No. 2023-2048

In the United States Court of Appeals
For the Federal Circuit

In re: XENCOR, INC.,
Appellant

On Appeal from the Patent Trial and Appeal Board
PTAB Appeal No. 2022-001944

BRIEF OF APPELLANT

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CLAIMS AT ISSUE

This appeal involves two claims. Claim 8 is written in the Jepson format:

> 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.

Claim 9 is a method claim that includes a means-plus-function limitation:

> 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 Fe 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.

CERTIFICATE OF INTEREST

Case Numbers	2023-2048
Short Case Caption	*In re: Xencor, Inc.*
Filing Party/Entity	Appellant Xencor, Inc.

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

/s/ William R. Peterson
William R. Peterson
Counsel for Appellant,
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Dated: September 29, 2023

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Xencor, Inc.		BlackRock, Inc.; PRIMECAP Management Company; T. Rowe Price Group, Inc.; The Vanguard Group, Inc.

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☑ None/Not Applicable

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes ☑ No ☐ N/A (amicus/movant)

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable

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STATEMENT OF RELATED CASES

No other appeal from this proceeding has previously been before this or any other appellate court. Undersigned counsel is unaware of any case that will directly affect or be directly affected by this Court's decision in this case.

STATEMENT OF JURISDICTION

This Court has jurisdiction over this appeal from a decision from the Patent Trial and Appeal Board. 28 U.S.C. § 1295(a)(4)(A). The Board denied rehearing on June 1, 2023, and Xencor filed a timely notice of appeal on June 14, 2023. Appx1581-1582.

STATEMENT OF THE ISSUES

Issues Regarding Claim 9

The Board rejected Claim 9, a method claim that includes a means-plus-function limitation, for indefiniteness and lack of written description.

1. Whether, as the Board previously acknowledged and extensive evidence shows, the specification's reference to "5G1.1" discloses specific structure to skilled artisans to make the means-plus-function limitation definite.

2. Whether, for a means-plus-function limitation, a patentee must satisfy written description for all "equivalents" of a claimed structure.

Issue Regarding Claim 8

The Board rejected Claim 8, a Jepson claim, for lack of written description.

3. Whether, for a patent claiming an improvement using a Jepson format, a patentee must satisfy the written description requirement only for the claimed improvement or must also satisfy the written description requirement for the conventional elements to which the improvement is applied.

Issue Regarding Both Claims

4. Whether the Board erred by rejecting Claim 8 and Claim 9 for obviousness-type double patenting, despite the Examiner's failure to present a prima facie case of unpatentability and the absence of a motivation to combine and of an expectation of success.

INTRODUCTION

This Court is familiar with ongoing developments in the law regarding functionally claimed antibodies. *E.g.*, *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023) (holding that claims covering a functionally defined genus of antibodies were not enabled); *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330, 1338-39 (Fed. Cir. 2021) (holding that claims covering a genus of scFvs (antibody fragments) defined using functional language did not satisfy written description).

The Board erroneously overread this precedent in the decision below, effectively treating it as prohibiting any claim involving antibodies. In rejecting the proposed claims at issue, the Board misapplied both the indefiniteness standard for means-plus-function claims and the law of written description.

Appellant Xencor, Inc. did not invent new antibodies and does not seek to claim a functionally defined genus of antibodies. Xencor instead invented a structural modification that improves certain antibodies. This structural modification is two specific amino acid substitutions made to the Fc domain of an anti-C5[1] antibody, which increase its in vivo half-life. Xencor did not invent and does not claim the entire genus of antibodies that bind C5. Xencor seeks only to claim treatments using anti-C5 antibodies with its improvement.

[1] By "C5," we refer to the human C5. Claim 9 expressly requires a "means for binding human C5 protein." And Claim 8 involves "a method of treating a patient," which skilled artisans would understand requires binding human C5 protein.

In its patent application, Xencor claims that improvement to an anti-C5 antibody in two ways. First, in Claim 9, Xencor claims a method for treating a patient with a means-plus-function limitation. In this claim, the "means for binding human C5 protein" is limited to the structures disclosed in the specification. The specification's reference to "5G1.1" discloses at least one structure well known to skilled artisans.

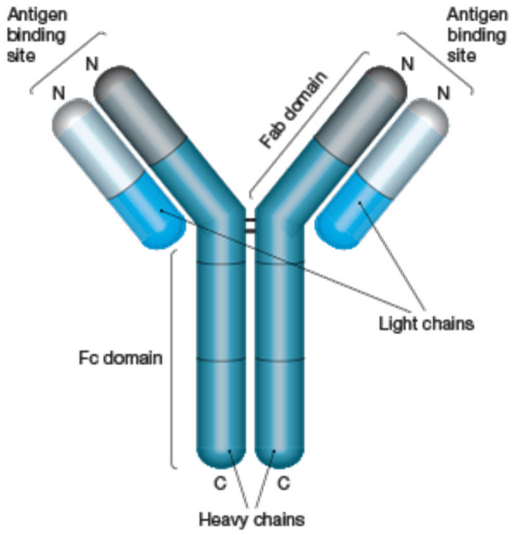
Second, in Claim 8, Xencor claims the improvement itself (when applied to methods of treating a patient using an anti-C5 antibody) in the form of a Jepson claim, acknowledging that anti-C5 antibodies are conventional and claiming its improvement to these well-known antibodies. Xencor claims a specific structural improvement, which the specification confirms the inventors possessed.

The Board erred by conflating these claims, which concern the improvement invented by Xencor, with the claims to anti-C5 antibodies generally. And as a result, the Board erroneously held that they failed to satisfy written description.

This appeal presents this Court with the opportunity to clarify that restrictions on claiming a functionally defined genus of antibodies do not bar all antibody claims, much less claims to the specific structural improvement invented by Xencor.

STATEMENT OF THE CASE

Antibodies are proteins that bind a specific target, called an "antigen." Appx93; Appx104. Many antibodies occur naturally, while others have been engineered for therapeutic uses. Appx96. An example is illustrated below:



Appx817. The "variable region" of an antibody is responsible for binding the target antigen, *id.*, and the "constant region" provides a structural framework. One portion of the constant region, at issue here, is called the "Fc domain."

One set of therapeutically useful antibodies bind the C5 complement[2] molecule. Appx1127. These "anti-C5" antibodies have an anti-inflammatory effect, Appx1135, and may help treat conditions such as rheumatoid arthritis, Appx1128;

[2] The "complement system" is a diverse group of serum proteins which interact to eliminate cellular and viral pathogens. Appx1138. Several diseases, such as autoimmune diseases, involve the complement system attacking the body's own cells. As a result, "inhibition of the complement cascade at C5 or later may provide clinical benefit." Appx1139.

rejection of inter-species organ transplants, Appx1153, Appx1158; and autoimmune disorders, Appx1187; *see also* Appx1138 ("[A] monoclonal antibody (N19-8) that recognizes the human complement protein C5 has been shown to effectively block the cleavage of C5 into C5a and C5b, thereby blocking terminal complement activation.").

Xencor is a pioneering drug development company, which has developed a pipeline of proprietary antibody drug candidates. Appx613. Xencor did not invent anti-C5 antibodies or discover their use in medical treatment. This appeal instead concerns a modification invented by Xencor scientists that applies to the Fc domain of anti-C5 antibodies.

Modern antibody engineering techniques allow scientists to modify antibodies, substituting, deleting, or replacing particular amino acids in an antibody's amino acid sequence. Appx100.

Xencor discovered that making particular substitutions[3] to the amino acids in the Fc domain of an anti-C5 antibody improves the "in vivo half-life," allowing these

[3] The claimed modification is "M428L/N434S," which skilled artisans would understand to describe a specific modification to an antibody's amino acid sequence: "M428L/N434S defines an Fc variant with the substitutions M428L and N434S." Appx453. Skilled artisans understand that "M248L" means that amino acid "M" (i.e., "Methionine") normally found at position 428 (according to the EU index of Kabat) is replaced with amino acid "L" (i.e., "Leucine"). *Id.*; *see also* Appx1040 (amino acid abbreviations). "N434S" involves a similar replacement of amino acid N at position 434 with amino acid S. This phrase thus conveys a specific, structural change to antibodies.

antibodies to last longer in the human body. Antibodies "involved in the treatment of autoimmune diseases" often "require multiple injunctions over long time periods," Appx472, and the "longer serum half-lives" enabled by the invention mean that patients require "less frequent treatments." *Id.*

The invention is undeniably valuable. The inventors' work has already been applied—after the critical date—to the drug eculizumab, an anti-C5 antibody marketed under the name Soliris®, to create the new antibody ravulizumab, now marketed under the name Ultomiris®. Appx156. The claimed amino acid substitutions to the antibody's Fc domain significantly improved its half-life, Appx156, and the developers of ravulizumab cited the work of the Xencor inventors as the impetus for these changes. Appx157.

The Examiner Rejects Xencor's Claims Based on a Lack of Written Description and Obviousness-Type Double Patenting

Xencor filed the application at issue—U.S. Patent Application No. 16/803,690—as a continuation of several earlier applications and claims a priority date of February 25, 2008. Appx277. Following an initial rejection, Appx314, the claims were amended to their present form in August 2020. Appx369.

The application claims a method of treating patients with the improved anti-C5 antibody in two ways. Appx370. First, Claim 8 recites the claim in a Jepson improvement format. It acknowledges that the "method of treating a patient by administering an anti-C5 antibody with an Fc domain" is well-known but recognizes

that the invention is an "improvement" to this method through "amino acid substitutions M428L/N434S as compared to a human Fc polypeptide" that causes the anti-C5 antibody to have "increased in vivo half-life."

As a Jepson claim, Xencor explained, the proper "written description inquiry is whether one of skill in the art would recognize that Applicants had possession of the claimed **improvement**," namely "incorporation of the Fc domain variants into conventional antibodies." Appx372. Xencor is "not claiming a 'genus of anti-C5 antibodies.'" *Id.* "[T]he anti-C5 antibody . . . is conventional," and Xencor claims "the improvement of incorporating two particular amino acid substitutions into the Fc domain of a conventional anti-C5 antibody." Appx373.

Second, Claim 9 recites a method of treatment with a means-plus-function limitation: "an anti-C5 antibody" comprising a "means for binding human C5 protein" and an Fc domain with "amino acid substitutions M428L/N434S."

Xencor explained that the phrase "5G1.1" in the specification disclosed a corresponding structure to skilled artisans. Appx378. Although "the sequence of 5G1.1 is not recited in the specification," the nomenclature "indicate[s] to one skilled in the art the precise structure of the means for performing the recited function." Appx379.

Following repeated communications with the Examiner, the claims were finally rejected in March 2021. Appx784. Both Claims 8 and 9 were rejected for

failing to comply with the written description requirement. Appx786. Regarding Claim 9, the Examiner appeared to acknowledge that the corresponding structure was "named antibody 5G1.1," Appx792, but appeared to conclude that "5G1.1" "does not teach specific structure." *Id*.

The claims were also rejected for obviousness-type double patenting over certain claims of U.S. Patent No. 10,336,818 and U.S. Patent No. 8,546,543. Appx801. The Examiner's explanation was terse and conclusory:

> The combination of the patented claims 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.
>
> Given the applicability of anti-C5 antibodies to inhibit the activation of the complement in methods of treatment, it would have been 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.
>
> Therefore, the claims are obvious of one another.

Appx802.

Xencor Appeals to the Patent Trial and Appeal Board

Xencor appealed the Final Rejection to the Patent Trial and Appeal Board. Appx808. Xencor explained that the Examiner erred by "appl[ying] a traditional written description analysis to Claim 8," not recognizing that because of the Jepson format, "it is the improvement, not the prior art of the preamble, which must meet the written description requirement." Appx820. According to Xencor, anti-C5 antibodies were well-known in the art, Appx829, and the improvement—"the

improved Fc domain with the M428L/N434S" substitution—satisfied written description. Appx830.

For Claim 9, Xencor explained that the specification's reference to 5G1.1 (which it identifies as an anti-complement (C5) antibody) "sufficiently identifies at least one specific structure for binding human C5 protein." Appx836. An affidavit submitted by Xencor confirmed that "5G1.1 refers to specific antibodies that bind the human C5 protein, including eculizumab." Appx837.

Finally, Xencor explained that the Examiner erred in rejecting both Claims 8 and 9 under the judicially created doctrine of obviousness-type double patenting by finding them unpatentable over Claims 1 through 5 of U.S. Patent No. 10,336,818 (the "'818 Patent"), Appx860-955, in view of U.S. Patent Application Publication No. 2006/0018896 ("Schwaeble"), Appx1017-1115. The Examiner failed to present a prima facie case of obviousness because his analysis was conclusory, and given Schwaeble's focus on a different antibody, MAp19, he failed to show a motivation to combine the references with a reasonable expectation of success. Appx847-853.[4]

The Examiner Withdraws the Written Description Rejections

In response, the Examiner recognized the persuasiveness of Xencor's arguments and withdrew the written description rejections:

[4] Xencor also responded to the obviousness-type double patenting rejection over U.S. Patent No. 8,546,543 and Schwaeble. Appx853.

> Upon reconsideration of applicant's arguments, Exhibits and 132 Declarations, filed the previous rejection under 35 U.S.C. 112(a) or 35 U.S.C. 112 (pre-AIA), first paragraph, written description, has been withdrawn.

Appx1453.

But the Examiner maintained the double-patenting rejections, copying nearly word-for-word the same conclusory statement regarding the rejection. Appx1454. In responding to Xencor's point that Schwaeble is directed to anti-MAp19 inhibitory agents rather than anti-C5 antibodies, the Examiner maintained that the reference still reasonably suggests using anti-C5 antibodies because Schwaeble cites to them. Appx1455.

The Board Overlooks the Examiner's Withdrawal

The Board initially issued a decision in December 2022. Inexplicably, this decision failed to recognize that the Examiner had withdrawn the written description rejections. *See* Appx1526 ("The Examiner rejected claims 8 and 9 under 35 U.S.C. § 112(a) as lacking a written description . . . ."). Apparently recognizing its error, it sua sponte vacated the decision. Appx1562-1563.

In January 2023, the Board reissued its decision on appeal. Appx1. Although the result was unchanged, the revised decision describes written description as a new ground of rejection. Appx2. The Board also added an indefiniteness rejection of Claim 9. Appx1-2.

The Board acknowledged that Claim 8 is a "Jepson claim in which the preamble is statement [sic] of the prior art (treating a patient with the antibody) and the body of the claim recites the improvement (the mutated Fc region) to the admitted prior art method." Appx5. But the Jepson format, the Board explained, "does not change [its] analysis" of written description. Appx25. Even though Xencor claimed only the improvement, the Board stated that the "entirety of the claim" must be described for written description. Appx27.

For the means-plus-function limitation of Claim 9, the Board correctly identified the function of the recited means as "binding the human C5 protein." Appx29. Earlier in the opinion, the Board had recognized that "5G1.1" disclosed "a specific antibody that binds to human C5":

> The only specific antibody disclosed in the Specification is "5G1.1." 5G1.1 was known in the prior art before the effective filing date of the application . . . . Based on our review of the publications describing 5G1.1 and the testimony by Dr. Bassil Dahiyat, we consider the term "5G1.1" disclosed in the Specification to be a specific antibody that binds to human C5 and includes the monoclonal antibody and humanized versions.

Appx7 (internal citations omitted). When analyzing Claim 9, however, the Board stated that the corresponding structure "is not restricted by the Specification to this specific antibody species [5G1.1]." Appx29. As a result, the Board thought it irrelevant whether the "antibody structure of the 5G1.1 antibody" was sufficiently disclosed. Appx29.

Because "the Specification does not disclose sufficient structure corresponding to the claimed function," the Board rejected claim 9 as "lack[ing] adequate written description" and as "indefinite." Appx30.

Finally, regarding obviousness-type double patenting, the Board rejected Xencor's arguments relating to the '818 Patent.[5] The Board found the Examiner's prima facie case of obviousness sufficient. Appx33. The Board also held that because Schwaeble refers to anti-C5 antibodies in describing the prior art and the '818 Patent claims recite the claimed mutated Fc domain, Claims 8 and 9 were rendered obvious. Appx32-33.

Xencor Seeks Rehearing and the Board Changes Some of the Reasoning Behind Its Rejections

Xencor sought rehearing before the Board. Appx1564. For Claim 8, Xencor explained that patents must provide a written description of the invention: "The 'invention' here is the claimed Fc domain substitutions, and the Board did not dispute the specification supports this invention. That should have ended the inquiry." Appx1571-1572 (internal citations omitted). "The inventors did not invent

[5] The Examiner separately rejected Claims 8 and 9 in view of obviousness-type double patenting based on U.S. Patent No. 8,546,543 and Schwaeble. The Board reversed the Examiner on that point, agreeing with Xencor "that there would be no reason to modify the claim of the '543 patent with Schwaeble to make the claimed anti-C5 antibody comprising the mutated Fc region." Appx34.

anti-C5 antibodies (which are well-known) but merely invented the improvement of their half-life through amino acid substitutions." Appx1574.

For Claim 9, Xencor explained that the Board erred by failing to identify "the 5G1.1 antibody as the structure performing the claimed function." Appx1577; *see also id.* (the specification "does provide a structure clearly linked to the function recited in the claim because 5G1.1 is a specific antibody that binds human C5 protein"). The Board erred by finding it indefinite and unsupported by written description.

Regarding the remaining obviousness-type double patenting rejection for both claims, Xencor reiterated that the Examiner's conclusory analysis fails to show motivation to combine and a reasonable expectation of success. Appx1579.

