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 LENGNAU AG, Defendants.	Civil Action No. 17-914-RGA

MEMORANDUM OPINION

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March 5, 2020

ANDREWS, UNITED STATES DISTRICT JUDGE:

Before me are five motions submitted by Bioverativ and CSL Behring. This memorandum opinion will address Defendants' Motion for Summary Judgment of Invalidity of All Asserted Patent Claims. (D.I. 210). I have reviewed the parties' briefing and related papers. (D.I. 217, 227, 237). I heard oral argument on February 21, 2020. After full consideration of the briefing, the motion is resolved as follows.

I. BACKGROUND

Plaintiffs Bioverativ Inc., Bioverativ Therapeutics Inc., and Bioverativ U.S. LLC filed this lawsuit against Defendants CSL Behring LLC, CSL Behring GmbH, and CSL Behring Lengau AG on July 7, 2017, asserting infringement of U.S. Patent Nos. 9,670,475 ("the '475 patent"), 9,623,091 ("the '091 patent"), and 9,629,903 ("the '903 patent") (collectively, "the Asserted Patents"). (D.I. 1). Defendants move for summary judgment of insufficient written description and/or lack of enablement under 35 U.S.C. § 112 of claims 1, 14, 17-19, and 29 of U.S. Patent No. 9,670,475; claims 1 and 22 of U.S. Patent No. 9,629,903; and claims 1 and 24 of U.S. Patent No. 9,623,091.

Hemophilia B is a bleeding disorder that results from a deficiency of FIX protein that is necessary for blood clotting. (Ex. 1, '475 patent at 1:62-65). Hemophilia B is treated by administering replacement FIX "on demand" to stop active bleeding or "prophylactically" to prevent bleeding before it occurs. (*Id.* at 1:65-2:1, 12:66-13:3). The asserted claims are directed to regimens for controlling bleeding and preventing spontaneous bleeding in patients with hemophilia B by administering FIX fusion proteins comprising an Fc or albumin polypeptide. (Ex. 1, '475 patent at Claim 1, 14, 17-19, 29; Ex. 2, '903 patent at Claims 1, 22; Ex. 3, '091 patent at Claims 1, 24).

Plaintiffs' Alprolix and Defendants' accused product Idelvion are both extended half-life FIX products approved by the United States Food and Drug Administration for on-demand treatment and prophylaxis. (Ex. 26, Alprolix Label at 1; Ex. 27, Idelvion Label at 1). Alprolix is a recombinant fusion protein in which FIX is fused to an Fc domain of a human immunoglobulin antibody. (Ex. 26, Alprolix Label at 13). Idelvion is a recombinant fusion protein in which FIX is fused to another protein, human serum albumin, via a linker that is cleaved by the same enzyme that activates FIX in the coagulation process. (Ex. 27, Idelvion Label at 4).

The Asserted Patents share a common specification and claim priority to a provisional application filed on July 9, 2010. (Ex. 1, '475 patent; Ex. 2, '903 patent; Ex. 3, '091 patent). For the purposes of the enablement and written description analysis, I will consider the '475 patent and its specification to be representative of all of the patents-in-suit.

II. LEGAL STANDARD

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The moving party has the initial burden of proving the absence of a genuinely disputed material fact relative to the claims in question. *Celotex Corp. v. Catrett*, 477 U.S. 317, 330 (1986). Material facts are those "that could affect the outcome" of the proceeding, and "a dispute about a material fact is 'genuine' if the evidence is sufficient to permit a reasonable jury to return a verdict for the nonmoving party." *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). When determining whether a genuine issue of material fact exists, the court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. *Scott v. Harris*, 550 U.S. 372, 380 (2007); *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007).

III. DISCUSSION

Defendants ask the court for summary judgment of invalidity for lack of written description and no enablement. (D.I. 217 at 1). Plaintiffs assert that genuine issues of material fact preclude summary judgment. (D.I. 227 at 2). I agree with Plaintiffs. Because I find that the same issues of material fact preclude summary judgment on the basis of both written description and enablement, I will discuss them together.

Defendants assert that summary judgment of invalidity for lack of written description should be entered for the patents in suit because Plaintiffs' patents do not contain adequate written description for the claimed methods of using the vast number of chimeric FIX polypeptides that the inventors never made or tested. (D.I. 217 at 8). Plaintiffs assert that the written description requirement is fulfilled because the asserted claims are sufficiently described by the specification, particularly when viewed with the knowledge of a person of skill in the art. (D.I. 227 at 2).

The written description requirement contained in 35 U.S.C. § 112, ¶ 1 requires that the specification "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm. Inc., v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (cleaned up). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Id.* The written description inquiry is a question of fact. *See id.* Although it is a question of fact, "[c]ompliance with the written description requirement . . . is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008). "A party must prove invalidity for lack of written

description by clear and convincing evidence." *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015).

With respect to the enablement requirement, Defendants argue that Plaintiffs' patents do not enable a skilled artisan to make and use the full scope of the claimed methods without undue experimentation. (D.I. 217 at 13). Plaintiffs contend that a skilled artisan would not require undue experimentation in order to practice Plaintiffs' claims over their full scope because the dosing information is stated in the claims, along with how to make and use the chimeric FIX polypeptides, which are comprised of components well-characterized in the prior art. (D.I. 227 at 12).

