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BEFORE THE APPEALS REVIEW PANEL OF THE
PATENT TRIAL AND APPEAL BOARD

Ex parte AARON KEITH CHAMBERLAIN,
BASSIL DAHIYAT, JOHN R. DESJARLAIS,
SHER BAHADUR KARKI, and GREGORY ALAN LAZAR

Appeal 2022-001944
Application 16/803,690
Technology Center 1600

Before KATHERINE K. VIDAL, *Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office*, VAISHALI UDUPA, *Commissioner for Patents*, and SCOTT R. BOALICK, *Chief Administrative Patent Judge*.

PER CURIAM.

DECISION ON APPEAL

I. INTRODUCTION

The Director convened this Appeals Review Panel to clarify the Office's position and issue a revised decision on the proper analysis of Jepson and means-plus-function claims in this case. This decision supersedes the prior rejections of the Examiner and decisions of the Board, except to the extent we explicitly adopt or rely on them. Our review is

limited to the Examiner's rejections and the new grounds of rejection entered by the Board, which are as follows:

- Claims 8 and 9 stand rejected under 35 U.S.C. § 112, first paragraph (written description). Decision 3–30 (entering new ground of rejection).[1]
- Claim 9 stands rejected under 35 U.S.C. § 112, second paragraph (indefiniteness). Decision 28–30 (entering new ground of rejection).
- Claims 8 and 9 stand rejected for non-statutory obviousness-type double patenting over claims 1–5 of U.S. Patent 10,336,818 ("the '818 patent")[2] and Schwaeble.[3] *See* Final Act. 17–18[4]; Decision 30–34.
- Claims 8 and 9 were rejected for non-statutory obviousness-type double patenting over claim 1 of U.S. Patent 8,546,543 ("the '543 patent")[5] and Schwaeble. Final Act. 17.[6]

On review, we maintain the Board's new ground of rejection of claims 8 and 9 for lack of written description, but we do not maintain the Board's new ground of rejection of claim 9 for indefiniteness. We further reverse the Examiner's obviousness-type double patenting rejection of claims 8 and 9 over claims 1–5 of the '818 patent and Schwaeble. Finally, we adopt the Board's decision reversing the Examiner's obviousness-type

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[1] Board Decision ("Decision"), issued January 10, 2023.

[2] Chamberlain, US 10,336,818 B2, issued July 2, 2019.

[3] Schwaeble, US 2006/0018896 A1, published Jan. 26, 2006 ("Schwaeble").

[4] Examiner's final rejection ("Final Act."), issued March 26, 2021.

[5] Lazar, US 8,546,543 B2, issued Oct. 1, 2013.

[6] The Board reversed the rejection of claims 8 and 9 for non-statutory obviousness-type double patenting over claim 1 of the '543 patent and Schwaeble. *See* Decision 34–35. We do not disturb the Board's decision reversing this rejection by the Examiner.

double patenting rejection of claims 8 and 9 over claim 1 of the '543 patent and Schwaeble.

We have jurisdiction under 35 U.S.C. § 6(b).

II. BACKGROUND

A. Claimed Invention

Application No. 16/803,690 ("the '690 application") relates to antibodies, and specifically to optimized IgG immunoglobulin variants, engineering methods for their generation, and their application, particularly for therapeutic purposes. Specification ("Spec.") ¶ 3. When disclosing antibodies "used for the treatment of autoimmune, inflammatory, or transplant indications," the Specification refers to, among a large list of other antibodies, "anti-complement (C5) antibodies such as 5G1.1." *Id.* ¶ 133.

Claim 8, which is drafted in Jepson form, and claim 9, which includes a means-plus-function limitation, are the sole claims at issue and are reproduced below:

> 8. In a method of treating a patient by administering an anti-C5 antibody with an Fc domain,
>
> the improvement comprising said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat,
>
> wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

> 9. A method of treating a patient by administering an anti-C5 antibody comprising:
>
> a) means for binding human C5 protein; and
>
> b) an Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide,
>
> wherein numbering is according to the EU index of Kabat,
>
> wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions.

Appeal Br. 46 (Claims Appendix) (paragraphing added).

B. Procedural History

On March 26, 2021, the Examiner issued a final rejection rejecting: (1) claims 8 and 9 under 35 U.S.C. § 112, first paragraph (written description); (2) claims 8 and 9 for obviousness-type double patenting over claims 1–5 of the '818 patent and Schwaeble; and (3) claims 8 and 9 for obviousness-type double patenting over claim 1 of the '543 patent and Schwaeble.

On August 25, 2021, Appellant filed an Appeal Brief ("Appeal Br.") with the Board. The Examiner entered an Examiner's Answer on December 15, 2021, in which the Examiner withdrew the written description rejection of claims 8 and 9. On February 14, 2022, Appellant filed a Reply Brief ("Reply Br.").

On January 10, 2023, the Board issued a Decision. In the Decision, the Board entered new grounds of rejection of claims 8 and 9 under 35

U.S.C. § 112, first paragraph (written description).[7] The Board explained that "[t]he rejection [of claims 8 and 9] is the same as the written description rejection set forth in the Final Office Action, supplemented by additional reasoning." Decision 8. The Board also entered a new ground of rejection against claim 9 under § 112, second paragraph (indefiniteness). In addition, the Board affirmed the Examiner's rejection of claims 8 and 9 for obviousness-type double patenting over claims 1–5 of the '818 patent and Schwaeble, but reversed the Examiner's obviousness-type double patenting rejection of claims 8 and 9 over claim 1 of the '543 patent and Schwaeble.

On March 10, 2023, Appellant filed a request for rehearing of the Decision ("Reh'g Req."), which the Board denied in a Decision on June 1, 2023 ("Rehearing Decision").

On June 14, 2023, Appellant filed a notice of appeal under 37 C.F.R. § 90.2(a) to the Federal Circuit.

On November 27, 2023, the U.S. Patent and Trademark Office ("Office") filed a motion requesting that the Federal Circuit administratively remand the proceeding to the Office in order to convene an Appeals Review Panel to clarify the Office's position on the proper analysis of "Jepson-format and means-plus function claims in the field of biotechnology, and particularly in the antibody art" and "to issue a revised decision." *See In re*

[7] The Examiner indicates that the claims were examined under the pre-AIA provisions of 35 U.S.C. Final Act. 2. We note that the Board's Decision referenced the post-AIA version of the statute. The result would be the same under either version. We refer only to the pre-AIA version in this decision. The application claims priority to a non-provisional application (Application No. 12/341,769) filed December 22, 2008, and to various provisional applications filed in 2008.

Xencor, Case No. 2023-2048, Motion (Fed. Cir. Nov. 27, 2023);[8] *see also* Appeals Review Panel, www.uspto.gov/patents/ptab/appeals-review-panel.

On January 23, 2024, the Federal Circuit granted the motion. *Id.*, Order (Fed. Cir. Jan. 23, 2024) (mandate issued March 15, 2024).

III. ANALYSIS

A. Written Description Rejection of Claim 8

For the reasons discussed below, we determine that the preamble of claim 8 is entitled to patentable weight. We further determine that the Specification of the '690 application does not provide adequate written description support for the broad genus of any "anti-C5 antibody" and does not provide adequate written description support for "treating a patient" as broadly claimed. We therefore maintain the Board's rejection of claim 8 for lack of adequate written description under 35 U.S.C. § 112 ¶ 1.

