IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MORPHOSYS AG, Plaintiff, v. JANSSEN BIOTECH, INC., GENMAB US, INC. and GENMAB A/S, Defendants.	C.A. No. 16-221-LPS

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MEMORANDUM OPINION

January 25, 2019
Wilmington, Delaware

UNSEALED ON
JANUARY 28, 2019

STARK, U.S District Judge:

MorphoSys, Inc. ("MorphoSys" or "Plaintiff") sued Janssen Biotech, Inc., Genmab US, Inc., and Genmab A/S (together, "Janssen" or "Defendants") for infringement of three patents on antibodies that bind to the CD38 protein. (D.I. 205) Pending before the Court are summary judgment motions filed by both sides. Janssen moves for summary judgment of (1) non-infringement of the "human" antibody claims (D.I. 384) and (2) invalidity for lack of written description, lack of enablement, and indefiniteness (D.I. 382). MorphoSys moves for summary judgment of no invalidity for lack of enablement. (D.I. 390) The Court heard argument on November 27, 2018.[1] (D.I. 461) ("Tr.")

For the reasons stated below, the Court will grant summary judgment as to non-infringement of the human antibody claims; grant-in-part and deny-in-part summary judgment of invalidity for lack of written description; deny summary judgment of invalidity for indefiniteness; and grant summary judgment of invalidity for lack of enablement.

I. BACKGROUND

MorphoSys alleges infringement of U.S. Patent Nos. 8,263,746 ("the '746 patent"), 9,200,061 ("the '061 patent"), and 9,758,590 ("the '590 patent").[2] The asserted patents describe antibodies that can be used to treat blood cancer. ('746 patent, Abstract) Specifically, in certain kinds of blood cancer, a protein called CD38 appears on the surface of cancerous cells. (*Id.* at 1:14-19) The patents describe antibodies that bind to CD38, thus causing the destruction of the

[1] The parties also argued other summary judgment motions (D.I. 391, 388), *Daubert* motions (D.I. 380, 393, 395, 396, 398), and motions to strike (D.I. 419, 435). The Court has already ruled on these motions. (Tr. 113-19; D.I. 452)

[2] The Court will cite the '746 patent, but similar passages can be found in the '061 and '590 patents.

cancerous cells. (*Id.* at 1:49-63, 2:33-42) More specifically, the antibodies disclosed by the patents are "human or humanized" – they appear human to the human immune system, and therefore they do not trigger a deleterious immune response. (*Id.* at 6:55-60) Janssen produces an antibody drug, Darzalex (chemical name "daratumumab"), that MorphoSys contends infringes the asserted patents. (D.I. 205)

II. LEGAL STANDARDS

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, "[t]he 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." The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by citing to "particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials," or by "showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact." Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then "come forward with specific facts showing that there is a genuine issue for trial." *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475

U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). The "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). "If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted." *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial"). Thus, the "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient to defeat a motion for summary judgment; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Anderson*, 477 U.S. at 252.

III. NON-INFRINGEMENT OF THE "HUMAN" ANTIBODY CLAIMS

Some of the asserted claims are directed to solely "human" antibodies (e.g., claim 1 of the '746 patent, which claims "[a]n isolated human antibody") while other asserted claims are directed to "human or humanized" antibodies (e.g., claim 14 of the '746 patent, which claims "[a]n isolated human or humanized antibody or antibody fragment thereof"). The terms "human" and "humanized" are defined in the specifications ('746 patent, 6:61-7:22), and these definitions were adopted by the Court in its claim construction order (D.I. 102):

Human	**Humanized**
one that is not chimeric (e.g., not "humanized") and not from (either in whole or in part) a nonhuman species	one that is (i) derived from a non-human source (e.g., a transgenic mouse which bears a heterologous immune system), which antibody is based on a human germline sequence; or (ii) chimeric, wherein the variable domain is derived from a non-human origin and the constant domain is derived from a human origin or (iii) CDR-grafted, wherein the CDRs of the variable domain are from a nonhuman origin, while one or more frameworks of the variable domain are of human origin and the constant domain (if any) is of human origin

Based on these constructions, in order for an antibody to be "human," it must ***not*** be any of the following: (i) chimeric, (ii) humanized, and (iii) derived even in part from a nonhuman species. In other words, if an antibody is chimeric, humanized, ***or*** derived even in part from a nonhuman species, then it is ***not human***. Additionally, if an antibody satisfies one or more of the three sets of conditions for being characterized as "humanized" then that antibody is ***not human***. This is because in order to be "human" an antibody must be "not humanized" and, as a matter of logic, the same antibody cannot be both "humanized" and "not humanized."[3]

Janssen moves for summary judgment of non-infringement of the "human" antibody claims,[4] contending that daratumumab is not a "human" antibody either (1) literally (D.I. 385 at 4-7); or (2) under the doctrine of equivalents (*id.* at 7-10).

For the reasons below, the Court concludes that no reasonable factfinder could find infringement of the "human" antibody claims either literally or under the doctrine of equivalents.

[3] The explanation in this paragraph is based on the Court's understanding of the claim constructions it adopted, which are fully supported by the intrinsic evidence. To the extent MorphoSys contends that these conclusions are based on arguments Janssen made in connection with claim construction and subsequently waived, the Court disagrees.

[4] The "'human' antibody claims" are claims 1, 6, 7, 8, 12, and 13 of the '746 patent, claim 15 of the '061 patent, and claims 1, 2, and 3 of the '590 patent. (D.I. 425 at i)

1. Literal Infringement

Janssen contends that the "human" antibody claims are not literally infringed because, under the Court's claim construction, daratumumab is "humanized" and not "human." (*Id.* at 4-7) Specifically, Janssen argues that (1) "human" and "humanized" are mutually exclusive (*id.* at 4-6); and (2) undisputed facts establish that daratumumab is humanized (*id.* at 6-7). Thus, to Janssen, non-infringement of the "human" claims can be determined as a matter of law. (*Id.*)

In its briefing, MorphoSys countered that: (1) an antibody can be both "human" and "humanized" (D.I. 425 at 4-6); and (2) even if "human" and "humanized" are mutually exclusive, a reasonable factfinder could conclude that daratumumab is "human" (*id.* at 2-4). MorphoSys contends that substantial evidence exists for finding that the accused antibodies are "human" because: (a) daratumumab is derived from human genes (albeit in mice); (b) Janssen has characterized the accused product as "human" in representations to regulators and other parties; and (c) the antibodies are not chimeric, and therefore, not "humanized" under the Court's constructions. (*Id.* at 2-4)

However, during the hearing, MorphoSys dropped its argument that an antibody can be both "human" and "humanized." Instead, MorphoSys acknowledged that "human" and "humanized" are mutually exclusive terms, though still contended that daratumumab is a "human" antibody:

> THE COURT: [Y]our view [is] that the accused compound is both human and humanized; correct?
>
> COUNSEL: That is not our position . . . under the law we have from the Court now, that is not our position.
>
> THE COURT: So what is your position?
>
> COUNSEL: ***Our position is that [daratumumab] meets every, every part of the definition of "human," and it does not meet the definition of "humanized antibody."*** Specifically, that little

> Roman numeral (i) which says "derived from a nonhuman source." It doesn't meet that because that means that the source contributed to the sequence.
>
> THE COURT: So you do agree then that ***a compound is either human or humanized*** in the context of this patent, these patents?
>
> COUNSEL: Under the claim constructions that the Court has given as they exist now, our understanding, ***yes***.
>
> THE COURT: ***So they're mutually exclusive; correct?***
>
> COUNSEL: If the claim construction is as we see it, ***yes.***
>
> THE COURT***: Under my claim construction as you understand it, "human" and "humanized" are mutually exclusive; correct?***
>
> COUNSEL: ***Yes.***

(Tr. 21-22) (emphases added)

The Court agrees with Janssen that no reasonable juror could conclude that daratumumab is a human antibody. This conclusion follows from the Court's claim construction and undisputed facts.

First, any reasonable juror would conclude that daratumumab is a humanized antibody. The relevant facts are not in dispute: MorphoSys agrees that daratumumab was made using a transgenic mouse bearing a heterologous immune system and is based on a human germline sequence. (*See* D.I. 389 Ex. 17, Davis Dep.[5] 115-16, 133; Tr. 19-20) Thus, daratumumab is a humanized antibody as defined under romanette (i) of the Court's construction of "humanized." Since daratumumab is "humanized," it is ***not "not humanized***," and, therefore, is ***not "human."***

MorphoSys contends, nonetheless, that there is sufficient evidence to find that daratumumab is not "derived from a non-human source" because the antibody is derived entirely

[5] Dr. C. Geoffrey Davis is one of MorphoSys' technical experts.

from human genes. (D.I. 425 at 3) But MorphoSys' argument is premised on a flawed interpretation of "derived from a non-human source." MorphoSys' interpretation excludes the specification's sole example of an antibody "derived from a non-human source": "a transgenic mouse which bears a heterologous immune system." (*See* '746 patent, 6:61-7:22) Thus, MorphoSys' argument fails as a matter of law. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996).

The conclusion that daratumumab is not a human antibody follows from the Court's conclusion that daratumumab is a humanized antibody and MorphoSys' admission that "human" and "humanized" are mutually exclusive. Even without MorphoSys' admission, the Court concludes that an antibody produced using a transgenic mouse is a humanized antibody because it is, as any reasonable factfinder would conclude, "from (either in whole or in part) a nonhuman species." Further, it is not a human antibody because it is ***not*** "not from . . . a nonhuman species."

MorphoSys notes that Janssen has characterized daratumumab as "human" to regulators. (D.I. 425 at 1) In those contexts, however, Janssen was not using the term "human" as it appears in the patents or, crucially, as construed by the Court. At best, Janssen's usage of "human" might be considered extrinsic evidence as to the ordinary meaning of the claim term, but such extrinsic evidence may not be used to modify the meaning clearly directed by the intrinsic evidence. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005).

2. Doctrine of Equivalents

MorphoSys contends that even if the "human" antibody claims are not literally infringed, they are infringed under the doctrine of equivalents. (D.I. 425 at 6-10) Janssen argues that the doctrine of equivalents does not apply for three reasons: (1) the disclosure-dedication rule; (2) the specific exclusion principle; and (3) prosecution history estoppel. (D.I. 385 at 7-10)

The Court finds that both disclosure-dedication and specific exclusion apply and will not reach the issue of prosecution history estoppel.

a. Disclosure-Dedication

Under the "disclosure-dedication" rule, the doctrine of equivalents is unavailable for subject matter disclosed in a patent but not included in the claims at issue. *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054-55 (Fed. Cir. 2002) (en banc). "[T]he relevant test is whether one of ordinary skill in the art reading the patent could identify a specific, unclaimed alternative and understand that it could be used as a substitute for the claimed matter." *Cent. Inst. for Experimental Animals v. Jackson Lab.*, 726 F. Supp. 2d 1045, 1048 (N.D. Cal. 2010); *see also Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1334 (Fed. Cir. 2004). Disclosure-dedication is a question of law. *See Toro*, 383 at 1331.

In the view of Janssen, the patents note that humanized antibodies could be made from transgenic mice but do not claim (in the relevant claims) such antibodies. (D.I. 385 at 7-8) MorphoSys counters that the disclosure-dedication rule does not apply because the patents do not describe "humanized" antibodies as an alternative to "human" antibodies. (D.I. 425 at 9-10)

The Court concludes that the disclosure-dedication doctrine applies here. A person of ordinary skill reading the patent would identify humanized antibodies as an alternative to human antibodies. *See, e.g.*, '746 patent, 6:57-60 ("The antibodies of the invention . . . may be human or humanized"); *id.* 6:61-7:22 (defining "human" antibody as "not humanized," and defining "humanized" antibody as having "non-human" source or origin); *id.*, cl. 1 (claiming "human or humanized" antibodies). Therefore, having claimed only human antibodies in some claims, MorphoSys cannot now argue that those claims should also cover humanized antibodies under the doctrine of equivalents.

b. Specific Exclusion

Under the "specific exclusion" principle, the doctrine of equivalents cannot broaden a claim to cover a feature that is "the opposite of, or inconsistent with, the recited limitation." *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014). Whether a purported equivalent is specifically excluded is a question of law. *See Lockheed Martin Corp. v. Space Sys./Loral, Inc.*, 324 F.3d 1308, 1318 (Fed. Cir. 2003).

Janssen contends that daratumumab is specifically excluded because it is a humanized antibody, which is the "opposite[]" of a human antibody. (D.I. 385 at 8-9) In its briefing, MorphoSys contended that specific exclusion does not apply because "human" and "humanized" are not mutually exclusive. (D.I. 425 at 10) However, as noted above, MorphoSys admitted during oral argument that "human" and "humanized" are mutually exclusive terms, as construed by the Court. (Tr. 21-22)

The Court concludes that humanized antibodies are specifically excluded from the claims directed solely to human antibodies. This conclusion follows logically from MorphoSys' admission; given that a human antibody cannot also be a humanized antibody (and vice versa), the terms are "inconsistent with each other." *Augme*, 755 F.3d at 1335. Moreover, a holding that humanized antibodies were equivalent to human antibodies would render the claim term "human or humanized" redundant. *Cf. Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("It is important to ensure that the application of the doctrine [of equivalents], even as to an individual element, is not allowed such broad play as to effectively eliminate that element in its entirety."). Therefore, daratumumab is specifically excluded from the "human" antibody claims.