The enablement requirement, considered a separate and distinct requirement contained in 35 U.S.C. § 112, ¶ 1, assesses whether "one skilled in the art, after reading the specification, could practice the claimed invention without undue experimentation." *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999 (Fed. Cir. 2008). Because the enablement inquiry takes into account what is known to one skilled in the art, the Federal Circuit has "repeatedly explained that a patent applicant does not need to include in the specification that which is already known to and available to one of ordinary skill in the art." *Koito Mfg. Co. v. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1156 (Fed. Cir. 2004). "Enablement is a legal question based on underlying factual determinations." *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 684 (Fed. Cir. 2015). Factors considered in assessing the enablement requirement include:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). "A party must prove invalidity for lack of enablement by clear and convincing evidence." *Vasudevan*, 782 F.3d at 684.

The asserted claims cover methods of treating hemophilia B "with a vast genus of chimeric FIX polypeptides," according to Defendants, "including a class of FIX-albumin polypeptides for which the specification contains no working examples or information." (D.I. 217 at 14). Defendants argue that the written description is insufficient due to the sheer breadth of the claims, which they contend include "at least millions" of chimeric FIX polypeptides. (*Id.*; citing Ex. 4, Camire Dep. at 90:12-91:8; Ex. 12, Pierce Dep. at 218:14-219:10). Defendants assert that the claims lack written description because a skilled artisan "could not predict whether a chimeric FIX polypeptide meeting the structural limitations would meet the functional limitations of the claims based on the amino acid sequence." (D.I. 217 at 6). Defendants contend that the asserted claims are not limited to the administration of FIX polypeptides "consisting of" only an FcRn binding partner, but instead use the open-ended term "comprising." (D.I. 237 at 2). Therefore, the asserted claims encompass chimeric proteins that could include "not only variants of each component part (*i.e.*, FIX, Fc, and albumin) in a multitude of configurations, but also an unlimited number of additional components." (*Id.*). As such, a skilled artisan could not envision the claimed genus with reference to the structural features alone. (*Id.* at 4).

Plaintiffs assert that Defendants' written description argument fails to consider a skilled artisan's knowledge of the prior art. (D.I. 227 at 3). Information that is well known in the art need not be described in detail in the specification. *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1359 (Fed. Cir. 2019) ("a patentee may rely on information that is well-known in the art for purposes of meeting the written description requirement, because the specification is viewed from the perspective of [a skilled artisan].") (cleaned up). According to Plaintiffs, a skilled artisan would have been aware of the representative species of chimeric FIX-albumin fusions and could "immediately visualize the members of the genus as containing FIX and albumin or Fc and

variants thereof." (D.I. 227. at 4, 8). Plaintiffs point to the Schulte and Metzner scientific publications[1] to establish prior art supporting that a skilled artisan would have been aware of the FIX-albumin constructs taught therein. (*Id.* at 3).

Plaintiffs also argue that the enablement requirement is satisfied because, after accounting for the required biological functionality, a skilled artisan would not have to make and test chimeric polypeptides meeting the structural limitations of the asserted claims to determine the scope of the genus because the scope is already limited only to those species with functional FIX, Fc, and albumin components. (*Id.* at 9, 19). To fall within the scope of the recited genus, Plaintiffs argue that a chimeric FIX polypeptide must not only comprise FIX and either albumin or Fc but must also be biologically functional. (*Id.* at 10). Plaintiffs state that the claim constructions require that the chimeric FIX polypeptides comprise (1) FIX functional in its normal role in coagulation and (2) albumin or Fc able to be bound by and transported by FcRn. (*Id.* at 8, citing D.I. 122).

The written description requirement demands that persons of ordinary skill in the art be able to recognize that the inventor invented what is claimed. *See Ariad Pharm.*, 598 F.3d at 1351. Here, there is a genuine dispute as to the scope of the genus described in the claims and whether a skilled artisan could envision the claimed genus with reference to its structural features alone. *See, e.g.*, D.I. 237 at 2-4. The parties meaningfully disagree about whether a skilled artisan could determine whether certain chimeric FIX polypeptides would meet the functional limitations of the asserted claims such that the inventor's possession over the claimed subject matter would be clear. *See id.* at 4, 8-9; D.I. 227 at 17-18.

[1] Schulte is incorporated by reference into the specification. Metzner is cited in Schulte.

Similar to their arguments for sufficient written description, Plaintiffs attempt to satisfy the enablement requirement of § 112 largely in reliance on their assessment of a skilled artisan's knowledge of the prior art. *See, e.g.*, D.I. 227 at 14, 16.

A specification that requires a skilled artisan to "engage in an iterative, trial-and-error process to practice the claimed invention" does not provide an enabling disclosure. *Idenix Pharms. LLC v. Gilead Scis., Inc.*, 941 F.3d 1149, 1161 (Fed. Cir. 2019). With regards to the presence of absence of working examples and the amount of direction or guidance presented to one skilled in the art, Plaintiffs assert that because all of the species within the recited genus of chimeric FIX polypeptides share key structural similarities, the asserted claims are fully supported by "relatively few representative examples or formulas." (D.I. 227 at 5-6). Plaintiffs suggest that undue experimentation is not necessary here where, "Based on the substantial information in the prior art, a POSA would have had reasonable confidence that any embodiment falling within the scope of the claims could be made and used according to the teachings of the specification." (*Id.* at 16). However, there remains a genuine dispute of material fact as to the nature of the alleged invention and the scope of the claims, specifically, the size of the genus of claimed chimeric FIX polypeptides.

Therefore, I will deny Defendants' motion for summary judgment of lack of written description and for lack of enablement.

IV. CONCLUSION

For the reasons discussed above, I will deny Defendants' motion. An accompanying order will be entered.