1. The preamble of claim 8—"a method of treating a patient by administering an anti-C5 antibody with an Fc domain"—is entitled to patentable weight

a) The preamble is limiting given the Jepson form of the claim

Under the "broadest reasonable interpretation" standard, the Board construes the claims based on the intrinsic evidence as a matter of law, while also making subsidiary factual findings as to any extrinsic evidence. *See St. Jude Med., LLC v. Snyders Heart Valve LLC*, 977 F.3d 1232, 1238 (Fed.

[8] We note that the case caption at the Board in an *ex parte* appeal uses the name of the inventors, rather than the real party-in-interest.

Cir. 2020) (citing *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 325–27 (2015)).

Claim 8 is in Jepson form, as Appellant acknowledges. Appeal Br. 8. A claim in Jepson form recites a preamble that sets forth what is impliedly admitted to be prior art, followed by the body of the claim, which describes a recited improvement, with the two parts separated by a transitional phrase such as "wherein the improvement comprises." 37 C.F.R. § 1.75(e) (2023); *see Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985) (citing MPEP § 608.01(m) (5th ed. 1983); 37 C.F.R. § 1.75(e) (1984)).

The first issue to resolve is whether the preamble of Jepson claim 8 requires written description support. To do so, we examine whether the preamble is limiting as a matter of claim construction. *See Arctic Cat Inc. v. GEP Power Prod., Inc.*, 919 F.3d 1320, 1327 (Fed. Cir. 2019).

Appellant argued in its rehearing request to the Board that Jepson claim preambles are not necessarily limiting. Reh'g Req. 4, 5–6. We disagree. The preamble of a Jepson claim is limiting, by necessity, because it defines the scope of the claim. *Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) ("When [Jepson] claim form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope."); *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1029 (Fed. Cir. 2002) ("[T]he preamble is a limitation in a Jepson-type claim.") (citing *Pentec*, 776 F.2d at 315); *see also Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1344 (Fed. Cir. 2008); MPEP § 608.01(m) (9th ed. rev. 07-2022 Feb. 2023) (discussing 37 C.F.R. § 1.75(e)) ("The preamble of this form of claim is considered to positively and clearly include

all the elements or steps recited therein as a part of the claimed combination.").

The decisions upon which Appellant relies for the opposite result are unavailing. The primary case Appellant cites found the disputed language of the Jepson claim preamble to be limiting and did not cite or distinguish *Rowe*, *Epcon*, or *Pentec*. *See Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1572–73 (Fed. Cir. 1996). The remaining cases to which Appellant points us, Reh'g Req. 6, are not from the Federal Circuit. They are also unpersuasive because they fail to reconcile their reasoning with the controlling precedents we have cited above. In addition, Appellant's affirmative choice to invoke Jepson claim language—by reciting a claim for an improvement that has specific reference to the preamble for "all the elements or steps of the claimed combination which are conventional or known"—weighs against construing the preamble of claim 8 under the case law for non-Jepson claims. *See* 37 C.F.R. § 1.75(e) (2009); *see also Arctic Cat*, 919 F.3d at 1330 (examining consequence of not using Jepson form).

For these reasons, we find the entire preamble of claim 8 to be limiting, and therefore the entire preamble requires written description support. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (*en banc*).

Furthermore, even if we did not find the preamble to be limiting based on the Jepson form of the claim, we would still conclude that the entire preamble of claim 8 is limiting under the more general case law guiding the construction of claim preambles for the reasons discussed in Sections III.A.1.b. and III.A.1.c. below.

b) The phrase "administering an anti-C5 antibody with an Fc domain" in the preamble is limiting under ordinary claim construction principles

Next, we consider whether the portion of the preamble that recites "administering an anti-C5 antibody with an Fc domain" ("'administering' portion") should be construed as limiting. As we conclude in Section III.A.1.a. above, the entire preamble is limiting and therefore the "administering" portion is limiting. *See Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1371 (Fed. Cir. 2020). Independent of that conclusion, we consider whether, even if the claim were not in Jepson form, the "administering" portion would nonetheless be limiting.

As to claim construction, Appellant admits that the "administering" portion of the claim 8 preamble is limiting. Reh'g Req. 4. In doing so, Appellant acknowledges that the "administering" portion of the preamble "provides antecedent basis to the remaining claim limitations and provides the structural component . . . upon which the claimed improvement in the Fc region is implemented." *Id.*

The Federal Circuit has "repeatedly held a preamble limiting when it serves as antecedent basis for a term appearing in the body of a claim." *In re Fought*, 941 F.3d 1175, 1178 (Fed. Cir. 2019) (collecting and citing multiple cases). Claim 8 includes limitations directed to "said Fc domain" and "said anti-C5 antibody" that each find their antecedent basis in the "administering" portion of the preamble. The antecedent recitations in the preamble are thus "necessary to understand positive limitations in the body of" claim 8. *See Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1024 (Fed. Cir. 2015). For example, the recited "said Fc domain" is not *any* Fc domain, but rather the Fc domain of "an anti-C5 antibody" as required by

the preamble. *See, e.g.*, *Eaton Corp. v. Rockwell Int'l Corp.*, 323 F.3d 1332, 1339 (Fed. Cir. 2003) ("When the body of the claim refers to '*said* vehicle master clutch (8),' and '*said* drive train,' it is referring back to the particular clutch and the particular drive train previously described in the preamble.").

Finally, claim 8 is a method claim and the improvement recited in the body of the claim does not include any method steps so, as Appellant acknowledges, Reh'g Req. 4 ("sole claimed step of 'administering'"), *at least* the "administering" portion of the preamble must be limiting. We thus agree with Appellant, *see id.*, and conclude that the "administering an anti-C5 antibody with an Fc domain" portion of the claim 8 preamble should be construed as limiting, even without taking into consideration the Jepson form of the claim. Accordingly, "administering an anti-C5 antibody with an Fc domain" requires written description support.

c) The phrase "treating a patient" in the preamble is limiting under ordinary claim construction principles and is broad in scope

We next consider whether the portion of the preamble that recites "treating a patient" should be construed as limiting. As we conclude in Section III.A.1.a. above, the entire preamble is limiting and therefore "treating a patient" is limiting. *See Bio-Rad Labs.*, 967 F.3d at 1371. Setting aside that conclusion, we consider whether, even if the Jepson form of the claim were not controlling, "treating a patient" would be limiting.

In its request for rehearing of the Board Decision, Appellant argues that "treating a patient" is not limiting because it "merely states an intended purpose, which the Federal Circuit has repeatedly held to be non-limiting." Reh'g Req. 5 (citing, *e.g.*, *Bristol-Myers Squibb Co. v. Ben Venue Labs.*,

Inc., 246 F.3d 1368, 1375–76 (Fed. Cir. 2001)). Appellant relatedly argues that "treating a patient" provides no antecedent basis to the rest of the claim, and does not require any functional result or effect different from "administering," such as an "effective amount." *See id.* at 4 (citing *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1342 (Fed. Cir. 2021)).

The Board was not persuaded by these arguments. In claim 8, after reciting a "method of treating a patient" in the preamble, the body of the claim recites that the anti-C5 antibody with certain amino acid substitutions "has increased in vivo half-life." Based on this claim language, the Board determined that treatment is the "*raison d'être*" (reason for existence) of the claimed method, and the purpose of increasing the half-life of the antibody, as recited in the body of the claim, is to improve its efficacy when administered as a therapeutic agent when treating a patient. Rehearing Decision 7–8 (quoting *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003)). We agree with the Board's conclusion.