IV. INVALIDITY

Janssen moves for summary judgment of invalidity of all asserted claims for failure to comply with the written description and enablement requirements of 35 U.S.C. § 112. (D.I. 382). Janssen also moves for summary judgment of invalidity of the Binding Claims[6] due to indefiniteness. (*Id.*) MorphoSys moves for summary judgment of no invalidity for lack of enablement on the 192-206 Claims.[7] (D.I. 390)

Section 112[8] provides, in pertinent part, that:

> The specification shall contain a written description of the invention and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

Section 112 sets out separate requirements for written description and enablement. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1344 (Fed. Cir. 2010) (holding that written description and enablement requirements are separate). Still, these requirements "often rise and fall together." *Id.* at 1352.

For the reasons below, the Court will grant-in-part and deny-in-part Janssen's motion and will deny MorphoSys' motion.

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[6] The Binding Claims are claims 14, 15, 18, 27, and 28 of the '746 patent; claims 1, 5, 6, 11, 12, and 15 of the '061 patent; and claims 1, 2, and 3 of the '590 patent. (D.I. 383 at v)

[7] The "192-206 Claims" are claim 18 of the '746 patent; claims 1, 5, 6, 11, 12, and 15 of the '061 patent; and claims 1-3 of the '590 patent.

[8] The statute was amended in September 2011 by the America Invents Act ("AIA"). *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 300-01 (2011). The pre-AIA version of § 112 applies in this case. The post-AIA version of this portion of the statute is identical to the pre-AIA version.

A. Written Description

1. Applicable Standard

Whether a specification satisfies the written description requirement is a question of fact. *See GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014). To comply with the written description requirement, a patent's specification "must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad*, 598 F.3d at 1351 (internal alterations and quotation marks omitted). To meet this standard, the specification must convey that the patentee "had possession of the claimed subject matter as of the filing date." *Id.* at 1350. To show possession of a genus, a patentee must disclose (1) "a representative number of species falling within the scope of the genus" or (2) "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." *Id.*

"[A]n adequate written description requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). "[F]unctional claim language can meet the written description requirement when the art has established a correlation between structure and function." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002). The adequacy of the disclosure is evaluated in view of "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Ariad*, 598 F.3d at 1351.

2. Analysis

Janssen contends that the claims lack sufficient written description because the patents fail to disclose (1) any species of the Binding Claims (D.I. 383 at 13-17), (2) sufficiently

representative species for any claimed genus (*id.* at 19-24), and (3) common structural features sufficient to visualize or recognize the claimed genera (*id.* at 24-26).

For the reasons below, the Court concludes that a reasonable factfinder could find that: (1) a species was disclosed for the Binding Claims; and (2) representative species were disclosed for all asserted claims. The Court also concludes that any reasonable factfinder would find that the patents fail to disclose structural features common to the members of the genus in a manner sufficient to meet the written description requirement.

a. Binding Claims

Janssen first argues that the patents lack written description for the Binding Claims, which are claims on antibodies that bind to certain parts of the CD38 protein. (D.I. 383 at 12-17) Specifically, Janssen contends that the patents fail to show actual possession of ***any*** species of the Binding Claims. (*Id.* at 13-14) To Janssen, the specification identifies only binding sites using peptide mapping experiments, and a person of ordinary skill in the art ("POSA") would know that peptide mapping experiments do not reliably identify binding sites. (*Id.* at 14-16) Janssen further contends that the binding sites identified in Figure 7 of the patents for one particular antibody (MOR03080) are demonstrably false; Janssen conducted an x-ray crystallography experiment that, according to Janssen, proves that MOR03080 does not actually bind to CD38 at the locations identified in Figure 7. (*Id.* at 16-17) Janssen also cites results obtained by MorphoSys in another peptide mapping study ("the Replitope Report") that showed different binding locations for MOR03080, and contends that the Replitope Report further illustrates the unreliability of the binding data disclosed in the patent. (*Id.* at 7-8) In view of all this evidence, Janssen asserts that no reasonable factfinder could find the specification conveys that MorphoSys was in actual possession of ***any*** antibodies that bind to the regions of CD38 claimed in the patents. (*Id.* at 13)

MorphoSys counters that even though peptide mapping results "do not necessarily perfectly correspond" to the binding location in a patient, peptide mapping is a "valid tool" that, at the time of the patent, was "widely used" to predict binding. (D.I. 424 at 17-18) MorphoSys notes that Defendants have also used peptide arrays to characterize binding and have presented these results to the PTO and the FDA. (*Id.* at 17-18) MorphoSys contends that Janssen's x-ray experiment is not relevant to the written description inquiry because it occurred after the priority date of the patents, and, in any event, that the x-ray crystallography data does not disprove the results disclosed in Figure 7. (*Id.* at 16-17)

Having considered the parties' arguments and evidence, the Court concludes that there are genuine disputes of material fact that preclude summary judgment of lack of written description for the Binding Claims. A reasonable factfinder could find that peptide mapping was recognized as sufficiently reliable to demonstrate possession to a POSA. (*See e.g.*, D.I. 387 Ex. 12, Messing[9] Reb. ¶¶ 77, 387, 386, 388, 456-460; D.I. 387 Ex. 11, Hubbard[10] Reb. ¶¶ 51-54) Janssen is correct that post-priority-date evidence can be considered where, as here, it is used to evaluate whether the disclosed species sufficiently represent the claimed genera. *See Amgen, Inc v. Sanofi*, 872 F.3d 1367, 1379 (Fed. Cir. 2017). Even so, based on the record evidence, a reasonable factfinder – taking the evidence in the light most favorable to MorphoSys – could find that Figure 7 of the patents conveys possession, notwithstanding the x-ray crystallography data and the Replitope Report. (*See e.g.*, D.I. 389 Ex. 15A, Robinson[11] Op. ¶ 43; D.I. 426 Ex.

[9] Dr. Joachim Messing is one of MorphoSys' technical experts.

[10] Dr. Stevan R. Hubbard is one of MorphoSys' technical experts.

[11] Dr. William H. Robinson is one of Janssen's technical experts.

59, Ravetch[12] Dep. 296; D.I. 387 Ex. 12, Messing Reb. ¶ 454; D.I. 426 Ex. 54, Eck Dep. 78-79, 80, 85, 107, 113-14, 177; D.I. 426 Ex. 58, Féthière[13] Dep. 46-47, 85-86; D.I. 387 Ex. 12, Messing Reb. ¶ 95)

Therefore, the Court will deny this portion of Janssen's summary judgment motion.

b. Representative species

Janssen next argues that the patents do not provide "a representative number of species" for ***any*** of the claimed genera. (D.I. 383 at 19-24); s*ee also Ariad*, 598 F.3d at 1350. To Janssen, this conclusion follows from the following facts that Janssen contends are not in genuine dispute: (1) the claims cover a very large number of actual and potential antibodies (D.I. 383 at 18-19); (2) the four disclosed antibodies differ dramatically from one another and from the other antibodies that fall within the scope of the claims (D.I. 383 at 20-21; D.I. 444 at 6-7); (3) the potential variants of the four disclosed antibodies are not representative of the full claim scope (D.I. 383 at 21-22; D.I. 444 at 5-6); and (4) daratumumab binds to completely different parts of CD38 than the disclosed antibodies and could never have been made using the phage display method described in the patent (D.I. 383 at 22-23; D.I. 444 at 6). Janssen also contends that Dr. Messing's testimony that the four disclosed antibodies are representative is flawed because he applied the wrong standard. (D.I. 383 at 23-24)

MorphoSys counters that there is a genuine issue as to the representativeness of the disclosed species because: (1) genuine disputes of fact exist regarding the size of the claimed genera (D.I. 424 at 18-22); (2) daratumumab and MOR03079 have substantial structural similarity, including 90% sequence similarity (D.I. 424 at 13); (3) daratumumab could have been

[12] Dr. Jeffrey V. Ravetch is one of Janssen's technical experts.

