IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIOVERATIV INC., BIOVERATIV THERAPEUTICS INC., and BIOVERATIV U.S. LLC, Plaintiffs, v. CSL BEHRING LLC, CSL BEHRING GMBH, and CSL BEHRING RECOMBINANT FACILITY AG, Defendants.	Civil Action No. 1:17-cv-00914-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Presently before me is the issue of claim construction of multiple terms in U.S. Patent Nos. 9,670,475 ("'475 Patent"), 9,629,903 ("'903 Patent") and 9,623,091 ("'091 Patent"). (D.I. 88). I have considered the Parties' Joint Claim Construction Brief. (*Id.*). I heard oral argument on February 27, 2019. (D.I. 109).

I. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (citation omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315.

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [This is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13. "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321. "In some cases, the ordinary meaning of claim language

as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely on the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based on consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317-19. Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation omitted).

II. BACKGROUND

The patents-in-suit relate generally "to the field of therapeutics for hemostatic disorders." ('475 Patent at 1:35-36).

The Parties dispute terms that appear in the claims of the '475 Patent. Claim 1 is representative:

> 1. A method of *controlling a bleeding episode* in a human subject in need thereof, *comprising administering* to the subject multiple doses of about 25 IU/kg to about 50 IU/kg of a chimeric Factor IX ("FIX") polypeptide *comprising* FIX and an FcRn binding partner ("FcRn BP") at a dosing interval of about 7 days between two doses, wherein the FcRn BP *comprises* Fc or albumin and wherein the subject exhibits the plasma FIX activity above 1 IU/dL during the dosing interval.

('475 Patent, claim 1 (disputed terms italicized)).

The Parties dispute terms that appear in the claims of the '903 Patent. Claim 1 of the '903 Patent is representative:

> 1. A method of treating hemophilia B in a human subject in need thereof, *comprising* intravenously *administering* to the subject multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric Factor IX ("FIX") polypeptide *comprising* FIX and an FcRn binding partner ("FcRn BP") at a dosing interval of about 10 days to about 14 days between two doses, wherein the FcRn BP *comprises* Fc or albumin, wherein *the trough level of the plasma FIX activity after each administration is at least 3 IU/dL after six days*, and wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

('903 Patent, claim 1 (disputed terms italicized)).

The Parties dispute terms that appear in the claims of the '091 Patent. Claim 1 is representative:

> 1. A method of treating hemophilia B in a human subject in need thereof *comprising* intravenously *administering* to the subject multiple doses of about 50 IU/kg to about 100 IU/kg of a chimeric factor IX ("FIX") polypeptide *comprising* FIX and an FcRn binding partner ("FcRn BP") at a dosing interval of about 10 days to about 14 days between two doses, wherein the FcRn BP *comprises* Fc or albumin, wherein the administration maintains the plasma FIX activity of the subject above 1 IU/dL between the dosing interval, and wherein the administration treats the human subject by reducing the frequency of spontaneous bleeding.

('091 Patent, claim 1 (disputed terms italicized)).

The Parties agree on constructions for twelve additional terms. (D.I. 101 at 1-3). Of importance, the Parties agree that "trough" or "trough level" means: "the lowest plasma Factor IX activity level reached after administering a dose of chimeric Factor IX polypeptide and before

the next dose is administered, if any. Baseline Factor IX levels are subtracted from measured Factor IX levels to calculate the trough level." (*Id.* at 2).

III. CONSTRUCTION OF DISPUTED TERMS

1. "controlling a bleeding episode"[1]

a. *Plaintiffs' construction*:

"controlling (including suppressing or decreasing the incidence of) a bleeding episode but not eliminating 100% of bleeding in all patients all the time"

b. *Defendants' construction*:

plain meaning (i.e., treating in response to an existing bleeding episode)

Alternatively, indefinite.

c. *Court's construction*:

"controlling (including suppressing or decreasing the incidence of) a bleeding episode but not eliminating 100% of bleeding in all patients all the time"

This term appears in the preamble of claim 1 of the '475 Patent. The Parties agree that the preamble is limiting and agree that the term "controlling a bleeding episode" covers on-demand treatment of a bleed. (D.I. 88 at 10-46). The Parties disagree, however, on whether the term can also cover "inhibiting, suppressing, or decreasing the incidence and/or severity of a bleeding episode." (*Id.* at 10).