Setting aside Jepson claims, as a general matter there is no simple, single-factor or litmus test for determining whether a preamble is limiting. *Eli Lilly*, 8 F.4th at 1340. Instead, the proper construction of the preamble turns on the claim as a whole and the invention described in the patent. *Id.* (citing *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003)). The Federal Circuit has described the inquiry as follows:

> In general, a preamble limits the invention if it recites essential structure or steps, or if it is necessary to give life, meaning, and vitality to the claim. Conversely, a preamble is not limiting where a patentee defines a structurally complete invention in

> the claim body and uses the preamble only to state a purpose or intended use for the invention.

Shoes by Firebug LLC v. Stride Rite Children's Grp., LLC, 962 F.3d 1362, 1367 (Fed. Cir. 2020) (citations omitted). But, as the Court's repeated reference to "structure" makes clear, this description of the inquiry is focused on "more general claims directed to apparatuses or compositions of matter." *See Eli Lilly*, 8 F.4th at 1340–41.

With respect to method claims such as claim 8, the Federal Circuit has explained that:

> [P]reamble language will limit the claim if it recites not merely a context in which the invention may be used, but the essence of the invention without which performance of the recited steps is nothing but an academic exercise. This principle holds true here, as it frequently does for method claims: [where claim terms at issue] are not merely circumstances in which the method may be useful, but instead are the *raison d'être* of the claimed method itself.

Boehringer, 320 F.3d at 1345 (citation omitted); *accord Eli Lilly*, 8 F.4th at 1341. The Federal Circuit has further explained that "our claim construction analysis of statements of intended purpose in methods of using apparatuses or compositions has tended to result in a conclusion that such preamble language is limiting." *Eli Lilly*, 8 F.4th at 1341. In such cases, the intended purpose is a recitation of what the method claim "does" as opposed to what it "is." *Id.* For example, in *Eli Lilly*, the preamble's recitation of an intended purpose was limiting in part because the preamble embodied the essence of the claimed invention and "provide[d] the only metric by which one practicing the claim could determine whether the amount administered

is an 'effective amount [of an antibody],'" as recited in the body of the claim. *See* 8 F.4th at 1335, 1341, 1342.

We recognize that in *Bristol-Myers*, cited by Appellant, preamble phrases were not afforded patentable weight because they did not change or affect the very specific steps and dosage rate (*e.g.*, "135–175 mg/m2 taxol over about 3 hours") recited in the body of the claims at issue. *See* 246 F.3d 1368, 1371–72, 1375 (Fed. Cir. 2001). In *Bristol-Myers*, the Court found that the language of the claim itself strongly suggested the independence of the preamble from the body of the claim. *Id.* at 1375.

In this case, we do not view the body of the claim as independent from the preamble. We determine that "treating a patient" is necessary to give life, meaning, and vitality to both the "increased in vivo half-life" limitation recited in the body of the claim, and also to "administering," which is the sole method step recited in the claim. *See Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). We note that the meaning of the phrase "in vivo" is clarified and informed by the preamble's recitation of "a patient." *See Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1358 (Fed. Cir. 2012) (concluding "rotary cutter deck" in the preamble informed the meaning of the "torsional stiffness" limitation).

Next, as noted by the Board, the reason to increase an "in vivo" half-life of an antibody, as recited in claim 8, is to make it more effective when treating a patient. Rehearing Decision 7–8 (citing Spec. ¶¶ 128, 130–139, 141, 144–147 and noting repeated reference to beneficial use of the invention as applied to antibodies in clinical trials or otherwise intended for therapeutic use/treatment). Similarly, the Background of the Invention concludes with a statement that "Human IgG1 is the most commonly used

antibody for therapeutic purposes" and thus "[t]here is a further need to design [IgG] variants to . . . increase *in vivo* half-live as compared to native IgG polypeptides." Spec. ¶ 14. The sole portion of the Specification that references anti-C5 antibodies states that "the Fc polypeptides of the present invention are used for the treatment of autoimmune, inflammatory, or transplant indications" and lists "clinical products and candidates," including anti-C5 antibodies, that are relevant for these diseases. *Id.* ¶ 133. Further, we observe that claim 8 lacks a specifically recited dosage and rate, and thus a person of ordinary skill in the art reading the claims would have to read "increased in vivo half-life" in the claim body in the context of the preamble's recitation of "treatment of a patient" in order to understand the scope of the claim. For this reason, claim 8 far more closely resembles the claims in *Eli Lilly*, which required resort to the preamble to understand the scope of the claims, than the claims in *Bristol-Myers*, which did not change when viewed in light of the preamble language.

Finally, we note that the Federal Circuit has explained, outside of the context of Jepson claims, that one portion of a claim preamble may be limiting (*e.g.*, by providing antecedent basis) while another portion of the same preamble (*e.g.*, statement of intended use) is not. *See TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1323–24 (Fed. Cir. 2015). However, the Federal Circuit has cautioned that the preamble in *TomTom* was "neatly packaged into two separate portions" and construing each word of a preamble as separately limiting and non-limiting ("splicing it") should be avoided. *See Bio-Rad Labs.*, 967 F.3d at 1371. Here, where the claim limitation "in vivo half-life" finds context in "treating a patient" and "administering" is a necessarily limiting step of the method, we are similarly disinclined to

"splice" the "treating a patient by administering" portion of the claim 8 preamble into limiting and non-limiting parts.

We thus conclude that the "treating a patient" portion of the claim 8 preamble should be construed as limiting, even without taking into consideration the Jepson form of the claim.

Additionally, we agree with the Board that a person of ordinary skill in the art would have understood "treating a patient" to mean "treating any patient having any disease or condition" because the claim is open-ended and is not limited to the type of patient to be treated, *i.e.*, from what disease or condition the patient is suffering. *See* Decision 5. The claim here is thus not limited in the same way as the claims in *Eli Lilly*, which recited "treating headache." Moreover, the Specification defines "patient" to include both human and non-human animals, and therefore encompasses non-human patients suffering from any and all diseases or conditions. *See* Decision 5 (citing Spec ¶ 183).

Appellant argues that "claim 8 simply requires administering a C5 antibody with the claimed Fc domain substitutions." Reh'g Req. 5. This argument again appears to be premised on the view that "treating a patient" is not limiting, with which we disagree for the reasons discussed above.

Appellant similarly argues that "the sole claimed step of 'administering' the modified C5 antibody would be performed in the same way regardless of the 'method of treating a patient' language because the claim does not require any functional result or effect from 'administering.'" *Id.* at 4; *see also id.* at 7, 11 ("'Treating' does not connote any effectiveness or require any particular result. It merely refers to providing care (i.e., administering). And the remainder of the claim likewise lacks any required

efficacy or result deriving from the sole claimed step of 'administering.'"). But a person of ordinary skill in the art would not view "treating" as synonymous with "administering." *See, e.g.*, *Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (explaining "treatment" in preamble is "a statement of the intentional purpose for which the method must be performed").

