IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAXALTA INCORPORATED
BAXALTA US INC. and
NEKTAR THERAPEUTICS,

Plaintiffs;

v.

BAYER HEALTHCARE LLC,

Defendant.

Civil Action No. 17-1316-RGA

MEMORANDUM OPINION

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January 19 , 2021

/s/ Richard G. Andrews
ANDREWS, U.S. DISTRICT JUDGE:

Before me are Plaintiffs' motion for Partial Summary Judgment and to Exclude Certain Expert Opinions (D.I. 447) and Defendant's motion for Summary Judgment. (D.I. 450). Oral argument was held on November 12, 2020 (D.I. 601), and I have considered the parties' briefs and supplemental materials. (D.I. 448, 451, 462, 463, 468, 469, 602, 603, 613, 614). For the reasons set forth below, Plaintiffs' motion is GRANTED in part and DENIED in part. Defendant's motion is GRANTED in part and DENIED in part.

I. BACKGROUND

Plaintiffs Baxalta Incorporated, Baxalta US Inc., and Nektar Therapeutics (collectively "Baxalta"[1]) filed this action for patent infringement against Bayer Healthcare LLC on September 15, 2017. (D.I. 1). The parties provide competing treatments for hemophilia A: Bayer's Jivi and Baxalta's Adynovate. (D.I. 281 ¶¶ 64, 66, 77).

Baxalta asserts two patent families against Bayer, the Bossard Patents and the Bentley Patents. (*See* D.I. 281 ¶ 1; D.I. 1 ¶ 1 in 18-cv-01355). The Bossard Patents are directed to PEGylated Factor VIII conjugates. (D.I. 448 at 5; *see also* '223 Patent). Following claim narrowing, the seven remaining Bossard Patents are: U.S. Patent No. 7,199,223 ("the '223 Patent"), U.S. Patent No. 7,863,421 ("the '421 Patent"), U.S. Patent No. 8,247,536 ("the '536 Patent"); U.S. Patent No. 8,519,102 ("the '102 Patent"), U.S. Patent No. 8,618,259 ("the '259 Patent"), U.S. Patent No. 8,889,831 ("the '831 Patent"), and U.S. Patent No. 9,999,657 ("the '657 Patent"). (D.I. 533). These patents share a common specification and claim priority to a 2003 provisional application. (D.I. 448 at 5 (citing U.S. Patent Application No. 60/450,578)).

[1] Because I think it sounds better, I refer to Plaintiffs as plural and Baxalta as singular, but they are the same.

The Bentley Patents are not specific to Factor VIII but claim "branched reactive polymers that may be conjugated with biologically active molecules to form a biologically active conjugate." (D.I. 448 at 5). The three remaining Bentley Patents are U.S. Patent No. 8,809,453 ("the '453 Patent"), U.S. Patent No. 8,273,833 ("the '833 Patent"), and U.S. Patent No. 9,187,569 ("the '569 Patent"). (D.I. 533). These patents share a common specification and claim priority to a 2002 non-provisional application. (D.I. 448 at 5 (citing U.S. Patent Application No. 10/290,892)).

Baxalta moves for partial summary judgment of no-invalidity for lack of utility under § 101, prior invention under § 102(g), derivation under § 102(f), and obviousness under § 103 based on §§ 102(f) & 102(g) prior art. (D.I. 447). Baxalta also moves to exclude certain opinions of Bayer's expert, Dr. Russell. (*Id.*).

On both the Bossard and Bentley Patents, Bayer moves for summary judgment of lack of enablement, lack of utility under § 101, lack of adequate written description, anticipation, no willful infringement, and no induced infringement. (D.I. 450). Bayer's anticipation argument rests on U.S. Patent No. 5,643,575 (the "Martinez Patent"). (D.I. 451 at 2). Bayer also moves for summary judgment of non-infringement of the '569 Patent as matter of law, and non-infringement of the Bentley Patents under the doctrine of equivalents. (D.I. 450).

II. LEGAL STANDARD

A. Summary Judgment

"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). Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011) (quoting *Anderson v. Liberty Lobby,*

Inc., 477 U.S. 242, 248 (1986)). "[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." *Id.* The burden on the moving party may be discharged by pointing out to the district court that there is an absence of evidence supporting the non-moving party's case. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986).

The burden then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp*., 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: "(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations . . . , admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute . . . ." FED. R. CIV. P. 56(c)(1). The non-moving party's evidence "must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance." *Williams*, 891 F.2d at 461.

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. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). If the non-moving party fails to make a sufficient showing on an essential element of its case with respect to which it has the burden of proof, the moving party is entitled to judgment as a matter of law. *See Celotex Corp.*, 477 U.S. at 322.

B. Claim Construction

"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) (internal quotation marks 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, 977–80 (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 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which 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 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "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 upon 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 upon 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 (internal quotation marks omitted). 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 and internal quotation marks omitted).

C. Daubert

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

FED. R. EVID. 702. The Third Circuit has explained:

> Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that "a broad range of knowledge, skills, and training qualify an expert." Secondly, the testimony must be reliable; it "must be based on the

> 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his o[r] her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity." Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that "Rule 702's 'helpfulness' standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility."
>
> By means of a so-called "*Daubert* hearing," the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) [of the Federal Rules of Evidence] whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404–05 (3d Cir. 2003) (footnote and internal citations omitted).[2]

III. DISCUSSION

A. Plaintiffs' Partial Motion for Summary Judgment

1. Utility

In order to satisfy the utility requirement under 35 U.S.C. § 101, "a patent must have specific and substantial utility." *Grunenthal GmbH v. Alkem Labs. Ltd.*, 919 F.3d 1333, 1345 (Fed. Cir. 2019). Specific utility is satisfied when the patent "provide[s] a well-defined and particular benefit to the public." *Id.* (quoting *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005)).

[2] The Court of Appeals wrote under an earlier version of Rule 702, but the subsequent amendments to it were not intended to make any substantive change.

Substantial utility, also referred to as practical utility, requires that "the claimed invention has a significant and presently available benefit to the public." *Id.* (quoting *In re Fisher*, 421 F.3d at 1371). In the pharmaceutical context, such substantial utility "may be shown by adequate evidence of any pharmacological activity." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1564 (Fed. Cir. 1996).

a. The Bossard Patents

Baxalta argues that the Bossard Patents are entitled to summary judgment of no invalidity for lack of utility. (D.I. 448 at 8). Generally, Baxalta asserts that the Factor VIII activity of the claimed conjugates and compositions is sufficient to satisfy the utility requirement because the activity is "reasonably indicative of a pharmaceutical response." (*Id.* at 9). Three of the conjugates described in the Bossard specification[3] were tested *in vitro* and determined to be "bioactive." '223 Patent at 50:20-22. Citing *Grunenthal*, Baxalta argues that this data is sufficient to demonstrate practical utility. (D.I. 448 at 10). Baxalta argues that the '223 Patent specification shows that Factor VIII had a "well established" therapeutic benefit as a treatment for hemophilia A as of the filing date of the Bossard Patents. (*Id.*). In light of this therapeutic benefit, Baxalta asserts that specific utility is satisfied because the claimed conjugates have "Factor VIII activity" and "their compositions may act as Factor VIII replacement therapy for treatment of hemophilia A." (*Id.*).

Bayer argues that the data indicating bioactivity is insufficient to meet even the low bar of utility because the Bossard specification presents "no indication of what 'bioactive' means and nothing to suggest that the 'determined' activity was reasonably indicative of treating hemophilia." (D.I. 463 at 4). Bayer also cites to the wide range of potential retained activity

[3] For convenience, references to the '223 Patent specification are used to refer to the common Bossard specification.

levels contained in the specification – 2% through 100% - as evidence that the specification does not explain how to obtain conjugates with therapeutically useful levels of Factor VIII activity. (*Id*. at 3).

I believe that Bayer has raised a sufficient dispute of material fact with respect to the expert interpretation of the '223 Patent specification's *in vitro* test results. While the Court in *Grunenthal* outlined a low standard for utility, a patent must still demonstrate specific and substantial utility. *Grunenthal*, 919 F.3d at 1345. Where a patentee provides test results in support of its utility arguments, the *Grunenthal* Court noted that the tests do not "need to prove the claimed utility." *Id*. at 1346. Rather, "[a]ll that is necessary is evidence that a POSA would accept the claimed utility as correct." *Id.*

Bayer's expert, Dr. Ravetch, opined that, as the '223 specification does not disclose the activity levels obtained in Examples 6, 7, and 8, they could be as low as 2%. (D.I. 449, Ex. 3 ¶ 1044). He continued, "given that the Bossard specification discloses random pegylation . . . there is no disclosure as to how such pegylation would achieve activity levels sufficient to have any therapeutic effect. A POSA would not understand this disclosure as describing a well-defined and particular benefit to the public." (*Id*.). Baxalta's expert, Dr. Walensky, disagreed. (*See* D.I. 470, Ex. 27 ¶ 1375 (stating that "a POSA would understand that the PEGylated Factor VIII conjugates of the claimed invention have Factor VIII activity and would be able to promote the procoagulant function of the Factor VIII molecule, which is a pharmacologic activity")).

In light of the experts' genuine dispute of material fact, I will not grant summary judgment on the matter of utility as to the Bossard Patents. Baxalta's motion is therefore DENIED.

b. The Bentley Patents

With respect to the Bentley Patents, Baxalta argues that the '072 Patent specification demonstrates both substantial and specific utility.[4] (D.I. 448 at 11). The central dispute between the parties on summary judgment appears to be the lack of any test data or potential activity levels supporting the Bentley Patents. (*Id.* at 10; D.I. 463 at 5). Test data is not always required to demonstrate utility, but "it is proper for the examiner to ask for substantiating evidence unless one with ordinary skill in the art would accept the allegations as obviously correct." *Rasmusson v. SmithKline Beecham Corp*., 413 F.3d 1318, 1323 (Fed. Cir. 2005).

