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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

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[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.

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

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS

In re application of:	Conf. No.: **5148**
Chamberlain et al.	Art Unit: **1644**
Application No. **16/803,690**	Examiner: **KOLKER, Daniel E.**
Appeal No. **2022-001944**	Certificate of Transmission (37 C.F.R. § 1.8) I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via the Office electronic filing system in accordance with § 1.6(a)(4) on March 10, 2023.
Filed: **February 27, 2020**	
For: **Fc VARIANTS WITH ALTERED BINDING TO FCRN**	/ Leonor Rivera-Huerta / Leonor Rivera-Huerta

REQUEST FOR REHEARING UNDER 37 C.F.R. §§ 41.50, 41.52

Mail Stop Appeal Brief—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This Request for Rehearing is filed in response to the Decision on Appeal mailed January 10, 2023 (hereinafter, "the Decision").

To the extent any fees are due, the Commissioner is hereby authorized to charge any required fee(s) to Morgan, Lewis & Bockius LLP Deposit Account No. 50-0310 (Attorney Docket No. 067461-5026-US-27).

I. INTRODUCTION

The inventions of 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 increased in vivo half-life as compared to an antibody lacking these Fc substitutions. The specification details these claimed Fc domain substitutions and describes that they achieve increased *in vivo* half-life for antibodies, which the Board did not dispute. Despite the inventors' clear possession of these inventions, the Board erroneously issued new grounds rejecting claims 8-9 for lack of written description support. Decision at 36.

For claim 8—a *Jepson* claim—the Board improperly imparted patentable weight to the entire preamble and then further inferred from that language a functional efficacy limitation. The Board erred by failing to recognize that claim 8 claims a novel Fc domain modification applied by a predictable art to well-known anti-C5 antibodies, which are possessed generally (and not merely by the inventors), as the *Jepson* claim format indicates.

For claim 9—a means-plus-function claim—the Board again misapprehended the claim scope. It not only gave patentable weight to the preamble's "treating a patient" phrase, but it also ignored the specification's clear description of corresponding structure. The Board's erroneous claim construction led the Board to improperly finding claim 9 indefinite and consequently also lacking written description support.

Finally, the Board affirmed the Examiner's obviousness-type double patenting ("ODP") rejection of claims 8 and 9 based on claims 1-5 of U.S. Patent No. 10,336,818 ("the '818 Patent") in view of U.S. Publication No. 2006/0018896 to Schwaeble ("Schwaeble"). Appellant seeks rehearing on this affirmance because the Board overlooked that the Examiner failed to establish a *prima facie* case of nonstatutory obviousness-type double patenting.

Appellant respectfully requests that the Board withdraw the new grounds of rejection under 35 U.S.C. § 112(a) and § 112(b) and reverse its affirmance of the Examiner's ODP rejection such that this application may proceed to issuance with claims 8 and 9.[1]

II. ARGUMENT

A. The Board Erred by Rejecting Claim 8 Under 35 U.S.C. § 112(a)

Claim 8 is a *Jepson* claim, which includes a preamble reciting "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. *See* 37 C.F.R. § 1.75(e); Decision at 4-5.

Claim 8 is reproduced below with the preamble bolded:

> **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.

Because of claim 8's *Jepson* format, the law presumes that the preamble is conventional or known. The Board concurred: "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." Decision at 3.[2] The remainder of the claim is directed to that "which the applicant considers as the new or improved portion." *See* 37 C.F.R. § 1.75(e).

The Board identified the improvement, i.e. the invention, as an "Fc domain comprising the amino acid substitutions M428L/N434S as compared to a human Fc polypeptide." Decision at 3-

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[1] Appellant notes that the application is a pre-AIA application such that 35 U.S.C. § 112, first and second paragraph applies, not 35 U.S.C. § 112(a) and § 112(b).

[2] Emphasis added unless otherwise indicated.