Given the lack of specificity in the claim itself, we also turn to the Specification to aid in interpreting the scope and meaning of "treating a patient." *See BTG Int'l Ltd. v. Amneal Pharms. LLC*, 923 F.3d 1063, 1071 (Fed. Cir. 2019) ("[A]ny definition of 'treatment' must encompass the full range of the therapeutic agent's effects disclosed in the specification."). Here, the lack of written description, as discussed in further detail below, is apparent. The Specification does not define the term "treating," and it does not describe or provide any data associated with treating any patient with any disease or condition with any anti-C5 antibody, including an anti-C5 antibody with the claimed Fc modifications. In one embodiment, the Specification merely mentions three classes of diseases/conditions that might benefit from administration of antibodies with an Fc modification, including anti-C5 antibodies such as 5G1.1. *Id.* ¶ 133. This brief mention of several disease types in a single embodiment does not limit the breadth of "treating" and "patient" in the claim.

Appellant cites two non-precedential Board decisions to support its argument that even if "treating a patient" is limiting, it does not require a specific, therapeutic result. Reh'g Req. 11 (citing *Fresenius Kabi USA, LLC v. Chugai Seiyaku Kabushiki Kaisha*, IPR2021-01024, Paper 23, at 6–7 (PTAB Jan. 6, 2022); *Mylan Pharm. Inc. v. Regeneron Pharm., Inc.*,

IPR2021-00881, Paper 21, 18–21 (PTAB Nov. 10, 2021)). Neither decision is binding or persuasive. Furthermore, neither decision would lead us to a different result.

The cited decision in *Fresenius* is unpersuasive because: (1) it is an institution decision in an AIA proceeding rather than a final decision, and thus represents only the panel's preliminary position based on a limited record; (2) the claim at issue included two separate "effective amount" limitations that were construed as part of other limitations rather than in conjunction with "treating"; and (3) the patent owner's preliminary response stated only that it did not oppose the petitioner's construction because the "treating" limitation did "not, by itself, requir[e] the treatment to be effective." *See Fresenius*, Paper 23, at 1, 6–7; Paper 8, at 17 n.3.

The cited institution decision in *Mylan* concluded that the claim language did not *require* a particular level of efficacy, as the specification described the dosing as therapeutically effective in most, but not all, cases. *See Mylan*, Paper 21, at 20–21. But in both the institution decision and the final decision in *Mylan*, the Board concluded that the claim preamble, "[a] method for treating an angiogenic eye disorder in a patient," was limiting. *Mylan*, Paper 21, at 16, 18–19, Paper 94, at 12, 17–18. There is no tension between *Mylan* and this decision.

Further, Federal Circuit precedent encourages applicants to seek a patent on a specific use for which they have provided written description support (and have enabled), while still allowing others to develop other therapies based on other uses of the same compound. *See, e.g.*, *In re Shetty*, 566 F.2d 81 (CCPA 1977); *accord In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990). The principles underlying the Court's precedent animates

here. It would discourage invention of new uses for known compounds if an applicant can obtain a broad claim for "treating a patient," *i.e.*, any patient, having any disease or condition (for all uses of a compound) without providing written description support (and enablement) therefor, depriving the public of their part of the bargain struck in our patent laws. Thus, it is preferable to require a claim to recite treatment of a specific disease or condition, such as "treating headache," as recited in the claim in *Eli Lilly*, rather than claiming a treatment without limitation, unless "treating a patient" can be adequately supported for all patients and all diseases without limitation.

We, therefore, determine that "treating a patient" is limiting and accordingly requires written description support. We further determine that "treating a patient" means "treating all patients and all diseases."

2. Claim 8 Lacks Adequate Written Description

a) The Specification does not provide adequate written description support for the broad genus of any "anti-C5 antibody," as recited in claim 8

Appellant argues that there is adequate written description support in the Specification for "an anti-C5 antibody" and that "[t]he specification says relatively little about anti-C5 antibodies because they are so well-known in the art and already in the possession of skilled artisans." Reh'g Req. 10. We disagree.

Claim 8 uses functional language to claim a genus because it claims all antibodies that bind to C5. *See Juno Therapeutics, Inc. v. Kite Pharm., Inc.*, 10 F.4th 1330, 1335 (Fed. Cir. 2021) (discussing "genus claims using functional language, like the binding function of the [antibody fragment]

claimed"). "Generally, a genus can be sufficiently disclosed by 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." *Id.* (citation omitted). "For genus claims using functional language, . . . the written description 'must demonstrate that the applicant has made a generic invention that achieves the claimed result and do so by showing that the applicant has invented species sufficient to support a claim to the functionally-defined genus.'" *Id.* (quoting *Ariad Pharms.*, 598 F.3d at 1349).

A "representative number of species" means any such number of species that adequately describes the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. *See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (Fed. Cir. 2014). Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the inventor was in possession of the necessary common attributes or features possessed by the members of the genus in view of the species disclosed. *See generally* MPEP § 2163 (9th ed. rev. 07-2022 Feb. 2023).

The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure "indicates that the patentee has invented species sufficient to constitute the gen[us]." *See Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 966–67 (Fed. Cir. 2002); *Noelle v. Lederman*, 355 F.3d 1343, 1350 (Fed. Cir. 2004) (Fed. Cir. 2004). For inventions in an unpredictable art, adequate written

description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus. *See Regents of the Univ. of Calif. v. Eli Lilly,* 119 F.3d 1559, 1568 (Fed. Cir. 1997). Instead, the disclosure must adequately reflect the structural diversity of the claimed genus, either through the disclosure of sufficient species that are "representative of the full variety or scope of the genus," or by the establishment of "a reasonable structure-function correlation." *See AbbVie,* 759 F.3d at 1300–01. "It is true that functionally defined claims can meet the written description requirement if a reasonable structure-function correlation is established, whether by the inventor as described in the specification or known in the art at the time of the filing date." *Id.* at 1301.

"[T]he test for sufficiency [of written description] 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 time of filing." *Ariad Pharms.*, 598 F.3d at 1351. *Ariad* explains that "the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Id.*

Nevertheless, "[t]he 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge." *Capon v. Eshhar*, 418 F.3d 1349, 1358, 1360–61 (Fed. Cir. 2005) (holding that the Board erred in requiring recitation of a DNA sequence "when that sequence is already known in the field"). "The predictability or unpredictability of the science is relevant to deciding how much experimental support is required to adequately describe the scope of an

invention." *Id.* at 1360; *see also Boston Sci. v. Johnson & Johnson*, 647 F.3d 1353, 1366 (Fed. Cir. 2011) ("Because the specification is viewed from the perspective of one of skill, in some circumstances, a patentee may rely on information that is 'well-known in the art' for purposes of meeting the written description requirement.").

For example, in *Juno*, the Federal Circuit found that the written description requirement was not met. 10 F.4th at 1342. Although single-chain antibody variable fragments (scFvs) in general were known, the realm of possible scFvs that bind to CD19 (a protein that appears on the surface of certain cells) was vast and the number of known CD19-specific scFvs was small (five at most). *Id.* The patent at issue there provided no details about which scFvs bind to CD19 in a way that distinguishes them from scFvs that do not bind to CD19. *Id.*

"[T]he purpose of the written description requirement is to 'ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification.'" *AbbVie*, 759 F.3d at 1299 (quoting *Ariad*, 598 at 1353–54); *see also Amgen, Inc. v. Sanofi*, 872 F.3d 1367, 1377–78 (Fed. Cir. 2017) ("We cannot say that this particular context, involving a 'newly characterized antigen' and a functional genus claim to corresponding antibodies, is one in which the underlying science establishes that a finding of 'make and use' (routine or conventional production) actually does equate to the required description of the claimed products.").

