high performance liquid chromatography ("HPLC"), used to separate the components of a heterogeneous mixture based on the physical or chemical properties of those components";

2) "non naturally occurring sugar" means "a sugar having a structure that does not normally exist in heparin in nature";

3) "a structural signature" means "information regarding the identity, number and physiochemical properties of the mono- and di-saccharide building blocks of a polysaccharide";

4) "a structural signature associated with the non-naturally occurring sugar associated with peak 9 [of Fig. 1]" means "a structural signature which bears a relationship to the non-naturally occurring sugar which corresponds to Peak 9 [of Fig. 1]";

5) "two or more structural signatures" incorporates the meaning of "structural signature" and is otherwise accorded its plain and ordinary meaning;

6) "the structural signatures of the non naturally occurring sugars are associated with peaks 9 and 10 of fig. 1" means "the structural signatures are associated with the non-naturally occurring sugars which correspond to peaks 9 and 10, respectively, of Fig. 1";

7) "a reference standard" means "pre-selected values";

8) "an enoxaparin sample" means "an enoxaparin composition which is derived from and representative of a particular batch of enoxaparin";

9) "making a determination about the enoxaparin sample", "a method for analyzing an enoxaparin sample", "to thereby analyze the enoxaparin sample", "the quality of the sample" and "keep or discard the sample" incorporate the meaning of sample and are otherwise accorded their plain and ordinary meanings;

10) "exhaustively digested" means "sugar chains of enoxaparin that have been broken down as far as the two or more heparin degrading enzymes of the claim will permit";

11) "selecting a batch" means "selecting a quantity of enoxaparin that was produced in a single process for further testing or processing";

12) "in a second batch of enoxaparin" means "in a second quantity of enoxaparin that was produced in a single process";

13) "a preselected range" is accorded its plain and ordinary meaning.

The disputed claim terms in the '466 patent are construed as follows:

1) "strong anion exchange high performance liquid chromatography (HPLC)" means "a type of anion exchange HPLC that is used for analyzing negatively charged analytes based on the relative strength of their negative charges. The stationary phase in the column is attached to positively charged functional groups, the positive charge in the functional groups on the stationary phase is present across the entire pH range, and a high salt concentration is usually employed to release the analyte";

2) "whether a tetrasaccharide structure is present" means "whether one or more of the tetrasaccharide structures identified in the claim is present";

3) "if said structures are present" means "if one or more of the tetrasaccharide structures identified in the claim is present";

4) "a method of processing an enoxaparin preparation" means "a method of processing enoxaparin drug substance or drug product";

5) "providing an isolated tetrasaccharide fraction" means "providing a preparation containing tetrasaccharides which is substantially free of saccharides of different lengths, and substantially free means that at least 70% of different-length saccharides have been removed";

6) "providing a high performance liquid chromatography determination" is accorded its plain and ordinary meaning;

7) "Range A, Range B, Range C" means "the percent area under an HPLC curve between and including the lower and upper values listed; and, in two instances specified in the claim, presence or detectability";

8) "maintaining the process based, at least in part, on the analysis" means "continuing the process of making an enoxaparin preparation based, at least in part, on the analysis of the tetrasaccharide fraction"; and

9) the terms "if one or more [said] chains are present", "a method of analyzing an enoxaparin preparation"; "analyzing the tetrasaccharide fraction", "amount identified [or provided] in the following table", "processing said preparation, wherein processing includes one or more of selecting, accepting, processing into drug product, shipping, formulating, labeling, packaging or selling said preparation", "a method of analyzing a process of making an enoxaparin preparation" and "thus analyzing the enoxaparin preparation" incorporate, where applicable, the definition of "enoxaparin preparation" but otherwise are accorded their plain and ordinary meanings.

So ordered.

/s/ Nathaniel M. Gorton

Nathaniel M. Gorton
United States District Judge

Dated June 27, 2012