The Bentley Patents disclose "branched, reactive water-soluble polymers useful for conjugation to biologically active molecules in a manner that tends to avoid a significant reduction in the biological activity of the molecule while still providing the benefits of water-soluble polymer conjugation." '072 Patent 2:12-15. Beginning with substantial utility, Baxalta points to Examples 5 and 6 – two Lysozyme conjugates – in support of its argument. (D.I. 448 at 11). Both examples conclude with the statement, "Example [5 or 6] demonstrates the utility of the polymers of the invention in forming conjugates . . ." '072 Patent 24:4-5; 24:39-40. However, I agree with Bayer that these sentences seem to refer the ability of the PEG polymers to attach rather than their overarching utility. (D.I. 463 at 6). If, as Baxalta states, "it is undisputed that the object of the invention is to retain a form of biological activity," Examples 5 and 6 are, on their own, insufficient to demonstrate this utility. (D.I. 468 at 3).

Bayer also cites the Bentley Patents' use of random PEGylation in challenging their utility. (D.I. 463 at 6-7). In its "Background of the Invention" section, the Bentley specification mentions that the prior art approaches involve "random attachment of numerous polymer arms to

[4] The '072 Patent is no longer asserted in this action, but the Bentley Patents share a common specification. Citations to the '072 Patent are used for convenience to refer to this common specification.

the molecule, thereby increasing the risk of a reduction or even total loss in bioactivity of the parent molecule." '072 Patent 1:46-50. This passage suggests a difficulty with "random attachment," which I understand to refer to random PEGylation. Baxalta's Reply Brief, however, does not address Bayer's charge that the Bentley Patents use random PEGylation or how such use would impact the bioactivity of the resulting conjugate.

On the record as it stands, I cannot conclude that a POSA would accept the allegations of the Bentley specification as "obviously correct" and thus negate any need for substantiating evidence. *Rasmusson*, 413 F.3d at 1323. Given the material disputes remaining, Plaintiffs' summary judgment motion as to the utility of the Bentley Patents is DENIED.

2. Prior Invention under § 102(g)

Section 102(g) provides that one shall be entitled to a patent unless, "before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2) (pre-AIA). "A patent is invalid under [§ 102(g)(2)] if the claimed invention was made in this country by another inventor before the patent's priority date." *Solvay S.A. v. Honeywell Int'l. Inc*., 742 F.3d 998, 1000 (Fed. Cir. 2014). Additionally, the prior inventor must not have abandoned, suppressed, or concealed the invention. *Apotex USA, Inc. v. Merck & Co.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001).

The Federal Circuit has outlined a burden-shifting framework within the confines of § 102(g). *Id.* at 1037. Once the party challenging a patent under § 102(g) has proven prior invention by clear and convincing evidence, "the burden of production shifts to the patentee to produce evidence sufficient to create a genuine issue of material fact as to whether the prior inventor has suppressed or concealed the invention." *Id.* If the patentee satisfies this burden, the

burden reverts to the challenger to "rebut any alleged suppression or concealment with clear and convincing evidence to the contrary." *Id*. at 1038.

When examining abandonment, suppression, or concealment under § 102(g), the Federal Circuit differentiates between two types of conduct. *Eolas Techs. Inc. v. Microsoft Corp.*, 399 F.3d 1325, 1333 (Fed. Cir. 2005) (citing *Apotex*, 254 F.3d at 1038). A prior inventor may "actively conceal his invention from the public." *Id*. Or, "abandonment, suppression, or concealment may be inferred based upon the prior inventor's unreasonable delay in making the invention publicly known." *Id*. (quoting *Dow Chem. Co. v. Astor-Valcour, Inc.*, 267 F.3d 1334, 1342 (Fed. Cir. 2001)). The Federal Circuit has cautioned, "There is no particular length of delay that is per se unreasonable." *Checkpoint Sys., Inc. v. U.S. Int'l Trade Comm'n*, 54 F.3d 756, 761 (Fed. Cir. 1995).

In its motion for summary judgment of no invalidity under § 102(g), Baxalta seeks a legal inference that Bayer abandoned its prior invention based on an unreasonable delay. (D.I. 448 at 21-22). For the purposes of its motion, Baxalta assumes for the sake of argument that Bayer's Dr. Milan Tomic conceived of and reduced to practice the asserted claims; Baxalta focuses its briefing on the ten-year delay between Dr. Tomic's 1990s research and Bayer's 2004 patent application. (*Id.* at 20-21). Baxalta argues that Dr. Tomic "never published the alleged invention in any form" and disputes the relevance of later Bayer patents which were filed after the priority dates of the Bossard and Bentley Patents and which do not name Dr. Tomic as an inventor. (*Id.* at 21). Dr. Tomic never applied for or received a patent for his research and he did not publish it publicly. (*Id.* at 20-21; D.I. 463 at 20).

Bayer argues that it never abandoned Dr. Tomic's work and engaged in internal efforts to perfect his invention, culminating in the filing of the Pan Patents.[5] (D.I. 463 at 21-22). Dr. Tomic stopped his work on PEGylated Factor VIII in January 1995 (D.I. 448 at 20 (citing D.I. 449, Ex. 9 at 175:10-24)), but Bayer argues that the company continued to perfect his initial invention until it was ready and useful for patient treatment. (D.I. 601 at 43:22, 45:23-25). In the alternative, Bayer claims that even if a period of delay occurred, Bayer resumed work on Dr. Tomic's invention (albeit without Dr. Tomic himself) before Nektar "entered the field." (D.I. 463 at 22).

As an initial matter, the parties dispute whether Dr. Tomic's invention is included in the Pan Patents. (*Id.*; D.I. 468 at 11-12). Dr. Tomic is not listed as an inventor on these patents, though, at oral argument, Bayer's counsel suggested that this should not matter because his concepts are included. (D.I. 601 at 48:20). This argument, it seems, requires the inference that the Pan Patents embody a distinct invention from what Dr. Tomic reduced to practice in 1995 yet can also serve as a disclosure of Dr. Tomic's 1995 invention sufficient to avoid a finding of abandonment. However, I do not take this to be Bayer's argument. Rather, Bayer's briefing argues that the Pan Patents represent the public disclosure of the "perfected invention." (D.I. 463 at 22). *See Eolas Techs.*, 399 F.3d at 1333 ("[C]reating an improved version of an invention does not in any sense abandon the original invention."). Baxalta replies that these issues need not be resolved because the Pan Patents are directed to a different invention than Dr. Tomic's 1995

[5] The "Pan Patents" refer to U.S. Patent Nos. 9,364,520 and 7,632,921 obtained by a Bayer employee—Dr. Clark Pan—who first filed a patent application in 2004. (D.I. 463 at 21-22).

invention, and Bayer's work on a different invention cannot constitute "perfecting" Dr. Tomic's invention. (D.I. 468 at 12).[6]

The parties have raised a dispute of material fact with respect to whether Dr. Tomic's invention is included in the Pan Patents or whether these patents constitute an entirely different invention. This is crucial in identifying whether Dr. Tomic's work was abandoned in 1995 for a different invention or whether it is reflected in Bayer's final product, the Pan Patents. Bayer has pointed to evidence in the record demonstrating that the company moved forward with Dr. Tomic's research in an effort to continue to develop and to improve the invention through the date of the Pan Patents application. (*See* D.I. 463 at 20-22). Viewing the evidence in the record in the light most favorable to Bayer, as I am required to do, a reasonable jury may conclude that Bayer's efforts between 1995 and 2004 were directed toward perfecting Dr. Tomic's invention. Thus, summary judgment is precluded.

For the reasons set forth above, Baxalta's motion for summary judgment of no invalidity of the Bossard Patents under § 102(g) is DENIED.

3. Derivation under § 102(f)

Similarly to § 102(g), § 102(f) provides that an individual may obtain a patent unless "he did not himself invent the subject matter sought to be patented." 35 U.S.C. § 102(f) (pre-AIA). "Assertion of this subsection as a defense amounts to a claim that the patentee derived the invention from another." *Robert Bosch, LLC v. Pylon Mfg. Corp.*, 700 F. Supp. 2d 625, 640 (D. Del. 2010). The party raising § 102(f) must demonstrate (1) prior conception and (2)

[6] Baxalta argues that Bayer cannot successfully mount a "resumption of activity" argument because Dr. Tomic himself never resumed activity on his invention. The "resumption of activity" argument only makes sense if Bayer, not Dr. Tomic, were named the "first inventor." (D.I. 468 at 12-13). Only individuals, not corporations, can be an inventor. I do not understand Baxalta to raise the same objection with respect to Bayer's continuous activity argument.

communication to the patentee by clear and convincing evidence. *Gambro Lundia AB v. Baxter Healthcare Corp.*, 110 F.3d 1573, 1576 (Fed. Cir. 1997) (citing *Price v. Symsek*, 988 F.2d 1187, 1190 (Fed. Cir. 1993)). This communication must "enable one of ordinary skill in the art to make the patented invention." *Eaton Corp. v. Rockwell Int'l Corp*., 323 F.3d 1332, 1344 (Fed. Cir. 2003). It is insufficient to convey only "so much of the claimed invention as would have made it obvious to one of ordinary skill in the art." *Gambro*, 110 F.3d at 1578 (finding that previous caselaw "did not incorporate an obviousness test into the § 102(f) analysis"). The communication must be of the "entire conception." *Id*. at 1577.

Baxalta asserts that Bayer cannot meet its burden of proving an enabling communication occurred. (D.I. 448 at 13). In response, Bayer marshals several theories of communication based on circumstantial evidence. At oral argument, the parties confirmed that Bayer now only asserts derivation against claims 16, 19, and 23 of the '536 Patent. (D.I. 601 at 7:5-9; 29:4-8).[7] Accordingly, Bayer must raise a genuine issue of material fact with respect to the limitations embodied in claims 16, 19, and 23 to survive summary judgment.[8]

First, Bayer argues that Dr. Tomic communicated his research to Dr. Milton Harris (then-President of Shearwater, which later merged with Nektar), who subsequently communicated it to named inventors Dr. Bentley and Dr. Bossard. (D.I. 463 at 6, 10). While Bayer describes several instances of communication between Dr. Harris and Dr. Tomic, the centerpiece of

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[7] Following briefing on this motion, the number of asserted claims was significantly reduced. (D.I. 533).