Sufficiency of written description is a question of fact. *See Knowles Elecs. LLC v. Cirrus Logic, Inc.*, 883 F.3d 1358, 1365 (Fed. Cir. 2018).

In this case, claim 8 recites "an anti-C5 antibody," *i.e.*, an antibody that binds C5. The only disclosure in the Specification of "an anti-C5 antibody" is "anti-complement (C5) antibodies such as 5G1.1." Spec. ¶ 133. Thus, 5G1.1 is the only specifically disclosed example of an anti-C5 antibody.[9]

We agree with the Examiner that, in contrast to this limited disclosure of 5G1.1, the genus of anti-C5 antibodies is a broad genus because it encompasses various specificities and epitopes. *See* Final Act. 10. We agree with the Examiner that there was a "well known high level of polymorphism of immunoglobulin/antibodies" and, correspondingly, a "vast repertoire of antibodies" encompassed by the claimed invention. *Id.* at 12. We further agree with the Board's finding that "the claimed anti-C5 antibody represents a broad genus of antibodies unrestricted in their variable region structure, epitopes to which they bind, function, mechanism of action in treatment, etc." Decision 6. For these reasons, we find that the disclosure of a single species, 5G1.1, of the genus of anti-C5 antibodies is not enough to provide a representative number of species to sufficiently support the functionally-defined genus of all antibodies that bind C5. *Juno*, 10 F.4th at 1335.

Nor does the Specification provide a structure-function relationship sufficient to enable a person of ordinary skill in the art to "visualize or recognize" members of the genus. *Id.* As the Board explains,

> there is no information in the Specification [as to] how much variation is permissible for it still to bind C5 and treat a patient nor an amino acid sequence which enables it to do so. Without

[9] The Specification also lists C5 as one target in a long list of potential targets of IgG variants. Decision 11 (citing Spec. ¶ 126).

> such a description, one of ordinary skill would be unable to distinguish which anti-C5 antibodies having the claimed Fc domain substitution would fall within the scope of claim 8 and which would not.

Decision 12. We also agree with the Examiner's explanation that single amino acid changes, *e.g.*, to a complementarity-determining region, can result in a decreased affinity of antigen or even ablation of antibody binding and specificity. *See* Final Act. 13.

For these reasons, we agree with the Board that the Specification does not demonstrate that a person of ordinary skill in the art would view Appellant as having possession of the entire genus at the time of filing. *See Juno*, 10 F.4th at 1337 ("[T]he written description must lead a person of ordinary skill in the art to understand that the inventors possessed the entire scope of the claimed invention.").

Appellant argues that "[t]he specification says relatively little about anti-C5 antibodies because they are so well-known in the art and already in the possession of skilled artisans." Reh'g Req. 10. Appellant argues that "the exhibits cited in Appellant's Opening Brief, as well as Dr. Dahiyat's Declaration, confirm that much was known about anti-C5 antibodies at the time of the invention." *Id.*

We consider whether anti-C5 antibodies were sufficiently well-known in the art such that it is not necessary for the Specification to disclose them in more detail. *See Boston Sci.*, 647 F.3d at 1366.

We agree with and adopt the Board's analysis of the exhibits to the Dahiyat Declaration, in which the Board found that the examples of anti-C5 antibodies in the prior art were insufficient to establish that anti-C5 antibodies were well-known and thus did not require further written

description support in the Specification. *See* Decision 13–27. The Board found that "Dr. Dahiyat does not explain how the publications, coupled with the [disclosure] of the 5G 1.1 antibody in the Specification, convey possession of the full scope of the claimed genus." Decision 25; *see also id.* at 27 ("Appellant did not adequately explain how the cited references in the Exhibits provided to the Examiner provide a complete description of the structure of the claimed anti-C5 antibodies used to treat the patient, and the conditions treated in the patient, that is commensurate with the full scope of the claim."). Because of the large number of possible antibodies in the genus, we do not find that the genus of anti-C5 antibodies was sufficiently well-known such that additional written description support would not be required. *See Juno*, 10 F.4th at 1341; *cf. Amgen Inc. v. Sanofi*, 598 U.S. 594, 600 (2023) (although discussing enablement rather than written description, recognizing that scientists understand that "changing even one amino acid in the sequence can alter an antibody's structure and function.").

Appellant argues that "[t]he Board erroneously focused on whether the exhibits disclosed treating a patient, noting that 'many of them do not disclose treating a patient with an anti-C5 antibody with an Fc domain,'" and erroneously accorded little weight to the Dahiyat Declaration because the Board required treatment. Reh'g Req. 8 (citing Decision 13).

But, the Board explained:

> [A]lthough there is general statement of anti-C5 antibodies, there is no description of this genus that permit one of ordinary skill in the art to recognize the members of the genus which can be used to treat patients. The only detailed disclosure is of "anti-complement (C5) antibodies such as 5G1.1" Spec. ¶ 133. We cannot square the requirement in 35 U.S.C. § 112(a) that the "specification shall contain a written description of the

> Invention" with Appellant's position that the single mention of one species in the Specification coupled with a limited number of species in the prior art is a description of a genus in the "four comers of the specification" of the genus of anti-C5 antibodies. Indeed, as explained below, this view was rejected in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Circ. 2021).

Decision 23. The Board reasoned that "*Juno* is on point with the instant appeal because both involve the written description of antibodies and the specificity of an antibody for its target. The court did not find that the inventors were in possession with an antibody even limited to binding CD 19. We find that the same reasoning applied to antibodies that bind C5." Decision 24.

Further, the Board indicated, and we agree, that independent of the "treating a patient" limitation, the full scope of the genus of anti-C5 antibodies (recited in the body of the claim) is still not supported by the evidence of record. *See* Decision 18 ("More importantly, whether the list includes four antibodies used for treatment or many more than that number if the list in Table 1 is inclusive, Appellant still has not explained how this list provides a written description of the claimed broad genus of anti-C5 antibodies and treatment indications.").

For these reasons, we find that Appellant has not shown that it was in possession of "an anti-C5 antibody" at the time of filing. Thus, we conclude the term lacks adequate written description support.

b) The Specification does not provide adequate written support for "treating a patient," as broadly recited in claim 8

Appellant argues that even if the "method of treating a patient" preamble language is limiting, claim 8 still has adequate written description

support. Reh'g Req. 10–11. In Section III.A.1.c. above, we determined that a person of ordinary skill would understand "treating a patient" to mean "treating all patients and all diseases." Therefore, we must determine whether the Specification shows possession of the full breadth of the claim scope, which is a genus of treating all patients and all diseases.

As we have discussed in the preceding section, for a genus, an applicant must set forth a representative number of species or provide a structure-function relationship to allow a person of ordinary skill in the art to recognize the members of the genus. *See Juno*, 10 F.4th at 1335 (citing *Ariad*, 598 F.3d at 1349).

On the facts of this case, the claim language of "treating a patient," without specifying the type of patient and/or the type of disease to be treated, is overbroad. The Specification does not describe what patients with what diseases or conditions can be successfully treated with an anti-C5 antibody possessing the claimed Fc modifications. Nor is there a single working example describing treatment of patients with a disease or condition with an anti-C5 antibody possessing the claimed Fc modifications. At best, the Specification lists three classes of diseases/conditions that might benefit from administration of various antibodies with an Fc modification, and lists various unmodified antibodies, including an anti-C5 antibody (5G1.1), that could be modified and used to that end. Spec. ¶ 133 ("In one embodiment, the Fc polypeptides of the present invention are used for the treatment of autoimmune, inflammatory, or transplant indications.").