[13] Dr. James Féthière is one of Janssen's technical experts.

made by a POSA employing the teachings of the patents (D.I. 424 at 13); and (4) besides daratumumab, Janssen has not actually identified any antibodies that are effective but are not variants of the disclosed antibodies and yet fall within the scope of the claims (D.I. 424 at 13-14).

The Court concludes that there are genuine issues of material fact that preclude summary judgment here. For example, a reasonable factfinder could find that the four disclosed antibodies are representative of all known members of the claimed genera, including daratumumab. (*See, e.g.*, D.I. 386 Ex. 4C, Bradbury[14] Rep. ¶ 175; D.I. 387 Ex. 12, Messing Reb. ¶ 277; D.I. 426 Ex. 56, Bradbury Dep. 274)

Therefore, the Court will deny this portion of Janssen's summary judgment motion.

c. Common structural features

Janssen also contends that the patents fail to disclose any structural elements that would "inform one of skill how to identify antibodies possessing the claimed properties." (D.I. 383 at 24).

The Court agrees. As Janssen points out, the claims "cover any and all CD38 antibodies that satisfy broad functional tests, yet the specification does not teach the necessary correlation between those claimed ***functional*** properties (i.e., binding within specific locations or different cell-killing activities) and the ***structural characteristics*** (e.g., the amino acid sequence) of antibodies having those properties." (*Id.* at 17) Indeed, multiple MorphoSys witnesses admit that an antibody's sequence cannot be used to predict its binding properties. (*See, e.g.*, D.I. 392 Ex. 20, Messing Dep. 210-12 (stating that "you couldn't say in terms of the primary sequence

[14] Dr. Bradbury is one of Janssen's technical experts.

anything about the properties of the protein"); D.I. 387 Ex. 12, Messing Reb. ¶ 282 (stating that "sequence similarity . . . does not tell you about binding properties of antibodies"); D.I. 392 Ex. 21, Landes[15] Dep. 79-80 (stating that "[t]he primary sequence can't tell you where it's going to bind")) In fact, it is undisputed that even small changes to an antibody's sequence, particularly in the antibody's complementarity determining regions, can have dramatic and unpredictable effects on function. (*See* D.I. 392 Ex. 22, Lund[16] Dep. 183-84 (stating that "a single point mutation . . . maybe . . . would change the binding of the antibody . . . to its target"); D.I. 392 Ex. 20, Messing Dep. 163-64 (agreeing that "you can't necessarily predict what the result of the change [to an antibody's sequence] is, but you can screen for it") MorphoSys' expert, Dr. Messing, when asked in deposition if he would know whether a change made to an antibody's sequence would "make the antibody better, worse or the same," answered: "No. . . . [T]hat's why you have to do the validation, the experiment." (D.I. 392 Ex. 20, Messing Dep. 164)

Given the undisputed lack of a known relationship between an antibody's structure (its sequence) and its function (its binding properties), the only reasonable conclusion is that the specification does not sufficiently disclose structural features common to the members of the genus. *See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1301 (Fed. Cir. 2014).

MorphoSys contends that a POSA could visualize the claimed genera because the claims recite structural limitations. (*See* D.I. 424 at 14-15) In particular, MorphoSys cites certain claims' limitations to "human or humanized" antibodies, limitations to "IgG" or "IgG1" antibodies, and limitations to antibodies with "VH3 heavy chain" and a "kappa light chain."

[15] Dr. Gregory Landes is one of MorphoSys' technical experts.

[16] Dr. Frances Lund is one of MorphoSys' technical experts.

(*Id.*) As Janssen points out, it is undisputed that the structural features are present in many antibodies that do not bind to CD38, and some of the disclosed anti-CD38 antibodies do not possess these limitations. (D.I. 383 at 24-25) (citing D.I. 386 Ex. 4A, Bradbury Op. ¶¶ 256, 475-76) Thus, the asserted claims' structural limitations do not provide structure sufficient to satisfy the written description requirement.

MorphoSys also contends that the "unique structural motif" identified by Dr. Messing provides substantial evidence of common structural features. (D.I. 424 at 14-15) Dr. Messing obtained the motif ("the pentapeptide motif") by looking at a disclosed embodiment, MOR03079, and daratumumab, and identifying what MorphoSys contends are common structural features between the parts of the two antibodies that bind to the 192-206 region of the CD38 protein. (*Id.*) However, the pentapeptide motif is not properly considered because it relies on knowledge that a POSA did not have at the priority date of the patents – namely, daratumumab's amino acid sequence and the knowledge that daratumumab binds to CD38. *See Ariad*, 598 F.3d at 1351 ("[A] written description analysis occurs 'as of the filing date sought.'"). MorphoSys admits that the motif is post-priority-date evidence, but likens it to evidence allowed in *Amgen*, 872 F.3d at 1379. (D.I. 424 at 15-16) MorphoSys' analogy is unpersuasive. In *Amgen*, the post-priority-date evidence – including the existence of the accused compound – was held admissible because it was relevant to the number and nature of species that actually exist within the claimed genus. *See* 872 F.3d at 1373. The pentapeptide motif, on the other hand, "is evidence illuminating the state of the art subsequent to the priority date" and, therefore, "is not relevant" to the written description inquiry. *Id.*

For these reasons, the Court will grant summary judgment with respect to the "structural features" prong of the written description issue.

B. Enablement

1. Applicable Law

"Enablement is a question of law based on underlying factual findings." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380 (Fed. Cir. 2012). "Enablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed invention." *Id.* at 1380-81.

"To be enabling, the specification of a patent must teach those skilled in the art how to make and use the ***full scope*** of the claimed invention without undue experimentation." *Id.* at 1380 (internal quotation marks omitted; emphasis added). "Thus, a patentee chooses broad claim language at the peril of losing any claim that cannot be enabled across its full scope of coverage." *Id.* at 1381. "The scope of the claims must be less than or equal to the scope of the enablement to ensure that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims." *Id.* (internal quotation marks omitted).

"Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Although "a specification need not disclose what is well known in the art," "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997). In addition, a patent "cannot simply rely on the knowledge of a person of ordinary skill to serve as a substitute for the missing information in the specification." *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 941 (Fed. Cir. 2010).

2. The requirement to enable the "full scope" of the claims

Each party contends that the other misstates the law for enablement, particularly regarding the requirement to teach the "full scope" of the invention. (D.I. 399 at 30; D.I. 418 at 4-15; D.I. 442 at 17-19) Given the parties' dispute, the Court will describe its understanding of the "full scope" requirement in further detail.

The "full scope" requirement does not require the specification to "provide a detailed recipe for preparing every conceivable permutation" of a claimed embodiment. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 967 (Fed. Cir. 2014). Nor need a specification disclose which specific compounds are covered by a claim and which are not. *See Application of Angstadt*, 537 F.2d 498, 502 (C.C.P.A. 1976).

However, it is not always sufficient if a specification merely enables a POSA to practice an embodiment of the claimed invention. To the contrary, the Federal Circuit has repeatedly found claims not enabled despite a specification's disclosure of operative embodiments. *See, e.g., Wyeth & Cordis Corp. v. Abbott Labs.*, 720 F.3d 1380, 1384 (Fed. Cir. 2013); *MagSil Corp. v. Hitachi Global Storage Techs., Inc.*, 687 F.3d 1377, 1382-83 (Fed. Cir. 2012); *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 999-1000 (Fed. Cir. 2008). For example, in *Sitrick*, 516 F.3d at 999-1001, claims directed to integrating audio into a pre-existing video game or movie were not enabled, even though the specification enabled the technique for video games, because the specification did not enable the technique for movies. In *MagSil*, 687 F.3d at 1379-84, claims to a semiconductor device that could change in resistance by "at least 10%" were not enabled, even though the specification enabled a device that changed resistance by 11.8%, because the specification did not enable devices that changed resistance by 100% or 1000% percent. In *Wyeth*, 720 F.3d at 1382, the patent claimed methods of treating an arterial disease using any rapamycin compound with specified structural and functional properties and disclosed a

rapamycin compound, sirolimus, that has the specified properties. The Court held that the claims were not enabled because the specification did not enable the making of any claimed rapamycin compound other than sirolimus. *See id.* at 1382-86.

The pattern the Court discerns from these cases is this: the full scope of a claim is not enabled when there is an embodiment within the claim's scope that a person of ordinary skill, reading the specification, would be unable to practice without undue experimentation.

3. Pertinent facts that are either undisputed or, based on the record, can only reasonably be resolved in Janssen's favor

a. The number of unique human antibodies that bind to CD38 is very large

Any reasonable factfinder would have to find that very many unique anti-CD38 antibodies exist. Dr. Bradbury "very conservative[ly]" estimates that there are 10^{19} (ten quintillion) anti-CD38 antibodies. (D.I. 386 Ex. 4A, Bradbury Op. ¶¶ 184-250) Although MorphoSys disputes Dr. Bradbury's methodology and this particular number (D.I. 424 at 18-22; D.I. 424 at 33-38; D.I. 442 at 20), MorphoSys does not genuinely dispute that the accurate number is very large. (*See, e.g.*, D.I. 392 Ex. 20, Messing Dep. at 126-27 (Dr. Messing agreeing there are "millions" or "billions" of variations of disclosed antibodies); *id.* 134 ("[T]here are so many . . . you couldn't write them out . . . one neither can [write] them out or make them")) MorphoSys' expert, Dr. Messing, when asked in deposition "how many antibodies are thought to bind to a single antigen," responded: "that number's, of course, very large." (D.I. 392 Ex. 20, Messing Dep. at 244-45)

b. A very large number of human anti-CD38 antibodies also meet each asserted claim's other limitations

Each of the asserted claims limits the recited human anti-CD38 antibodies in multiple ways. For example, certain claims limit the antibodies to (1) being IgG or IgG1 antibodies;[17] (2) having a specified antibody dependent cellular cytotoxicity (ADCC) or cell dependent cytotoxicity (CDC) effectiveness;[18] (3) binding to specific epitopes;[19] (4) being used in treatment;[20] and (5) having specific structural characteristics.[21]

According to Dr. Bradbury's estimates, which he characterizes as "very conservative," the most limiting claim (claim 3 of the '590 patent) would cover 0.5% of all human anti-CD38 antibodies. (D.I. 386 Ex. 4A, Bradbury Op. ¶ 300) In his estimation, every other claim would cover an even greater percentage of all human anti-CD38 antibodies. (*Id.* ¶ 301)

MorphoSys does not appear to dispute Dr. Bradbury's estimates of the percentage of human anti-CD38 antibodies that would meet the claims' various other limitations. Indeed, many of Dr. Bradbury's estimates are based on testimony by MorphoSys' experts. (*See, e.g.*, *id.* ¶ 258 (relying on Dr. Ravetch's testimony); *id.* ¶ 268 (relying on Dr. Eck's testimony))

It follows that any reasonable factfinder would have to find that each claim covers a very large number of antibodies.

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[17] Claims 6, 7, 12, and 13 of the '746 patent; claim 1 of the '590 patent.

[18] Claims 1, 6, and 7 of the '746 patent, and claims 8, 12, and 13 of the '746 patent, respectively.

[19] Claims 14, 15, 18, 27, and 28 of the '746 patent; claims 1, 5, 6, 11, 12, and 15 of the '061 patent; and claims 1, 2, and 3 of the '590 patent.

[20] Claims 1, 5, 6, 11, 12, and 15 of the '061 patent.

[21] Claims 1, 2, and 3 of the '590 patent.

c. "Non-conservative" variants of known antibodies would have to be screened to determine their effectiveness

It is undisputed that there are two ways of making new antibodies that come within the scope of the claims: (1) *de novo*, through methods like phage display (which were used to discover the antibodies expressly disclosed in the patents) and transgenic mice (which were used to discover daratumumab); or (2) by making variants of known effective antibodies. ('746 patent, 10:44-15:51; D.I. 387 Ex. 12, Messing Reb. ¶¶ 212-27, 360) It is also undisputed that variants of an antibody can be made by substituting amino acids in either the framework regions of the antibody or in the CDRs of the antibody. ('746 patent, 10:65-12:2, 15:3-8; D.I. 387 Ex. 12, Messing Reb. ¶¶ 212-27)

It is further undisputed that "conservative" variants of antibodies that are known to be effective would be "reasonably expected" to be effective. (D.I. 386 Ex. 4C, Bradbury Rep. ¶ 110; D.I. 426 Ex. 56, Bradbury Dep. 202:7-16) Here, "conservative" refers to "conservative point substitutions," a process by which one makes substitutions only within the framework regions of an antibody. (D.I. 387 Ex. 12, Messing Reb. ¶¶ 212, 320) Based on the record, a reasonable factfinder would have to find that such "conservative point substitutions" would have a "small impact" on the antibody's functional properties, including whether it binds to CD38. (D.I. 387 Ex. 12, Messing Reb. ¶¶ 212, 320)