[8] The three asserted claims are dependent claims that all depend from independent claim 1 through at least dependent claims 12, 13, and 14. I would summarize claim 14 as requiring a composition that is free of albumin comprising a conjugate that comprises one, two, or three water-soluble polymers that are the same poly(ethylene glycol) covalently attached to one of various Factor VIII polypeptides [including, among other options, B-domain deleted Factor VIII]. For claim 16, the PEG is terminally capped with methoxy or hydroxy. For claim 19, the composition has a nominal average molecular weight from about 10,000 to 85,000 Daltons. For claim 23, which in the originally-issued patent appears to have been meant to depend from claim 22 and not claim 14, the composition is a branched PEG with two polymer arms.

Bayer's communication argument appears to be a 1994 meeting between Dr. Tomic, Dr. Harris, and additional Bayer scientists, discussing PEGylation. (*Id.* at 10). Bayer, citing testimony from Dr. Tomic, asserts that the binding of "few PEGs" was discussed. (*Id.*). Notes taken at this meeting, which was to discuss the "PEG-FactorVIII Project" and had as one agenda item the "Quantitation of PEG," include mention of a "desire" for "one → two 25 kD PEG residues." (D.I. 464, Ex. 11; *see* D.I. 463 at 11). The notes also mention branched PEGs, which Bayer points out are embodied in claim 23 of the '536 Patent. (D.I. 463 at 12).

There is no dispute that Dr. Tomic never communicated directly with the named inventors. Nevertheless, Bayer argues that Dr. Harris, while President of Shearwater, made Dr. Tomic's inventive concept "the focus of [Shearwater]." (*Id*. at 15). In support of this theory, Bayer cites several Shearwater publications and articles authored by Dr. Harris that include large branched PEGs with fewer attachment sites and monopegylated conjugates (*id*. at 14-15), concepts he apparently learned from Dr. Tomic. (*Id*. at 10-12). Dr. Harris and named inventor Dr. Bossard confirmed that the "benefits of few, large PEGs" were "generally known" within Shearwater. (*Id*. at 14). Bayer also connects Dr. Harris to named inventor Dr. Bentley directly by citing Dr. Bentley's testimony that he would have discussed PEGylated Factor VIII with Dr. Harris while at Nektar. (*Id*. at 15).

Second, Bayer alleges "additional circumstances" of communication involving Dr. Charles at PolyMasc in 1998 and Dr. Bossard in 2003. (*Id*. at 17). In 1998, representatives from Bayer met with Dr. Charles to discuss a potential collaboration with PolyMasc. (*Id*. at 18). Dr. Michael Fournel, then-VP of R&D with Bayer, "recalled telling Dr. Charles about Bayer's earlier findings with pegylated Factor VIII, including the use of large PEGs over 20 kDa." (*Id.* at 18). In June 2003, an email to Dr. Bossard and Dr. Bentley mentions asking Dr. Charles "to share

some of his (non-confidential) experience at PolyMasc." (D.I. 464, Ex. 39). Subsequently, an August 2003 powerpoint from Dr. Charles' presentation to Nektar includes a line stating, "[Dr. Charles] is aware of the reasons that the Bayer-PolyMasc collaboration did not deliver the desired results." (D.I. 464, Ex. 40 at 3).

In reply to these arguments, Baxalta argues that Bayer still falls short of its burden as a matter of law. (D.I. 468 at 4). Baxalta points to elements of the '536 Patent that are "glosse[d] over" in Bayer's brief. (*Id*. at 5). For example, all claims of the '536 Patent require a "composition free from albumin." '536 Patent 73:50.

Further, much of Bayer's evidence rests on the conclusion that Dr. Harris brought Dr. Tomic's "core concept" to Shearwater, namely, the use of "few, large PEGs attached to Factor VIII." (D.I. 463 at 8). Baxalta argues that communication of such a generalized concept cannot meet the standard required for derivation. (D.I. 468 at 5). I agree. Viewing Bayer's evidence that Dr. Harris publicized this concept within Shearwater in the light most favorable to Bayer, it is insufficient to demonstrate that Dr. Harris transmitted an enabling communication specific to the contents of the '536 Patent to a named inventor. *See Cumberland Pharm. Inc. v. Mylan Institutional LLC,* 846 F.3d 1213, 1219 (Fed. Cir. 2017) (stating that a "communication of an idea different from the claimed invention even where that idea would make the claimed idea obvious" or a "general research suggestion" is insufficient for derivation); *see also Robert Bosch*, 700 F. Supp. 2d at 643 (rejecting a derivation claim where, among other things, the defendant "fail[ed] to compare the alleged disclosure to the limitations of the [patent]").

For the reasons stated above, Bayer has failed to raise a genuine issue of material fact with respect to the derivation of the '536 Patent. As such, Baxalta's summary judgment motion of no invalidity for derivation of the asserted claims of the '536 patent is GRANTED.

4. Prior Invention and Derivation of the Bentley Patents

Baxalta moves for summary judgment of no invalidity of the Bentley Patents under § 102(f) and § 102(g) on the theory that Bayer's experts did not offer expert testimony on the issue of prior invention and derivation as applied to the Bentley Patents. (D.I. 448 at 23). As was clarified at oral argument, Bayer only asserts § 102(f) against the '536 Patent (of the Bossard Family). Thus, I need not address the potential application of § 102(f) to the three remaining Bentley Patents.

In support of its argument under § 102(g), Baxalta points to the deposition of one of Bayer's experts, Dr. Russell, in which he confirms that he does not offer an independent opinion on Bayer's 1990s research. (D.I. 448 at 23). In response, Bayer cites portions of Dr. Russell's expert report in which he discusses how Dr. Tomic's conception of large, branched PEGs anticipates claims in the Bentley Patents. (D.I. 463 at 24). This citation is sufficient to avoid summary judgment on the issue of prior invention premised upon a failure to offer opposition expert testimony. I agree with Bayer that there is no requirement that Dr. Russell opine on the "ultimate issue" of prior invention while offering an analysis of relevant facts in dispute. (*Id.* at 26). Baxalta's summary judgment motion in relation to the Bentley Patents is DISMISSED as moot as to derivation and DENIED as to prior invention.

5. Obviousness under § 103

Based on its § 102(f) and § 102(g) arguments, Baxalta moves for summary judgment of no invalidity under § 103 based on Dr. Tomic's 1990s research. (D.I. 448 at 22-23). In an obviousness analysis, "subject matter derived from another not only is itself unpatentable to the party who derived it under § 102(f), but, when combined with other prior art, may make a resulting obvious invention unpatentable." *OddzOn Prods., Inc. v. Just Toys, Inc.*, 122 F.3d

1396, 1403-04 (Fed. Cir. 1997). Similarly, "§ 102(g) prior art established by prior reduction to practice [or by prior conception and later diligent reduction to practice] could constitute prior art under § 103." *Tyco Healthcare Grp. LP v. Ethicon Endo-Surgery, Inc.*, 774 F.3d 968, 976 (Fed. Cir. 2014).

As I am granting summary judgment of no-invalidity for derivation (Section III.A.3 *supra*), I will grant Baxalta's motion with respect to Dr. Tomic's research under § 102(f). However, I am not granting summary judgment on the issue of prior invention. Thus, I will deny Baxalta's motion for summary judgment that Dr. Tomic's research is not § 102(g) prior art that can be used in an obviousness combination. Plaintiffs' motion is GRANTED in part and DENIED in part.

B. Plaintiffs' *Daubert* Motions

1. Dr. Russell's Testimony Based on Incorporation by Reference

Plaintiffs seek to exclude any anticipation arguments from Defendant's expert, Dr. Russell, that rely on the incorporation-by-reference of the Harris '462 Patent into the 2000 Shearwater Catalog. (D.I. 448 at 25-26).

In his expert report, Dr. Russell noted that the 1997 and 2000 Shearwater Catalogs referenced the Harris '462 Patent. (D.I. 449, Ex. 4 ¶ 121). The 1997 Catalog mentioned only that "a U.S. patent had been applied for with respect to the branched PEG." (*Id.*). The 2000 Catalog explicitly cited to the Harris '462 Patent in a footnote. (*Id.*; *see also* D.I. 449, Ex. 21 at 13 n.3). Dr. Russell explained that the '462 Patent contained information on "[t]he availability of higher molecular weights, different reactive functional groups, and various linkages in attaching PEGs to 'backbones' as variations on the PEG2-NHS and PEG2-maleimide for sale to customers in the catalogs." (D.I. 449, Ex. 4 ¶ 120). For the purposes of anticipation, Dr. Russell and Defendant

claim that the content of the '462 Patent has been incorporated by reference into the Shearwater 2000 Catalog. (D.I. 463 at 27).

Incorporation by reference is a question of law. *Adv. Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1283 (Fed. Cir. 2000). "To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents." *Id*. at 1282. In examining whether a reference has been incorporated, the court may consider how many prior art documents the host document cites, common ownership of the host document and the reference, and the prominence of the discussion of the reference. *Sunovion Pharm. Inc. v. Dey Pharma., L.P.*, 2012 WL 289957, at *3 (D. Del. Jan. 18, 2012) (discussing "additional factors" supporting the finding of incorporation by reference). However, a single footnote reference, without more, cannot support a finding of incorporation by reference. *Commonwealth Sci. & Indus. Rsch. Org. v. Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1372 (Fed. Cir. 2008).

The catalog cited by Dr. Russell references the '462 Patent in a single footnote. (D.I. 449, Ex. 21 at 13 n.3). There is no language implying that the patent is incorporated into the catalog or otherwise directing readers of the catalog to the contents of the '462 Patent. (*See* D.I. 449, Ex. 21 at 13). Defendant relies on the fact that the '462 Patent is a "prominent citation" and that the '462 Patent and the 2000 Catalog have common ownership. (D.I. 463 at 29). However, these factors cannot overcome the fact that the '462 Patent is cited as a footnote reference with none of the "detailed particularity" that the standard requires. *Adv. Display Sys.*, 212 F.3d at 1282; *see Commonwealth Sci.*, 542 F.3d at 1372.