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[1] These Parties litigated the construction of this term before the ITC. (D.I. 90, Exh. 16 ("ITC Action") (In the Matter of Certain Recombinant Factor IX Products, Inv. No. 337-TA-1066, USITC Pub. No. 15 (Jan. 31, 2018))). The Administrative Law Judge ("ALJ") in that matter arrived at a construction that, to use the ALJ's description, "does not make sense." *Id.* at 18. Claim constructions that do not make sense are generally disfavored. Accordingly, I will engage in an independent evaluation of the claim term rather than accord the ALJ's opinion persuasive weight.

Plaintiffs argue that their construction is consistent with how a POSA would understand the language of the claim. (*Id.* at 11-12, 21-33). They identify phrases that appear in the body of the claim, such as "dosing interval of about 7 days" and "multiple doses," as contextual clues that would guide a POSA away from understanding the claimed method as an on-demand treatment. (*Id.* at 12). Defendants do not disagree with this proposition, effectively conceding the issue. I find that Plaintiffs' point is plainly apparent from an analysis of the claim and, thus, that the language of the claim as a whole supports an understanding that the claim is not limited to on-demand treatment.

Defendants argue that the language of the claim, when correctly situated within its patent family, demands a temporal limitation—that the claimed method be administered after, and in response to, a bleeding episode. (D.I. 88 at 20-22, 41-43).[2] They support this argument primarily by comparing the asserted claims of the '475 Patent with claim language found in related patents. (*Id.* at 20-21). They point out that the other patents-in-suit broadly claim "method[s] of treating hemophilia B." (*Id.* at 20). They also note that claims 1, 19, and 21 of U.S. Patent No. 9,233,145 ("'145 Patent"), which shares a specification with the '475 Patent, distinguish between "controlling the incidence of a bleeding episode" and "controlling a bleeding episode." (*Id.*). Further, they observe that claims 1 and 2 of U.S. Patent No. 9,867,873 ("'873 Patent") distinguish between a "method of controlling a bleeding episode" and a "method of prophylactic treatment of hemophilia B." (*Id.*). Plaintiffs respond that a court may properly

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[2] Defendants also assert that Plaintiffs' construction changes the object of the verb "controlling" from "bleeding episodes" to "incidence" via the parenthetical. (D.I. 88 at 22). Plaintiffs respond that the parenthetical merely clarifies the meaning of "controlling." (*Id.* at 32). I agree with Plaintiffs' understanding of the parenthetical.

construe similar language in related patents to have identical meanings and that the examples selected by Defendants are not inconsistent with Plaintiffs' construction. (*Id.* at 38-39).

"Where multiple patents derive from the same parent application and share many common terms, [the court] must interpret the claims consistently across all asserted patents." *SightSound Techs., LLC v. Apple Inc.*, 809 F.3d 1307, 1316 (Fed. Cir. 2015) (cleaned up). However, this is not inconsistent with the conclusion that "[d]ifferently worded but similar claims in related patents can be construed identically." *Shire LLC v. Abhai*, LLC, 219 F. Supp. 3d 241, 246 (D. Mass. 2016). That is, although a court must construe like terms in closely related patents identically, the court is not prevented from construing unlike terms in closely related patents identically.

The terms that the Patentee used to claim its invention in other Patents are not plainly inconsistent with Plaintiffs' proposed construction of the claim term at issue in this case. And, although I do not have the complete intrinsic records of the '145 and '873 Patents, Defendants have not established why Plaintiffs' proposed construction of "controlling a bleeding episode" would be improper for those patents. Thus, I find that the claims of patents related to the '475 Patent do not weigh against adopting Plaintiffs' proposed construction.