That limited disclosure is inadequate to demonstrate possession of a method of treating any particular disease/condition with the claimed anti-C5 antibodies, let alone all diseases/conditions within the three enumerated

classes or all diseases/conditions more generally, including those that affect non-human patients. And even if we were to credit the mention of the three enumerated classes of diseases/conditions as adequate written description, we find that the enumerated classes of diseases, which were disclosed in the only embodiment mentioning anti-C5 antibodies, are not representative of the scope of the claimed genus, i.e., all diseases, nor does the Specification provide features common to all members of the genus such that one of skill could recognize all diseases that are encompassed. *See Juno, Inc.*, 10 F.4th at 1342.

We next consider whether "treating a patient" with an anti-C5 antibody was sufficiently well-known such that it would not have to be additionally described in more detail in the Specification. We determine that the prior art does not support the full breadth of the claim limitation, i.e., treating all patients and all diseases. *See* Decision 5, 7–8, 27.[10] Further, we agree with the Board that there is an inadequate description of the claimed invention within the "four corners of the specification" to show that the inventors were in possession of the claimed invention, which is not cured by the level of skill and knowledge in the art. *See* Decision 19–24 (citing

[10] We observe that Exhibit F to the Dahiyat Declaration discloses that there had been suggestions or investigations to explore treating various diseases with eculizumab; however, almost all of these trials had been discontinued well before the time of filing and one of ordinary skill in the art would not rely on them as evidence that eculizumab treats those diseases. We also note that the Board found that other exhibits suggest that a few different anti-C5 antibodies may treat animal models of a few diseases. Decision 14–17. However, based on our review of the record, we do not find that the prior art supports the full breadth of the claim limitation, *i.e.*, treating all patients and all diseases.

Boston Sci., 647 F.3d. at 1366; *Juno*, 10 F.4th at 1337).

Appellant argues that even if the "method of treating a patient" preamble language is limiting, claim 8 still has adequate written description support. Reh'g Req. 10–11. Appellant argues that efficacy is not required. *Id.* at 11. This is essentially the same claim construction argument we have addressed above, i.e., where we conclude this claim's intentional purpose to treat a condition is limiting. *See* Section III.A.1.c. Appellant argues that the Board does not dispute that the Specification supports the claimed Fc domain substitutions (citing Decision 6), that anti-C5 antibodies were known in the art, or that the Specification describes a specific example of anti-C5 antibodies (5G1.1). *Id.* at 11–12. However, as set forth above, the Board concluded that the disclosure of a single anti-C5 antibody was not sufficient to provide written description support for the claimed genus, which was not cured by the prior art. Appellant does not argue other written description support for "treating a patient."

Accordingly, we find that Appellant has not provided adequate written description support for the full breadth of the genus of "treating a patient."

B. Written Description and Indefiniteness Rejections of Claim 9

As discussed below, we first determine that the limitation "treating a patient" in the preamble of the claim 9 is entitled to patentable weight, just as for claim 8. We also determine that the phrase "means for binding human C5 protein" is a means-plus-function limitation subject to 35 U.S.C. § 112 ¶ 6.

Under this claim construction, we find that the disclosure in the Specification of 5G1.1, which identifies two specific antibodies (murine and eculizumab) known in the prior art, is the corresponding structure for

"means for binding human C5 protein." We also conclude that it is not necessary for the Specification to describe equivalents of 5G1.1 to meet the definiteness requirement. We therefore conclude that the "means for binding human C5 protein" is adequately described under 35 U.S.C. § 112 ¶ 1 (written description) and definite under 35 U.S.C. § 112 ¶ 2.

We find, however, that the Specification does not provide adequate written description support for the full breadth of "treating a patient." We therefore maintain the Board's rejection of claim 9 under 35 U.S.C. § 112 ¶ 1 (written description) (*see* Decision 3–27).

1. Claim Construction

a) The phrase "treating a patient" in the preamble is limiting

Appellant argues that "[t]he Board should afford Claim 9's recitation of '[a] method of treating a patient' in the preamble no patentable weight." Reh'g Req. 15 n.10. Appellant argues that this language is nothing more than a statement of intended purpose and is therefore not limiting. *Id.* (citing *Bristol-Myers*, 246 F.3d at 1375). Appellant argues that the "proper scope of claim 9 thus requires only the specific 5G1.1 antibody and its equivalents having the claimed Fc modification." *Id.*

"[T]reating a patient" in the preamble of claim 9 gives life, meaning, and vitality to the body of the claim. Thus, for the reasons discussed in Section III.A.1.c. above in relation to claim 8, "treating a patient" in the preamble of claim 9 is an intended purpose of the claim that is limiting.

As in claim 8, the phrase "increased in vivo half-life" is a limitation recited in the body of claim 9. As described in more detail above for claim 8, the preamble's "treating a patient" language is necessary to give life, meaning, and vitality to both the "increased in vivo half-life" limitation

recited in the body of the claim, and also to "administering," which is the sole method step recited in the claim. As in Section III.A.1.c. above, "treating a patient" is construed as "treating all patients and all diseases."

Appellant had notice and an opportunity to respond to the Board's conclusion that "treating a patient" in claim 8 is limiting (*e.g.*, in the rehearing request from the Board's Decision), and arguments from Appellant in this regard apply equally to both claims 8 and 9. Further Appellant reiterated this argument with respect to claim 9. Reh'g Req. 15 n.10. Both claims recite the same relevant language in the preamble, as well as "said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life" in the body of the claim. *See id.* at 4–8. We addressed these arguments in our analysis above with respect to claim 8, as did the Board in its Rehearing Decision. *See* Rehearing Decision 7–8.

b) The limitation "means for binding human C5 protein" is a means-plus-function limitation

We must first resolve whether "means for binding human C5 protein" invokes 35 U.S.C. § 112 ¶ 6.

Appellant agrees that by incorporating the limitation "means for binding human C5 protein," claim 9 invokes 35 U.S.C. § 112 ¶ 6. *See* Reh'g Req. 12.

The use of the word "means" in a claim element creates a rebuttable presumption that § 112 ¶ 6 applies. *Williamson v. Citrix Online*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) (*en banc*). The standard for whether a claim phrase overcomes the presumption and avoids § 112 ¶ 6 is whether the words of the claim are understood by persons of ordinary skill in the art to

have a sufficiently definite meaning as the name for structure. *See id.* at 1349.

We determine that one cannot reasonably understand the claim phrase "means for binding human C5 protein" to have a sufficiently definite meaning as the name for structure because it merely recites the function of binding to human C5 protein. Thus, we determine that "means for binding human C5 protein" falls under § 112 ¶ 6.[11]

2. Written Description and Indefiniteness Rejections of Claim 9

a) The limitation "means for binding human C5 protein" is adequately described and definite

i. The disclosure of 5G1.1 in the Specification provides adequate structure corresponding to the "means for binding human C5 protein," thereby satisfying the written description requirement

The Board rejected claim 9 on written description grounds based in-part on the recitation of "means for binding human C5 protein." Appellant argues that the term 5G1.1 refers to both the murine and humanized version of 5G1.1 and includes eculizumab and, thus, satisfies the written description requirement. Appeal Br. 29–30; Reh'g Req. 12–15. As set forth above, sufficiency of written description is a question of fact. *See Knowles Elecs.*, 883 F.3d at 1365.