Thus, I will grant Plaintiffs' *Daubert* motion to strike Dr. Russell's anticipation opinions that rest on the improper legal conclusion that the '462 Patent is incorporated by reference into the 2000 Shearwater Catalog. Baxalta's *Daubert* motion on this issue is GRANTED.

2. Dr. Russell's Use of the Term "Comprising"

Baxalta moves to exclude the portions of Dr. Russell's opinion that rely on the use of the term "comprising" in interpreting the "R" limitation of the Bentley Patents. (D.I. 448 at 26). Baxalta asserts that Dr. Russell's use of the term "comprising" is incorrect as a matter of law and must be excluded, as must any opinions that rely on this use of the term. (*Id.*).

The "R" term refers to the aliphatic hydrocarbon limitation. (*Id.* at 27). Previously, I construed "aliphatic hydrocarbon" to mean "a chain that must include carbons and hydrogens and may include heteroatoms." (D.I. 273 at 1). The parties agreed that the term "polymer having the structure," which appears in '833 Patent claim 1 and '569 Patent claim 1, and the term "conjugate has the structure" which appears in '453 Patent claim 1, mean "polymer comprising the structure" and "conjugate comprises the structure" respectively. (D.I. 185 at 2). Dr. Russell has interpreted the agreed constructions to indicate that "the polymer structures in the asserted claims can have additional atoms." (D.I. 448 at 27). Baxalta argues that Dr. Russell's addition of a carbonyl group (*i.e.*, C=O) to the aliphatic hydrocarbon limitation "abrogate[es] the "hydrogen limitation" included in the court's construction. (*Id.* at 28).

The Federal Circuit has stated that the term "'comprising' creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements." *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350, 1358 (Fed. Cir. 2016). Baxalta acknowledges this presumption but argues that Dr. Russell has applied the term in a way that "abrogates" the R limitation as construed. (D.I. 448 at

28). In support of this argument, Baxalta cites several cases constraining the use of the term "comprising." (*Id*. (citing *In re Varma*, 816 F.3d 1352, 1362 (Fed. Cir. 2016) (stating that "[comprising] does not render each limitation or phrase within the claim open-ended"); *Mitsubishi Chem. Corp. v. Barr Labs., Inc.*, 435 F. App'x 927, 935 (Fed. Cir. 2011) (rejecting the interpretation of "comprising" as permitting the addition of unrecited compounds that "would defeat the 'pharmaceutical' character" of the composition); *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1354 (Fed. Cir. 2010) (holding that "comprising" cannot "negate a claimed requirement")).

In response, Bayer argues that Dr. Russell's application is correct because the claimed R structure is present. (D.I. 463 at 31). Bayer characterizes Dr. Russell's opinion as adding only two pendent oxygen atoms to the first and fifth carbon in the R structure, rather than adding two carbonyl groups. (*Id*. at 31-32 (citing D.I. 454, Ex. 19 ¶ 203)). Bayer further argues that Baxalta's cited cases are inapposite because the inclusion of pendent oxygen atoms or carbonyl groups does not negate the fact that, as interpreted by Dr. Russell, the "R core has 'at least' or 'comprises' three carbon atoms." (D.I. 463 at 33-34).[9]

As it appears that the fundamental R structure required by the claims is present in Dr. Russell's analysis, I do not find that Dr. Russell's opinions are incorrect as a matter of law. The term "comprising" permits the addition of elements so long as this fundamental structure is satisfied, and I agree with Bayer that Dr. Russell's opinions do not amount to an abrogation of the R term. *In re Varma*, 816 F.3d at 1362 ("'Comprising' means that the claim can be met by a system that contains features over and above those specifically required by the claim element,

[9] Claim 1 of the '569 Patent 24:22-23, claim 1 of the '453 Patent 24:19-20, and claim 1 of the '833 Patent 24:15-16 define R as "an aliphatic hydrocarbon having a length of at least three carbon atoms."

but only if the system still satisfies the specific claim-element requirements…"). To the extent that Plaintiffs disagree with Dr. Russell's analysis, Plaintiffs may cross-examine him on the topic. Baxalta's *Daubert* motion on "comprising" is DENIED.

3. Dr. Russell's "practicing the prior art" Opinions

Baxalta moves to exclude the opinions contained in four paragraphs of Dr. Russell's Responsive Report (D.I. 454, Ex. 31) that recite a "practicing the prior art" defense to infringement. (D.I. 448 at 29). Bayer responds that the cited paragraphs do not assert such a defense but explain that "Plaintiffs' theory of infringement under the doctrine of equivalents would expand the claims to read on that [prior] art and demonstrate invalidity of the Bentley patents." (D.I. 463 at 37).

The Federal Circuit has stated on numerous occasions that a "practicing the prior art" defense to infringement is impermissible. *See Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1365 (Fed. Cir. 2002) ("there is no 'practicing the prior art' defense to literal infringement"); *see also 01 Communique Lab., Inc. v. Citrix Sys., Inc.*, 889 F.3d 735, 742 (Fed. Cir. 2018) (same). A practicing the prior art defense entails "compar[ing] the accused infringing behavior to the prior art in an attempt to prove that its conduct is either noninfringing or the patent is invalid as anticipated because the accused conduct is simply 'practicing the prior art.'" *Cordance Corp. v. Amazon.com, Inc.*, 658 F.3d 1330, 1337 (Fed. Cir. 2011). To the extent that Dr. Russell's opinions in the cited paragraphs amount to this invalid defense, I will exclude them in accordance with *Daubert* and Rule 702 of the Federal Rules of Evidence.

Baxalta challenges Paragraphs 10, 29, 32, and 40 of Dr. Russell's report. (D.I. 448 at 29). I will examine them briefly in turn.

Paragraph 10 of Dr. Russell's report contains a statement of legal standards, including, "an entity cannot be liable for infringement if it is using what has already been disclosed in the prior art. This is known as practicing the prior art." (D.I. 454, Ex. 31 ¶ 10). This plainly recites an impermissible defense as outlined in *Tate* and, as such, I will strike Paragraph 10. Given the surrounding language, it is possible that, as Bayer argues, Dr. Russell was attempting to explain that "if a claim term must be broadly interpreted to read on an accused device, then this same broad construction will read on the prior art." *01 Communique*, 889 F.3d at 742-43. While Bayer's attempt to save the paragraph may be based on a correct statement of law, no one claims Dr. Russell is a legal expert, and Dr. Russell is not the proper vehicle to make this argument. The plain text of Paragraph 10 recites an erroneous legal standard and I must exclude any testimony based on it. *See Herbert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed Cir. 1996) ("Incorrect statements of law are no more admissible through "experts" than are falsifiable scientific theories."); *Koki Holdings Co. v. Kyocera Senco Indus. Tools, Inc.*, 2020 WL 5633361, at *1-2 (D. Del. Sep. 21, 2020) (excluding expert testimony under Rule 702 that was contrary to a "well-established patent law principle").

I will strike the last two sentences of Paragraph 29 for the same reason. As part of Dr. Russell's non-infringement report, he discusses NOF patent applications that disclose "NOF's method of using a glycerol core to add POLY directly to the core." (D.I. 454, Ex. 31 ¶ 29). Dr. Russell continues, "Jivi® simply uses the NOF prior art." (*Id.*). As part of a non-infringement opinion, I agree with Baxalta that this amounts to an impermissible "practicing the prior art" argument. (D.I. 448 at 29).

Paragraphs 32 and 40 do not present the same improper analysis. (*See* D.I. 454, Ex. 31 ¶¶ 32, 40).

In Paragraph 32, Dr. Russell mentions NOF's characterization of Jivi and Plaintiffs' characterization of Jivi in opining that Jivi does not infringe claim 1 of the '072 Patent under either characterization. (D.I. 454, Ex. 31 ¶ 32). This analysis does not amount to alleging that Jivi merely practices NOF prior art.

In Paragraph 40, Dr. Russell states, "If the direct connection between POLY and R in the Jivi® PEG is no different than the single coupling atom in the claim as [Plaintiffs' expert] suggests, the claims are invalid because the prior art, such as the NOF patent discussed above and described in my Opening Report, discloses the connection we see in the Jivi® PEG." (D.I. 454, Ex. 31 ¶ 40). The prohibition on defending infringement via "practicing the prior art" does not "preclude a *litigant* from *arguing* that if a claim term must be broadly interpreted to read on an accused device, then this same broad construction will read on the prior art." *01 Communique*, 889 F.3d at 742 (emphasis added).[10] Dr. Russell's opinion in Paragraph 40 appears to support an argument that would fit into the category of argument permitted by the Federal Circuit in *01 Communique*. Thus, I decline to strike Paragraph 40 from Dr. Russell's report on the basis that it is an impermissible "practicing the prior art" defense.[11]

For the reasons set forth above, Baxalta's *Daubert* motion is GRANTED as to Paragraphs 10 and 29 and DENIED as to Paragraphs 32 and 40.

4. Dr. Russell's Opinions Concerning Random/Non-Random PEGylation

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[10] The case *01 Communique* relies upon most strongly for this proposition, *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1380 (Fed. Cir. 2007), was not a "practicing the prior art" case. Rather, it was a case where Plaintiff's requested broad claim construction led to a finding of non-enablement.

[11] *01 Communique* addresses an issue that is often problematic in application. I emphasize "litigant" and "arguing" in the text because: (1) the Court is supposed to do claim construction, and the experts and parties are supposed to accept it; (2) technical experts such as Dr. Russell should not be commenting on claim construction; (3) testimony by an expert making an *01 Communique* argument is apt to have a high potential for confusing the issues; and (4) cross-examination should often be a better tool for pointing out the other side's expert's inconsistent application of a claim limitation. By denying the *Daubert* motion, I do not intend to grant a blank check to Defendant and Dr. Russell.

Baxalta moves to strike Dr. Russell's opinions concerning random/non-random PEGylation on the grounds that (1) they are not tied to the claimed inventions and (2) are based on an ambiguous, unreliable methodology. (D.I. 448 at 30, 35). Dr. Russell's opinions concern both the Bossard Patents and a subset of the Bentley Patents referred to as the Bentley conjugate claims. (*Id*. at 30).