The '475 Patent's specification clearly contemplates that the invention relates to a prophylactic treatment to reduce breakthrough bleeding and to decrease the severity of any bleeds that do occur. ('475 Patent at 7:28–33, 16:44-46, 16:57-67). It also clearly indicates a preferred dosing regimen that is consistent with prophylactic treatment. (*Id.* at 18:45-63). Defendants do not address the fact that their construction excludes the preferred embodiments described in the '475 Patent's specification.

Plaintiffs argue that the '475 Patent's specification supports understanding that claim 1 covers prophylactic treatment. Specifically, claim 1 recites administering "multiple doses of . . . chimeric Factor IX." This mirrors the definition of prophylactic treatment in the specification. ('475 Patent at 16:38-40). Claim 1 also recites "a dosing interval of about 7 days between two doses." Likewise, the specification associates such dosing intervals with prophylactic treatment. (*Id.* at 4:27-29). Furthermore, claim 1 recites "wherein the subject exhibits the plasma FIX activity above 1 IU/dL during the dosing interval." The stated goal of prophylactic treatment is "to increase the level of Factor IX activity in a subject's plasma" over a period of time. (*Id.* at 16:38-41).

Defendants disagree with Plaintiffs' assessment. They note that the specification consistently references "control or prevention" and argue that this sets up a dichotomy between the two terms. (D.I. 88 at 22-24). I find, as discussed more fully below, that the prosecution history provides important context that would inform a POSA's understanding of the difference between "control" and "prevention." While Defendants read prevention to mean prophylaxis, a POSA would understand "prevention" in the specification to mean 100% prevention of bleeding episodes. Consistent with that understanding, a POSA would understand "control" to mean anything less than 100% prevention of bleeding.

On balance, the specification provides strong support for Plaintiffs' proposed construction. The specification as a whole clearly contemplates that the inventive method is a dosage regime that a patient takes prophylactically to treat bleeding episodes. It also states that the preferred embodiment of the invention is a dosage regime that a patient takes prophylactically. Defendants do not provide a reason that a POSA, reading the claim and the specification, would understand the claim not to cover the preferred embodiment. Furthermore,

Defendants' understanding of "prevention" is not consistent with a POSA's understanding of "prevention" in the context of the Patent.

The prosecution history provides additional support for Plaintiffs' proposed construction. During prosecution, the Examiner rejected the then-pending claims that included the phrase "control or prevention of bleeding." (D.I. 89-2, Exh. 6 at 3-4 ('475 Patent File History: Office Action (Sept. 28, 2015) at 3-4)). The Examiner described his understanding that "controlling" meant "inhibiting or decreasing bleeding tendencies" while "prevention" meant "0% bleeding in 100% of patients 100% of the time." (*Id.*). The Applicant responded to this rejection by noting the Examiner's correct understanding of "controlling," disagreeing with the Examiner's understanding of "prevention," and removing "prevention" from the claims to "expedite prosecution." (D.I. 89-2, Exh. 7 at 10-11 ('475 Patent File History: Reply to Non-Final Office Action (Dec. 28, 2015) at 10-11)). Defendants make much of the Applicant's disagreement with the Examiner's basis for rejection, arguing that the exchange cannot be lexicography. (D.I. 88 at 25-27).

Although I do not find that the exchange between the Examiner and the Applicant amounts to lexicography, I do find that the exchange would inform a POSA's understanding of the term "controlling" in the context of the '475 Patent. Specifically, a POSA would read the exchange and be guided to review the Examiner's basis for understanding the meanings of "prevention" and "control." The paragraph of the specification that the Examiner references discusses prophylactic treatment. ('475 Patent at 16:38-48). The Examiner discussed "controlling" in terms of prophylactic treatment, which would lead a POSA to understand that "controlling" is not inconsistent with prophylaxis. This information, when combined with the

language of the claim and the specification, supports Plaintiffs' position on the plain and ordinary meaning of "controlling a bleeding episode" in the context of the intrinsic record.