4. The Board never once suggested that this improvement did not satisfy the written description requirement.

The Board incorrectly focused on the preamble language, concluding that the "method of treating a patient by administering an anti-C5 antibody with an Fc domain" renders the claim invalid for lack of written description. Decision at 8-27. The Board, however, misinterpreted the proper scope of the claim—erroneously treating "method of treating a patient" as limiting—and thus misapplied 35 U.S.C. § 112, first paragraph. It also overlooked the exhibits and expert declaration cited in Appellant's Opening Brief. Even though the limiting portion of the preamble—"administering an anti-C5 antibody with an Fc domain"— must satisfy written description, ample evidence demonstrates that the inventors (and skilled artisans generally) are in possession of these antibodies. The Board should reverse its written description rejection of claim 8.

1. The Board Erroneously Assumed the Preamble Phrase "Method of Treating a Patient" is Limiting and Thus Forms Part of the Written Description Analysis

The Board began its written description analysis by construing claim 8's preamble "to determine the objective reach of the claim." Decision at 4. Without any explanation or support, 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. But the phrase "method of treating a patient" is not, and the Board's contrary assumption fatally infected its written description analysis. Notably, the Board never contested that the claimed improvement is sufficiently described under § 112 standards.

The law imposes no "litmus test" for determining when a preamble is limiting. *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006). "Whether to treat a preamble as a claim

limitation is determined on the facts of each case in light of the claim as a whole." *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003).

The preamble of claim 8 includes two distinct components: (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. Appellant agrees that the second component ("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.

But the first component ("a method of treating a patient") is not limiting because it merely describes that treating patients with anti-C5 antibodies was known. *See Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1571 (Fed. Cir. 1996) (when analyzing the preamble of a *Jepson* claim 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.").

Two key factors support this conclusion. First, the phrase "method of treating a patient" provides no antecedent basis to remaining claim limitations. Second, the sole claimed step of "administering" the modified C5 antibody would be performed in the same way regardless of the "method of treating a patient" language because the claim does not require any functional result or effect from "administering." 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." *See 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").

Instead, "method of treating a patient" merely states an intended purpose, which the Federal Circuit has repeatedly held to be non-limiting. *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 Montgomery*, 677 F.3d 1375, 1389-81 (Fed. Cir. 2012) ("A method for the treatment or prevention of stroke or its recurrence . . ." is not limiting).

Thus, when properly construed, claim 8 simply requires administering a C5 antibody with the claimed Fc domain substitutions. The preamble phrase "method of treating a patient" neither defines the claimed invention nor forms part of the written description analysis.

There is nothing improper in deconstructing a preamble into non-limiting and limiting features. The Federal Circuit 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, 1354–55 (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.").

Claim 8's *Jepson* format does not change the analysis of the preamble. In *Applied Materials,* the Federal Circuit assessed the preamble of a *Jepson* claim, instructing 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 at 1571. Thus, the Federal Circuit has not set a *per se* rule that the entire preamble in *Jepson* claims must always be limiting.

In *Ex Parte Gregg*, the Board likewise did not exempt *Jepson* claims from the traditional preamble analysis. Using a rationale that applies equally to claim 8, the Board determined the preamble of the *Jepson* claim was not limiting: "[W]hen a structurally complete invention is defined in the claim body and the preamble only states a purpose or intended use for the invention, the preamble is not a claim limitation." 2013 WL 6681555, at *4 (P.T.A.B. Dec. 13, 2013); *see also L'Oreal S.A. v. Johnson & Johnson Consumer Companies, Inc.*, No. CV 12-98-GMS, 2013 WL 3788803, at *1 (D. Del. July 19, 2013); *see also Eazypower Corp. v. Jore Corp.*, 2008 WL 3849921, *3–*4 (N.D. Ill. 2008) (rejecting argument that preambles in *Jepson* claims were *per se* claim limitations).

The Board erred in assuming the "method of treating a patient" phrase is limiting and affording it patentable weight such that it must meet the written description requirement under 35 U.S.C. § 112.