The Board denied rehearing. Appx39. In its analysis of Claim 8, the Board hypothesized that a non-limiting claim preamble might still be subject to the written description requirement:

> In each of these cases, the determination of whether the claim preamble was 'limiting' was for the purpose of ascertaining whether the preamble limits the scope of the claim in the context of prior art. In contrast, the issue in this appeal is whether it is necessary to consider the claim preamble when determining compliance with the written description requirement of section 112(a). The two questions are different.
>
> The determination that a claim preamble does not limit the scope of the claim for prior art purposes does not mean the preamble can be ignored when ascertaining whether the claim complies with the written description requirement.

Appx42; *see also* Appx43 ("[W]here the inventors regard their invention as 'a method of treating a patient by administering an anti-C5 antibody with an Fc domain,' they have the statutory burden under the written description requirement of section 112(a) to describe such a method, including the treating aspect of the claim recited in the claim preamble.").

In analyzing Claim 9 on rehearing, the Board correctly identified "5G1.1" as the corresponding structure. Appx52. But in contrast to its previous findings, Appx7, and the Examiner's findings, the Board stated without explanation that Xencor "has not established that the structure of the 5G1.1 antibody was known at the time the application was filed." Appx52; *see also* Appx53 ("[W]e discern no error in the rejection of claim 9 as indefinite[.]").

For purposes of written description, the Board treated Claim 9 as covering "a chemical genus" because under Section 112(f), a means-plus-function claim "cover[s] the binding structure disclosed in the Specification 'and equivalents thereof.'" Appx51. The Board stated that the "equivalents thereof" language means that any means-plus-function claims "broadens any structure disclosed in a specification to a group or genus of structures." Appx51. As a result, the Board reasoned, even if the disclosed corresponding structure is a specific antibody, Xencor still had to satisfy this Court's written description requirement for a genus of functionally defined antibodies. *See* Appx51 (citing *Ariad Pharms., Inc. v. Eli*

Lilly & Co., 598 F.3d 1336, 1354 (Fed. Cir. 2010) (en banc)). The Board thus renewed the written description rejection of Claim 9.

For obviousness-type double patenting, the Board provided no further analysis, instead noting it addressed Xencor's arguments in its initial decision. Appx53-54.

This appeal followed. Appx1581-1582.

SUMMARY OF THE ARGUMENT

Although this appeal presents two issues regarding written description, each requires a separate analysis from this Court.

One issue concerns Claim 9 and involves the Board's failure to apply well-established principles regarding means-plus-function claims. The error is both obvious and straightforward.

The Specification discloses "5G1.1" as a structure corresponding to the function "means for binding human C5 protein." As the Board previously recognized, 5G1.1 teaches a "specific antibody" that "was known in the prior art before the effective filing date of the application." Appx7. Xencor cited extensive evidence that its structure—its amino acid sequence—was known to skilled artisans. The means-plus-function limitation thus satisfies the requirements of pre-AIA Section 112, paragraph 6, and the Board erred in rejecting Claim 9 as indefinite.

The Board also erred in rejecting Claim 9 for lack of written description. The truism that means-plus-function claims include structural equivalents does not transform Xencor's claim to disclosed structure into a genus claim. The Board's treatment of Claim 9 as an antibody genus claim and corresponding rejection of Claim 9 for lack of written description is both illogical and unprecedented. This Court should reject the Board's misapplication of well-established precedent regarding means-plus-function limitations and hold Claim 9 patentable.

In contrast, the written description issue regarding Claim 8 requires this Court to break new ground. It presents a novel issue regarding the interaction of the written description requirement and the Jepson claim format. Xencor did not invent anti-C5 antibodies or the method of treating a patient using anti-C5 antibodies. And Xencor acknowledges that it did not possess the entire genus of anti-C5 antibodies and did not provide a written description for this entire genus.

As the Jepson format indicates, Xencor invented and claimed a specific improvement to treating patients using an anti-C5 antibody, an improvement that constitutes specific amino acid substitutions to the antibody's Fc domain that improve its in vivo half-life. For this improvement, Xencor linked a specific structural change to a specific functional benefit. Xencor unquestionably possessed the full scope of the improvement and provided an adequate written description.

Nothing more should be required. No policy is served by requiring Xencor to show possession of the entire genus of anti-C5 antibodies, a genus over which it does not claim a patent monopoly. Xencor invented an improvement that can be used with any species in this genus, and it should be entitled to claim that improvement. This Court should reverse the written description rejection of Claim 8.

Finally, the Board improperly affirmed the Examiner's rejection of both Claims 8 and 9 under obviousness-type double patenting as unpatentable over Claims 1 through 5 of the '818 Patent in view of Schwaeble. But the Examiner's

rejection is procedurally and substantively deficient. It is conclusory, and substantial evidence does not support either finding a motivation to combine the claims of the ’818 Patent (which are directed to the Fc variant with no disclosure of the increased in vivo half-life requirement or suggestion of its use with an anti-C5 antibody) with Schwaeble (which is directed to a different antibody and mentions anti-C5 antibodies in describing the prior art) or finding a reasonable expectation of success in doing so to achieve the claimed invention.

STANDARD OF REVIEW

This Court reviews the Board's legal determinations de novo and its factual findings for substantial evidence. *E.g.*, *In re Couvaras*, 70 F.4th 1374, 1378 (Fed. Cir. 2023). "A finding is supported by substantial evidence if a reasonable mind might accept the evidence as adequate to support the finding." *Id.*

ARGUMENT

I. The Board Erred in Concluding that the Means-Plus-Function Limitation of Claim 9 Lacks Corresponding Structure and Written Description.

Claim 9 is directed to a method of treatment with a means-plus-function[6] limitation: a "means for binding human C5 protein." Appx28; Appx39; Appx51-52. Analyzing a means-plus-function limitation involves "first identify[ing] the claimed function" and then "determin[ing] what structure, if any, disclosed in the specification performs that function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351 (Fed. Cir. 2015) (en banc). "If the patentee fails to disclose adequate corresponding structure, the claim is indefinite." *Id.* at 1352.

Here, the claimed function is "binding human C5 protein." Appx28-29; Appx52. The only indefiniteness dispute is whether the specification adequately discloses a corresponding structure that performs that function.

On rehearing, the Board correctly recognized that skilled artisans would identify "5G1.1" as the corresponding structure. Appx52. But inexplicably, the Board abandoned its earlier finding that skilled artisans would understand "5G1.1" to teach a known structure, Appx7, and ignored the extensive evidence. This was error.

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[6] Because this is a pre-AIA application, paragraph 6 of pre-AIA Section 112 applies, not the AIA version of Section 112(f); Xencor is aware of no substantive difference between how claims are analyzed under the two statutes for these issues.

A. As the Board Acknowledged, a Skilled Artisan Would Identify "5G1.1" as a Corresponding Structure.

A structure is "corresponding structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim." *Sony Corp. v. Iancu*, 924 F.3d 1235, 1239 (Fed. Cir. 2019). The question is whether skilled artisans "would understand the written description itself to disclose such a structure" to perform the claimed function. *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

The specification recites "anti-complement (C5) antibodies such as 5G1.1" as performing the claimed function. Appx123. The phrase "anti-complement (C5) antibodies" refers generally to antibodies with the function of binding human C5 protein. Xencor acknowledges that this phrase alone does not disclose any particular structure.

In its initial decision, the Board erroneously identified the entire genus of "anti-complement (C5) antibodies" as a corresponding structure: "The term 'anti-complement (C5) antibodies' is generic. . . . Even were the antibody structure of the 5G1.1 antibody sufficient, the claimed 'means for' is not restricted by the Specification to this specific antibody species." Appx29. Not so. A means-plus-function claim is limited to structures disclosed in the specification, and the phrase "anti-complement (C5) antibodies" discloses nothing about structure. It is not a "corresponding structure" for purposes of a means-plus-function claim.

Xencor explained this error on rehearing, and the Board agreed. 5G1.1 is an "example disclosed in the Specification of the claimed 'means for binding human C5 protein,'" and "only one structure is required to meet the statutory requirement." Appx52. The only remaining dispute is whether "5G1.1" discloses a structure to skilled artisans or whether the term is indefinite.

B. Skilled Artisans Would Recognize "5G1.1" as Disclosing Specific Structure.

The Board erred in finding on rehearing that Xencor "has not established that the structure of the 5G1.1 antibody was known at the time the application was filed." Appx52.

"It is well-established that a patent specification need not re-describe known prior art concepts." *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049, 1064 (Fed. Cir. 2020); *see also Capon v. Eshhar*, 418 F.3d 1349, 1358 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge."). For example, where the structure of a "selector" was "well known in th[e] art," the specification did not need to describe "the electronic structure of the selector and the details of its electronic operation" to satisfy Section 112, paragraph 6. *S3 Inc. v. NVIDIA Corp.*, 259 F.3d 1364, 1370 (Fed. Cir. 2001); *see also id.* at 1371 ("It is not the criterion for compliance with § 112 [paragraph 6], whether a lay person having no skill whatsoever in this field would know how a selector is constructed.").

Although "[t]here must be structure in the specification, . . . the knowledge of one skilled in the particular art may be used to understand what structure(s) the specification discloses." *Atmel Corp. v. Info. Storage Devices, Inc.*, 198 F.3d 1374, 1382 (Fed. Cir. 1999); *see also id.* (noting testimony that an article's "title alone was sufficient to indicate to one skilled in the art the precise structure of the means recited in the specification"). This Court has specifically rejected the "forced recitation of known sequences in patent disclosures." *Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006). Here, ample evidence indicates that specific antibody structure corresponding to "5G1.1" was already known and available to skilled artisans.

As the Examiner recognized (by withdrawing the rejection, Appx1453) and the Board previously acknowledged, Appx7, skilled artisans would understand that "5G1.1" discloses at least one specific structure that performs the claimed function.

"Antibodies are made up of amino acids, and scientists commonly identify a particular antibody according to its specific sequence of amino acids—what they call an antibody's primary structure." *Amgen*, 598 U.S. at 600 (quotations omitted). To know (or identify) a "particular antibody" thus means to know its "specific sequence of amino acids."

In its initial decision, the Board correctly recognized that 5G1.1 was "a specific antibody species" that was "known in the prior art." Appx7.[7] In particular, skilled artisans were aware of "eculizumab":

> The only specific antibody disclosed in the Specification is "5G1.1." 5G1.1 was known in the prior art before the effective filing date of the application as indicated by the Jepson format and the publications provided by Appellant. According to the "Eculizumab" publication (Exhibit F [Appx1127-1134]), 5G1.1
>
> > is a monoclonal antibody that binds to the C5 complement molecule, thereby blocking the progression of the complement cascade at this point. By binding to C5, eculizumab prevents generation of the potent anaphylatoxin C5a and the cytolytic C5b-9 complex, or membrane attack complex.
>
> "Eculizumab" ([Appx1127]) 61.
>
> Eculizumab ([Appx1127]) discloses that "Eculizumab is a long-acting, humanised version of the anti-C5 antibody [h5G1.1]." *Id.* (brackets in original). The only specific antibody species disclosed in the Specification is "5G1.1." Based on our review of the publications describing 5G1.1 and the testimony by Dr. Bassil Dahiyat, we consider the term "5G1.1" disclosed in the Specification to be a specific antibody that binds to human C5 and includes the monoclonal antibody and humanized versions.

Appx7 (internal citations omitted).

Xencor submitted extensive evidence showing that the 5G1.1 structure was known in the art. 5G1.1 was described as early as 1996 and was subsequently modified, humanized, and marketed as "eculizumab" in 2002, long before the 2008

[7] More technically, skilled artisans understand "5G1.1" to include variants, including murine and humanized versions. But for validity purposes, all that matters is that skilled artisans would understand that the phrase discloses at least a single structure. *See infra* pp. 28-29.

priority date. Appx1573 n.6. The declaration of Dr. Bassil Dahiyat, a named inventor, states that "5G1.1 refers to specific antibodies that bind the human C5 protein, including eculizumab." Appx1117. A 2002 press release discussed Alexion Pharmaceuticals, Inc.'s phase II trial for "its anti-inflammatory C5 inhibitor antibody, 5G1.1, now called eculizumab." Appx1125; *see also* Appx1127 ("Eculizumab [*long-acting anti-C5 monoclonal antibody 5G1-1, 5G1.1, h5G1.1, monoclonal antibody 5G1.1, Soliris*™] is a monoclonal antibody that binds to the C5i complement molecule[.]" (brackets in original));[8] Appx1129 (listing the "CAS number" [9] of eculizumab as "219685-50-04"); Appx1135-1136 (explaining that "5G1.1 is currently being tested in Phase II safety and efficacy trials"); Appx1137 (referring to Alexion Pharmaceuticals' "humanized monoclonal[ ]antibody C5

[8] This article also notes that Eculizumab "is covered by US Patent No. 6,355,245." Appx1128. This patent includes significant information about the structure of 5G1.1, including sequences for the light and heavy chain variable regions. U.S. Patent No. 6,355,245, Figs. 18 & 19; *see also* '245 Patent at 9:65-10:20. And it directs the reader to a publicly available deposited hybridoma: "A particularly preferred antibody of the invention is the 5G1.1 antibody (5G1.1, produced by the 5G1.1 hybridoma, ATCC designation HB-11625)." '245 Patent at 19:46-49.; *see also* '245 Patent at 39:24-30 (discussing "Hybridoma 5G1.1"); '245 Patent, Fig. 18-19 (listing 5G1.1 sequences). This Court can "take judicial notice of published patents." *Pepitone v. Am. Standard, Inc.*, 983 F.2d 1087 (Fed. Cir. 1992).

[9] According to Chemical Abstracts Service, a division of the American Chemical Society, a "CAS Registry Number" is "a unique numeric identifier" that "[d]esignates only one substance" and links to "a wealth of information about a specific chemical substance." https://www.cas.org/support/documentation/chemical-substances/faqs#:~:text=A%20CAS%20Registry%20Number%20is,does%20CAS%20assign%20Registry%20Numbers%3F.

complement inhibitor, 5G1.1"). One patent application, published in 2005, recites, "Certain preferred embodiments employ pexelizumab or eculizumab as the antibody therapeutic." Appx1414. And it claims: "The method of claim 1, wherein the antibody is eculizumab or pexelizumab." Appx1430.

In other words, skilled artisans understood "5G1.1" to refer to at least one well-known, specific antibody (with a specific amino acid sequence) and thus to specific, known structure. In light of the extensive evidence detailed by Xencor in its appeal, the Examiner withdrew the written description rejections. Appx1453.

The Board's decision on rehearing makes no attempt to harmonize its findings with its previous findings that "5G1.1 was known in the prior art before the effective filing date of the application" and is a "specific antibody." Appx7. The Board provides no analysis or explanation for its about-face on this issue and appears to have overlooked Xencor's evidence and its own previous finding.

That disclosure of the 5G1.1 antibody structure is all that is required to provide a corresponding structure for the claimed function of "binding human C5 protein." A "claim is valid even if only one embodiment discloses corresponding structure." *Cardiac Pacemakers, Inc. v. St. Jude Medical, Inc.*, 296 F.3d 1106, 1113-14 (Fed. Cir. 2002); *see also Creo Prods., Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1346 (Fed. Cir. 2002) (same).

Claim 9 should thus be construed to cover the corresponding structure for the "means for binding human C5 protein": the antibody 5G1.1. 35 U.S.C. § 112, ¶ 6. Because skilled artisans would understand 5G1.1 to refer to a specific, known structure, the means-plus-function claim is not indefinite.

C. The Board Erred by Holding that Written Description Required the Specification to Disclose "Equivalents" of the 5G1.1 Structure.

Given this known structure, Claim 9 easily satisfies the written description requirement. The relevant structure—5G1.1—is known to skilled artisans.

Written description requires that the specification "reasonably conve[y] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). For Claim 9, the claimed subject matter is limited to particular structures disclosed in the specification corresponding to the "means for binding human C5 protein."

"[A] patentee can rely on information that is 'well-known in the art' to satisfy the written description." *Streck, Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012). As detailed above, "5G1.1" discloses particular structure to skilled artisans, showing that the inventors were in possession of Claim 9. Written description requires nothing more. *See Capon*, 418 F.3d at 1358 (holding that written description did not require a specification to "reiterate the structure or formula or chemical name" for "known DNA sequences of known function").

The Board's analysis of written description went badly astray. On rehearing, the Board first announced that it could not find "any cases in which § 112(f) has been applied to an antibody claim, or more broadly to a protein or DNA claim." Appx50. Rather than discussing the narrow scope of Claim 9 in particular (or a means-plus-function limitation in general), the Board proclaimed that it would "take guidance from" cases "involving a **chemical genus**." *Id.* (emphasis added; quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997)).

The Board justified this approach—and characterizing "the recited 'means for binding human C5 protein' [as] a chemical genus"—based on the truism that means-plus-function claims cover "equivalents" of the corresponding structure. Appx51; 35 U.S.C. § 112, ¶ 6 [pre-AIA]. The Board reasoned (incorrectly), that because of the "equivalents," Claim 9 covered a "genus" of antibodies and thus that the specification was required to provide a written description of the entire genus (i.e., every "equivalent" of 5G1.1). *See* Appx51 ("The 'equivalents thereof' broadens any structure disclosed in a specification to a group or genus of structures.").

The Board then applied this Court's cases concerning functional genus claims to hold that written description was not satisfied. *See* Appx50-52 (citing, *e.g.*, *Regents*, 119 F.3d at 1568; *Ariad*, 598 F.3d at 1354; *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002)).

The Board offered no support for its novel—and radical—approach to written description. We have identified no case in which this Court has held (or suggested) that means-plus-function covering "equivalents" somehow transforms a species claim into a genus claim. Nor has this Court ever suggested that a patentee must satisfy written description for all "equivalents" of claimed structures in a means-plus-function limitation.