"Construing a means-plus-function claim term" subject to 35 U.S.C. § 112 ¶ 6 "is a two-step process. The [tribunal] must first identify the

[11] In the phrase "an anti-C5 antibody comprising," we understand the word "comprising" to modify "an anti-C5 antibody" such that the subsequently recited "means" and "Fc domain" are both components of the recited "anti-C5 antibody."

claimed function." *Williamson*, 792 F.3d at 1351. "Then, the [tribunal] must determine what structure, if any, disclosed in the specification corresponds to the claimed function." *Id.* As discussed above, the phrase "means for binding human C5 protein" recites the function of binding human C5 protein. Appellant agrees. Reh'g Req. 12. Thus, we determine the claimed function is "binding human C5 protein."

Appellant argues that a person of skill in the art would have understood that the latter portion of the Specification phrase "anti-complement (C5) antibodies such as 5G1.1" provides a structure clearly linked to the function of binding human C5 protein. Reh'g Req. 13. The only disclosure in the Specification of an anti-C5 antibody is 5G1.1. Spec. ¶ 133. ("Target antigens and clinical products and candidates that are relevant for such diseases include but are not limited to . . . anti-complement (C5) antibodies such as 5G1.1. . . ."). Thus, we determine that 5G1.1 is the sole structure disclosed in the Specification that performs the claimed function of binding human C5 protein.[12]

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[12] We note that claim 9 states that the anti-C5 antibody comprises a) means for binding human C5 protein; and b) an Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide. The corresponding structure, monoclonal antibody 5G1.1, has an antigen binding region and an unmodified Fc region. If the corresponding structure is the full antibody 5G1.1, then the claim would appear to recite an anti-C5 antibody with an antigen binding region and two Fc regions, where the first Fc region was unmodified (as part of 5G1.1) and the second Fc region was modified (as claimed in part b of the claim). However, such an antibody with two Fc regions is not what Appellant appears to assert its invention to be (*i.e.*, an antibody with only one modified Fc region). *See* Appeal Br. 7–8. In order for the claim to encompass an antibody with only one Fc region, the corresponding structure would be understood by a person of ordinary skill to

An applicant need not disclose a nucleotide or amino acid sequence of claimed antibodies in order to satisfy the written description requirement if such sequences are already known in the prior art. *See Juno*, 10 F.4th at 1337 (discussing scFv antibody fragments) (citing *Capon*, 418 F.3d at 1360–61). Additionally, a deposit may also meet the written description requirement instead of a description of structure. *See Goeddel v. Sugano*, 617 F.3d 1350, 1356 (Fed. Cir. 2010) ("[D]epositing an actual sample may meet the written description requirement when science is not capable of a complete written description."); *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 965 (Fed. Cir. 2002) ("[R]eference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112, ¶ 1."). As further discussed below, we find that a person of ordinary skill in the art would have known the structure of 5G1.1 based on the teachings in the prior art, and thus the "means for binding human C5 protein" is adequately described in the Specification.

ii. A person of ordinary skill in the art would understand the meaning of 5G1.1 and thus the limitation "means for binding human C5 protein" is definite

Appellant argues that the term 5G1.1 is definite because the literature refers to both the murine and humanized version of 5G1.1 and includes eculizumab. Appeal Br. 29–30; Reh'g Req. 12–15. Definiteness is a question of law. *Niazi Licensing Corp. v. St. Jude Medical S.C., Inc.*, 30

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be a fragment of 5G1.1 which contains the antigen binding region. *See* Spec. ¶¶ 82–86 (antibody can refer, *inter alia*, to the F(ab')2 fragments).

F.4th 1339, 1346–47 (Fed. Cir. 2022). A claim is indefinite when it contains words or phrases whose meaning is unclear. *See In re Packard*, 751 F.3d 1307, 1310, 1314 (Fed. Cir. 2014).

The record indicates that the term 5G1.1 was originally understood to refer to a particular mouse monoclonal antibody, which was produced from a deposited hybridoma. *See* Casadevall Decl. ¶¶ 72, 214–215 (citing Evans); Evans (US 6,355,245 B1, issued Mar. 12, 2002), 39:24–28, 144:19–20. Evans also disclosed the sequence of the variable heavy chain and variable light chain of the 5G1.1 mouse antibody. *See* Casadevall Decl. ¶¶ 214–215 (citing Evans Figs. 18 & 19).

Further, based on the prior art of record, the term 5G1.1 was also used to refer to eculizumab, a humanized antibody developed by Alexion, which was also known in the prior art. *See* Dahiyat Decl. Ex. F. Eculizumab was called 5G1.1 in prior art describing various clinical trials. *See id.* Ex. F & Table II. The sequence of eculizumab was known. *See, e.g.*, Application for Extension of Patent Term Under 35 U.S.C. §156 and 37 C.F.R. §1.740, Ex. K, Application No. 08/487,283 (Evans) (May 11, 2007). Accordingly, we determine, based on the evidence before us, that a person of ordinary skill in the art would have understood "5G1.1" to refer to two related antibodies: the original mouse monoclonal antibody and eculizumab, a humanized version of the mouse antibody.[13]

We accordingly find the term "means for binding human C5 protein" definite and withdraw the Board's rejection for claim 9 on indefiniteness grounds.

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[13] Neither Appellant nor the Examiner has pointed us to prior art of record that would indicate that 5G1.1 was used to refer to other antibodies.

iii. The Disclosure of Equivalents is Not Necessary to Satisfy the Written Description and Indefiniteness Requirements for a Means-Plus-Function Claim Term

The Board, in part, based its written description and indefiniteness rejections on the fact that the Specification did not describe equivalents of 5G1.1. We disagree with the Board that the Specification must disclose or describe the equivalents of the corresponding structure, in this case 5G1.1, for a means-plus-function claim limitation under 35 U.S.C. § 112 ¶ 6, in order to meet the requirements of § 112 ¶ 1 (written description) and ¶ 2 (definiteness).[14]

We start with the language of the statute. The first paragraph of 35 U.S.C. § 112 provides: "[t]he specification shall contain a written description of the invention." 35 U.S.C. § 112 ¶ 1 (2006). The invention in § 112 ¶ 1 is generally understood to be the claimed invention. *See In re Moore*, 439 F.2d 1232, 1235 (CCPA 1971) ("[W]hen the first paragraph speaks of 'the invention', it can only be referring to that invention which the applicant wishes to have protected by the patent grant, i.e., the claimed invention."). The second paragraph of § 112 requires that claims "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112 ¶ 2 (2006).

Under 35 U.S.C. § 112 ¶ 6, the claim covers structures described in the Specification and equivalents thereof:

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[14] The Board stated that "[e]quivalence under section 112(f) cannot be determined for claim 9 because there is no disclosed structure to make that determination." Rehearing Decision at 13–15. The Board stated that: "The 'equivalents thereof' broadens any structure disclosed in a specification to a group or genus of structures." *Id.* at 13.

> An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Id. The statute clearly distinguishes between what must be "*described* in the specification" and "equivalents." *Id.* (emphasis added).