However, it is further undisputed that an antibody made via ***non-conservative*** changes, especially by changes to the antibody's complementarity-determining regions (CDRs), would have to be screened in order to determine its effectiveness. (*See, e.g.*, '746 patent, 15:3-17 (discussing making "variants . . . by diversifying one or more amino acid residues . . . preferably . . . in one or more CDRs, and by screening the resulting collection of antibody variants for variants with improved properties"); D.I. 386 Ex. 4C, Bradbury Rep. ¶ 38; D.I. 392 Ex. 20,

Messing Dep. 162-63 (stating it "makes sense" that "changes to the CDR region would be more likely to affect the activity of the antibody"); *id*. 163-64 (agreeing "you can't necessarily predict what the result of [changing a CDR] is, but you can screen for it"); *id.* 244-45; *see also id.* 100 (noting that when making changes to antibodies, "[y]ou would have to search out which change is good, and there could also be some that are not good"))

Thus, any reasonable factfinder would have to find that new antibodies within the claims can be discovered by varying known antibodies, and when this is done by non-conservative point substitutions, the resulting non-conservative variant would need to be screened to determine its effectiveness.

d. Daratumumab is not a conservative variant of any antibody disclosed in the patents

There is no genuine dispute that daratumumab is not a conservative variant of any disclosed antibody. This conclusion follows logically from the following undisputed facts. As discussed above, it is undisputed that an antibody's binding properties are substantially dependent on its CDR, and that changes to a CDR affect an antibody's binding properties in an unpredictable manner. Thus, substantially changing the CDR of an antibody is not a conservative variation. It is also undisputed that daratumumab's CDR is only 35% similar to that of MOR03079, the most similar disclosed antibody. (D.I. 386, Ex. 4D, Bradbury Corr. ¶ 319) Hence, the only reasonable conclusion is that daratumumab is not a conservative variant of MOR03079.

e. Obtaining antibodies within the claims that are not conservative variants of disclosed antibodies would require substantial time and effort by a POSA

While not undisputed, any reasonable factfinder would conclude that a POSA would require substantial time and effort to discover antibodies within the claims that are not

conservative variants of the disclosed antibodies. As discussed above, a POSA could obtain such an antibody either by: (1) designing a variant of a known antibody; or (2) by isolating an antibody using a *de novo* technique. In either case, as Janssen points out, "each [antibody] would need to be designed or isolated, synthesized, and then screened for cell-killing activity, binding to various regions of CD38, and/or treatment of cancer, and sequenced to determine whether it met the framework limitations of the '590 patent." (D.I. 383 at 29)

Based on the record evidence, the only reasonable conclusion is that these steps would take a substantial amount of time and effort. For example, three of MorphoSys' experts characterized screening techniques as "extremely laborious [and] involving trial-and-error experimentation," and exhibiting "a lot of variability," "tak[ing] a while to get them up and running," such as "a period of months" or "longer." (D.I. 387 Ex. 11, Hubbard Reb. ¶ 26 (describing x-ray crystallography); Landes Dep. at 192-93 (describing cell-killing assays); D.I. 392 Ex. 20, Messing Dep. 260 (describing cell-killing assays))

MorphoSys' own experience developing the disclosed antibodies supports this conclusion. It took MorphoSys four years between starting its CD38 program and filing its first provisional patent application. (D.I. 387 Ex. 12, Messing Reb. ¶ 363) Several months of that time were needed to isolate, purify, and characterize the four disclosed antibodies (D.I. 392 Ex. 28, Dep. Ex. 1006 at 30) That MorphoSys attempted to develop MOR202 continuously for 15 years and still failed to obtain clinical approval further demonstrates the difficulty of antibody development. (D.I. 392 Ex. 24, Urban Tr. at 384-86) While there may well be genuine disputes as to the precise degree of difficulty, and the specific amount of time and effort required by a POSA to obtain a non-conservative but claimed variant, any reasonable factfinder would have to find that the time and effort involved would be substantial.

4. Application of the *Wands* factors

In view of the factual conclusions above, any reasonable factfinder would find that practicing the claims' full scope would require experimentation. To determine whether that amount of experimentation is "undue," the Court will evaluate the *Wands* factors. *See Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014). The *Wands* factors are: "(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." 858 F.3d at 737.

Applying the *Wands* factors, the Court concludes, as a matter of law, that undue experimentation would be needed to practice the full scope of the claimed invention. First, with respect to "the quantity of experimentation necessary," the Court finds that obtaining antibodies within the claims (other than conservative variants of disclosed antibodies) would require substantial time and effort by a POSA. Turning to "the amount of direction or guidance presented" and "the presence or absence of working examples," the specifications are largely unhelpful. Although the patents provide four working examples, they do not teach a POSA how to predict from an antibody's sequence whether it will bind to CD38. Nor do the patents improve a POSA's ability to discover any of the countless antibodies within the scope of the claims that are not a conservative variant of a disclosed antibody. Rather, a POSA attempting to obtain a claimed antibody that is not a variant of a known antibody would have to do essentially the same amount of work as the inventors of the patents-in-suit; like the inventors, a POSA would have to discover these antibodies *de novo* through phage display or another technique. (*Compare* '746 patent, 22:26-28 (noting that disclosed embodiments were generated using phage

display) *with* D.I. 387 Ex. 12, Messing Reb. ¶ 352 (stating that POSA could use phage display or other techniques to generate further CD38 antibodies))

The specifications' deficiencies are particularly acute in view of the next four factors: "the nature of the invention," "the state of the prior art," "the relative skill of those in the art," and "the predictability or unpredictability of the art." A POSA would know that conservative variants of the disclosed antibodies could be designed and would be "reasonably expected" to be effective even without screening. However, not all antibodies covered by the claims are conservative variants of disclosed antibodies. That is, the claims also encompass non-conservative variants. A POSA would not be able to predict the function of these antibodies from their sequences. Rather, a POSA could only discover claimed embodiments that are non-conservative variants either (1) though trial and error, by making random, non-conservative changes to the disclosed antibodies and then screening those antibodies for desired binding properties, or (2) by discovering the antibodies *de novo* using, for example, phage display or transgenic mice. Each of these techniques would take a POSA substantial time and effort.

Turning to the final factor, the Court finds that "the breadth of the claims" here is vast. There are a very large number of anti-CD38 antibodies, and a very large number of them meet the claims' other limitations. Where, as here, the claims recite functional limitations that cover countless embodiments in an unpredictable field, the specification must do more than place a POSA at "a starting point . . . for further research" and instruct them to "engage in an iterative, trial-and-error process." *ALZA Corp. v. Andrx Pharmaceuticals, LLC,* 603 F.3d 935, 941 (Fed. Cir. 2010). Yet, with respect to the claimed non-conservative variants, that is essentially what the patents here do.