The Board appeared to misunderstand the reference to "equivalents thereof" in Section 112, paragraph 6. The phrase does not expand Claim 9 to all anti-C5 antibodies (i.e., the entire genus of antibodies that perform the claimed function). A means-plus-function claim includes only **structural equivalents**: "To determine whether a claim limitation is met literally, where expressed as a means for performing a stated function, the court must compare the accused structure **with the disclosed structure**, and must find equivalent **structure** as well as identity of claimed function for that structure." *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (emphases in original); *see also Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1309 (Fed. Cir. 1998) (noting that the test concerns "the differences between the structure[s]"). Thus, the "equivalents" of 5G1.1 would not be all antibodies that bind human C5 protein but only antibodies with "equivalent structure" to 5G1.1. The Board's suggestion that "equivalents thereof" means that Claim 9 covers a broad genus of

structurally unrelated antibodies is wrong. By definition, the genus of "equivalents" has "structural features common to [its] members." *Ariad*, 598 F.3d at 1350.

More fundamentally, the Board erred by applying the written description requirement to equivalents. Written description requires that the specification "reasonably conve[y] to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad*, 598 F.3d at 1351. The focus of written description is on the "claims," not any equivalents under Section 112, paragraph 6, or equivalents under the doctrine of equivalents.[10] This Court has never suggested that a specification must provide a written description for "equivalents" to what is in the claims.

Xencor does not argue, as the Board suggested, "that a different standard for compliance with the written description requirement should be applied to an antibody claim simply because the claim is written in means-plus-function format." Appx52. All claims must satisfy the written description requirement, but the disclosure required to satisfy written description depends on the scope of the claims (and thus by the claim language). *E.g.*, *Ariad*, 598 F.3d at 1351 ("the claimed subject matter").

[10] Equivalence is not limited to means-plus-function claims. *See Chiuminatta Concrete Concepts*, 145 F.3d at 1310 ("Although an equivalence analysis under § 112, ¶ 6, and the doctrine of equivalents are not coextensive . . . , their tests for equivalence are closely related.").

The meaning of the Board's statement—"It is inconsistent to arrive at a different result for an antibody claim comprising a means-plus-function element than for claim [sic] reciting the same antibody element without invoking § 112(f)," Appx52—is far from clear. If the Board meant that the written description analysis should be identical for two claims with the same scope, it erred in claim construction by misunderstanding the claim's scope. A means-plus-function limitation extends only to structures disclosed in the specification (and their equivalents), not to every antibody with the same function. Claim 9 does not "recit[e] the same antibody element" as the functional genus claims at issue in *Regents*, *Ariad*, and *Enzo Biochem*.

If the Board meant that it would be inconsistent to hold that a narrow means-plus-function limitation claiming a particular structure satisfies written description while holding that a broad limitation covering an entire genus of antibodies with a particular function does not, its analysis is simply a non-sequitur, unsupported by either law or logic. Claim scope matters to written description, and there is nothing "inconsistent" in holding that narrower claim to specific structure satisfies written description while a broader claim to a functional genus does not.

In truth, it is the Board, not Xencor, that applied a special and novel rule of written description to Claim 9, requiring that the specification provide a written

description not only for the claims but also for an unclaimed "genus" of functional equivalents. No precedent supports this radical expansion of written description.

The reference to "5G1.1"—a known antibody with known structure—fully conveys to skilled artisans that Xencor "had possession of the claimed subject matter" of Claim 9 "as of the filing date." *Ariad*, 598 F.3d at 1351. Written description is satisfied.

D. Antibodies Are Properly Claimed through Means-Plus-Function Claims.

Xencor's approach to claiming is exactly what Mark Lemley and Jacob B. Sherkow encourage in their recent article in The Yale Law Journal, *The Antibody Patent Paradox*:

> For antibodies, the means-plus-function claim format offers an intriguing intermediate possibility between pure functional claims and narrow species claims. If a patent owner claims "means for binding to antigen X," that claim would presumably not be invalid under the Federal Circuit's current written description or enablement precedents because it would be interpreted to cover only those means for binding to antigen X that are disclosed in the patent plus other means that are equivalent to the ones disclosed. This means that such a claim would satisfy written description requirements because it would not "cover an enormous number (millions of billions) of . . . candidates"—only those disclosed in the specification.
>
> . . .
>
> We strongly suggest that patentees interested in avoiding this structure trap begin to think about means-plus-function claims when filing new antibody patents.

Mark A. Lemley, Jacob S. Sherkow, *The Antibody Patent Paradox*, 132 Yale L.J. 994, 1057, 1060 (2023).

This analysis captures Xencor's claims precisely: Claim 9 "cover[s] only those means for binding to [C5] that are disclosed in the patent plus other means that are equivalent to the ones disclosed," i.e., 5G1.1 and its structural equivalents. *Id.* at 1057. It does not cover an enormous number of candidates, only 5G1.1, the structure disclosed in the specification (and any structural equivalents).

As Lemley and Sherkow recognize, antibody patents are tremendously valuable: "[P]atents covering antibodies are among the most valuable in the patent system." *Id.* at 994. Unlike recent antibody patents that this Court has struck down for lack of enablement or written description, Xencor has not attempted to claim a genus of antibodies. Instead, Claim 9's reference to a "means for binding human C5 protein" covers only a specific, known antibody: 5G1.1. Claim 9 exemplifies how antibodies can be claimed. The Board's rejections for indefiniteness and lack of written description should be reversed.

II. The Board Erred in Rejecting Claim 8, a Jepson Claim, Based on Written Description

Where correcting the Board's error regarding Claim 9 merely requires this Court to apply well-established precedent, analyzing Claim 8 requires this Court to address a novel issue: How does the Jepson claim format interact with the written description requirement?

When a claim is written in the Jepson format, the preamble recites "elements or steps of the claimed combination which are conventional or known" and then adds

new subject matter after a phrase such as "wherein the improvement comprises" that represents the novel aspect of the claimed invention. 37 C.F.R. § 1.75(e); *see also* Appx4-5; Appx39.

The Manual on Patent Examining Procedure explains that Jepson claims are "particularly adapted" for "improvement-type inventions":

> The form of claim required in 37 CFR 1.75(e) is particularly adapted for the description of improvement-type inventions. It is to be considered a combination claim. 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.

MPEP § 608.01(M).

Because of the Jepson format, the law presumes that the preamble is conventional or known. As the Board explained, "the preamble serves as an admission that a method of treating a patient with 'an anti-C5 antibody with an Fc domain' **was known in the prior art**." Appx3 (emphasis added). The remainder of the claim—the "Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide"—is that "which the applicant considers as the new or improved portion." 37 C.F.R. § 1.75(e).

The Examiner withdrew this written description rejection, Appx1453, recognizing that the specification provides an adequate written description of the improvement, but the Board erred by rejecting Claim 8 under it as a new ground.

A. Claim 8's Improvement Has Adequate Written Description Support.

The written description requirement "limits patent protection to those who actually perform the difficult work of 'invention.'" *Ariad*, 598 F.3d at 1353. "[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.'" *Id.* (quoting *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920 (Fed. Cir. 2004)). It "ensure[s] that inventors have actually invented the subject matter claimed." *Ariad*, 598 F.3d at 1342.

1. The inventors provided an adequate written description of their invention: the structural antibody improvement.

Claim 8 fully complies with these requirements. Xencor's inventors did not "recite a description of the problem to be solved while claiming all solutions to it." *Ariad*, 598 F.3d at 1353. Their contribution to the field of art is an increased half-life for anti-C5 antibodies, and the specification explains precisely how to achieve it: by replacing specific amino acids at positions 428 and 434 of "a human Fc polypeptide." There is, in other words, a disclosed "correlation between structure and function." *Id.* at 1350.

Claim 8 is limited to treating patients with an anti-C5 antibody containing this specific improvement (i.e., these particular amino acid substitutions). Xencor

disclosed "structural features common to the members of the genus." *Ariad*, 598 F.3d at 1350. These structural features would allowh skilled artisans to "recognize the members of the genus." *Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350, 1356 (Fed. Cir. 2023). Treating a patient with an antibody with an unmodified human Fc polypeptide would be outside the claim; only a treatment using an anti-C5 antibody having these particular amino acid substitutions would fall within it.

This is not a "broad outline of a genus's perimeter." *Id.*; *see also Ariad*, 598 F.3d at 1349 (holding that an inventor may not claim "a vast genus of chemical compounds"). These amino acid substitutions are produced only through intentional antibody engineering, and the claims can be practiced only if an artisan consciously chooses to treat a patient with an artificial anti-C5 antibody created by modifying an anti-C5 antibody according to Xencor's invention.

This Court has held that the test for written description is flexible:

> [T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. . . . [W]e do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied.

Ariad, 598 F.3d at 1351. Here, where Claim 8 recites a particular improvement to anti-C5 antibodies, the specification's description of this improvement fully suffices to demonstrate that "the inventor[s] actually invented the invention claimed." *Id.*

The Board correctly identified the improvement, *i.e.*, the invention, as an "Fc domain compris[ing] amino acid substitutions M428L/N434S as compared to a human Fc polypeptide." Appx3-4; *see also* Appx44 ("The improvement recited in the method claim is an 'Fc domain' of an anti-C5 antibody[.]"). Xencor provided an adequate written description of this improvement; the Board did not contest written description of the improvement; and on the facts of this technology and these claims, that should have ended the inquiry.

The phrase "administering an anti-C5 antibody with an Fc domain" undoubtedly limits the scope of claims. *E.g.*, *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) ("Jepson claiming generally indicates intent to use the preamble to define the claimed invention, thereby limiting claim scope."); *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1030 (Fed. Cir. 2002) ("Since both claims are in Jepson format, the phrase recites elements that define the scope of the claimed invention."). A person who applied Xencor's improvement to an antibody that does not bind C5 would not infringe.

But limiting the claim's scope (by limiting the antibodies to which the improvement applies) should not create a heightened written description requirement. Consider a claim for an improved steering wheel that has particular value in four-wheeled vehicles. In a Jepson format, the claim might recite: "In a

four-wheeled vehicle, the improvement comprising a novel steering wheel." There are, of course, many types of four-wheeled vehicles (such as cars, trucks, RVs, vans, tractors, electric cars, and others), but the steering wheel's inventor should not be required to provide a written description of this entire genus. The invention is the steering wheel—the four-wheeled vehicle is simply where the steering wheel should be used.

Perhaps the inventor could have claimed the new steering wheel, without limiting its use, and noted in the specification that it had particular value for four-wheeled vehicles, but an inventor who limits the claims for four-wheeled vehicles with the steering wheel should be rewarded for claiming a narrower scope, not punished with a heightened written description requirement.

Consider the Jepson claim at issue in *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, which involved an improvement to a "micronized anti-diabetic pharmaceutical composition":

> 1. In an [sic] micronized anti-diabetic pharmaceutical composition as a unit dose, containing one or more pharmaceutically acceptable excipients, **the improvement which comprises**: spray-dried lactose as the preponderant excipient in said composition, being present therein at about not less that [sic] seventy percent (70%) by weight of the final composition.

170 F.3d 1373, 1375 (Fed. Cir. 1999) (emphasis added). Although the claim was held invalid as obvious, the written description requirement was satisfied because the specification (and the claim) fully described the improvement, the "spray-dried

lactose as the preponderance excipient." The inventors did not invent (and did not claim) all "micronized anti-diabetic pharmaceutical composition[s]," and it would have been absurd to require them to provide a written description for all such compositions.

Similarly, in *Kegel Co. v. AMF Bowling, Inc.*, the inventors were not required to provide a written description of the entire genus of "bowling lane maintenance machine[s]" to which their improvement applied. 127 F.3d 1420, 1426 (Fed. Cir. 1997). With a Jepson claim, the inventors satisfy written description by providing an adequate description that demonstrates their possession of the claimed improvement.

2. The Board erroneously applied a heighted written description requirement to Jepson claims.

The Board erred by applying a heightened written description requirement for Jepson claims, holding that claims might be construed differently for written description than for anticipation or obviousness.

The Board held that claim construction is "different" when considering "whether the preamble limits the scope of the claim in the context of the prior art" versus "whether it is necessary to consider the claim preamble when determining compliance with the written description requirement." Appx42; *see also* Appx43 (suggesting that even when "the preamble is not limiting for the purpose of determining whether a claim is patentable under [anticipation] or [obviousness]," it

must still satisfy the written description requirement). According to the Board, "[t]he determination that a claim preamble does not limit the scope of the claim for prior art purposes does not mean the preamble can be ignored when ascertaining whether the claim complies with the written description requirement." Appx42. The Board cites no authority in support of this novel assertion, which conflicts with this Court's established precedent.

In *Intirtool, Ltd. v. Texar Corp.*, this Court held if a preamble is not limiting, then a court is "not justified in applying the preamble language . . . as a claim limitation in making its written description finding." 369 F.3d 1289, 1296 (Fed. Cir. 2004). If a preamble is not limiting, then the patentee need not provide an adequate written description of the preamble. *Id.* The Board's contrary theory is illogical and inconsistent with *Intirtool*.

B. In the Alternative, Claim 8 Satisfies Ordinary Written Description Requirements.

Even if this Court disagrees that written description of a Jepson claim should focus on the improvement, Claim 8 still satisfies traditional written description standards.

1. The "method of treating a patient" language from the preamble is either not limiting or has adequate written description.

The preamble of Claim 8 includes two phrases: (i) "a method of treating a patient," which recites a statement of intended purpose; and (ii) "administering an

anti-C5 antibody with an Fc domain," which provides antecedent basis to remaining claim limitations.

Under a traditional preamble analysis the first—"a method of treating patients"—is not limiting. And even if it were, Xencor provided adequate written description.

a. The intended purpose of treating a patient is not limiting.

This Court summarized construction of preambles in *Arctic Cat Inc. v. GEP Power Products, Inc.*:

> As an overarching idea, we have said that 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. We also have said that whether to treat a preamble as a limitation is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history. And this court has recognized that as a general rule preamble language is not treated as limiting.

919 F.3d 1320, 1327 (Fed. Cir. 2019) (internal citations and quotation marks omitted). In *Applied Materials, Inc. v. Advanced Semiconductor Materials America, Inc.*, this Court instructed that "[w]hether a preamble stating the purpose and context of the invention constitutes a limitation of the claimed process is determined on the facts of each case in light of the overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history." 98 F.3d 1563, 1572-73 (Fed. Cir. 1996). Thus, Court has not set a *per se* rule that the **entire**

preamble in claims must always be limiting. Rather, when analyzing the preamble it is appropriate to determine whether the term in the preamble serves to define the invention that is claimed, or is simply a description of the prior art.

Under this standard, the phrase "a method of treating a patient" is not limiting because it merely describes an intended purpose. It does not define the claimed invention.[11] *See, e.g., Bristol-Myers Squibb Co. v. Ben Venue Lab'ys, Inc.*, 246 F.3d 1368, 1375-1376 (Fed. Cir. 2001) (preamble language "[a] method of treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity" is non-limiting because it is "only a statement of purpose and intended result"); *In Re: Copaxone Consol. Cases*, 906 F.3d 1013, 1023 (Fed. Cir. 2018) (preamble reciting a "method of alleviating a symptom of relapsing-remitting multiple sclerosis" is not limiting because it "does not change the express dosing amount or method already disclosed in the claims, or otherwise result in a manipulative difference in the steps of the claims)"; *In re*

[11] There is nothing improper in deconstructing a preamble into non-limiting and limiting features. This Court has advised "[a] conclusion that some preamble language is limiting does not imply that other preamble language, or the entire preamble, is limiting." *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348, 1355 (Fed. Cir. 2020); *see also Marrin v. Griffin*, 599 F.3d 1290, 1295 (Fed. Cir. 2010) ("[T]he mere fact that a structural term in the preamble is part of the claim does not mean that the preamble's statement of purpose or other description is also part of the claim.").

Montgomery, 677 F.3d 1375, 1380-81 (Fed. Cir. 2012) (preamble language "method for the treatment or prevention of stroke or its recurrence" is not limiting).

The phrase "method of treating a patient" provides no antecedent basis to the remaining claim limitations. The 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." Unlike cases where courts have held "method of treating" language limiting, Claim 8 does not require any "effective amount" or efficacious result deriving from the step of "administering." *Compare Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1342 (Fed. Cir. 2021) (preamble limiting because claim required administering an "effective amount").

The Board erred when it described Claim 8's "essence of the invention" as treating a patient with some efficacious result. Appx43-45; *see also* Appx45 ("[T]he purpose of increasing the binding and half-life of the Fc region of the antibody is to improve its efficacy when administered to a human as a therapeutic agent.").

Based on this faulty premise, the Board erroneously required the specification to distinguish anti-C5 antibodies that treat patients from those that cannot. Appx23.

But the essence of the invention is not treating a patient. The language "treating a patient" is just an intended use; it is not relevant to written description because it should be given no patentable weight.

When properly construed, Claim 8 requires only administering an anti-C5 antibody with the claimed improvement to the Fc domain. Appx6.

b. Even if the "method of treating a patient" preamble language were limiting, Claim 8 still has written description support.

As used in Claim 8, "treating" does not require any effectiveness or any particular result. "Treating" merely refers to providing care (i.e., administering). The remainder of Claim 8 likewise lacks any required efficacy or result deriving from "administering."

Claim 8 is similar to claims where the Board found "method of treating" language did "not require achieving a recognizable therapeutic benefit in the patient." *See, e.g.*, *Fresenius Kabi USA, LLC v. Chugai Seiyaku Kabushiki Kaisha*, IPR2021-01024, Paper 23, 6-7 (PTAB Jan. 6, 2022) (phrase reciting "[a] method for treating rheumatoid arthritis . . . in a patient [did] not require achieving a recognizable therapeutic benefit" but only "attempting to cause such a therapeutic improvement in the patient's disease"); *see also Mylan Pharm Inc. v. Regeneron Pharm, Inc.*, IPR2021-00881, Paper 21, 18-21 (PTAB Nov. 10, 2021) (preambles reciting "[a] method for treating an angiogenic eye disorder in a patient" describe "the specific purpose of treating an angiogenic eye disorder in a patient" but "do not require the recited method steps to provide an effective treatment").