Defendants identify additional support for their construction in extrinsic evidence. (D.I. 88 at 27-28). I find, however, that the intrinsic evidence clearly informs a POSA's understanding of the claim term.

Defendants' proposed construction blindly ignores the entire body of the claim, the substance of the specification, and the clear understanding of the Applicant and Examiner during prosecution. I do not believe, however, that a POSA would be so blind. Thus, based on extensive support in the intrinsic record, I will construe "controlling a bleeding episode" to mean "controlling (including suppressing or decreasing the incidence of) a bleeding episode but not eliminating 100% of bleeding in all patients all the time."

2. "the trough level of the plasma FIX activity after each administration is at least 3 IU/dL after six days"[3]

a. *Plaintiffs' proposed construction*:

"the trough level of the plasma FIX activity (calculated by subtracting baseline) is at least 3 IU/dL and occurs later than 6 days after each administration"

b. *Defendants' proposed construction*:

"the trough level of the plasma FIX activity occurs at six days after each administration and is at least 3 IU/dL"

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[3] These Parties also litigated the construction of this term in the ITC Action. The ALJ arrived at a construction that, to use the ALJ's description, "results in a nonsensical claim and excludes all of the embodiments disclosed in the '903 patent." ITC Action at 39. Claim constructions that are nonsensical and exclude preferred embodiments are generally disfavored. Accordingly, I will engage in an independent evaluation of the claim term rather than accord the ALJ's opinion persuasive weight.

b. *Court's construction*:

> "the trough level of the plasma FIX activity (calculated by subtracting baseline) is at least 3 IU/dL and occurs later than 6 days after each administration"[4]

The Parties agree that the terms "trough" and "trough level" mean "the lowest plasma Factor IX activity level reached after administering a dose of chimeric Factor IX polypeptide and before the next dose is administered, if any." (D.I. 88 at 50-51). The Parties also agree that the "trough level" will always occur just before the next dose. They further agree that requiring a trough level to occur on day 6 of a 10- to 14-day dosing interval would render the claims inoperable and nonsensical. (*Id.* at 57, 62, 69). The Parties disagree, however, on whether the claim's "at least 3 IU/dL after six days" limitation is merely redundant or necessitates Plaintiffs' proposed inoperable and nonsensical construction.

The resolution of the Parties' disagreement hinges on the meaning of "after" in the claim. Plaintiffs argue that "after" in the context of the claim means "later than." (*Id.* at 46-47). With this understanding, the limitation would mean, "the lowest Factor IX activity level, subtracting baseline, must be above at least 3 IU/dL . . . , and that minimum level must continue to a point after six days following the dose (and before next dose)." (*Id.* (emphasis omitted)). Defendants disagree with Plaintiffs' dictionary-definition approach to understanding the claims. (*Id.* at 52). They note that standard dictionaries, including the one referenced by Plaintiffs, define "after" to mean "following the expiration of." (*Id.*). Because the Parties' proposed ordinary-meaning

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[4] The Parties agree that this construction applies equally to those claims of the '903 Patent that claim a plasma FIX activity of "at least about 5 IU/dL." (*See* D.I. 101 at 7-8).

definitions are both equally reasonable when read in a vacuum, I find that general purpose dictionaries are not helpful to determine the meaning of "after" in this claim.[5]

The Parties disagree on the importance of the '903 Patent's specification to understanding the meaning of "after." Plaintiffs argue that the specification clearly indicates that the invention is "a method to extend the desired trough level to beyond six days, not providing a method to reach the trough at exactly six days." (*Id.* at 47). They further argue that Defendants' construction excludes clearly-described preferred embodiments of the invention. (*Id.* at 62). Defendants do not substantively respond to these arguments. Rather, Defendants attempt to establish a definition of "after" by identifying instances of the word in the specification to show how the Applicant used the preposition. (*Id.* at 53-54, 68-69).