By the terms of § 112 ¶ 6, what must be "described in the specification" is "the corresponding structure, material, or acts" for the "means . . . for performing a specified function." Based on our reading of § 112 ¶ 6, in conjunction with § 112 ¶ 2, we understand that a Specification must provide a corresponding structure for a recited mean-plus-function claim limitation or else the claim is indefinite under § 112 ¶ 2. *See Aristocrat Techs. Australia Pty Ltd. v. Int'l Game Tech.*, 521 F.3d 1328, 1331 (Fed. Cir. 2008) (citing *In re Donaldson*, 16 F.3d 1189, 1195 (Fed. Cir. 1994) (*en banc*)); *Atmel Corp. v. Information Storage Devices*, Inc., 198 F.3d 1374, 1382 (Fed. Cir. 1999).

It is true that § 112 ¶ 6 provides that a means-plus-function element "shall be construed to cover the corresponding structure, material, or act described in the specification ***and equivalents thereof***." *Id.* (emphasis added). That is, the claim is interpreted to cover both the corresponding structure, material, or act described in the Specification, as well as equivalents of that structure, material, or act. Notably, § 112 ¶ 6 does not state that the Specification must also *describe* equivalents of that structure. If Congress had intended the statute to require a description of equivalents, it could have placed "and equivalents thereof" before "described in the specification," which it did not do.

The Supreme Court's interpretation of § 112, ¶ 6 is similarly in accordance with the plain language of the statute. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 28 (1997) ("Section 112, ¶ 6, now expressly allows so-called 'means' claims, with the proviso that application of the broad literal language of such claims must be limited to only those means that are 'equivalen[t]' to the actual means shown in the patent specification."). The Federal Circuit's discussion of § 112 ¶ 6 also supports reading "equivalents" to cover structures, materials or acts beyond what is explicitly described in the Specification. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1347 (Fed. Cir. 2001) ("Drafters of means-plus-function claim limitations are statutorily guaranteed a range of equivalents extending beyond that which is explicitly disclosed in the patent document itself."); *D.M.I., Inc. v. Deere & Co.*, 755 F.2d 1570, 1574 (Fed. Cir. 1985) ("The statute, § 112–6, was written precisely to avoid a holding that a means-plus-function limitation must be read as covering only the means disclosed in the specification.").

Accordingly, we hold that it is not necessary for the Specification here to describe equivalents of 5G1.1 to meet the definiteness or written description requirements.

b) The Specification does not provide adequate written description for the limitation "treating a patient" in claim 9

Both claims 8 and 9 include the same "method of treating a patient by administering" language in their preambles, and the same "wherein said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life as compared to said antibody without said substitutions" limitation in the claim body. Accordingly, we uphold the Board's written description

rejection of claim 9 based on the rationale we provided above as to claim 8. As the preamble claim language is the same, our rationale for concluding it is limiting is the same, and our reasoning for finding it is not adequately described in the Specification is the same as for claim 8. *See supra* Section III.B.1.a. The Specification does not provide adequate disclosure to support treating any and all human and non-human patients having any and all diseases with 5G1.1.

We note that claim 9 is narrower than claim 8 because the "means for binding human C5 protein" in claim 9 limits the claim to 5G1.1, *i.e.*, the original mouse monoclonal antibody and eculizumab, and equivalents thereof, as discussed above, rather than encompassing all anti-C5 antibodies. Regardless, Appellant's arguments (*see* Reh'g Req. 4–8, 10–11) and the Board's reasoning in relation to claim 8 applies with equal force to claim 9, *i.e.*, the Specification does not describe treating any disease or condition with an anti-C5 antibody, and merely mentions three general classes of diseases/conditions as possible avenues to pursue, and the prior art does not establish that "treating a patient" (*i.e.*, treating all patients and all diseases) was sufficiently well-known in the art for the purposes of meeting the written description requirement. Whether the recited antibody in question is any anti-C5 antibody or 5G1.1 and equivalents thereof, per claim 8 or claim 9, respectively, the Specification fails to provide adequate written description to support a "method of treating a patient" with the recited antibody.

Appellant had notice and an opportunity to respond to the Board's conclusion that "treating a patient" in claim 8 is limiting (*e.g.*, in the rehearing request from the Board's Decision) and lacks written description

support, and arguments from Appellant in this regard apply equally to both claim 8 and 9. *See* Reh'g Req. 4–8, 10–11, 15 n.10. Both claims recite the same relevant language in the preamble, as well as "said anti-C5 antibody with said amino acid substitutions has increased in vivo half-life" in the body of the claim. We addressed Appellant's arguments in our analysis above, as did the Board in its Rehearing Decision. *See* Rehearing Decision 7–8.

Because Appellant had an opportunity to address this issue, we do not designate this as a new ground of rejection. Thus, Appellant has the right to immediate appeal as to this issue. To the extent Appellant disagrees, it may file a request for rehearing to request designation of this rejection of claim 9 as a new ground of rejection pursuant 37 C.F.R. § 41.50(c), explaining why it did not have an adequate opportunity to address this rejection.

C. Obviousness-Type Double Patenting Rejection of Claims 8 and 9

The Examiner relies on claims 1–5 of the '818 patent to disclose the Fc mutations M428L/N434S. *See* Final Act. 18. The Examiner relies on Schwaeble to disclose the use of complement inhibitors including anti-C5 antibodies and "consideration of half-life." *See id.* The Examiner determines that the combination of the claims of the '818 patent and the teachings of Schwaeble "would have made it obvious to the ordinary artisan to incorporate the Fc mutations M428L/N434S to increase the half-life of therapeutic anti-C5 in methods of treating." *See id.*

Appellant argues that the Examiner failed to adequately provide support for the assertion that a person of skill in the art would have been motivated to make such a combination, let alone that such a combination would have had a reasonable expectation of success. *See* Reh'g Req. 15.

We agree. The paragraphs of Schwaeble relied upon by the Examiner for considerations of half-life do not disclose Fc mutations M428L/N434S as a way to increase half-life. The cited paragraphs of Schwaeble disclose, *inter alia*, using peptide inhibitors, flanking sequences of RNA or DNA, or polymers such as polyethylene glycol, *see* Schwaeble ¶¶ 298, 331, 382, but do not disclose using the recited mutations as a way to increase half-life.

We, therefore, reverse the Examiner's rejection of claims 8 and 9 for obviousness-type double patenting for at least these reasons.

IV. CONCLUSION

In sum, we maintain the Board's written description rejections of claims 8 and 9; we do not maintain the Board's indefiniteness rejection of claim 9; we reverse the Examiner's non-statutory obviousness-type double patenting rejection of claims 8 and 9 over claims 1–5 of the '818 patent and Schwaeble; and we reverse the Examiner's obviousness-type double patenting rejection of claims 8 and 9 over claim 1 of the '543 patent and Schwaeble.[15, 16]

TIME PERIOD FOR RESPONSE

[15] This last ground of rejection was previously reversed by the Board, and we do not disturb that conclusion.

[16] In the event of further prosecution of this application (including any review for allowance), the Examiner may wish to consider whether there is adequate written description and enabling disclosure under 35 U.S.C. § 112 ¶ 1 for "an increased *in-vivo* half-life," as recited in both claims 8 and 9 (emphasis added). Also, for claim 8, the Examiner may wish to consider whether the genus of "an anti-C5 antibody" is adequately enabled.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).