As discussed below, ample written description supports the "administering" step. "Treating" is either not limiting (as a statement of intended purpose) or equivalent to the administering step.

2. Claim 8 has adequate written description support for the remainder of the preamble.

Xencor agrees that the second component ("administering an anti-C5 antibody with an Fc domain") provides antecedent basis to the remaining claim limitations and provides the structural component ("anti-C5 antibody with an Fc domain") upon which the claimed improvement in the Fc region is implemented.

Anti-C5 antibodies were indisputably well-known in the art. Appx820; Appx824-828 (detailing a wealth of evidence affirming these antibodies were well-known, which the Board did not dispute).

These facts demonstrating the well-known nature of anti-C5 antibodies distinguish Claim 8 from the claims at issue in *Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021), on which the Board relied. The Board erroneously treated *Juno*, in effect, as creating a legal rule regarding written description of antibodies. Appx24. But *Juno* itself emphasized the fact-bound nature of the inquiry, noting that "the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology," including factors such as "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." *Juno*, 10 F.4th at 1341.

Here, the exhibits submitted and Dr. Dahiyat's Declaration confirm that anti-C5 antibodies were well known at the time of the invention.[12] The prior art included numerous specific examples of the antibodies—far more than the limited number known in *Juno*—and the technology was mature.

Unlike the claims in *Juno*, the evidence here demonstrates that anti-C5 antibodies were well-known and already used by skilled artisans, as was their administration. The specification says relatively little about anti-C5 antibodies because they were so well-known in the art and already in the possession of skilled artisans.

The inventors did not invent anti-C5 antibodies (which were well-known) and did not claim them in Claim 8. The inventors invented and claimed a method of treating patients with anti-C5 antibodies with an improved in vivo half-life based on specific amino acid substitutions. The inventors disclosed a link between function

[12] The Board also accorded little weight to Dr. Dahiyat's expert declaration, erroneously reasoning that the claim "requires that the antibodies must be well-known for treating a patient," and "Dr. Dahiyat did not testify that any of the publications in the submitted exhibits describe treating a patient with an anti-C5 antibody." Appx25. The Board's rationale for ignoring the expert declaration is immaterial because the claimed invention does not require treating a patient.

and structure, and there can be no doubt that they invented (and possessed) what they claimed.

The claims are thus perfectly suited to the Jepson format. The rejection of Claim 8 for lack of written description should be reversed.

III. The Board Erred by Affirming the Examiner's Nonstatutory Obviousness-Type Double Patenting Rejection.

The Examiner separately rejected Claims 8 and 9 under the judicially created doctrine of obviousness-type double patenting in view of Claims 1 through 5 of the '818 Patent and Schwaeble. Appx53. But the Examiner's response failed to present a prima facie case of obviousness, and the record is void of a motivation to combine and a reasonable expectation of success. The Board erred in holding otherwise.

A. Obviousness-Type Double Patenting Generally Follows Ordinary Obviousness Principles.

The doctrine of non-statutory double patenting is intended to "prevent the extension of the term of a patent . . . by prohibiting the issuance of the claims in a second patent not patentably distinct form the claims of the first patent." *In re Longi*, 759 F.2d 887, 892 (Fed. Cir. 1985).

"A later patent claim is not patentably distinct from an earlier claim if the later claim is obvious over, or anticipated by, the earlier claim." *Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 689 F.3d 1368, 1376 (Fed. Cir. 2012) (quoting *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 968 (Fed. Cir. 2001)). The purpose of

obviousness-type double patenting is to thwart gamesmanship by preventing applicants from receiving an improper extension of patent exclusivity for claims that are not "patentably distinct" from earlier claims. *Longi*, 759 F.2d at 892.

As this Court noted, "a double patenting of the obviousness type rejection is analogous to [a failure to meet] the non-obviousness requirement" of Section 103 except that the patent principally underlying the double patenting rejection is not considered prior art. *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1297 (Fed. Cir. 2012). The analysis employed in an obviousness-type double patenting rejection is similar to the analysis of a Section 103 obviousness determination. *See, e.g.*, *In re Braat*, 937 F.2d 589 (Fed. Cir. 1991). But there are some differences. *Otsuka Pharm.*, 678 F.3d at 1297. Unlike in a traditional Section 103 obviousness analysis, the specification from the primary patent is not prior art: "[I]t is the claims that are compared when assessing double patenting." *Ortho Pharm. Corp. v. Smith*, 959 F.2d 936, 943 (Fed. Cir. 1992).

"The obviousness-type double patenting analysis entails two steps: (1) construction of the claims in the earlier patent and the claim in the later patent to identify any differences, and (2) determination of whether the differences in subject matter between the claims render the claims patentably distinct." *Amgen Inc. v. F. Hoffman-La Roche Ltd*, 580 F.3d 1340, 1361 (Fed. Cir. 2009). The second step "entails determining, inter alia, whether one of ordinary skill in the art would have

had reason or motivation to modify the earlier claimed compound to make the compound of the asserted claim with a reasonable expectation of success." *Otsuka Pharm.*, 678 F.3d at 1298.

B. Claims 1-5 of the '818 Patent Are Only Directed to Making the Fc Variant, and Schwaeble Is Directed to a Distinct Antibody.

Claims 1-5 of the '818 Patent are directed to "a polypeptide comprising a variant Fc region as compared to a parent Fc region, said variant Fc region comprising amino acid substitutions M428L/N434S." Appx955. These claims do not identify the inclusion of a polypeptide in any antibody, much less the specific anti-C5 antibodies claimed in Claims 8 and 9, and they do not include the limitation that the modification increases the in vivo half-life.

Claims 8 and 9 are directed to M428L/N434S amino acid substitutions in the Fc region of an anti-C5 antibody that provide for an increase in vivo half-life as compared to an antibody lacking these Fc substitutions. Claims 1-5 of the '818 Patent lack the key limitations of antibodies, anti-C5 antibodies, and increased in vivo half-life.

To fill this gap, the Examiner relied upon Schwaeble. Appx801. Although Schwaeble recognizes the existence of anti-C5 antibodies, it is directed to anti-MAp19 inhibitory agents. Appx1036 at [0016]. Schwaeble does not teach or suggest the use of M428L/N434S amino acid substitutions in the Fc region of an anti-C5 antibody to increase its in vivo half-life.

Anti-MAp 19 inhibitory agents are distinct from the anti-C5 antibodies in Claims 8 and 9. Schwaeble teaches that the complement system should be inhibited by inhibiting the MAp19 protein rather than inhibiting C5. Appx1041-1042 at [0125]. These are alternatives:

> It was found that anti-C5 MoAb prevents HAR [hyperacute rejection]. The inventors thus believe that other targets in the complement cascade, such as MAp19, may also be valuable for preventing HAR and acute vascular rejection in future clinical xenotransplantation.

Appx1053 at [0205] (internal citations omitted). According to Schwaeble, "[t]he preferred protein component to target in the development of therapeutic agents to specifically inhibit the lectin-dependent complement activation system is MASP-2 or MAp19." Appx1041 at [0125]; *see also* Appx1041-42 at [0125] ("MASP-2 and MAp19 are unique to the lectin-dependent complement activation system and required for the system to function.").

Although Schwaeble identifies anti-C5 antibodies, its references are to the prior art generally to show why inhibiting MAp19 rather than C5 is preferred. Of the eighteen citations by the Examiner to anti-C5 antibodies in Schwaeble, seven of them are to pexelizumab. *See, e.g.*, Appx1042-1043 at [0133]; Appx1047 at [0165] and [0166]. Pexelizumab is a single chain Fv protein, which does not contain an Fc domain. Appx1043 at [0133]. With no Fc domain, pexelizumab could not be combined with the Fc region substitutions taught in Claims 1-5 of the '818 Patent.

The remaining citations to anti-C5 antibodies in Schwaeble are general discussions of the prior art. *See, e.g.*, Appx1048 at [0172] ("Further evidence of the importance of C5 and complement in RA has been provided by the use of anti-C5 monoclonal antibodies (MoAbs)."); *id.* at [0174] ("A humanized anti-C5 MoAb (5G1.1) that prevents the cleavage of human complement component C5 into its proinflammatory components is under development by Alexion Pharmaceuticals, Inc."); Appx1050 at [0183] ("The anti-C5 MoAb inhibits cleavage of C5[.]"); Appx1087 at [0527] ("[A]dministration of an anti-C5 MoAb in the NZB/W F1 mouse model resulted in significant amelioration of the course of glomerulonepthritis[.]"); Appx1088 at [0534] ("[T]reatment of CLP animals with anti-C5a antibodies resulted in reduced bacteremia and greatly improved survival.").

Although Schwaeble discusses making amino acid substitutions, its discussion concerns only modifying antibodies to "reduc[e] effector function":

> In some embodiments of this aspect of the invention, the anti-MApl9 antibodies have reduced effector function in order to reduce inflammation that may arise from the activation of the classical complement pathway. . . . [A]ntibodies with reduced effector function can be generated as the result of lacking the Fc portion of the molecule, by having a genetically engineered Fc sequence that minimizes effector function, or being of either the human IgG_2 or IgG_4 isotype.
>
> Antibodies with reduced effector function can be produced by standard molecular biological manipulation of the Fc portion of the IgG heavy chains[.]

Appx1061-1062 at [0271]-[0272]. Reducing effector function is distinct from binding to the FcRn receptor and increasing in vivo half-life. Appx98; Appx103; Appx125.

In short, Schwaeble is directed to anti-MAp 19 inhibitory agents. Although Schwaeble recognizes anti-C5 antibodies, nothing in Schwaeble provides a motivation (or an expectation of success) for skilled artisans to combine anti-C5 antibodies with the claims of the ’818 Patent to increase in vivo half-life.

C. The Obviousness-Type Double Patenting Rejection Over Claims 1-5 of the ’818 Patent in View of Schwaeble Should Be Reversed.

The Examiner and Board erred by rejecting Claims 8 and 9 for obviousness-type double patenting.

1. The Examiner and the Board failed to present a prima facie case of unpatentability.

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a prima facie case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). As this Court has explained, the prima facie case is “a procedural device that enables an appropriate shift of the burden of production.” *Hyatt v. Dudas*, 492 F.3d 1365, 1369 (Fed. Cir. 2007). The Examiner must satisfy the initial burden of production by “adequately explain[ing] the shortcomings [he or she] perceives so that the applicant is properly notified and able to respond.” *Id.* at 1370.

The Examiner must "notify the applicant . . . [by] stating the reasons for [the] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application." 35 U.S.C. § 132. That section "is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990).

This Court recently vacated the Board's affirmance of an examiner rejection of a proposed claim because "it provided little more than the conclusory statement" on the motivation to combine. *In re Theripion, Inc.*, No. 2022-1346, 2023 WL 5125187, at *7 (Fed. Cir. Aug. 10, 2023). "The Board made findings regarding what each prior art reference taught in isolation and failed to articulate any reason why a skilled artisan would have modified Knudsen's system with Ledbetter's linker—other than [an] unexplained assertion[.].'" *Id.* This Court criticized the Board for failing to "identify any evidence for its conclusion that a person of ordinary skill in the art would have viewed Ledbetter's DNase fusion-protein data as instructive with respect to the biological activity of ApoA1-Fc, an entirely different fusion protein." *Id.* The Board "must articulate a reason why" a person of skill would be motivated to combine references. *Id.* "Conclusory statements alone are insufficient" to permit review of the Board's motivation analysis. *Id.*; *see also Personal Web Techs., LLC v. Apple, Inc.*, 848 F.3d 987, 993-94 (Fed. Cir. 2017) (holding that conclusory

unsupported assertions are "not enough" and that the Board must provide "a motivation to pick out those two references and combine them to arrive at the claimed invention").

The Board committed the same error here that it did in *Theripion* and *Personal Web*. The Examiner's obviousness analysis comprises three conclusory sentences, which fail to adequately explain the alleged obviousness of Xencor's invention:

> The combination of the patented claims 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.
>
> Given the applicability of anti-C5 antibodies to inhibit the activation of the complement in methods of treatment, it would have been 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.
>
> Therefore, the claims are obvious of one another.

Appx802. The first and third sentences simply recite conclusions, with no reasoning.

The second sentence attempts to explain the rejection, but it does not cite any evidence. It is also far too broad, identifying just (1) "the applicability . . . to inhibit the activation of the complement" and (2) what the application's specification demonstrates—that the combination increases the half-life of therapeutic anti-C5 antibodies in methods of treatments.

The Examiner's rejection appears to rely on hindsight from the claims under review (which include the only disclosure of increased half-life), not from the prior

art. This is error. *See TQ Delta, LLC v. CISCO Sys., Inc.*, 942 F.3d 1352, 1359 (Fed. Cir. 2019) (explaining that such a "conclusory assertion" tracks the hindsight reasoning "*KSR* warned of and fails to identify any actual reason why a skilled artisan would have combined the elements in the manner claimed"); *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570 (Fed. Cir. 1996) ("To draw on hindsight knowledge of the patented invention, when the prior art does not contain or suggest that knowledge, is to use the invention as a template for its own reconstruction—an illogical and inappropriate process by which to determine patentability").

The Examiner's analysis says nothing about why a skilled artisan would have been motivated to combine the anti-C5 antibody specifically with the Fc mutations, where that motivation would come from, and why a skilled artisan would have a reasonable expectation of success. As for Schwaeble, the Examiner pointed to discrete paragraphs mentioning anti-C5 antibodies but failed to explain how these paragraphs teach modifying the Fc region of an anti-C5 antibody to increase the antibody's in vivo half-life, as required by the claims. Appx1455-1456.

Xencor identified the Examiner's deficiencies in its Appeal Brief to the Board, explaining that the Examiner's ipse dixit statement quoted above "fails to address where the art teaches or suggests this limitation." Appx1472. But the Board found no "deficiency in the Examiner's fact-finding or reasoning." Appx33.

"If the examiner fails to establish a prima facie case, the rejection is improper and will be overturned." *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993) (citing *In re Fine*, 837 F.2d 1071, 1074 (Fed. Cir. 1988)). The Examiner failed to establish a prima facie case of unpatentability, and the obviousness-type double patenting rejection must be overturned.

2. Substantial evidence does not support a motivation to combine the claims of the '818 Patent with Schwaeble.

An applicant may rebut a prima facie case of obviousness by providing a "showing of facts supporting the opposite conclusion." *In re Kumar*, 418 F.3d 1361, 1368 (Fed. Cir. 2005). Such a showing dissipates the prima facie holding and requires the examiner to "consider all of the evidence anew." *Id.*

Even if the Examiner adequately stated a prima facie case of unpatentability, the Board's decision should be reversed on the merits. Nothing in the '818 Patent or Schwaeble provides any motivation for a skilled artisan to combine these teachings, let alone a motivation for a skilled artisan to add the specific mutations (M428L/N434S) claimed in the '818 Patent to an anti-C5 antibody to increase its in vivo half-life. The claims of the '818 Patent say nothing about increasing in vivo half-life, and Schwaeble does not suggest increasing half-life by Fc modifications. Nor does Schwaeble say anything about—or provide any motivation regarding—the desirability of modifying or increasing the half-life of anti-C5 antibodies.

Although Schwaeble describes known anti-C5 antibodies used to treat various diseases, the focus of Schwaeble is not on the use of anti-C5 antibodies but on MAp19 inhibitory agents. *See, e.g.*, Appx1017; Appx1036-1037; Appx1043 at [0134]; Appx1044 at [0140], [0145]; Appx1045 at [0151]; Appx1046 at [0159]; Appx1047 at [0167]; Appx1049 at [0179]; Appx1050 at [0187]; Appx1052 at [0197]; Appx1053 at [0209]; Appx1054 at [0218]; Appx1056 at [0227]; Appx1057 at [0234], [0240]; Appx1058 at [0247]; Appx1059 at [0253]; Appx1060 at [0257]. The Examiner improperly selected discrete portions of the Schwaeble reference that make a cursory mention of an anti-C5 antibody to cobble together an obviousness rejection.

When assessing obviousness, "a prior [art reference] must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the invention in suit." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F .2d 1561, 1568 (Fed. Cir. 1987). One cannot "stitch together an obviousness finding from discrete portions of prior art references without considering the references as a whole." *In re Enhanced Sec. Rsch., LLC*, 739 F.3d 1347, 1355 (Fed. Cir. 2014).

A skilled artisan reading Schwaeble would not have been motivated to combine an anti-C5 antibody with Claims 1-5 of the '818 Patent to arrive at the claimed invention. The rejection is especially egregious as to Claim 9, which is limited to a specific structure: "5G1.1."

The closest Schwaeble comes to discussing increasing half-life is mentioning associating these inhibitors with other molecules:

> The MAp19 inhibitory antibodies and polypeptides may be introduced in association with another molecule, such as a lipid, to protect the polypeptides from enzymatic degradation.

Appx1075 at [0382]. Schwaeble does not suggest that Fc modifications would increase an antibody's in vivo half-life. Schwaeble lacks any teaching or suggestion to a skilled artisan that there would be any benefit to making M428L/N434S substitutions to an anti-C5 antibody.

The Board's obviousness-type double patenting rejection should be reversed due to lack of evidence of a motivation to combine.

3. Substantial evidence does not support a reasonable expectation of success in combining the '818 Patent claims with Schwaeble to achieve the claimed invention.

Because "[a]n obviousness determination requires finding . . . 'that the skilled artisan would have had a reasonable expectation of success in [combining the teachings of the prior art],'" the Board's opinion separately must be reversed due to no evidence of a reasonable expectation of success. *In re Stepan Co.*, 868 F.3d 1342, 1345-46 (Fed. Cir. 2017).

"The reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention." *Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021). It is not enough that "one would reasonably

expect the prior art references to operate as those references intended once combined"—"one must have . . . a reasonable expectation of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016).