The fact that Defendants' construction reads out preferred embodiments weighs against finding that their construction is correct. "[A] claim interpretation that excludes a preferred embodiment from the scope of the claim is rarely, if ever, correct." *Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1326 (Fed. Cir. 2013). Moreover, although prepositions such as "after" are the proper subject of claim construction, I think they are uniquely poor candidates for definition by examination of use in the intrinsic record. Because such a term is so regularly used in normal English speech, and has so many closely-related proper usages, it is unlikely that a POSA, reading the specification, would discern a special meaning for the word. It is equally unlikely that the Applicant intended to give such a word a particular meaning through

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[5] Defendants argue that the Applicant, in claim 2 of the '475 Patent, used "after at least" when it meant "later than." (*Id.* at 51-52). As I discuss above, a court may give similar terms in related Patents identical constructions. I find that this is even more reasonable when considering the meaning of a preposition that an Applicant is unlikely to have imbued with a special meaning. Thus, I find Defendants' argument unpersuasive.

its usage in the specification. Thus, I find that the specification supports a construction of "after" that is consistent with the preferred embodiments.

The'903 Patent's prosecution history provides insight into why the Applicant added the "at least 3 IU/dL after six days" limitation. The claim was initially rejected as obvious over prior art that showed FIX deficient mice reaching baseline plasma FIX levels on the sixth day after a dose. (D.I. 89-2, Exh. 10 at 5-13 ('903 Patent File History: Office Action (June 2, 2016) at 5-13)). The Applicant amended its claims to clarify that the claimed dosing regime stayed above the trough level beyond the sixth day. (D.I. 89-2, Exh. 11 at 11-17 ('903 Patent File History: Reply to Non-Final Office Action (Sept. 2, 2016) at 11-17)). The Applicant explained,

> [A] skilled person would have had no reason to administer a FIX-FcRn BP polypeptide at a dose of about 50 IU/kg to 100 IU/kg at a dosing interval of about 10 to 14 days. Further, in the same vein, one of skill in the art would have had no reason to expect that a trough level of at least 3 IU/dL could be achieved after six days post-administration.

(*Id.* at 12-13). Defendants argue this explanation supports their construction. (D.I. 88 at 54-55). Plaintiffs argue that an understanding of the art that the Applicant was overcoming and a consideration of the scientific principles relevant to the invention support understanding "after" to mean "later than." (*Id.* at 48-50).

I agree with Plaintiffs' assessment. Contrary to Defendants' position, I find that the use of "after" in the Applicant's two-sentence explanation of a POSA's expectations is no clearer than the use of "after" in the claim. However, an understanding for the basis of the rejection and the resulting amendment supports the conclusion that the Applicant meant "later than" when it used "after."

The specification and the prosecution history support that a POSA would understand "the trough level of the plasma FIX activity after each administration is at least 3 IU/dL after six

days" in the context of the Patent to mean "the trough level of the plasma FIX activity (calculated by subtracting baseline) is at least 3 IU/dL and occurs later than 6 days after each administration." This is problematic, however, because such a construction renders the "after six days" limitation superfluous in view of the requirement of a "dosing interval of about 10 days to about 14 days." The claim requires a trough level above 3 IU/dL at the end of the dosing interval. Thus, the plasma FIX activity level will necessarily be above 3 IU/dL later than 6 days.

Among the many guiding principles of claim construction is the preference that a court give every term independent meaning within the claim. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim."); *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) ("A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so."); *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004) ("While not an absolute rule, all claim terms are presumed to have meaning in a claim."). However, "no canon of construction is absolute in its application." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). And "surplusage may exist in some claims." *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1312 n.6 (Fed. Cir. 2008).