Bayer argues that Dr. Russell's opinions are relevant to the enablement of the claims as they recite conjugates with biological activity. (D.I. 463 at 35). I agree with Bayer on this point. The parties agree that none of the claim constructions require a specific PEGylation method. (D.I. 448 at 32; D.I. 463 at 36). Dr. Russell opines that the reactions described in the Bossard and Bentley specifications are random PEGylation and cannot teach a POSA how to enable the claimed "active" conjugates. (*See, e.g.*, D.I. 454, Ex. 19 ¶¶ 482-484, 516).[12] While a specific PEGylation method is not recited in the claims, Dr. Russell's analysis is clearly relevant to determine whether a POSA could enable the activity that is claimed. (*See, e.g.*, D.I. 452, Ex. 2 ¶ 1002; D.I. 454, Ex. 19 ¶ 483). Thus, I do not agree that Dr. Russell's testimony on § 112 is inconsistent with the patents-in-suit. *See Homeland Housewares, LLC v. Whirlpool Corp*., 865 F.3d 1372 (Fed. Cir. 2017) (stating that the court "must disregard the testimony of an expert that is plainly inconsistent with the record"); *Inline Connection Corp. v. AOL Time Warner Inc.*, 2007 WL 275928, at *5 (D. Del. Jan. 29, 2007) (excluding expert opinion on enablement that did not address the claimed invention).

I do not find Dr. Russell's methodology to be unreliable. As noted by Bayer, Dr. Russell testified without issue in a previous action between these parties regarding random PEGylation

[12] Bayer's expert, Dr. Ravetch, relied on Dr. Russell's analysis in opining on the lack of enablement of the Bossard Patents. (D.I. 463 at 46 n.22).

in the Bossard specification. (D.I. 464, Ex. 4 at 1295:15-1301:22). In the paragraph of the expert report cited by Baxalta, Dr. Russell provides parameters governing his understanding of "potentially random chemistry." (D.I. 454, Ex. 19 ¶ 491). To the extent that Baxalta disagrees with these parameters or finds them to be inexact, this is an issue of weight and credibility, not methodology.

For the reasons set for above, Plaintiffs' motion to strike the random/non-random PEGylation portions of Dr. Russell's testimony under *Daubert* is DENIED.

C. Defendant's Motion for Summary Judgment

1. Utility

Bayer moves for summary judgment of lack of utility of the Bossard and Bentley Patents. (D.I. 451 at 15). The legal standard for utility is included above (Section III.A.1 *supra*). As with Baxalta's motion on this point, genuine disputes of material fact remain.

a. The Bossard Patents

Bayer argues that the Bossard Patents cannot demonstrate utility because the specification does not describe any conjugates that retain sufficient Factor VIII activity to be useful to a patient. (*Id.* at 16). The specification recites possible activity levels as low as 2% and Bayer's expert testified that a Factor VIII product with "limited potency" is not viable because one cannot simply infuse more to make up the difference. (D.I. 453, Ex. 18 at 276:14-19). Bayer adds that the higher claimed PEG sizes also lack utility because they create stability problems and may become too viscous to administer routinely to patients. (D.I. 451 at 17; D.I. 452, Ex. 4 at 171:7-172:4; D.I. 453, Ex. 17 ¶¶ 76-78).

In reply, Baxalta argues that the Bossard Patents claim conjugates with Factor VIII activity, which has a well-established therapeutic effect. (D.I. 462 at 14; *see also* D.I. 466, Ex. 6 ¶¶ 74-

75). Baxalta also cites the fact that the specification includes examples of conjugates that were determined to be "bioactive" and argues that a POSA would read this to indicate Factor VIII activity. (D.I. 462 at 14; '223 Patent 50:21-23). In contrast to Bayer's arguments about the potential issues with administering certain claimed conjugates to patients, Baxalta counters that the appropriate standard is whether the patent is "totally incapable of achieving a useful result." (D.I. 462 at 17 (citing *Grunenthal GmbH*, 919 F.3d at 1345)).

I agree that Baxalta need not demonstrate that all claims of the Bossard Patents have an immediate use in patient care. The Federal Circuit has recently emphasized that the bar for utility is "not high." *Grunenthal GmbH*, 919 F.3d at 1345. While Bayer has offered evidence that there may be issues with translating certain Bossard claims into medical treatments, on this record I cannot find that the Bossard Patents are incapable of producing a useful result. Thus, Bayer has not carried its burden of demonstrating a lack of utility by clear and convincing evidence. *See Taurus IP, LLC v. DaimlerChrysler Corp.*, 726 F.3d 1306, 1322 (Fed. Cir. 2013). Bayer's motion for summary judgment is DENIED.

b. The Bentley Conjugate Claims

Bayer's primary attack on the Bentley specification appears to be that it lacks any data demonstrating half-life extension and lacks specific activity levels. (D.I. 451 at 16). I also understand Bayer's arguments about higher PEG sizes to apply to the Bentley claims as well. (*Id.* at 17).

As noted above, the lack of any data is a difficult hurdle to overcome, but it is not necessarily fatal to a patentee's utility arguments. *Rasmusson*, 413 F.3d at 1323. Baxalta cites to an expert report opining that "the utility of the branched reactive polymers is to conjugate to biologically active molecules and 'impart the advantageous characteristics typically associated with PEG

polymer attachment, such as increased water solubility and circulating half life while not adversely impacting the bioactivity of the parent molecule.'" (D.I. 462 at 15 (citing D.I. 467, Ex. 13 ¶ 364)). Baxalta also points to the fact that the molecules included in the Bentley specification have known activity. (*Id.*; *see also* D.I. 465 Ex. 3 ¶ 1389). Thus, Bayer argues, the resulting conjugates possess "both 'real-world value' and an 'immediate benefit to the public.'" (D.I. 462 at 16-17 (citing *In re Fisher*, 421 F.3d at 1371)).

In response, Bayer reiterates the fact that the Bentley specification does not contain any data or discussion demonstrating that the bioactivity of the parent molecule was unaffected by conjugation. (D.I. 469 at 13-14). As a lack of data is not *per se* invalidating, this absence does not amount to clear and convincing evidence that the Bentley Patents lack utility. Bayer's motion for summary judgment is DENIED.

2. Enablement

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.

a. The Bossard Patents

Bayer moves for summary judgment of non-enablement of the Bossard Patents on the grounds that a POSA cannot practice the full scope of the claims without undue experimentation. (D.I. 451 at 6). The parties do not dispute that the Bossard Patents encompass a genus but do dispute the breadth of the claims. (*Id*. at 11; D.I. 601 at 66:5-6).

Bayer's argument rests on several recent cases from the Federal Circuit and this District finding that very broad genus claims were not enabled across their full scope. *See Idenix Pharm. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1162 (Fed. Cir. 2019) (finding that the "immense breadth of screening required" constituted undue experimentation); *Enzo Life Scis., Inc. v. Roche Molecular Sys., Inc.*, 928 F.3d 1340, 1348-49 (Fed. Cir. 2019) (finding the "breadth of the claims" to be "particularly troubling" in light of the unpredictability of the art); *MorphoSys AG v. Janssen Biotech, Inc.*, 358 F. Supp. 3d 354, 372 (D. Del. 2019) (granting summary judgment of non-enablement where the specification instructed a POSA to "engage in an iterative, trial-and-error process.") (internal quotation omitted). In response, Baxalta argues that the guidance provided in the Bossard specification is sufficient to enable conjugates with Factor VIII activity. (D.I. 462 at 4).

Genuine disputes of material fact remain with respect to several of the relevant *Wands* factors. First, the parties dispute the scope of the prior art that may be rightfully omitted from

the specification. *See Streck, Inc. v. Rsch. & Diagnostic Sys. Inc.*, 665 F.3d 1269, 1288 (Fed. Cir. 2012) ("It is well-established, however, that a specification need not disclose what is well-known in the art"). Baxalta argues that "the specification teaches that Factor VIII activity may decrease if polymers are attached at sites necessary for activity" and that sites with Factor VIII activity were known in the art as of the date of the Bossard filing. (D.I. 462 at 4). In its reply brief, Bayer faults the specification for *not* including any known sites for Factor VIII activity. (D.I. 469 at 3). The parties also dispute at several points what a POSA would know and what should have been included in the specification. (*Compare* D.I. 462 at 5 (arguing "a POSA would recognize that the preferred sites for conjugation are also the preferred sites for mutation")), *with* D.I. 451 at 10 (noting that "the specification provides no guidance on where to mutate").

Second, the parties argue for very different interpretations of what guidance may be found in the specification. For example, Bayer asserts that the Bossard specification "does not tell a POSA where or what to mutate." (D.I. 469 at 4). Citing its expert, Dr. Walensky, Baxalta argues that the specification contains sufficient guidance in the form of preferred sites for conjugation and "teaching of the native Factor VIII amino acid sequence" to teach a POSA where to mutate. (D.I. 462 at 5). While Dr. Walensky testified that there are "two handfuls of locations" where a POSA would begin mutagenesis (*Id.* at 6 (citing D.I. 466, Ex. 8 at 245:24-247:24)), Bayer argues that the specification actually teaches a POSA *not* to mutate these sites. (D.I. 469 at 4).

While Bayer has offered expert testimony supporting its assertion that the Bossard Patents encompass a very large genus claim, I will not grant summary judgment where material disputes remain on, at a minimum, the contents of the relevant prior art, the knowledge of a POSA, and the guidance provided by the specification. Defendant's motion is DENIED.

b. The Bentley Conjugate Claims

Bayer moves for summary judgment of non-enablement on a subset of the Bentley claims it identifies as the "Bentley conjugate claims." (D.I. 451 at 12, 14). These are claim 6 from the '072 Patent, claim 12 of the '453 Patent, and claim 12 of the '569 Patent. (*Id*. at 14). Now only claim 12 of the '453 Patent remains. (D.I. 533).