MorphoSys contends that any experimentation required to practice the invention would be "routine." (*See, e.g.*, D.I. 424 at 27-28; D.I. 399 at 28-33; D.I. 442 at 13-15) In particular, MorphoSys contends that a POSA could "readily" generate a number of antibodies, including MOR03079 and related antibodies, which a POSA could "reasonably expect" to come within the claims. (D.I. 399 at 29; D.I. 424 at 27; D.I. 442 at 13) To MorphoSys, the specification "supplement[s] the knowledge of a POSA that amino acid substitutions between sequences are often tolerated without giving rise to substantial differences in behavior." (D.I. 424 at 27) (internal quotation marks omitted) But this contention – even accepted as true at this stage – does not get to the relevant question: whether the ***full scope*** of the claims, which is quite broad, is enabled. While certain conservative amino acid substitutions would create new antibodies while preserving a known antibody's properties, many claimed antibodies could not be discovered by making conservative substitutions.

For all of these reasons, application of the *Wands* factors leads the Court to conclude that the claims are not enabled.

5. Comparison to *Wyeth, Enzo,* and *Idenix*

Janssen analogizes the instant case to those confronted by the Federal Circuit in *Wyeth* and by this Court in *Enzo* and *Idenix* (the cases collectively referred to as "*WEI*"). *See Wyeth*, 720 F.3d at 1380; *Enzo Life Scis., Inc. v. Gen-Probe Inc.*, 2017 WL 2829625 (D. Del. June 28, 2017); *Idenix Pharm. LLC v. Gilead Scis., Inc.*, 2018 WL 922125 (D. Del. Feb. 16, 2018). The Court agrees with Janssen that these three cases further support the Court's conclusion here of non-enablement.

As in *WEI*, the claims here are directed to a composition of matter genus that is claimed partially by the composition's structure and partially by its function. *Compare* '590 patent, cl. 1 (claiming antibody with recited structural features and binding properties) *with Wyeth*, 720 F.3d

at 1382-83 (claiming treatment of restenosis using effective amount of rapamycin compound); *Enzo*, 2017 WL 2829625, at *1-4 (claiming oligo or polynucleotide with recited structural features that hybridizes to nucleic acid sequence of interest and is detectable after hybridization); *and Idenix*, 2018 WL 922125, at *10 (claiming treatment of hepatitis C using nucleoside with recited structural properties).

Similarly to *WEI*, the specification here allows a POSA to readily make and use some species. *Compare* '746 patent, Fig. 7, 15:17-27 (disclosing four antibodies and describing process of making conservative variants) *and* D.I. 386 Ex. 4C, Bradbury Rep. ¶ 159 ("I do not dispute that the specification enables one of skill in the art to make the four antibodies actually disclosed in sequence terms therein . . . .") *with Wyeth*, 720 F.3d at 1381 (disclosing sirolimus, a working embodiment); *Enzo*, 2017 WL 2829625, at *5-6 (disclosing "Example V"); *and Idenix*, 2018 WL 922125, at *11 (disclosing working example nucleosides).

However, also as in *WEI*, the compositions disclosed in the patents are only a small subset of those that satisfy the claims' structural limitations. (*Compare supra* IV.B.3.d, *with Wyeth*, 720 F.3d at 1384 (finding that "tens of thousands" of compounds met structural limitations of claims); *Enzo*, 2017 WL 2829625, at *6 (finding there were "a vast number" of possible variants to claimed invention); *and Idenix*, 2018 WL 922125, at *12 (finding that structural limitations were satisfied by "billions" of compounds).

Like in *WEI*, the invention here is in an unpredictable field; a POSA could not determine a new composition's functional properties solely from its structure. (*Compare supra* IV.B.3.d *with Wyeth*, 720 F.3d at 1385 (finding that "even minor alterations" to disclosed species could impact its efficacy); *Enzo*, 2017 WL 2829625, at *6 ("[T]he relevant field [here] is even more unpredictable than in *Wyeth.*"); *and Idenix*, 2018 WL 922125, at *19 (finding that "the activity of

a modified nucleoside, and especially its effectiveness in treatment of HCV, is unpredictable – even for compounds satisfying the Structural Limitations").

And, importantly, as in *WEI*, a POSA would need to engage in time-consuming, non-routine trial-and-error testing in order to obtain claimed-but-not-disclosed compositions. (*Compare supra* IV.B.3.e *with Wyeth*, 720 F.3d at 1385 (stating that POSA would need to engage in "laborious iterative process" to determine what candidates fall within claimed genus); *Enzo*, 2017 WL 2829625, at *6 (stating that POSA "would have no choice but to make and test a vast number of possible variants to the claimed invention"); *and Idenix*, 2018 WL 922125, at *19 (finding that screening compounds that met structural limitations to determine if they also met functional limitations would take "substantial time and effort"). For all of these reasons, here, as in *WEI*, the full scope of the claims is not enabled.

MorphoSys' attempts to distinguish *WEI* are unpersuasive. MorphoSys contends that here, unlike in *Wyeth*, a POSA would not need to conduct complicated experiments to generate operative embodiments. (D.I. 424 at 28) Instead, according to MorphoSys, the specification here "guides POSAs to 'preferred substitutions' that lead to antibodies with predictable properties." (*Id.*) That contention may well accurately describe the process by which a POSA would make conservative variants of the disclosed antibodies. However, to enable the ***full scope*** of the claims as construed by the Court, it is not sufficient that the patent allows a POSA readily to make and use ***some*** species within the broad, claimed genus. Even the patents in *Wyeth* did that much. *See* 720 F.3d at 1381 (disclosing sirolimus as working example). Instead, the specification must enable the ***full scope*** of the claims. *See id.* at 1385. Here, that includes antibodies that are not merely conservative variants of the disclosed antibodies – and, here, the

patent does not allow a POSA to readily make and use (or even identify) all such embodiments. Instead, undue experimentation is required.

MorphoSys' attempt to distinguish *Idenix* fails for similar reasons. MorphoSys contends that "[u]nlike in *Idenix*, it is undisputed that a POSA could readily generate a number of antibodies falling within the scope of the claims and that the specification enables one of skill in the art to make exemplary antibodies from the specification." (D.I. 399 at 36) (internal citations, quotation marks, and emphases omitted) It is true that a POSA, armed with MorphoSys' patents, could "readily" create conservative variants of the disclosed antibodies and "reasonably expect" them to work. (D.I. 386 Ex. 4C, Bradbury Rep. ¶ 110; D.I. 426 Ex. 56, Bradbury Dep. 202) But, again, this is inadequate. The patentee in *Idenix*, too, disclosed working embodiments. *See* 2018 WL 922125, at *22. These working embodiments, however, were only a subset of all embodiments covered by the claims, and a POSA could not have discovered the non-disclosed working embodiments without undue experimentation. *See id.* at *21-22. The same circumstances are present here, warranting the same conclusion: the full scope of the claims is not enabled.