A review of the intrinsic record strongly supports finding that this term is a rare instance of "surplusage." The individual words of the term have meaning, but the term does not add a new limitation because it is inherent in the rest of the claim. This result is disfavored, but it is the only reasonable result considering the intrinsic record. The term was added during prosecution to clarify that the patented invention maintains a blood concentration above 3 IU/dL beyond the six days that was disclosed in the prior art. The specification also demands such a

construction as it describes a dosing method to maintain a blood concentration level above 3 IU/dL for the longer dosage interval of ten to fourteen days. Given this intrinsic record, the only reasonable conclusion is that the plain and ordinary meaning of "after" to a POSA in the context of the patent is "later than."

Defendants' proposed construction is based, almost exclusively, on the idea that the term *must* be construed to add an additional and unique limitation to the claim. However, this is not how a POSA would understand the claim. Rather, consistent with normal claim construction principles, a POSA would understand that the term holds a meaning consistent with the intrinsic record and basic science.

Thus, I will construe "the trough level of the plasma FIX activity after each administration is at least 3 IU/dL after six days" to mean "the trough level of the plasma FIX activity (calculated by subtracting baseline) is at least 3 IU/dL and occurs later than 6 days after each administration."

3. "administering"

a. *Plaintiffs' proposed construction*:

"giving a pharmaceutically acceptable Factor IX polypeptide of the invention to a subject via a pharmaceutically acceptable route"

b. *Defendants' proposed construction*:

"giving a pharmaceutically acceptable Factor IX polypeptide of the invention to a subject via a pharmaceutically acceptable route (e.g., intravenous, subcutaneous, intramuscular, oral, nasal, or pulmonary)"

c. *Court's construction*:

"giving a pharmaceutically acceptable Factor IX polypeptide of the invention to a subject via a pharmaceutically acceptable route"

The Parties dispute whether the full scope of the lexicographic definition of "administering" includes the routes of administration identified in the specification. (D.I. 88 at 70-73). The Patentee defined the term in a paragraph of the specification:

> "Administering," as used herein, means to give a pharmaceutically acceptable Factor IX polypeptide of the invention to a subject via a pharmaceutically acceptable route. Preferred routes of administration are intravenous, e.g., intravenous injection and intravenous infusion, e.g., via central venous access. Additional routes of administration include subcutaneous, intramuscular, oral, nasal, and pulmonary administration, preferably subcutaneous.

('475 Patent at 7:18-25). It is settled that the specification may define a claim term and that, when it does, "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. The first sentence of the paragraph provides a definition and is clearly lexicography. The "preferred routes" and "additional routes" sentences, however, are clearly exemplary, rather than definitional, and not lexicography. Therefore, I will construe "administering" to have its lexicographical definition: "giving a pharmaceutically acceptable Factor IX polypeptide of the invention to a subject via a pharmaceutically acceptable route."

4. "comprising"/ "comprises"

a. *Plaintiffs' position*:

CSL has identified these terms for construction. Bioverativ states that no construction of these terms is necessary, particularly in light of the Parties' agreed-upon constructions.

b. *Defendants' proposed construction*:

"including but not limited to" / "includes but is not limited to"

d. *Court's construction*:

"including but not limited to" / "includes but is not limited to"

The Parties disagree on whether the Court ought to construe this term. (D.I. 88 at 73-77). Plaintiffs take the position that the "proposed construction could be misused to confuse the jury and invite jurors improperly to expand claim scope." (*Id.* at 74). The remainder of their argument on this issue is a theory that Defendants plan to misuse these well understand, generally uncontroversial, patent terms. Plaintiffs do not, however, identify specific instances of the terms "comprising" or "comprises" in the patent claims that are not consistent with the ordinary meaning of those terms. Defendants respond that there is no indication that the patents-in-suit give the terms "anything other than [their] ordinary, well-understood meaning in patent law." (*Id.* at 76). Plaintiffs do not disagree with that proposition. Thus, as it is my job to give the terms of the asserted claims meaning, I will construe "comprising" to mean "including but not limited to" and "comprises" to mean "includes but is not limited to."

IV. CONCLUSION

Within five days the Parties shall submit a proposed order consistent with this Memorandum Opinion.