Bayer's argument for non-enablement rests primarily on the size of the genus and the lack of any guidance or examples on how to achieve PEGylated conjugates with activity. (D.I. 451 at 14-15). In response, Baxalta argues that Bayer offers no evidence as to the size of the genus and only points to Baxalta's expert's testimony that he was "not sure" how big the genus would be. (D.I. 462 at 11 (citing D.I. 467, Ex. 15 at 244:21-245:11)). Baxalta also points to expert testimony as to the quantity of experimentation required and how a POSA would interpret the Bentley specification, issues that are addressed only briefly and conclusorily by Bayer. (*See, e.g.*, D.I. 467, Ex. 13 at ¶¶ 355, 361-62; D.I. 467, Ex. 15 at 237:16-238:20).

The factual disputes remaining between the parties with respect to several *Wands* factors are appropriately left to the trier of fact. Bayer's motion for summary judgment of non-enablement with respect to the remaining Bentley conjugate claim is DENIED.

3. Written Description

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) (alteration in original) (internal quotation marks omitted). "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*, 782 F.3d at 682.

Bayer recycles its non-enablement arguments and argues that all Bossard claims and the Bentley conjugate claims lack an adequate written description for the same reasons that they are not enabled. (D.I. 451 at 15). In support of this argument, Bayer offers one specific example, muteins, asserting that "there is no genuine dispute that the specifications fail to identify a single amino acid position to mutate, what to change it to, how many positions to mutate, what PEG should be used with that mutein – or any mutein with activity." (*Id.*).

Both the Bossard and Bentley Patents recite genus claims. In order to satisfy the written description requirement for a genus claim, the patentee must disclose "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014). Considering the sufficiency of a written description involves "how large a genus is involved and what species of the genus are described in the patent." *Id.* "[E]very species in a genus need not be described in order that a genus meet the written description requirement." *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997).

Bayer's single paragraph (D.I. 451 at 15) referencing its lack of enablement arguments fails to present clear and convincing evidence that the Bossard Patents and the Bentley conjugate claims lack written description. Enablement and the adequacy of the written description are separate inquiries and, on the evidence presented, I cannot conclude that the specifications would not allow a POSA to "recognize that [the inventor] invented what is claimed." *Ariad Pharm*., 598 F.3d at 1351. Additionally, as discussed above, the parties have several outstanding factual disputes with respect to enablement, including how a POSA would understand the Bossard specification's guidance on muteins. (*See, e.g.*, D.I. 466, Ex. 8 at 262:8-263:22). Bayer's motion for summary judgment of invalidity for lack of written description is DENIED.

4. Anticipation

"To show that a patent claim is invalid as anticipated, the accused infringer must show by clear and convincing evidence that a single prior art reference discloses each and every element of a claimed invention." *Silicon Graphics, Inc. v. ATI Tech., Inc.*, 607 F.3d 784, 796 (Fed. Cir. 2010). "[E]very element of the claimed invention [must be described], either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1346 (Fed. Cir. 2009). As with infringement, the court construes the claims and compares them against the prior art. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010). "While anticipation is a question of fact, it may be decided on summary judgment if the record reveals no genuine dispute of material fact." *Encyclopaedia Britannica, Inc. v. Alpine Elecs. of Am., Inc.*, 609 F.3d 1345, 1349 (Fed. Cir. 2010).

Bayer alleges that all asserted Bossard and Bentley claims are anticipated by U.S. Patent No. 5,643,575 ("Martinez"). (D.I. 451 at 17). The Martinez Patent was issued in 1997, predating

the priority dates of both the Bentley and Bossard families. (*Id.*). In addition to briefing on this matter, the parties have helpfully provided claim charts addressing the subset of remaining asserted claims. (*See* D.I. 602, 603, 613, 614).

a. The Bossard Patents

Seven Bossard Patents remain in this action: the '223 Patent, '421 Patent, '536 Patent, '102 Patent, '259 Patent, '831 Patent, and '657 Patent. (D.I. 533). In an effort to avoid summary judgment of anticipation, Baxalta points to several areas in which the parties' experts disagree on how to read Martinez.

First, the parties dispute how much is inherently disclosed by Martinez. Bayer cites a passage in Martinez discussing the "therapeutic applications" for "mammals in need of treatment" and adding blood factor treatment as an example. (D.I. 603-2 at D10). From this reference, Bayer argues that the albumin-free limitations in the '259 and '536 Patents, the lyophilized limitation in claim 29 of the '223 Patent, and the dose limitations of the '831 Patent are disclosed. (D.I. 451 at 22-23).[13] In response, Baxalta asserts that this infers too much from the brief discussion in Martinez. (D.I. 462 at 24).

With respect to albumin, Bayer argues, without citation, that "the hemophilia community wanted albumin-free Factor VIII due to perceived risk of HIV and hepatitis C contamination decades before the Bossard filing or the 1993 Martinez filing." (D.I. 451 at 23). I cannot accept unsupported factual assertions. And, even assuming Bayer is accurate, Baxalta's expert, Dr. Walensky, cites Factor VIII replacement products containing albumin as of 1993 (the filing date

[13] I think Bayer's arguments about inherency are based on a misunderstanding about what is required for inherency. "The inherent result must inevitably result from the disclosed steps; '[i]nherency . . . may not be established by probabilities or possibilities.'" *In re Montgomery*, 677 F.3d 1375, 1380 (Fed. Cir. 2012) (quoting *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 639 (Fed. Cir. 2011)).

of Martinez) and states that the Factor VIII replacement products continued to do so as of 2003. (D.I. 465, Ex. 3 ¶ 263). This is more than sufficient to raise a dispute of fact as to whether the albumin limitations contained in the '536 and '259 Patents are "necessarily present" in Martinez as a result of the PEGylation of Factor VIII. *See Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003).

Similarly, Bayer relies on the broad "treatment" disclosure in Martinez to inherently anticipate the specific dosing range of 0.001 mg to 100 mg claimed in the '831 Patent and the composition in a "lyophilized" form in claim 29 of the '223 Patent. (D.I. 451 at 22-23). Bayer's expert, Dr. Young, testified that Factor VIII products for treating hemophilia have been formulated in the same way for decades. (D.I. 453, Ex. 18 at 190:16-192:7). However, Dr. Walensky points to at least one study discussing Factor VIII products administered orally (i.e., not in lyophilized form). (D.I. 465, Ex. 3 ¶ 266). Bayer's briefing does not address the specific dosing range present in the '831 Patent, stating only that the limitations "parrot industry standards seen in FDA-approved Factor VIII products." (D.I. 451 at 22). In discussing this inherency argument, Bayer's expert, Dr. Ravetch, states "a hemophilia patient must be dosed with more than one molecule of pegylated Factor VIII, and Factor VIII is dosed in the range of 0.001 mg to 100 mg." (D.I. 452, Ex. 2 ¶ 543). Dr. Walensky argues that relying on FDA-approved products in comparison to the Factor VIII referred to in Martinez is improper and that a POSA would understand that "the properties of the Factor VIII replacement products relied on by Dr. Ravetch are not the same chemical or physical properties as the 'Factor VIII' that Dr. Ravetch relies upon in [Martinez]." (D.I. 465, Ex. 3 ¶ 415). In light of these disputes, summary judgment based on Bayer's inherent anticipation arguments must be denied.

Second, the parties dispute the appropriate scope of Martinez as applied to specific Bossard limitations. The Martinez specification notes that "mutant versions of proteins, such as mutant TNF's[14] and/or mutant interferons are also within the scope of the invention." '575 Patent 8:34-35. Bayer argues that this language includes the B-domain deleted limitations contained in several patents.[15] (D.I. 451 at 21). Bayer's primary support for this argument appears to be Dr. Walensky's testimony agreeing that "recombinant DNA methodology would include [muteins or mutations]" and a sentence in Dr. Walensky's expert report describing "B-domain deleted Factor VIII (which is a genetically engineered variant of Factor VIII)." (D.I. 452, Ex. 6 at 64:1-16; D.I. 453, Ex. 12 ¶ 136). Baxalta replies that the reference in Martinez to mutants is not sufficiently particular in its disclosure, *see Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1285 (Fed. Cir. 2017), with respect to any of the claims requiring B-domain deleted Factor VIII. (D.I. 462 at 22).

I agree that Bayer sweeps too broadly in its reliance on the reference in Martinez to "mutants." (D.I. 451 at 21). Bayer argues that this reference alone discloses the "'modified,' 'added,' 'substituted,' and [B-domain deleted] limitations in [all claims that contain them]." (*Id.*). This reading requires a POSA to select Factor VIII from the "peptides of interest" list and combine it with the disclosure of "mutants" to arrive at B-domain deleted Factor VIII. This series of steps does not amount to a "definite and limited class of compounds that enable[] a person of ordinary skill in the art to at once envisage each member" of a claimed genus. *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1376 (Fed. Cir. 2006). Bayer has not pointed to any preferences or guidance contained in Martinez that would direct a POSA to B-

[14] A TNF is a tumor necrosis factor. '575 Patent 7:66-67.
[15] B-domain deleted Factor VIII is an element of claim 16 of the '223 Patent, claim 1 of the '421 Patent, claim 4 of the '102 Patent, claim 1 of the '657 Patent, and claim 5 of the '259 Patent.

domain deleted Factor VIII. *See id.* (citing the express preferences contained in the prior art). On this record, I cannot conclude that Martinez undisputedly anticipates the B-domain deleted limitations in the Bossard Patents. This limitation is contained in all remaining Bossard claims not addressed by Bayer's inherency arguments. Thus, Bayer's motion for summary judgment of anticipation is DENIED.

b. The Bentley Patents

Bayer's anticipation arguments concerning the Bentley Patents raise a similar set of issues. The asserted Bentley claims recite branched PEGs of the formula Y—(X)*p*-R(—X'-POLY)$_q$. '569 Patent 24:20.[16] Martinez discloses polymers with the formula (R)$_n$L-A. '575 Patent 3:13. Thus, the anticipation analysis involves a comparison of two very broad genus claims.[17]

The crux of the dispute on summary judgment is the size of the claimed genus in Martinez. As Bayer notes, all the asserted Bentley claims require an oxygen atom in the X' position, making the linkage an "ether." (D.I. 451 at 25-26). Bayer argues that this limitation is satisfied by Martinez, which states, "A wide variety of linkages are contemplated between (R) and (L). Urethane (carbamate) linkages are preferred . . . Examples of other linkages between (R) and (L) include ether, amine, urea. . ." '575 Patent 4:4-5, 14-15. Claim 40 of Martinez discloses, "The polymer of claim 1, wherein said (R) is linked to said (L) by a linkage selected from the group consisting of urethane, amide, ether, amine urea, thio and thiol. '575 Patent cols. 21-22.