Here, the claims cover a method of treating a patient by administering an anti-C5 antibody comprising specifically claimed mutations in its Fc domain that increase its in vivo half-life. Although Schwaeble describes administering anti-C5 antibodies in the context of prior art therapeutic options distinct from its invention, it never describes modifying the Fc region of anti-C5 antibodies; nor does it teach that modification of the Fc region of these antibodies would lead to an increased in vivo half-life as required by the instant claims. The Examiner failed to identify any evidence that a skilled artisan combining the mutated Fc region described in the '818 Patent claims with the anti-C5 antibodies described in Schwaeble would have had a reasonable expectation of success in "achieving what is claimed in the patent-at-issue." *Id.* Indeed, the Examiner did not even make such an assertion.

Xencor noted this failure in its Appeal Brief to the Board, Appx1479, and the Board offered no response. The obviousness-type double patenting rejection should be reversed due to lack of evidence of a reasonable expectation of success.

4. Claims 8 and 9 do not raise the policy concerns obviousness-type double patenting is designed to address.

Finally, and as noted above, obviousness-type double patenting rejections provide the Patent Office with a means to thwart gamesmanship by preventing applicants from receiving an improper extension of patent exclusivity for claims that are not "patentably distinct" from earlier claims. *Longi*, 759 F.2d at 892. Nothing of the sort happened here. The earlier claims of the '818 Patent do not identify the inclusion of a polypeptide in any antibody, much less the specific anti-C5 antibodies claimed in Claims 8 and 9, and they do not claim any benefits from modifying the polypeptide. Claims 1-5 of the '818 Patent lack the key limitations added by the proposed claims of antibodies, anti-C5 antibodies, and increased in vivo half-life.

Claims 8 and 9 add significantly more to the art. They are directed to M428L/N434S amino acid substitutions in the Fc region of an anti-C5 antibody that provide for an increase in vivo half-life as compared to an antibody lacking these Fc substitutions. They are not just mere obvious modifications of Claims 1-5 of the '818 Patent. The claims at issue do not run afoul of the policy concerns that gave rise to the doctrine of obviousness-type double patenting.

CONCLUSION & PRAYER FOR RELIEF

For these reasons, this Court should reverse the rejections of Claim 8 and Claim 9 and hold the claims patentable.

Dated: September 29, 2023

Respectfully submitted,

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ADDENDUM

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE 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 RICHARD M. LEBOVITZ, TAWEN CHANG, and
JOHN E. SCHNEIDER *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

The Examiner rejected claims 8 and 9 under the doctrine of obviousness-type double-patenting. Pursuant to 35 U.S.C. § 134(a), Appellant[2] appeals from the Examiner's decision to reject the claims. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM and set forth new grounds of rejection under 35 U.S.C. § 112(a) and § 112(b) as authorized under 37 C.F.R. § 41.50(b).

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[1] This decision replaces the Decision entered on December 19, 2022, which has been vacated.

[2] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Xencor, Inc. Appeal Br. 1.

STATEMENT OF THE CASE

Claims 8 and 9 stand rejected by the Examiner in the Final Office Action ("Final Act.") as follows:

1. Claims 8 and 9 under the judicially created doctrine of obviousness-type double patenting as obvious in view of claims 1–5 of U.S. Patent No. 10,336,818 ("the '818 patent") and Schwaeble et al. (U.S. Pat. App. Pub. 2006/0018896 A1, published Jan. 26, 2006) ("Schwaeble"). Final Act. 17.

2. Claims 8 and 9 under the judicially created doctrine of obviousness-type double patenting as obvious in view of claim 1 of U.S. Patent No. 8,546,543 ("the '543 patent") and Schwaeble. Final Act. 17.

In the Final Office Action, the Examiner had also rejected claims 8 and 9 under 35 U.S.C. § 112(a) as failing to comply with the written description requirement. Final Act. 2. The Examiner, however, withdrew the rejection in the Answer upon reconsideration of "Exhibits and 132 Declarations, filed [in] the previous rejection." Ans. 1. The Examiner did not provide further explanation.

We have reviewed the written description rejection in the Final Office Action, and Appellant's response in the Appeal Brief, and have decided, pursuant to 37 C.F.R. § 41.50(b), to make a new ground of rejection of claims 8 and 9 under 35 U.S.C. § 112(a) as failing to comply with the written description requirement. We also make a new ground of rejection of claim 9 under 35 U.S.C. § 112(b) as indefinite.

Claims 8 and 9 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.

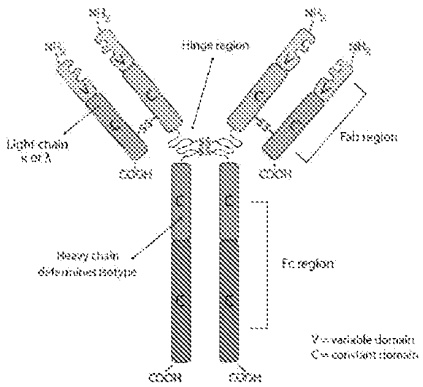
NEW GROUNDS OF REJECTION

A. Written Description Rejection of Claim 8

Claim 8 is directed to a method of treating a patient with an anti-C5 antibody having a Fc domain. The claim is in "Jepson" form. A Jepson claim has a preamble that recites what is "conventional or known," following by a recitation "which the applicant considers as the new or improved portion." 37 C.F.R. § 1.75(e). A Jepson claim is also called an "improvement" claim.

In claim 8, the preamble serves as an admission that a method of treating a patient with "an anti-C5 antibody with an Fc domain" was known in the prior art, and the body of the claim recites the improvement in which the Fc domain comprises "amino acid substitutions M428L/N434S as compared to a human Fc polypeptide." This improvement is said to provide the antibody with "increased in vivo half-life as compared to said antibody without said substitutions."

For clarity, we reproduce an image of an antibody below,[3] showing the "Fc" region and the part of the antibody that binds to the antigen or epitope of the antigen ("Fab region"), which here is "C5."



The image reproduced above shows an antibody having (1) an "Fc region," which is the mutated part of the antibody in claim 8, and (2) a "Fab region," attached to the Fc region, having a constant domain ("C") and a variable domain ("V"). The variable domain comprises the portion of the antibody that binds the antigen.

Claim interpretation

We begin with claim interpretation to determine the objective reach of the claim.

Claim 8 is directed to a method of "treating a patient" with "an anti-C5 antibody with an Fc domain," where the improvement is in the Fc domain "comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide." The claim, as explained above, is in the form of a

[3] https://bioxcell.com/educational-articles/antibody-structure/ (last accessed Nov. 12, 2022).

Jepson claim in which the preamble is statement of the prior art (treating a patient with the antibody) and the body of the claim recites the improvement (the mutated Fc region) to the admitted prior art method.

The claim recites "treating a patient," but it does not identify the condition or disorder that is being treated. The Specification indicates that an anti-C5 antibody can be used for treatment "of autoimmune, inflammatory, or transplant indications" (Spec. ¶ 133), but the claims are not limited to these indications, and we do not import limitations from the Specification into the claims. *SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) ("a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.").

The claim also does not provide any limitation on the "patient" who is treated, but the Specification discloses that "[a] 'patient' for the purposes includes humans and other animals, preferably mammals and most preferably humans." Spec. ¶ 183. The Specification definition is therefore not limiting.

The claimed method treats the patient with "an anti-C5 antibody." C5 is one of the complement proteins which "provide many of the effector functions necessary for the elimination of cellular and viral pathogens." Evans (Exhibit I) 1183. The enzyme C5 convertase cleaves C5 into C5a and C5b. *Id.* C5a and C5b are the active effectors in the complement pathway. *Id.* at 1183–1184. One mechanism of antibody treatment is using an antibody that inhibits C5 convertase cleavage. *Id.* 1185, 1192. However, the claim does not limit the antibody treatment to a specific mechanism of action.

We interpret an "anti-C5 antibody" to be an antibody that binds to the C5 complement protein in the normal way that antibodies bind to their cognate antigens (through the variable region of the antibody depicted in the image above).

The claim does not limit the structure of the variable region or function of the anti-C5 antibody. For example, there is:

1) no limitation on the structure of the variable region of the claimed anti-C5 antibody, such as no limitation on the amino acid sequences that comprise the antibody;

2) no limitation on what epitope(s) of C5 the antibody binds to;[4]

3) no function ascribed to the antibody, other than that it binds to the C5 complement protein and it being inferred that it treats the patient's unidentified condition or disorder. For example, as explained above, it is known that an anti-C5 antibody can block cleavage of C5 into C5a and C5b (Evans (Exhibit I) 1183, 1185), but not all anti-C5 antibodies have this activity and anti-C5 antibodies can have different activities (Vakeva (Exhibit X 2260 (anti-C5 mAb 18A blocked C5b activity, but anti-C5 mAb 16C did not)).

Thus, 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.

The Specification does not provide a definition of anti-C5 antibody or guidance on how it is selected for treating the unidentified condition or disease. The Specification only mentions anti-C5 antibodies (Spec. ¶¶ 126,

[4] The epitope is the part of the protein to which the antibody attaches itself. A protein has many different epitopes.

133), but identifies no properties, functions, or structure of the variable region. As shown in the antibody image reproduced above, the region of the antibody which attaches to the antigen is "variable," indicating that its sequence varies depending on the antigen epitope to which it binds. The only specific antibody disclosed in the Specification is "5G1.1." *Id.* 133 ("anti-complement (C5) antibodies such as 5G1.1"). 5G1.1 was known in the prior art before the effective filing date of the application as indicated by the Jepson format and the publications provided by Appellant. According to the "Eculizumab" publication (Exhibit F), 5G1.1

> is a monoclonal antibody that binds to the C5 complement molecule, thereby blocking the progression of the complement cascade at this point. By binding to C5, eculizumab prevents generation of the potent anaphylatoxin C5a and the cytolytic C5b-9 complex, or membrane attack complex.

"Eculizumab" (Exhibit F) 61.

Eculizumab (Exhibit F) discloses that "Eculizumab is a long-acting, humanised version of the anti-C5 antibody [h5G1.l]." *Id.* (brackets in original). The only specific antibody species disclosed in the Specification is "5G1.1." Final Act. 11. Based on our review of the publications describing 5G1.1 and the testimony by Dr. Bassil Dahiyat (Dahiyat Decl. ¶ 4),[5] we consider the term "5G1.1" disclosed in the Specification to be a specific antibody that binds to human C5 and includes the monoclonal antibody and humanized versions.

Although 5G1.1 prevents generation of C5a and C5b from C5, we do not read the claimed antibody to require this activity. First, the claims are not

[5] Declaration by Bassil Dahiyat, Ph.D. (executed Dec. 8, 2020). Dr. Dahiyat is a co-inventor of the instant application.

limited to 5G1.1. Second, the Specification discloses "anti-complement (C5) antibodies *such as 5G1.1*." Spec. ¶ 33 (emphasis added). 5G1.1 is therefore a species of the broader genus of anti-C5 antibodies, which is not restricted to specific mechanism of action or function.

As indicated from the discussion above, the claimed method of treating a patient is broad, comprising a broad genus of antibodies, treatment indications, and patients. In contrast, there is only one species disclosed in the Specification used to treat only three identified conditions. Spec. ¶ 33. The structure of the genus of antibodies is not sufficiently defined and no description is given whatsoever on what other species are included in the broad antibody genus.

Rejection

Claims 8 and 9 are rejected under 35 U.S.C. § 112(a) as lacking a written description of the claimed anti-C5 antibody. This is a new ground of a rejection. The rejection is the same as the written description rejection set forth in the Final Office Action, supplemented by additional reasoning.

The only anti-C5 antibody species disclosed in the Specification is "5G1.1." Spec. ¶ 126. Yet, as explained above, the claims are directed to a broad and complex genus of anti-C5 antibodies. We find that the disclosure of this single antibody species is insufficient to provide a description of the broadly claimed genus of antibodies which are used to treat a patient for an unspecified disease or condition.

Discussion I

We begin our analysis with a discussion of the requirements of written description under 35 U.S.C. § 112(a). "The 'written description' requirement

serves a teaching function, . . . in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'" *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 922 (Fed. Cir. 2004) (citation omitted). A "purpose of the 'written description' requirement is . . . [to] convey with reasonable clarity to those skilled in the art that, as of the filing date [], [the applicant] was in possession of the invention." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991); *see also Enzo Biochem Inc. v. GenProbe Inc.*, 296 F.3d 1316, 1329 (Fed. Cir. 2002). The requirement is satisfied when the specification "set[s] forth enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed." *University of Rochester*, 358 F.3d at 928.

The requirement that an inventor be in "possession" of the invention and to have "invented what is claimed" is an effort to restrain an inventor from extending their grasp beyond what the inventor invented. As explained in *O'Reilly v. Morse*, 56 U.S. 62, 120–21 (1853): "The evil is the same if he claims more than he has invented, although no other person has invented it before him. He prevents others from attempting to improve upon the manner and process which he has described in his specification — and may deter the public from using[] it."[6] (Emphasis omitted.) To this end, *Ariad Pharmaceuticals, Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1354 (Fed. Cir. 2010) held that "requiring a written description of the invention plays a vital

[6] Quoted in *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014).

role in curtailing claims . . . that have not been invented, and thus cannot be described."

As discussed above, a broad genus of antibodies, indications, and patients to be treated are claimed. The antibody genus is claimed functionally and by the result that it treats an unidentified condition or disease. "[W]hen a patent claims a genus by its function or result, the specification [must] recite[ ] sufficient materials to accomplish that function — a problem that is particularly acute in the biological arts." *Ariad*, 598 F.3d at 1352–1353. Here, claim 8 comprises treating with an "anti-C5 antibody" with no structural limitation to the antibody other than the recited Fc domain substitution. The antibody is claimed as a genus of antibodies because any antibody that binds to the C5 protein and is "treating a patient" is encompassed by the claim (so long as it also has the Fc domain substitution recited in the body of the claim). The antibody is not required to bind a specific epitope on the C5 protein or to have a specific structure, such as amino acid sequence, as long as it can treat an unnamed disease or condition. The essence of the antibody is functional — having the function to bind to C5 and result in a treatment. Only the treatment result is claimed with no mention of what specifically is treated. "When a patent claims a genus using functional language to define a desired result, 'the specification 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.'" *AbbVie*, 759 F.3d at 1299 (quoting *Capon v. Eshhar* 418 F.3d 1349 (Fed. Cir. 2005)). As explained below, the Specification here does not fulfill this role.

The Federal Circuit has held that

> a sufficient description of a genus . . . requires the disclosure of 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.

Ariad at 1350 (quoting *Eli Lilly*, 119 F.3d at 1568–69). But "merely drawing a fence around the outer limits of a purported genus is not an adequate substitute for describing a variety of materials constituting the genus and showing that one has invented a genus." *Id.*

We first turn to the Specification to determine what is disclosed about the anti-C5 antibody. There are only two pertinent disclosures in the Specification. First, the Specification discloses that "[v]irtually any antigen may be targeted by the IgG variants," and lists "C5" among a long list of target antigens. Spec. ¶ 126. Second, the Specification discloses that in one embodiment, "the Fc polypeptides of the present invention [namely, antibodies comprising the claimed mutated Fc region] are used for the treatment of autoimmune, inflammatory, or transplant indications." *Id.* ¶ 133. The Specification further discloses, in the same paragraph, that "[t]arget antigens and clinical products and candidates that are relevant for such diseases include but are not limited to," and lists "anti-complement (C5) antibodies such as 5G1.1" among a list of antibodies. *Id.* There is no other disclosure in the Specification that is pertinent to the claimed anti-C5 antibody.

We have discussed the breadth of claim 8 in the "Claim Interpretation" section. As mentioned in that section, there is no limitation on the structure or function of the antibody, or the epitope to which it binds. There is no correlation disclosed in the Specification between the function of

the antibody to bind to C5 and treat the patient and to a structure of the antibody. As shown in the antibody image reproduced on page 3, the binding part is variable, but there is no information in the Specification 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 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.

Appellant attempts to circumvent this lack of a description of the genus in the Specification by framing the claim as a Jepson claim, where the existence of anti-C5 antibodies for treatment is admitted to be prior art and the only improvement is to the Fc region. Appellant argues that the "Federal Circuit has repeatedly acknowledged that what is conventional or well-known to one of skill in the art need not be disclosed in detail in order to satisfy the written description requirement." Appeal Br. 12 (citing *Streck Inc. v. Rsch. & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1285 (Fed. Cir. 2012)). Appellant further states that the "Federal Circuit has reiterated that information that is 'well known in the art' may be used to supporting written description." *Id.* (citing *Boston Scientific Corp. v. Johnson & Johnson,* 647 F.3d 1353, 1366 (Fed. Cir. 2011)). Appellant also cited *Falko-Gunter Falkner v. Inglis,* 448 F.3d 1357, 1367 (Fed. Cir. 2006) as "expressly reject[ing] the argument that 'the specification must always recite the gene or sequence, regardless of whether it is known in the prior art.'" *Id.* at 13. In view of these asserted legal principles, Appellant provides evidence (the "Exhibits") that "that anti-C5 antibodies with an Fc domain are well-known" and "the literature is replete with anti-C5 antibodies, as evidenced by the

numerous articles and patent filings previously submitted during the prosecution of the present application showing anti-C5 antibodies existed prior to the filing date." Appeal Br. 14. Appellant provides Table 1 in its Appeal Brief, which is a list of the evidentiary Exhibits and "a summary of the plethora of anti-C5 antibodies known in the art at the time of the invention, including anti-human C5 antibodies suggested for use in treating patients." *Id.*

Exhibits

Claim 8 is directed to an improvement of "a method of treating a patient by administering an anti-C5 antibody with an Fc domain." Appellant seeks to provide evidence (among Exhibits A–Z) that the method was well-known in the prior art before the effective filing date of the application.