MorphoSys also argues that the claims in *WEI* covered "***different classes***" of compounds that could not be practiced without undue experimentation, whereas the claims here "all recite a ***single class*** of compounds well defined by a structure: an antibody." (D.I. 442 at 18-19) (emphasis added) Relatedly, MorphoSys contends that a specification only fails to enable the 'full scope' of a claim if there are "a ***significant subset of embodiments – generally an entire class***" – that a POSA would not have been able to make without undue experimentation. (*Id.* at 17) (emphasis added) It is unclear what MorphoSys means by "class" but, regardless, this characterization is unhelpful to MorphoSys. If MorphoSys means that a "class" is the type of

compound recited by the claims, then none of the claims at issue in *WEI* or here is directed to multiple classes. *Compare* '746 patent, cl. 1 (claiming an "antibody") *with Wyeth*, 720 F.3d at 1382 (claiming treatment method using a "rapamycin"); *Enzo*, 2017 WL 2829625, at *1 (claiming an "oligo–or polynucleotide"); *and Idenix*, 2018 WL 922125, at *12 (claiming treatment of hepatitis C with a "nucleoside"). On that view, the claims here and in *WEI* are not enabled because not every claimed compound – that is, not every member of the class – can be obtained by a POSA without undue experimentation.

Alternatively, if MorphoSys means by a "class" only those embodiments that a POSA could make without undue experimentation, then the claims here and in *WEI* are all directed to multiple classes. For example, in *Wyeth*, one (enabled) class of the claimed rapamycin would consist of sirolimus, the disclosed embodiment, and another (non-enabled) class would include all rapamycins that meet the claims' functional limitations but are not sirolimus. *See* 720 F.3d at 1381-85. Similarly, in *Enzo*, one (enabled) class of the claimed polynucleotide labelling technique would use the polynucleotide disclosed as Example 5 of the patent, and another (non-enabled) class would use any effective polynucleotide other than Example 5. *See* 2017 WL 2829625, at *1-4. Likewise, in *Idenix*, one (enabled) class of the claimed method of treating hepatitis C would use a nucleoside disclosed in the patent, and another (non-enabled) class would use a nucleoside that was effective but not disclosed in the patent. 2018 WL 922125, at *21. Here, on this view, one (enabled) class of the claimed antibody would include the disclosed antibodies and conservative variants thereof, and another (non-enabled) class would include all antibodies that met the claims' limitations but were not conservative variants of a disclosed antibody.

In the end, the conclusion is the same: the claims here are much like the claims in *WEI*, and, like those claims, they are invalid for lack of enablement.

6. Conclusion regarding enablement

As explained above, the record reveals no genuine disputes of material fact that preclude a conclusion of non-enablement. Accordingly, for the reasons stated above, the Court concludes that, even drawing all reasonable inferences in favor of MorphoSys, clear and convincing evidence shows that each of the patents-in-suit is invalid for lack of enablement. The Court will grant Janssen's motion for summary judgment of invalidity for lack of enablement and will deny MorphoSys' motion for summary judgment of no lack of enablement.

C. Indefiniteness

1. Applicable Law

A patent claim is indefinite if, "viewed in light of the specification and prosecution history, [it fails to] inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2129 (2014). A claim may be indefinite if the patent does not convey with reasonable certainty how to measure a claimed feature. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1341 (Fed. Cir. 2015). But "[i]f such an understanding of how to measure the claimed [feature] was within the scope of knowledge possessed by one of ordinary skill in the art, there is no requirement for the specification to identify a particular measurement technique." *Ethicon Endo–Surgery, Inc. v. Covidien, Inc.*, 796 F.3d 1312, 1319 (Fed. Cir. 2015).

2. Analysis

The Binding Claims[22] are claims directed to antibodies that bind to a specific part of the CD38 protein. Janssen contends that the Binding Claims are indefinite because the patents do not make sufficiently clear which measurement technique to use to determine whether an antibody meets the binding properties recited by the Binding Claims. (D.I. 383 at 31-35) The Court disagrees. As MorphoSys notes (D.I. 424 at 33-34), the patents clearly describe measuring binding using PepSpot, which is MorphoSys' tool for peptide mapping. ('746 patent, 26:27-27:36) As MorphoSys contends, a POSA would know to measure binding using PepSpot. (*Id.* at 34)

Janssen's analogies to *Teva* and *Dow* are not persuasive. (*See* D.I. 383 at 32-33) In *Teva*, the term found indefinite, "molecular weight," was used in the specification in a way that suggested "peak average molecular weight," defined by the patentee during prosecution as "weight average molecular weight," and then defined separately during prosecution as "peak average molecular weight." *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 789 F.3d 1335, 1344-45 (Fed. Cir. 2015). In *Dow*, the term found indefinite, "slope of strain hardening," could have been computed four different ways, yet the intrinsic evidence was entirely silent as to which method to use. *See Dow Chemical Co. v. Nova Chemicals Corp. (Canada)*, 803 F.3d 620, 634 (Fed. Cir. 2015). Here, by contrast, the intrinsic evidence repeatedly and consistently describes the use of PepSpot to measure binding properties. ('746 patent, 26:27-27:36)

Janssen contends that a POSA would not use PepSpot to measure binding because "there is no dispute that PepSpot cannot definitively measure binding to the actual CD38 protein." (D.I.

[22] The Binding Claims are claims 14, 15, 18, 27, and 28 of the '746 patent; claims 1, 5, 6, 11, 12, and 15 of the '061 patent; and claims 1, 2, and 3 of the '590 patent. (D.I. 383 at v)

444 at 17-18) In support of this contention, Janssen relies on binding data for MOR03080 from the Replitope Report and Janssen's x-ray crystallography experiment, which Janssen argues shows the inaccuracy of peptide mapping techniques like PepSpot. (*Id.*) But Janssen's extrinsic evidence – which would have been unavailable to a POSA at the pertinent date of the patent – is not relevant to the indefiniteness inquiry as the intrinsic evidence unambiguously conveys to a POSA that epitope mapping techniques like PepSpot can be used to measure an antibody's binding properties. ('746 patent, 26:1-27:36; *see also Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996))

For the above reasons, the Janssen has failed to meet its burden to show, by clear and convincing evidence, that the Binding Claims are indefinite.

V. CONCLUSION

For the reasons given above, the Court concludes that: (1) Janssen does not infringe the "human" antibody claims; (2) none of the patents-in-suit discloses sufficient structural features common to the members of the claimed genera to meet the written description requirement; and (3) each of the patents-in-suit is invalid for lack of enablement. Janssen's motions for summary judgment will be granted on those bases. The Court will: (1) deny the remainder of Janssen's motion for summary judgment with respect to written description; (2) deny Janssen's motion for summary judgment with respect to indefiniteness; and (3) deny MorphoSys' motion for summary judgment with respect to enablement. An appropriate order follows.