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[16] The other two Bentley Patents recite slight variations on this formula. The '833 Patent recites: Y—(X)*p*-R(—X-POLY)$_q$. '833 Patent 24:11. The '453 patent recites: D-L$_1$-(X)$_p$—R-(-X'-POLY)$_q$. '453 Patent 24:16.

[17] The three Bentley Patents show that Martinez was considered by the PTO during prosecution. *E.g.*, '833 Patent Face Page (56). For the other two patents, it was cited by the Examiner. '453 Patent Face Page (56); '569 Patent Face Page (56).

Baxalta argues that Bayer ignores the immense size of the Martinez genus, which Baxalta's expert places as "at least 3,000,000 polymer species." (D.I. 462 at 26 (citing D.I. 467, Ex. 13 ¶¶ 80, 185)). Examining the X' term specifically, Baxalta's expert opines "that the two linkages can be different," which would increase the size of the genus a POSA would have to consider. (D.I. 462 at 27). However, this opinion does not address the fact that that Claim 40 of Martinez narrows this selection to only six possible types of linkages. *See* '575 Patent cols. 21-22. Baxalta asserts that Claim 40's narrowing limitation does not help because a POSA would still have to consider millions of compounds in order to arrive at any species of the Bentley Patents. (D.I. 462 at 27 n.11).

The parties also dispute the range of molecular weight that is claimed in Martinez. (*Id*. at 19-20). Bayer's argument depends on interpreting Martinez to include polymers as large as 60 kDa. (D.I. 451 at 27). Bayer asserts that Baxalta's expert, Dr. Chyall, admitted this interpretation in his deposition testimony when he acknowledged that claim 6 of Martinez would cover "a PEG arm of molecular weight of about 200 to about 20,000 and there's three arms." (D.I. 452, Ex. 5 at 192:10-19). In response, Baxalta points to the deposition of another of its experts, Dr. Walensky, who opined that claim 6 is limited to two polymer arms. (D.I. 462 at 20 (citing D.I. 466, Ex. 8 at 57:2-60:9)). According to Baxalta, this limitation would result in a maximum weight of 40 kDa. (D.I. 462 at 20). As highlighted in the parties' claim charts, the dispute about the molecular weight is part of a larger dispute about whether the *n* term in the Martinez Formula should be interpreted to limit the R term or the L term. (D.I. 603-1 at A4-A5).

Viewing the record in the light most favorable to Baxalta, I believe that summary judgment is unwarranted. The parties' experts have several outstanding disputes about the proper scope and interpretation of Martinez, and thus Martinez's anticipation of the Bentley

claims is appropriately left for the trier of fact. Bayer's motion for summary judgment is DENIED.

5. Non-Infringement of Bentley '569 as a Matter of Law

Bayer moves for summary judgment of non-infringement of the Bentley '569 Patent as a matter of law. "Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp.*, 135 F.3d 1472, 1477 (Fed. Cir. 1998). "If any claim limitation is absent from the accused device, there is no literal infringement as a matter of law." *Bayer AG v. Elan Pharm. Rsch. Corp*., 212 F.3d 1241, 1247 (Fed. Cir. 2000). If an accused product does not infringe an independent claim, it also does not infringe any claim depending thereon. *See Wahpeton Canvas Co. v. Frontier, Inc.*, 870 F.2d 1546, 1553 (Fed. Cir. 1989). However, "[o]ne may infringe an independent claim and not infringe a claim dependent on that claim." *Monsanto Co. v. Syngenta Seeds, Inc.*, 503 F.3d 1352, 1359 (Fed. Cir. 2007) (internal quotations omitted).

When an accused infringer moves for summary judgment of non-infringement, such relief may be granted only if at least one limitation of the claim in question does not read on an element of the accused product, either literally or under the doctrine of equivalents. *See Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005); *see also TechSearch, L.L.C. v. Intel Corp.*, 286 F.3d 1360, 1369 (Fed. Cir. 2002) ("Summary judgment of noninfringement is . . . appropriate where the patent owner's proof is deficient in meeting an essential part of the legal standard for infringement, because such failure will render all other facts immaterial."). Thus, summary judgment of non-infringement can only be granted if, after viewing the facts in the light most favorable to the non-movant, there is no genuine issue as to whether the accused

product is covered by the claims (as construed by the court). *See Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1304 (Fed. Cir. 1999).

Bayer argues that it is entitled to summary judgment of non-infringement because Jivi does not meet the limitation of the "X linker" term contained in independent claim 1 of the '569 Patent. (D.I. 451 at 29). Claim 1 of the '569 Patent states, "X is a linker of 1 to ten atoms." '569 Patent 24:28. The parties disagree as to whether this X linker term is defined by its length or by the total number of atoms. (*Id.* at 29; D.I. 462 at 29). This is a claim construction dispute that the court must resolve before proceeding to Bayer's motion for summary judgment of non-infringement of the '569 Patent. *See Markman*, 52 F.3d at 977.

The '569 Patent (filed 2014, issued 2015) and the '072 Patent (filed 2006, issued 2011) share a common specification. Claim 1 of the '569 Patent, the only independent claim of the patent, recites:

> 1. A branched reactive polymer having the structure:
> Y--(X)*p*-R-(--X'-POLY)$_q$
> wherein:
> R is an aliphatic hydrocarbon having a length of at least three carbon atoms;
> each POLY is a poly(ethylene glycol) that terminates with a hydroxyl or methoxy group;
> X' is a heteroatom linkage selected from –NH--, --O--, or –S--;
> X is a linker of 1 to ten atoms;
> p is 0 or 1;
> q is 2 to about 10; and
> Y is a maleimide;
> and further wherein the branched reactive polymer has a molecular weight of about 500 Da to about 100,000 Da.

Claim 1 of the '072 Patent (which is no longer asserted) reads:

> 1. A biologically active conjugate comprising a branched polymer covalently attached to a biologically active molecule, wherein the conjugate has the structure:
> D-L$_1$-(X)*p*-R(--O-POLY)$_q$
> wherein:
> D is a biologically active molecule;

L_1 is a linkage resulting from the reaction of a functional group on the linker (X), when present, or on the aliphatic hydrocarbon having a length of at least three carbon atoms (R) of the branched polymer and a functional group of the biologically active molecule;
R is an aliphatic hydrocarbon having a length of at least three carbon atoms;
X is a linker of 1 to ten atoms in length;
p is 0 or 1; and
q is 2 to about 10,
and further wherein the branched polymer has a molecular weight of about 12,000 Da to about 100,000 Da.

The crux of Bayer's argument is that the '569 Patent does not use the words "in length" in describing X in claim 1 of the '569 Patent, in contrast to the '072 Patent, where the phrase is included. (D.I. 451 at 29). Bayer adds that, in attempting to import the phrase "in length" from the specification, Baxalta's expert improperly redefined X using a preferred embodiment. (*Id*. at 30). Baxalta argues that the common specification clearly defines X in terms of its "overall length" and that there is no support in the specification for defining X in terms of its total number of atoms. (D.I. 462 at 30).

Beginning with the claim language, in both claim 1 of the '569 Patent and claim 1 of the '072 Patent, the patentees included limitations specifying the length of a term. In claim 1 of the '569 Patent, the R term is defined as "having a length of at least three carbon atoms." '569 Patent 24:22-23. In claim 1 of the '072 Patent, both the X and R terms are defined by their length. '072 Patent 24:59-60, 63.

Turning to the specification, the patentee offers a description of the disputed X term. The specification states that "the structure of the X linkage is typically determined by the structure of the aliphatic hydrocarbon core used to form the polymers of the invention and has an overall length of from 1 to about 40 atoms, preferably 1 to about 10 atoms, and most preferably 1 to about 5 atoms." '072 Patent 10:20-24. I note the fact that this statement is not a definition, but only a disclosure about how the structure of X is "typically determined." *See Vitronics Corp.*

v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[A] patentee may choose to be his own lexicographer and use terms in a manner other than their ordinary meaning, as long as the special definition of the term is clearly stated in the patent specification or file history.").

In light of the above, I will not import the phrase "in length" into the X term of claim 1 of the '569 Patent. While it is axiomatic that one must read the claim language in light of the specification, the court will depart from the ordinary meaning of a claim term in "only two instances: lexicography and disavowal." *Hill-Rom Servs., Inc. v. Stryker Corp*., 755 F.3d 1367, 1371 (Fed. Cir. 2014). As noted above, the specification does not define the X term nor does it "demonstrate a clear intention to limit the claim scope." *Id*. at 1372. Further, reading the phrase "in length" into the X term would render the explicit limitation in claim 1 of the '072 Patent surplusage. *See 3rd Eye Surveillance, LLC v. United States*, 140 Fed. Cl. 39, 69 (Fed. Cl. 2018) ("[C]ourts should avoid claim constructions that render terms as surplusage."). At several points, the patentees clearly defined terms in the Bentley Patents in terms of length. *See* '072 Patent 24: 59-60, 63 (defining X and R); '569 Patent 24:22 (defining R). Baxalta does not explain the omission of the "in length" phrase from claim 1 of the '569 Patent, and, based on the intrinsic evidence before me, there is no basis to import it into the limitation. Thus, I agree with Bayer. (D.I. 451 at 29). I will adopt Defendant's construction (which I take to be the plain meaning to a POSA) of "X is a linker of 1 to ten atoms" as being what it says, that is, X is limited to one to ten atoms. (D.I. 451 at 29).

Accordingly, I will grant Bayer summary judgment of non-infringement of the '569 Patent. Plaintiffs do not dispute in their brief that adopting Defendant's construction would result in non-infringement as a matter of law. Indeed, Plaintiffs' expert concedes that this reading results in a finding that there are more than ten atoms present in the X linker, exceeding

the plain numerical limitation in claim 1 of the '569 Patent. (*See* D.I. 452, Ex. 5 at 169:2-4). Defendant's motion for summary judgment of literal non-infringement of the asserted claims of the '569 patent is GRANTED.