The Exhibits provided by Appellant are publications. Appellant provided limited analysis of the publications. Appeal Br. 14 (Table 1). We have reviewed these publications and determined that many of them do not disclose treating a patient with an anti-C5 antibody with an Fc domain, but describe only *in vitro* experiments, or in some of the publications, prophetic examples. We do not consider a description of only the antibody, or a proposed use of the antibody, sufficient to establish that the claimed treatment was well-known in the art prior to the application filing date because, if only the anti-C5 antibody activity was necessary to meet the claim limitation, it would essentially eliminate the requirement of the claim that it was used to treat a patient. In other words, we consider the preamble of the claim to be an admission that the antibody had actually been used in the prior art to treat a patient.

The following is our summary of the anti-C5 antibodies which had been used in the prior art to treat a patient. The anti-C5 antibodies in this summary has been culled from the Exhibits provided by Appellant that describe actual treatment of a patient with an antibody.

While we have summarized certain details disclosed in the publications, we rely principally on the antibody and the use of it in treating the patient. The other details are simply background. Each heading below is for a different antibody disclosed in the Exhibits provided by Appellant. Appeal Br. 14 (Table 1).

1. Monoclonal antibody N19-8 against human C5

Evans (Exhibit I) discloses the N19-8 antibody. The N19-8 antibody is a mouse monoclonal antibody. Evans (Exhibit I) 1185. Partial structure of the antibody is disclosed. *Id.* A scFv of N19-8 was also made. *Id.* Evans (Exhibit I) discloses that "N19-8 blocks complement activation by binding to human C5 and preventing its cleavage by C5 convertase." *Id.* 1192. Evans (Exhibit I) further teaches:

> The ability of N19-8 scFv and N19-8 mAb to inhibit complement *in vivo* was assessed in rhesus monkeys. Rhesus serum hemolytic activity was inhibited by greater than 50% for up to 2 hr following the administration of a 100 mg dose of N19-8 scFv (Fig. 8) and for at least 72 hr following the administration of a 100 mg dose of N19-8 mAb.

Id. 1193.

Evans (Exhibit I) concludes that, when administered to rhesus monkeys, sufficient *in vivo* concentrations of the antibody were achieved, indicating that it may be pharmacologically efficacious in settings such as reperfusion injury and cardiopulmonary bypass (CPB). *Id.* 1193.

Rinder (Exhibit L) used the same N19-8 antibody described in Evans (Exhibit I). Rinder (Exhibit L) teaches that CPB is associated with an inflammatory response. Rinder (Exhibit L) 1564. Rinder (Exhibit L) used an *in vitro* model of extracorporeal circulation a model to simulate platelet and leukocyte changes and complement activation induced by CPB. *Id.* The "results demonstrate that blockade of C5a and C5b-9 membrane attack complex formation during extracorporeal circulation with an mAb directed against human C5 [N19-8] effectively inhibits platelet and PMN activation." *Id.*

2. scFv TS-A12-22 anti-C5

Marzari (Exhibit R) discloses an anti-C5 antibody, scFv TS-A12-22, isolated from a human phage library display. Marzari (Exhibit R) 2773. The antibody was effective in treating a rat model of antigen-induced arthritis. The antibody is single-chain variable fragment and is not disclosed as having an Fc portion.

3. Anti-rat C5 mAb 18A

Zhou (Exhibit T) discloses anti-C5 mouse mAb 18A (IgG2b) that binds to the alpha-chain of rat C5. The antibody was used to treat Experimentally Acquired Myasthenia Gravis (EAMG) in rats. "In contrast to uniform severe weakness at 24 h requiring euthanasia in untreated animals, anti-C5 [18A] mAb-pretreated rats showed no weakness at 48 h." Zhou (Exhibit T) 8562. Zhou teaches that the antibody "is known to block C5b-9-mediated hemolysis and C5a-dependent neutrophil migration." *Id.* 8562–8563.

Peckham (Exhibit U) used mAb 18A to treat a rat model of hemorrhagic shock. Peckham (Exhibit U) 673.

Vakeva (Exhibit X) administered mAb 18A to a rat model of myocardial infarction and reperfusion (MI/R). Vakeva concluded that anti-C5 therapy in MI/R "significantly inhibits cell apoptosis, necrosis, and PMN infiltration in the rat despite CJ deposition," indicating that "that the terminal complement components C5a and C5b-9 are key mediators of tissue injury in MI/R." Vakeva (Exhibit X) 2259.

4. Anti-rat C5 mAb 16C

Zhou (Exhibit T) discloses that the "16C control mAb (control IgG) binds to rat C5 but does not block C5b-9-mediated hemolysis or C5a-dependent neutrophil migration." Zhou (Exhibit T) 8563. Only rats treated with mAb 18A abolished C5 activity, but 16C did not. *Id.* 8565. 16C "moderated disease severity [in EAMG] but not to the level observed for" mAb 18A. *Id.* 8566.

"18A effectively blocked C5b-9-mediated cell lysis and C5a-induced chemotaxis of rat polymorphonuclear leukocytes (PMNs), whereas 16C had no complement inhibitor activity." Vakeva (Exhibit X) 2259. "Infarct size was reduced by 50% . . . compared with control mAb 16C." *Id.* 2263.

5. Anti-mouse C5 mAb BB5.1

Wang (Exhibit V) showed that anti-mouse C5 mAb BB5.1 was efficacious in the treatment of collagen-induced arthritis in mice, an animal model for rheumatoid arthritis. Wang (Exhibit V) 8955. "[D]isease suppression by C5 blockade is evidence that the activated terminal

complement components C5a and C5b-9 are the predominant inflammatory mediators of the complement system in this setting." *Id.* 8958.

Ravirajan (Exhibit W) showed that BB5.1 treated glomerulonephritis caused by the human anti-DNA monoclonal antibodies in SCID mice. "Here we have shown that inhibition of the complement cascade with anti-C5-specific mAb markedly ameliorates the course of nephritis, clearly implicating the products of terminal complement activation in the inflammatory process leading to renal failure," suggested a benefit for the treatment of Systemic lupus erythematosus (SLE). *Id.* 444.

Discussion of Exhibits

As indicated above, we have summarized five different anti-C5 antibodies which were used prior to the application filing date to treat a patient. Appellant in Table 1 (Appeal Br. 14) lists each publication separately without disclosing that several of the publications, as summarized above, actually describe the same antibody. (For example, Zhou (Exhibit T), Peckham (Exhibit U), and Vakeva (Exhibit X), each describe mAb 18A, but the table lists the publications separately as if they describe different antibodies.)

Antibody scFv TS-A12-22 anti-C5 (2) is a single chain scFv antibody and therefore does not have an Fc region. This antibody, although provided by Appellant as evidence of what was well-known before the application filing date for purposes of the Jepson claim, falls outside the scope of claim 8 because it does not comprise an Fc region.

Antibody 16c (4) moderated disease severity in EAMG, but was less effective than antibody 18a (3), and in another publication (Vakeva (Exhibit

X) was used as the control because it was considered to lack complement inhibitor activity. Thus, not all C5 antibodies have the same activity, and some (16C) may even be inactive in certain animal models ("patients").

Appellant argues, referencing Table 1, that a "plethora of anti-C5 antibodies [were] known in the art at the time of the invention," but Appellant's list includes duplicates, triplicates, as well as antibodies not used for treatment of a patient. Appeal Br. 14. In contrast, we find that there are about four different antibodies in the prior art (*see* 1, 3, 4, and 5 above), in addition to 5G1.1, which had been used in the prior art to treat patients.

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. If we think of the genus as football field with yard lines across the playing field, Appellant has not explained how the "plethora" of antibodies[7] fills up the yard markers across the whole breadth of the field. Appellant has not adequately explained how its list of anti-C5 antibodies provide a written description of the claimed broad genus. Appellant has not identified a structure and function relationship between the antibody and the method of treatment nor explained how the antibodies are representative of the full playing field. *See Eli Lilly*, 119 F.3d at 1568–69.

[7] We found only about five anti-C5 antibodies had been used to treat patients, but our analysis would **not** change if there were more because Appellant provided no guidance in how they constitute a description of the full scope of the claim.

Discussion II

We are not persuaded by Appellant's argument that, when a claim is recited in the Jepson claim format, a written description of the claimed genus of anti-C5 antibodies can be established by reference to the prior art publications over which the improvement is claimed. We explain our reasoning below.

To begin, 35 U.S.C. § 112(a) requires that the *Specification* provide the written description;

> 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, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

Thus, by statute, it is the Specification that must provide "a written description of the invention," and not the prior art.

It is true that there are various cases, as cited by Appellant, which indicate that extrinsic prior art can be relied upon to satisfy the written description requirement. But none of these cases excuse an inventor from describing the claimed invention in the Specification.

Boston Scientific Corp. v. Johnson & Johnson, 647 F.3d. 1353 (Fed. Cir. 2011) cited by Appellant for holding "that what is conventional or well-known to one of skill in the art need not be disclosed in detail in order to satisfy the written description requirement," does not lead to a different conclusion. Appeal Br. 12. In *Boston Scientific*, 647 F.3d. at 1360–1361, 1364, a genus of compounds was claimed, but the Specification only disclosed one compound and no discussion on the genus of compounds

covered by the claims. The court acknowledged that some species of the genus were known in the art, but the court found that "[a]ny suggestion that these references represented existing knowledge in the art so well known as to excuse including a more detailed disclosure of the macrocyclic lactone analogs genus in the specification is belied by the state of the art at the time of the invention." *Id.* at 1364. The court further explained:

> When determining whether a specification contains adequate written description, one must make an "objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. 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. *See Falko–Gunter Falkner v. Inglis*, 448 F.3d 1357 1366–68 (Fed. Cir. 2006)

Boston Scientific at 1366.

The inquiry, as explained in *Boston Scientific*, is into the Specification. The prior art may supplement some missing information in the Specification to satisfy the written description requirement, but it does not replace the Specification's teaching role. Here, as explained above, there is no limitation on the variable region structure of the claimed anti-C5 antibody and no correlation disclosed in the Specification between the function of the antibody to bind C5 and treat a patient and antibody structure. Appellant did not establish that this deficiency is made up for by the prior art Exhibits. The existing knowledge about the structure of anti-C5 antibodies is limited, and the few prior art examples described by Appellant do not establish that the inventors invented the full scope of the claim.

Streck, Inc. v. Rsch. & Diagnostic Sys., Inc., 665 F.3d 1269, 1285 (Fed. Cir. 2012) is also cited by Appellant for the principle that information

that is "well known in the art" can be relied upon to satisfy the written description requirement. Appeal Br. 12.

In addressing the written description issue, the *Streck* court stated "this is not a case where a patentee attempts to claim a broad genus without defining specific species. Instead, as noted, *Streck* listed several specific "true reticulocytes in its specifications." *Streck*, 665 F.3d at 1286–1287. Here, in contrast, the claim is directed to a broad genus. *Streck* is therefore distinguishable from the facts presented in this appeal.

There is no question that in "some circumstances" (*Boston Scientific* at 1366) and "in some instances" (*Streck*, 665 F.3d at 1285[8]) information well-known in the prior art can be relied upon to satisfy the written description. We are cognizant of the statement in *Capon v. Eshhar*, 418 F.3d 1349, 1357 (Fed. Cir. 2005) that what is necessary to meet the written description requirement "varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *See* also *Ariad*, 598 F.3d at 1351. But *Capon* explained that when determining "the scope of coverage to which the inventor is entitled," "it is appropriate" in "'unpredictable' fields of science" "to recognize the variability in the science." *Capon* 418 F.3d at 1358. "Such a decision usually focuses on the exemplification in the specification." *Id.* Thus, even when what is well-known is being relied upon to satisfy the written description

[8] "The test [for written description] is whether the disclosure 'conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.' . . . This test requires an 'objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.' . . . Given this perspective, in some instances, a patentee can rely on information that is 'well-known in the art' to satisfy written description." (Internal citations omitted.)

requirement, the *starting point* is the Specification because it is the Specification which must communicate that the inventor had invented what is claimed.

As explained in *Ariad*, "the hallmark of written description is disclosure." *Ariad* 598 F.3d at 1351. But *Ariad* reminds us that "'possession as *shown in the disclosure*' is a more complete formulation." *Id.* (emphasis added).

> Yet whatever the specific articulation, 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. Based on that inquiry, the *specification must describe an invention* understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

Id. (emphasis added).

In this case, the Specification, which is the place to start, provides no description of a genus compliant with the principles enunciated in *Lilly* and *Ariad*. While there is a statement of the genus of "anti-complement (C5) antibodies," there is no adequate description of it. This issue was addressed in *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997). *Ariad* explained:

> we held in *Eli Lilly* that an adequate written description of a claimed genus requires more than a generic statement of an invention's boundaries. [*Eli Lilly*,] 119 F.3d at 1568. The patent at issue in *Eli Lilly* claimed a broad genus of cDNAs purporting to encode many different insulin molecules, and we held that its generic claim language to "vertebrate insulin cDNA" or "mammalian insulin cDNA" failed to describe the claimed genus because it did not distinguish the genus from other materials in any way except by function, *i.e.*, by what the genes

> do, and thus provided "only a definition of a useful result rather than a definition of what achieves that result." *Id.*

Ariad 598 F.3d at 1349–1350.

Thus, although 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 corners 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).

In *Juno*, 10 F.4th at 1334, the claim was to a "nucleic acid polymer encoding a chimeric T cell receptor," where the chimeric T cell receptor comprises, *inter alia*, "a binding element that specifically interacts with a selected target." One example of a binding element that was disclosed and claimed in the patent was a single-chain antibody variable fragment (scFv). *Id.* at 1336. The court focused on this element in its written description analysis. *Id.* at 1339–1340 (citing dependent claims 3 and 9 for the scFv; and dependent claims 5 and 11 for where the scFv binds to CD19). The court found that only two scFvs were disclosed in the patent specification, one of which binds to CD19 and the other which binds to PSMA, a prostate cancer antigen. *Id.* Appellant argued that the two examples were representative of the genus, but the court in *Juno* rejected this argument. Appellant

specifically had provided testimony from an immunological expert, but the court did not find the testimony compelling. The court explained:

> Nothing about that testimony explains which scFvs will bind to which target or cures the '190 patent's deficient disclosure on this score. Without more in the disclosure, such as the characteristics of the exemplary scFvs that allow them to bind to particular targets or nucleotide sequences, the mere fact that scFvs in general bind does not demonstrate that the inventors were in possession of the claimed invention.

Id. at 1337.

Consistent with *Capon*, the court did not reject the notion that what is well-known in the art cannot be relied upon to meet the written description requirement, but the court expressly held that that "the 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." *Juno*, 10 F.4th at 1337. Thus, while it was argued in *Juno* that "scFvs in general were well-known or have the same general structure," such prior art did "not cure" the deficiency in the disclosure of "only two scFv examples and provides no details regarding the characteristics, sequences, or structures that would allow a person of ordinary skill in the art to determine which scFvs will bind to which target." *Id.* at 1339–1340.

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 CD19. We find that the same reasoning applied to antibodies that bind C5.

As in *Juno*, there is expert testimony in this appeal by Bassil Dahiyat, Ph.D.. Dr. Dahiyat testified:

> 5. Additionally, as a person of skill in the art, I am aware of numerous anti-C5 antibodies that bind to the human C5 protein that were known as of the priority date of the present application. In addition to the anti-CS antibodies of previously submitted Exhibits A to J, which I have reviewed, there are numerous examples of prior art anti-C5 antibodies in the literature. Enclosed are additional Exhibits K to O, to support my position that anti-C5 antibodies were well known in the art prior to the priority date of the present invention.

Dahiyat Decl. ¶ 5.

Dr. Dahiyat provided no analysis of the publications ("Exhibits") which he asserts establish that anti-C5 antibodies were "well known in the art prior." He also did not address the full scope of claim 8 because he only discussed the binding of the antibodies to human C5. But the claim also requires that the antibodies must be well-known for treating a patient. Dr. Dahiyat did not testify that any of the publications in the submitted exhibits describe treating a patient with an anti-C5 antibody. In addition, Dr. Dahiyat does not explain how the publications, coupled with the disclosed of the 5G1.1 antibody in the Specification, convey possession of the full scope of the claimed genus. Accordingly, we accord little weight to his testimony.

Putting the claimed subject matter in the form of a Jepson claim does not change our analysis. The requirements of a Jepson or improvement claim is set forth in 37 C.F.R § 1.75(e):

> (e) Where the nature of the case admits, as in the case of an improvement, any independent claim should contain in the following order:
>
> (1) A preamble comprising a general description of all the elements or steps of the claimed combination which are conventional or known,

> (2) A phrase such as "wherein the improvement comprises," and
>
> (3) Those elements, steps and/or relationships which constitute that portion of the claimed combination which the applicant considers as the new or improved portion.

As disclosed in § 1.75(e), the purpose of the Jepson claim is to identify the part of the claim which the applicant considers to be "conventional or known" and the part which is considered to the "new or improved portion." Section 1.75(e) characterizes the claim as a "combination" because "the claimed invention consists of the preamble in combination with the improvement." *Pentec, Inc. v. Graphic Controls Corp.*, 776 F.2d 309, 315 (Fed. Cir. 1985). Thus, both parts of the claims constitute the claimed invention and must be addressed in combination when considering compliance with the written description requirement.

It is further explained in *In re Fout*, 675 F.2d 297, 299 (Fed. Cir. 1982):

> It is well established that the use of Jepson format is, in effect, an admission by appellants that the process steps recited in the preamble are known in the art, leaving for consideration whether the recitation following the improvement clause imparts patentability to the claims.