6. Infringement Under the Doctrine of Equivalents

Infringement under the doctrine of equivalents requires that "the accused product or process contain[s] elements identical or equivalent to each claimed element of the patented invention." *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 651 F.3d 1318, 1338 (Fed. Cir. 2011) (quoting *Warner-Jenkins Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)). This inquiry is guided by the function-way-result test, "which asks whether an element of an accused product 'performs substantially the same function in substantially the same way to obtain the same result.'" *Id.* On summary judgment, if "no reasonable jury could find equivalence," then summary judgment of noninfringement under this doctrine is appropriate. *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012).

Bayer moves for summary judgment of no infringement of the Bentley Patents under the doctrine of equivalents based on the theory of claim vitiation. (D.I. 451 at 31). The asserted claims of the Bentley Patents require a heteroatom linkage (X') between the POLY and R groups. '569 Patent 24:26; '453 Patent 24:28.[18] Bayer asserts that the absence of a separate oxygen heteroatom in Dr. Chyall's equivalents analysis of Jivi amounts to the vitiation of this requirement. (D.I. 451 at 31).

Plaintiffs reply that Dr. Chyall's analysis relies on the presence of an identified oxygen heteroatom in Jivi and thus factual issues remain with respect to the function-way-result test. (D.I. 462 at 31-32). The central dispute here appears to be whether the identified oxygen

[18] The parties do not address the absence of X' in claim 1 of the '833 Patent.

atom(s) are part of the R or POLY group or may properly be considered separate from both. (*See id.* at 31-32; D.I. 469 at 16). Both parties cite to deposition testimony from opposition experts allegedly confirming their view of Jivi's structure. (D.I. 451 at 31 (citing to D.I. 452, Ex. 5 at 153:3-154:19); 462 at 32 (citing to D.I. 467, Ex. 19 at 261:15-20)).

Given this is a matter of expert disagreement, I cannot find as a matter of law that the identified claim limitation is missing or that Dr. Chyall's identified equivalent is insufficient. *See Deere & Co.*, 703 F.3d at 1356-57 (stating "the vitiation test cannot be satisfied by simply noting that an element is missing from the claimed structure or process"). The material disputes of fact between the experts are properly left to the trier of fact. Defendant's motion for summary judgment is DENIED.

7. Willful Infringement

A determination of willfulness requires some finding of conduct that is "willful, wanton, malicious, bad-faith, deliberate, consciously wrongful, flagrant" or otherwise "characteristic of a pirate." *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 136 S.Ct. 1923, 1932 (2016); *see SRI Int'l, Inc. v. Cisco Systems, Inc.*, 930 F.3d 1295, 1309 (Fed. Cir. 2019) ("wanton, malicious, and bad-faith"), *cert. den.*, 140 S.Ct. 1108 (2020). A finding of "subjective willfulness," proof that the defendant acted in the face of a risk of infringement that was "either known or so obvious that it should have been known to the accused infringer," can satisfy this standard. *WesternGeco L.L.C. v. ION Geophysical Corp.*, 837 F.3d 1358, 1362 (Fed. Cir. 2016) (quoting *Halo*, 136 S.Ct. at 1930) (internal quotations omitted), *rev'd on other grounds*, 138 S.Ct. 2129 (2018).

Defendant argues it is entitled to a finding of no willful infringement of both the Bossard and Bentley patents, citing a lack of pre-suit knowledge of certain asserted patents, a good faith belief in the invalidity and its own non-infringement of the Bossard and Bentley Patents, and Dr.

Tomic's 1990s Factor VIII research. (D.I. 451 at 32-33, 35; D.I. 469 at 17). Plaintiffs point to several facts in reply, including that Bayer considered switching reagents in 2007 to avoid Nektar's patents and that Bayer launched the Jivi product at-risk after receiving the complaints in this action asserting the Bentley and Bossard Patents. (D.I. 462 at 33-34).[19]

Taking the facts in the light most favorable to the Plaintiffs, I determine that a reasonable jury could conclude that launching Jivi while on notice of the Bossard and Bentley Patents as part of this litigation constitutes a risk of infringement "either known or so obvious that it should have been known." *WesternGeco*, 837 F.3d at 1362. Further, Plaintiffs assert that Bayer did not attempt to design around the patents-in-suit despite pre-suit knowledge of, at a minimum, certain Bossard Patents. (D.I. 462 at 33). I note that the Defendants assert a total lack of pre-suit knowledge of the Bentley Patents and some of the Bossard Patents. (D.I. 469 at 16). However, even taken alone, Defendant's post-suit conduct with respect to these patents raises an issue of material fact that must be left to the jury. *See Zimmer Surgical, Inc. v. Stryker Corp.*, 365 F. Supp.3d 466, 492 (D. Del. 2019) (finding that post-suit conduct precluded summary judgment).

For the reasons stated above, Defendant's motion is DENIED.

8. Induced Infringement

In order to prove induced infringement, the patentee must demonstrate "that the alleged inducer knew of the patent in question and knew the induced acts were infringing." *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S.Ct. 1920, 1926 (2015) (citing *Global-Tech Apps., Inc. v. SEB S.A.*, 131 S.Ct. 2060, 2068-69 (2011)). Defendant moves for summary judgment of no induced

[19] Plaintiffs also improperly rely upon inadmissible evidence such as the lack of an advice of counsel defense and documents withheld pursuant to a claim of privilege. (D.I. 462 at 33-34).

infringement in a single paragraph,[20] reiterating its willful infringement arguments and asserting that its good-faith belief in non-infringement precludes induced infringement. (D.I. 451 at 35).

Plaintiffs reply that Jivi's packaging, which "instructs patients and caregivers to administer the infringing product, even referencing the 60 kDA PEG reagent conjugated to a cysteine at the A3 domain of Factor VIII" establishes Bayer's intent to infringe. (D.I. 462 at 36). Plaintiffs also reassert their willful infringement arguments with respect to Defendant's claim that it lacks the required knowledge of the patents to induce infringement. (*Id.*).

I cannot grant summary judgment of no induced infringement. Defendant's post-suit launch of Jivi establishes, at a minimum, that Defendant had knowledge of both patent families pre-launch of the potentially infringing product. (*Id.* at 34). Defendant's brief does not distinguish between pre- and post-suit induced infringement or direct the court's attention to any specific patents. I am unsure of the significance of Bayer's pre-suit knowledge with respect to only some of the patents-in-suit. Summary judgment is not appropriate. Defendant's motion is DENIED.

9. Requisite Nexus between Secondary Indicia and Claimed Inventions

Bayer moves for summary judgment on the failure of demonstrate the requisite nexus between secondary indicia of nonobviousness and the asserted claims. (D.I. 451 at 35-36). In particular, Bayer challenges the evidence that Baxalta's expert, Dr. Lynde, offers as to the commercial success of Adynovate and Jivi. (D.I. 451 at 36).

Commercial success as evidence of nonobviousness is only relevant "if there is a nexus between the claimed invention and the commercial success." *Ormco Corp. v. Align Tech., Inc*.,

[20] I believe all asserted claims are some variation of a conjugate, a composition, a unit dose, or a polymer. No method claims! I understand sales of Jivi are alleged to be directly infringing. In a case that will need to be simplified considerably before it can be tried, I am not sure why "induced infringement" is necessary or matters.

463 F.3d 1299, 1312 (Fed. Cir. 2006). It follows that "if the commercial success is due to an unclaimed feature of the device, the commercial success is irrelevant." *Id.* Additionally, the "the asserted commercial success of the product must be due to the merits of the claimed invention beyond what was readily available in the prior art." *J.T. Eaton & Co. v. Atlantic Paste & Glue Co.*, 106 F.3d 1563, 1571 (Fed. Cir. 1997) (stating that).

Bayer challenges Dr. Lynde's evidence on commercial success for (1) failing to identify any inventive features of the claims; (2) attributing the commercial success of Jivi and Adynovate to the asserted patents rather than the '520 and '921 Bayer Patents; and (3) attributing Adynovate's success to patents it does not practice. (D.I. 451 at 36-39).

Dr. Lynde's commercial success analysis centers on the extended half-life (EHL) of Jivi and Adynovate. (D.I. 467, Ex. 40 ¶ 63). Baxalta points to expert reports opining that the Bossard Patents solved the problems present in the prior art "by developing PEG-Factor VIII conjugates having 'one or very few large PEGs' that were expected to be 'longer acting and less immunogenic than current therapies.'" (D.I. 465, Ex. 3 ¶ 1233; D.I. 466, Ex. 6 ¶ 54). Bayer argues that it is an undisputed fact that "prior art discloses pegylating Factor VIII as a way of achieving EHL," and thus it cannot serve as evidence of the commercial success of the patent. (D.I. 451 at 37). Asserting that this broad concept was known in the art is insufficient to address whether the PEGylation technology contained in the asserted claims is inventive over the prior art.

Beyond this crucial issue, additional disputes remain. Baxalta's briefing challenges the asserted contribution of Bayer's '521 and '921 Patents and argues that activity retention attributable to these patents is also found in the patents-in-suit. (D.I. 462 at 39 (citing D.I. 466, Ex. 6 ¶¶ 54-55; D.I. 467, Ex. 13 ¶¶ 253-55)). Bayer credits the '520 and '921 Patents with the

EHL technology and Factor VIII activity retention that it argues are the true reason for Adynovate and Jivi's commercial success. (D.I. 451 at 37-38). However, Bayer does not cite its own economic analysis for this proposition but merely refers the court to its briefing on utility. (*Id*. at 37). Bayer maintains that its EHL mutein product (Jivi) is not taught in the asserted patents (*i=Id*. at 38), but that is a disputed material fact.

Given the breadth of the outstanding factual disputes between the parties, the issue of the nexus to the asserted claims is not amenable to summary judgment. Bayer's motion for summary judgment on this point is DENIED.

D. Conclusion

An appropriate order will issue.