The Jepson claim format is a contrivance for the *prior art* purpose of determining "whether the recitation following the improvement clause imparts patentability to the claims." *Fout*, 675 F.2d at 299. It is not an expedient to alleviate the burden on the inventor to describe in their Specification the full scope of the claim. Thus, the admission that "a method of treating a patient by administering an anti-C5 antibody with an Fc domain" was known in the prior art does not on its own establish that the genus of such antibodies complies with the written description

requirement as enunciated in *Lilly* and *Ariad*; patentability over the prior art under 35 U.S.C. §§ 102 and 103 is separate from the requirement of adequate written description under 35 U.S.C. § 112(a). Appellant has not directed us to any source for the principle that an admission in the claim that certain parts of the claim are "known or conventional" alleviates the requirement that the claim as a whole – the combination of the preamble and the improvement – must be described the Specification. It is the entirety of the claim that must be described, not just the improvement. *See Rowe v. Dror*, 112 F.3d 473, 479 (Fed. Cir. 1997) ("When [the Jepson form] is employed, the claim preamble defines not only the context of the claimed invention, but also its scope.").

As explained above, the Specification is the starting point in a written description analysis, and only after the disclosure in the Specification is addressed, does the person of ordinary skill in the art turn to the prior publications. 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. *Ariad*, 598 F.3d at 1360 (Newman, concurring) ("the patentee is obliged to describe and to enable subject matter commensurate with the scope of the exclusionary right").

For the forgoing reasons, we reject claim 8 as lacking a written description under 35 U.S.C. § 112(a).

B. Written description and indefiniteness rejections of Claim 9

Claim 9 recites administering "an anti-C5 antibody" comprising a "means for binding human C5 protein."

Appellant argues that "a claim utilizing means-plus-function language must adhere to the standards for § 112, 6th paragraph, these standards . . . are different from those that apply to a claim not containing means-plus-function language." Appeal Br. 22.

We agree with Appellant that the first question that must be addressed is whether the specific element in the claim should be construed as a "means-plus-function." As explained in *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Circ. 2015), "[m]erely because a named element of a patent claim is followed by the word 'means,' however, does not automatically make that element a 'means-plus-function' element under 35 U.S.C. § 112, ¶ 6." *Williamson* further explained:

> In making the assessment of whether the limitation in question is a means-plus-function term subject to the strictures of § 112, para. 6, our cases have emphasized that the essential inquiry is not merely the presence or absence of the word "means" but 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.

Id.

If the means recited in the claim has a definite structure by itself, then pre-AIA § 112, 6th paragraph or § 112(f) is not applicable. Here, there is no evidence of record that the claimed "means for binding human C5" would be "understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." Specifically, we have not been guided by Appellant to specific structures which represent the binding means. Accordingly, we find that § 112(f) applies to the claim.

Having found that the "means for binding human C5 protein" is subject to the application of § 112(f), we next determine the function of the means and whether the specification discloses sufficient structure that corresponds to the claimed function. "Construing a means-plus-function claim term is a two-step process." *Williamson*, 792 F.3d at 1351. First, the function is identified. *Id.* Second, it must be determined what structure, if any, disclosed in the specification corresponds to the claimed function. *Id.* If "adequate corresponding structure [is not disclosed], the claim is indefinite." *Id.* at 1352.

The function of the recited "means" is recited as "for binding the human C5 protein." Thus, the function of the "means" is to bind human C5.

Next, we turn to the disclosure in the Specification to determine the structure of the means. For support, Appellant points to paragraph 133 of the Specification which discloses "anti-complement (C5) antibodies such as 5G1.1." The term "anti-complement (C5) antibodies" is generic. As discussed for claim 8, there is inadequate disclosure of the antibody structure that binds to the C5 protein. *See Juno supra*. Not only is the structure undefined, but so is the epitope to which the "means" binds to on the C5 protein. Thus, our analysis for claim 8 applies equally here. Even were the antibody structure of the 5G1.1 antibody sufficient, the claimed "means for" is not restricted by the Specification to this specific antibody species.

"Sufficient structure must simply 'permit one of ordinary skill in the art to know and understand what structure corresponds to the means limitation' so that he may 'perceive the bounds of the invention.'" *In re Aoyama*, 656 F.3d 1293, 1298 (Fed. Cir. 2011) (citing *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1340–1341 (Fed. Cir. 2008). We find

that the Specification does not disclose sufficient structure corresponding to the claimed function for the reasons discussed above for claim 8. Accordingly, we find that claim 9 lacks adequate written description under 35 U.S.C. § 112(a) and is further indefinite under 35 U.S.C. § 112(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

The '818 patent claims are directed to host cells, expression vectors, and nucleic acids for making the same Fc variant recited in instant claims 8 and 9. The '543 patent claim is directed to an antibody conjugated to a drug ["ADC"], where the antibody comprises the same Fc variant which is claimed. Each of the claims is rejected by the Examiner as obvious in combination with Schwaeble.

The Examiner found that Schwaeble discloses anti-C5 antibodies for various utilities, including treatment ("therapeutics"). Final Act. 17. Prior art anti-C5 antibodies are disclosed in paragraphs 130, 172, 174, 178, 183, 205, and 527 of Schwaeble. For illustrative purpose, paragraphs 172, 174, and 178 are reproduced below:

> Further evidence of the importance of C5 and complement in RA [rheumatoid arthritis] has been provided by the use of anti-C5 monoclonal antibodies (MoAbs). Prophylactic intraperitoneal administration of anti-C5 MoAbs in a murine model of CIA [collagen-induced arthritis] almost completely prevented disease onset while treatment during active arthritis resulted in both significant clinical benefit and milder histological disease (Wang, Y., et al., Proc. Natl. Acad. Sci. USA 92:8955-59, 1995).

Schwaeble ¶ 172.

> A humanized anti-C5 MoAb (5G1.1) that prevents the cleavage of human complement component C5 into its proinflammatory

> components is under development by Alexion Pharmaceuticals, Inc., New Haven, Conn., as a potential treatment for RA.

Schwaeble ¶ 174.

> Results from animal models of SLE support the important role of complement activation in pathogenesis of the disease. Inhibiting the activation of C5 using a blocking anti-C5 MoAb decreased proteinuria and renal disease in NZB/NZW Fl mice, a mouse model of SLE (Wang Y., et al., Proc. Natl. Acad. Sci. USA 93:8563-8, 1996). Furthermore, treatment with anti-C5 MoAb of mice with severe combined immunodeficiency disease implanted with cells secreting anti-DNA antibodies results in improvement in the proteinuria and renal histologic picture with an associated benefit in survival compared to untreated controls (Ravirajan, C. T., et al., *Rheumatology* 43:442-7, 2004) . . . A humanized anti-C5 MoAb is under investigation as a potential treatment for SLE. This antibody prevents the cleavage of C5 to C5a and C5b. In Phase I clinical trials, no serious adverse effects were noted, and more human trials are under way to determine the efficacy in SLE (Strand, V., *Lupus* 10:216-221, 2001).

Schwaeble ¶ 178.

Rejection based on the '818 patent claims

The '818 patent claims are directed to host cells, expression vectors, and nucleic acids for making the same Fc variant recited in instant claims 8 and 9. The Examiner found that in view of "the applicability of anti-C5 antibodies to inhibit the activation of the complement in methods of treatment, it would have been obvious to the ordinary artisan to incorporate the Fc mutations M428L/N434S [of the '818 patent into the antibodies of

Schwaeble] to increase the half-life of therapeutic anti-C5 in methods of treating." Appeal Br. 18.

Appellant argues that "Schwaeble, taken as a whole, is clearly directed to anti-MAp19 inhibitory agents, which are distinct and separate from the anti-C5 antibodies in Claims 8 and 9." Appeal Br. 37. Appellant further argues that "a review of the application shows that the references to anti-C5 antibodies are **all** references to the prior art generally to show why inhibiting MAp19 rather than C5 might be desirable" and favored over inhibiting C5. *Id.* (citing Schwaeble 125).

This argument does not persuade us that the Examiner reversibly erred. It is irrelevant that Schwaeble's disclosure is directed to anti-MAp19 agents, while the reference to anti-C5 antibodies is only in the context of the prior art. "'The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain.'" *In re Heck*, 699 F.2d 1331, 1332–33 (Fed. Cir. 1983) (quoting *In re Lemelson*, 397 F.2d 1006, 1009 (CCPA 1968))." MPEP § 2123.I. As found by the Examiner, Schwaeble discloses the use of anti-C5 antibodies. *See* Schwaeble ¶¶ 130, 172, 174, 178, 183, 205, 527. While the discussion of anti-C5 antibodies is in reference to the prior art, this disclosure still provides the teaching of therapeutic anti-C5 antibodies relied upon by the Examiner.

We are also not persuaded by Appellant's argument that the anti-C5 antibodies are not obvious because inhibiting MAp19 is desirable and favored over C5. Appeal Br. 37. To the extent this statement is true (and we do not agree that it is), "[a] known or obvious composition does not become

patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994). "[J]ust because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *In re Mouttet*, 686 F.3d 1322, 1334 (Fed. Cir. 2012). Thus, even if inhibiting Map19 is more desirable than inhibiting C5, it does not make the use of the prior art anti-C5 antibodies any less obvious to one of ordinary skill in the art.

Appellant also contends that the Examiner's prima facie case is insufficient because it makes a ""mere conclusory statement"" concerning the obviousness of the claimed subject matter over the cited patents. Appeal Br. 42.

We do not agree. The Examiner explained that the combination of the patent claims and Schwaeble "would have made it obvious to the ordinary artisan to incorporate the Fc mutations M428L/N434S [of the '818 patent] to increase the half-life of therapeutic anti-C5 [of Schwaeble] in methods of treating." Final Act. 18. Appellant has not identified a deficiency in the Examiner's fact-finding or reasoning.

Appellant further argues that there is "no motivation to combine 428L/434S amino acid substitutions into anti-C5 scFvs such as pexelizumab, since pexelizumab does not contain an Fc domain." Appeal Br. 42.

Appellant is mistaken. The rejection is based on the disclosure in Schwaeble of anti-C5 antibodies, such as monoclonal antibodies, that contain the Fc region. The rejection is also based on the patented '818 claims which recite the same mutated Fc domain recited in the instant claims. Thus, while the Examiner cited portions of Schwaeble which discuss

the Fc portion of an antibody, we consider this evidence unnecessary because the '818 patent claims disclose the same mutated Fc employed in the instant claims. The Examiner gave an explicit reason to use this variant in an anti-C5 antibody. Final Act. 18. Appellant has not persuasively identified an error in the Examiner's reasoning.

The obviousness-type double-patenting rejection of claims 8 and 9 based on the '818 patent is affirmed.

Rejection based on the '543 patent claim

The '543 patent claim is directed to an ADC, where the antibody (but not an anti-C5 antibody) comprises the same Fc variant which is claimed. Appellant argues that it would not be obvious to combine the '543 patent with an anti-C5 antibody. Appeal Br. 44. Appellant relies on Dr. Dahiyat's statement in his declaration:

> Furthermore, ADC molecules are nearly always directed against target antigens that are expressed on the surface of a cell so that the drug conjugate can enter the cell, usually a tumor cell, for the purpose of killing it. C5 is a soluble antigen, e.g. not bound to a cell surface, and would not be considered as a useful molecule to target with an ADC at the time of the invention.

Dahiyat ¶ 11.

For this reason, Appellant contends there is no motivation to combine the '543 patent with Schwaeble (or the disclosure of any other anti-C5 antibody). Appeal Br. 44.

We agree with Appellant that there would be no reason to modify the claim of the '543 patent with Schwaeble to make the claimed anti-C5 antibody comprising the mutated Fc region.

"The doctrine of double patenting is intended to prevent a patentee from obtaining a time-wise extension of [a] patent for the same invention or an obvious modification thereof." *In re Lonardo*, 119 F.3d 960, 965 (Fed. Cir. 1997). "The judicially created doctrine of obviousness-type double patenting . . . prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a commonly owned earlier patent." *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

Here, as argued by Appellant, there is no reason to use the anti-C5 antibody to make the drug conjugate of the '543 patent because C5 is a soluble antigen, while, as testified by Dr. Dahiyat, drug conjugates "are nearly always directed against target antigens that are expressed on the surface of a cell so that the drug conjugate can enter the cell . . . for the purpose of killing it." Dahiyat ¶ 11. In response to Dr. Dahiyat's testimony, the Examiner did not provide a persuasive reason for conjugating a drug to soluble C5.

In sum, instant claims 8 and 9 are not an improper extension of the right to exclude through the claim of the '543 patent. The obviousness-type double-patenting rejection of claims 8 and 9 based on the '543 patent is reversed.

CONCLUSION

We set forth new grounds of rejection (1) of claims 8 and 9 under 35 U.S.C. § 112(a) as lacking adequate written description and (2) of claim 9 under 35 U.S.C. § 112(b) as indefinite. The obviousness-type double-patenting rejection of claims 8 and 9 based on the '818 patent is affirmed.

The obviousness-type double-patenting rejection of claims 8 and 9 based on the '543 patent is reversed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
8, 9	112(a)	Written Description			8, 9
9	112(b)	Indefiniteness			9
8, 9		Nonstatutory Double Patenting over the '818 patent	8, 9		
8, 9		Nonstatutory Double Patenting over the '543 patent		8, 9	
Overall Outcome			8, 9		8, 9

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review."

37 C.F.R. § 41.50(b) also provides that the Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of

the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
>
> (2) *Request rehearing*. Request that the proceeding be reheard under § 41.52 by the Board upon the same Record. . . .

Further guidance on responding to a new ground of rejection can be found in the Manual of Patent Examining Procedure § 1214.01.

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). *See* 37 C.F.R. § 41.50(f).

AFFIRMED; 37 C.F.R. § 41.50(b)

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE 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 RICHARD M. LEBOVITZ, TAWEN CHANG, and
JOHN E. SCHNEIDER, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

This is a decision on Appellant's Request for Rehearing under 37 C.F.R. § 41.52 of the Decision on Appeal mailed January 10, 2023 ("the Decision" or "Dec."). Only two claims are pending and on appeal, claims 8 and 9. Claim 8 is a Jepson claim. Claim 9 is a means-plus-function claim. The Rehearing is denied.

The Decision affirmed the obviousness-type double patenting rejection of claims 8 and 9 based on the combination of U.S. Patent No. 10,336,818 B2 ("the '818 patent") and Schwaeble et al. (U.S. Pat. App. Pub. No. 2006/0018896 A1, published Jan. 26, 2006) ("Schwaeble"); reversed the obviousness-type double patenting rejection of claims 8 and 9 based on the

combination of U.S. Patent No. 8,546,543 B2 ("the '543 patent") and Schwaeble; and set forth new grounds of rejection of claims 8 and 9 under 35 U.S.C. § 112(a) and § 112(b) as authorized by 37 C.F.R. § 41.50(b).

CLAIM 8 REJECTION

Claim 8 is rejected under 35 U.S.C. § 112(a) as lacking a written description of the full scope of the claim. Dec. 3, 8. Claim 8 is reproduced below from the "Claims Appendix" of the Appeal Brief (dated Aug. 25, 2021).

> 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.

Appeal Br. 46 ("Claims Appendix").

Is the preamble of claim 8 limiting?

Appellant contends that "the Board erroneously assumed that the entire preamble—reciting 'a method of treating a patient by administering an anti-C5 antibody with an Fc domain'—is limiting and thus must be included in the written description analysis." Req. Reh'g 3. Appellant asserts that the method of treating a patent is "an intended purpose." *Id.* at 5. On the other hand, Appellant asserts that the phrase "administering an anti-C5 antibody with an Fc domain" is "limiting because it provides antecedent basis to the remaining claim limitations and provides the structural component (i.e., anti-

C5 antibody with an Fc domain) upon which the claimed improvement in the Fc region is implemented." *Id.* at 4.

Appellant argues that the claim preamble is not limiting because the claim "does not require any 'effective amount' or efficacious result deriving, from the step of 'administering.'" Req. Reh'g 4 (citing *Eli Lilly & Co. v. Teva Pharms. Int'l GmbH*, 8 F.4th 1331, 1342 (Fed. Cir. 2021)). Appellant contends that the recitation of a "method of treating a patient" "merely states an intended purpose, which the Federal Circuit has repeatedly held to be non-limiting." *Id.* at 5 (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375–1376 (Fed. Cir. 2001); *In Re: Copaxone Consol. Cases*, 906 F.3d 1013, 1023 (Fed. Cir. 2018); *In re Montgomery*, 677 F.3d 1375, 1389–1381 (Fed. Cir. 2012).

We initially observe that the cases cited by Appellant in support of its argument that the preamble of claim 8 is "limiting" involved claim construction for the purpose of determining whether the claims were anticipated or obvious in view of prior art. *Lilly*, 8 F.4th at 1337;[1] *Bristol-Meyers Squib*, 246 F.3d at 1374;[2] *Copaxone*, 906 F.3d at 1022;[3]

---

[1] In the context of determining whether the claims would have been obvious in view of three cited prior art references, "[t]he Board also discussed how the claim construction affected Lilly's burden to demonstrate that a skilled artisan would have had a reasonable expectation of success in combining the teachings of the prior art to achieve the claimed invention."

[2] "Bristol argues that the court improperly read out the phrase '[a] method for treating a cancer patient to effect regression of a taxol-sensitive tumor, said method being associated with reduced hematologic toxicity' from claims 5, 6, 8, and 9 of the '537 patent. . . . Bristol argues that these expressions are limitations because they distinguish the new use of the process over the prior art."

[3] "Teva contends that the district court erroneously construed certain claim terms as non-limiting and disregarded them for nonobviousness purposes."

Montgomery, 677 F.3d at 1380–1381.[4] In each of these cases, the determination of whether the claim preamble was "limiting" was for the purpose of ascertaining whether the preamble *limits the scope of the claim* in the context of prior art.[5] In contrast, the issue in this appeal is whether it is necessary to consider the claim preamble when determining compliance with the written description requirement of section 112(a). The two questions are different.

The determination that a claim preamble does not limit the scope of the claim for prior art purposes does not mean the preamble can be ignored when ascertaining whether the claim complies with the written description requirement. Section 112(a) requires that "[t]he specification shall contain a written description of the invention." Thus, when the inventors claim their invention with language that includes a preamble, we understand the statute to require that the specification describe such an invention with all the language recited in the claim, including the claim preamble. While a court

---

[4] "We need not resolve this question [of whether the 'proper interpretation of the claims would include an efficacy requirement'], however, for we agree with the Board that even if the claim includes an efficacy requirement, efficacy is inherent in carrying out the claim steps. . . . We agree with the dissent that a result is only inherent if it inevitably flows from the *prior art disclosure*, but there is no question here that treating stroke-prone patients with ramipril [*as described in the HOPE publication*] does in fact inevitably treat or prevent stroke." (Emphasis added.)

[5] The Board, in a new ground of rejection, found that all the claims would have been obvious in view of prior art. The court held that the claim preamble "merely recites the purpose of the process; the remainder of the claim (the three process steps) does not depend on the preamble for completeness, and the process steps are able to stand alone. . . The Solicitor's interpretation of the preamble would improperly broaden the scope of the claim." *In re Hirao*, 535 F.2d 67, 70 (CCPA 1976).

may subsequently decide that the preamble is not limiting for the purpose of determining whether a claim is patentable under § 102 or § 103, etc., the statutory burden to *describe* the "invention" is still shouldered by the inventor(s) who determines the subject matter which they "regard[ ] as the invention." 35 U.S.C. § 112(b) (2018) ("The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."). Here, where the inventors regard their invention as "a method of treating a patient by administering an anti-C5 antibody with an Fc domain," they have the statutory burden under the written description requirement of section 112(a) to describe such a method, including the treating aspect of the claim recited in the claim preamble.

Contrary to Appellant's arguments, the recited preamble of treating a patient is an essential part of the claimed invention and therefore necessarily limiting. As explained in *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1345 (Fed. Cir. 2003):

> [An intended] use or purpose usually will not limit the scope of the claim because such statements usually do no more than define a context in which the invention operates. But as we explained in *Griffin v. Bertina*, 285 F.3d 1029, 62 USPQ2d 1431 (Fed. Cir. 2002), preamble 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. *Id.* at 1033, 62 USPQ2d at 1434.

To determine "the essence of the invention," we must turn to the specification, consistent with the need to consult the specification when determining the broadest reasonable interpretation of a claim. The "correct inquiry in giving a claim term its broadest reasonable interpretation in light

of the specification is . . . an interpretation that corresponds with what and how the inventor describes his invention in the specification, i.e., an interpretation that is 'consistent with the specification.'" *In re Smith Int'l, Inc.*, 871 F.3d 1375, 1382–1383 (Fed. Cir. 2017) (quoting from *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997)) (emphasis omitted).

The improvement recited in the method of claim 8 is an "Fc domain" of an anti-C5 antibody where "said Fc domain comprising amino acid substitutions M428L/N434S as compared to a human Fc polypeptide, . . . wherein said anti-C5 antibody with said amino acid substitutions has *increased in vivo half-life* as compared to said antibody without said substitutions." (Emphasis added.)

The Specification discloses that the reason to increase the *in vivo* half-life of an antibody is to use the antibody as a therapeutic. Spec. ¶ 10. A therapeutic is for the "treatment of diseases or disorders."[6] In its "Background" section, the Specification describes mutations to the Fc region of an antibody with respect to the administration of antibodies as "therapeutics":

> The administration of antibodies and Fc fusion proteins as therapeutics requires injections with a prescribed frequency relating to the clearance and half-life characteristics of the protein. Longer *in vivo* half-lives allow more seldom injections or lower dosing, which is clearly advantageous. Although the past mutations in the Fe domain have lead [sic, led] to some proteins with increased FcRn [(an Fc receptor)] binding affinity

[6] Therapeutic: "of or relating to the treatment of disease or disorders by remedial agents or methods." Merriam-Webster.com (last accessed May 15, 2023), www.merriam-webster.com/dictionary/therapeutic.

> and *in vivo* half-lives, these mutations have not identified the optimal mutations and enhanced in vivo half-life.

Spec. ¶ 10.

After describing the use of antibodies "for therapeutic use" (*id.* ¶ 12), the Specification discloses that "Human IgG1 is the most commonly used antibody for therapeutic purposes," and describes the need to improve its binding and half-life. *Id.* ¶ 14. "Additionally," the Specification discloses "there is a need to combine variants with improved pharmacokinetic properties with variants comprising modifications to improve efficacy through altered FcgammaR binding [(receptor for Fc portion of antibody)]. The present application meets these and other needs." *Id.* In other words, the purpose of increasing the binding and half-life of the Fc region of the antibody is to improve its efficacy when administered to a human as a therapeutic agent.

The Specification makes it clear from these disclosures that the "essence of the invention" is an improved Fc domain of an antibody to use the antibody therapeutically to *treat* a human patient. Consistently, the claim preamble recites "a method of treating a patient." Treatment is not merely a context in which the Fc domain is useful, but instead it is "the *raison d'être* of the claimed method itself." *Boehringer Ingelheim Vetmedica*, 320 F.3d at 1345. The Specification discloses that the choice of the antigen to which the antibody having the improved Fc domain binds, such as the C5 antigen, "depends on the desired application," and "therapeutic antibodies" are the primary focus of the applications disclosed in the Specification. Spec. ¶¶ 128, 130, 131 ("A number of antibodies and Fc fusions that are approved for use, in clinical trials, or in development may benefit from the Fc variants of the present invention. These antibodies and Fc fusions are herein referred

to as 'clinical products and candidates.'"), ¶¶ 132–139, 141 ("The present application also provides IgG variants that are optimized for a variety of therapeutically relevant properties."), ¶¶ 144–147.

Furthermore, a court will treat a preamble as a claim limitation if it "recites essential structure or steps." *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002). The only step in claim 8 is "administering" the antibody having the Fc domain and thus it is an "essential" step in the claim. The "administering" step, in the context of the Specification, is to treat a patient. Spec. ¶ 20 ("In another embodiment, the invention includes a method of treating a patient in need of said treatment comprising administering an effective amount of an Fc variant described herein."); *see* also ¶ 184. For this reason, we do not agree that it was erroneous to consider the preamble in its entirely as the "essence" of the claimed invention and to "define[s] the boundaries of the claimed invention." Req. Reh'g 6–7. Appellant's dicing the claim preamble into "treating," which is asserted not to be limiting, and "administering," which is asserted to be limiting, ignores the essence of the invention and the therapeutic purpose for which the antibody is administered. *Id.* at 4.

Appellant's attempt to circumvent the claim preamble by asserting that the claim scope is satisfied by a C5 antibody, alone, having "the claimed Fc modification" is erroneous because it construes the claim as a product, not a method which properly defines the claim scope. Req. Reh'g 7.

The preamble of a Jepson claim has been construed by the Federal Circuit. In *Rowe v. Dror*, 112 F.3d 473, 479–480 (Fed. Cir. 1997), the court

determined that the preamble of a Jepson claim was an "affirmative limitation" of the claim. The court explained:

> The Jepson form allows a patentee to use the preamble to recite "elements or steps of the claimed invention which are conventional or known." 37 C.F.R. § 1.75I (1996). When this form is employed, the claim preamble defines not only the context of the claimed invention, but also its scope. . . . United States Patent and Trademark Office, *Manual of Patent Examining Procedure* § 608.01(m) (6th ed. rev.Sept.1995) ("[The Jepson form of claim] is to be considered a combination claim. 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."). Thus, the form of the claim itself indicates Rowe's intention to use the preamble to define, in part, the structural elements of his claimed invention. The device for which the patent claims "an improvement" is a "balloon angioplasty catheter."

Id. at 479.

Although *Catalina*, 289 F.3d at 808, acknowledged that "[n]o litmus test defines when a preamble limits claim scope," the court recognized that "Jepson claiming generally indicates intent to use the preamble to define the claimed invention, thereby limiting claim scope" (citing *Rowe*; *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1029 (Fed. Cir. 2002)). *See also Kegel Co., Inc. v. AMF Bowling, Inc.*, 127 F.3d 1420, 1426 (Fed. Cir. 1997) ("As we recognized in *Rowe*, the fact that the patentee has chosen the Jepson form of the claim evidences the intention 'to use the preamble to define, in part, the structural elements of his claimed invention.' [*Rowe*, 112 F.3d at 479.] Thus, we conclude that the invention of claim 7 consists of the maintenance machine in combination with the improvement to the maintenance assembly.").

The court in *Artic Cat, Inc. v. GEP Power Products, Inc.*, 919 F.3d 1320, 1330 (Fed. Cir. 2019) consistently held:

> We have long held that preamble language is limiting when the claim recites a combination in the way specified in the one PTO regulation on preambles, *i.e.*, by describing the "conventional or known" elements in a "preamble," followed by a transition phrase "such as 'wherein the improvement comprises,'" and then an identification of elements that "the applicant considers as the new or improved portion." 37 C.F.R. § 1.75(e).

Appellant cites the analysis of a Jepson claim in *Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1573 (Fed. Cir. 1996) in which the court, "when analyzing the preamble of [the] *Jepson* claim," stated "it is 'appropriate to determine whether the term in the preamble serves to define the invention that is claimed, or is simply a description of the prior art.'" Req. Reh'g 4. However, while the *Applied Materials* court determined that the claim preamble "[i]n a cold purge process" was stated in the "context of the state of the art," the preamble was still considered a required "'limitation which the accused device must meet in order to literally infringe'" the patent at issue in the proceeding. *Id.* at 1571, 1572–1573. Claim 8 is no different.

Does claim 8 have written description support even if the preamble is limiting?

Appellant contends that when the claimed limitation of "method of treating a patient" is construed as limiting, claim 8 would still have written description support. Req. Reh'g 11. Appellant argues that "[t]reating" "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.'" *Id.*

The meaning and scope of a claim is interpreted in light of the detailed description of the invention in the specification. *Smith*, 871 F.3d at 1382–1383.The Specification discloses the "need" met by the Specification is to "combine variants with improved pharmacokinetic properties with variants comprising modifications to improve efficacy." Spec. ¶ 14. Appellant's statement that the claim does not require effectiveness or efficacy is incorrect because it does not consider what is described in the Specification and the stated need met by the invention. The PTAB cases cited by Appellant to support its argument are unavailing because they are based on different facts and specifications. Instead, the specification must be consulted when interpreting a claim. *Smith*, 871 F.3d at 1382–1383.

We have considered Appellant's further arguments that Specification provides an adequate written description of claim 8, but its arguments are similar to those made in the Appeal Brief and already addressed in detail in the Decision. Req. Reh'g 7–10.

CLAIM 9 REJECTIONS

Claim 9 is rejected under 35 U.S.C. § 112(a) as lacking a written description and under 35 U.S.C. § 112(b) as indefinite. Dec. 28–29.

Claim 9 is reproduced below from the "Claims Appendix" of the Appeal Brief:

> 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.

The element of the anti-C5 antibody that binds to the human C5 protein is claimed under 35 U.S.C. § 112(f) "as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof" which is "construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." For short-hand, this element is referred to as a "means-plus-function" element or the claim as a means-plus-function claim.

Appellant argues that only one disclosed embodiment having a structure is necessary to have a valid means-plus-function claim. Req. Reh'g 12–14 (citing *Cardiac Pacemakers, Inc. v. St. Jude Med, Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002); *Crea Products, Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1346 (Fed. Cir. 2002)).

Appellant has not directed us to any cases in which § 112(f) has been applied to an antibody claim, or more broadly to a protein[7] or DNA claim. Generally, to determine § 112(a) written description compliance for claims covering biotechnology inventions, including claims directed to proteins and DNA, we take guidance from *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) which held:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other

[7] An antibody is a protein.

> materials. [*Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993)]; *In re Smythe*, 480 F.2d 1376, 1383 . . . (Cust. & Pat.App.1973).

See also Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1354 (Fed. Cir. 2010).

Further guidance comes from *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 964 (Fed. Cir. 2002) which adopted guidelines issued by the USPTO that the written description requirement can be met by a "*disclosed correlation between function and structure*."

We consider the recited "means for binding human C5 protein" to be a chemical genus because § 112(f) construes the recited "means" as covering the binding structure disclosed in the Specification "and equivalents thereof." The "equivalents thereof" broadens any structure disclosed in a specification to a group or genus of structures.

The requirements to comply with the written description requirement of section 112(a) are not coincident nor fully satisfied by complying with section 112(f) for a claim in means-plus-function format. *See In re Dossel*, 115 F.3d 942, 946 (Fed. Cir. 1997) ("Paragraph 6 of § 112, which permits a claim in means-plus-function form and specifies 'such claim shall be construed to cover the corresponding structure, material, or acts described in the specification,' does not itself implicate the requirements of section 112 ¶ 1. Paragraph 1 provides the requirements for what must be contained in the written description *regardless of whether claims are written in means-plus-function form or not*.") (emphasis added); *Intellectual Prop. Dev., Inc. v. UA-Columbia Cablevision of Westchester, Inc.*, 336 F.3d 1308, 1319 (Fed. Cir. 2003) (In the context of a claim written in means-plus-function format, the court held "[f]ailure to disclose adequate structure corresponding to the recited function in accordance with 35 U.S.C. § 112, paragraph 1, results in

the claim being of indefinite scope, and thus invalid, under 35 U.S.C. § 112, paragraph 2."). Thus, even if only one structure is required to meet section 112(f), the inquiry for compliance with section 112(a) does not end there.

In sum, we do not agree with Appellant that a different standard for compliance with the written description requirement should be applied to an antibody claim simply because the claim is written in means-plus-function format. It is inconsistent to arrive at a different result for an antibody claim comprising a means-plus-function element than for claim reciting the same antibody element without invoking § 112(f). *See Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021); *AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech., Ltd.*, 759 F.3d 1285 (Fed. Cir. 2014) for their discussion of written description for antibody claims).

As discussed in the Decision, there is only one example disclosed in the Specification of the claimed "means for binding human C5 protein," "5G1.1," and no structure is disclosed for it. Dec. 29–30 (*see* Spec. ¶ 131). Appellant contends that the disclosure of the 5G1.1 antibody "is all that is required under 35 U.S.C. § 112, paragraph 6 for corresponding structure for the claimed function of 'binding human CS protein.'" Req. Reh'g 13. Appellant argues that only one structure is required to meet the statutory requirement. *Id.* at 14. But the structure of the 5G1.1 antibody is not defined or described in the Specification. Appellant has not established that the structure of the 5G1.1 antibody was known at the time the application was filed. Equivalence under section 112(f) cannot be determined for claim 9 because there is no disclosed structure to make that determination. The failure to "disclose adequate structure corresponding to the recited function . . . results in the claim being of indefinite scope, and thus invalid, under 35

U.S.C. § 112, paragraph 2." *Intellectual Prop. Dev.*, 336 F.3d at 1319. Thus, we discern no error in the rejection of claim 9 as indefinite under section 112(b).

OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 8 and 9 stand rejected by the Examiner under the judicially created doctrine of obviousness-type double patenting as obvious in view of claims 1–5 of the combination of the '818 patent claims and Schwaeble. Final Act. 17. The '818 patent claims are directed to host cells, expression vectors, and nucleic acids for making the same Fc variant recited in instant claims 8 and 9. Dec. 30. Schwaeble discloses anti-C5 antibodies. *Id.* We affirmed the rejection. *Id.* at 34.

Appellant contends that the Examiner's failure to provide a prima facie case of unpatentability for the nonstatutory obviousness-type double patenting rejection was "overlooked" in the Decision. Req. Reh'g 15. Appellant asserts that "the Examiner offered nothing more than a conclusory assertion without any citation support that it would have been obvious to combine the '818 Patent and Schwaeble." *Id.* Appellant further asserts that the Examiner "failed to explain why a person of skill in the art would have been motivated to make such a combination let alone that a person of skill in the art would have had a reasonable expectation of success in such a combination." *Id.*

These arguments were addressed in the Decision.[8] Dec. 31–34. We did not overlook the asserted deficiency in the prima facie case nor the Examiner's reason to combine the '818 patent claims and Schwaeble. The

[8] The reference to "Appeal Br. 18" on page 32, line 2, of the Decision is an error. The correct reference is "Final Act. 18."

Decision responded to Appellant's same arguments[9] made in the Appeal and Reply Briefs. *Id.* In the Request for Rehearing, Appellant does not identify an error or deficiency in our response.

CONCLUSION

The Request for Rehearing is denied.

DECISION SUMMARY

Outcome of Decision on Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Denied	Granted
8, 9	112	Written Description	8, 9	
9	112	Indefiniteness	9	
8, 9		Nonstatutory Double Patenting over '818 patent, Schwaeble	8, 9	
Overall Outcome			8, 9	

[9] "As explained in Appellant's Opening Brief and Reply Brief, incorporated herein, the Examiner offered nothing more than a conclusory assertion without any citation support that it would have been obvious to combine the '818 Patent and Schwaeble but failed to explain why a person of skill in the art would have been motivated to make such a combination let alone that a person of skill in the art would have had a reasonable expectation of success in such a combination." Req. Reh'g 15.

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Final Outcome of Appeal after Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed	New Ground
8, 9	112	Written Description			8, 9
9	112	Indefiniteness			9
8, 9		Nonstatutory Double Patenting over '818 patent, Schwaeble	8, 9		
8, 9		Nonstatutory Double Patenting over '543 patent, Schwaeble		8, 9	
Overall Outcome			8, 9		8, 9

DENIED

CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

1. This brief complies with the type-volume limitations of Federal Rule of Appellate Procedure 32(a)(7)(B) because this brief contains 13,350 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office 365 in Times New Roman 14-point font.

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Dated: September 29, 2023