The Board premised its written description analysis on its flawed interpretation that claim 8 requires treating a patient with some efficacious result and thus analyzed it as a genus claim using functional language to define the boundaries of the claimed invention. Decision at 10 ("The antibody genus is claimed functionally and by the result that it treats an unidentified condition or disease."); *id.* ("[t]he 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.").[3]

Based on this faulty premise, the Board erroneously found that the inventors were required to describe how a skilled artisan could distinguish anti-C5 antibodies with the modified Fc domain providing the functional effect of "treating" patients from those that cannot. When properly construed, the language "treating a patient" is irrelevant to the written description analysis. All that claim 8 requires is administering an anti-C5 antibody with a modified Fc domain. Thus, the Board's statement that "one of ordinary skill would be unable to distinguish which anti-C5 antibodies having the claimed Fc domain substitutions would fall within the scope of claim 8 and which would not," Decision at 12, is erroneous—the claim does not distinguish between such antibodies. If a C5 antibody has the claimed Fc modification, it falls within the scope of the claim.

When properly construed, claim 8 requires only administering an anti-C5 antibody with the claimed improvement to the Fc domain.[4] Decision at 6. And as Appellant will now show, claim 8 enjoys ample written description support under this construction.

2. The Invention of Claim 8 Has Adequate Written Description Support

The specification provides ample written description for claim 8's full scope. "Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention.'" *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010). The "invention" here is the claimed Fc domain substitutions, and the Board did not

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[3] *See also* Decision at 20 (the specification fails to disclose a "correlation" between "the function of the antibody to bind C5 and treat a patient and antibody structure."); *see also id.* at 23 ("although there is a 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.").

[4] With this proper construction in place, the Board's discussion of the specification not providing "a definition of anti-C5 antibody or guidance on how it is selected for treating the unidentified condition or disease" becomes irrelevant. Decision at 7.

dispute the specification supports this invention, Decision at 6. That should have ended the inquiry.

Even if the inventors were required to provide written description support for the limiting portion of the preamble of a *Jepson* claim, they did so. The Board's focus on the anti-C5 antibodies with the engineered Fc domain substitutions not only ignored the claimed invention but also ignored that C5 antibodies were indisputably well-known in the art. Appellant's Opening Brief proffered a wealth of evidence affirming these antibodies were well-known, which the Board did not dispute.[5] Br. at 10, 14-19.

Appellant's exhibits confirm this understanding. The Board erroneously focused on whether the exhibits disclosed treating a patient, noting that "many of them do not disclose treating a patient with an anti-C5 antibody with an Fc domain." Decision at 13; *see also id.* at 14-17; *id.* at 18 ("Appellant still has not explained how this list [of prior art antibodies] provides a written description of the claimed broad genus of anti-C5 antibodies and treatment indications"). But as discussed above, whether the exhibits described treating a patient is irrelevant.

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." Decision at 25. Putting aside the Board's error in failing to meaningfully address Dr. Dahiyat's declaration, Br. at 18-19 (discussing *In re Huai-Hung Kao*, 639 F.3d 1057, 1067 (Fed. Cir. 2021)), the Board's rationale for ignoring the expert declaration is immaterial because the claimed invention does not require treating a patient. The

[5] The recitation of anti-C5 antibodies in the preamble of the *Jepson* claim also supports that anti-C5 antibodies were "conventional or known." *See* 37 C.F.R. § 1.75(e).

specification also provides a specific example of an anti-C5 antibody (5G1.1) which the Board did not dispute.[6] Decision at 11.

The law requires nothing more. "[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); *see also* Br. at 12-13. Anti-C5 antibodies were indisputably well-known in the art, and "[i]t 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, 1357 (Fed. Cir. 2005) ("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge."); *Zoltek Corp. v. United States*, 815 F.3d 1302, 1308 (Fed. Cir. 2016) ("The written description need not include information that is already known and available to the experienced public.")). Indeed, the Board acknowledged that "[i]t 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." Decision at 19.

These facts demonstrating the well-known nature of anti-C5 antibodies distinguish *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. Decision at 24. But *Juno* itself emphasized the fact-bound nature of the inquiry. *See id.* at 1341 (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

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[6] 5G1.1 was described as early as 1996. That molecule was subsequently modified, humanized, and marketed as eculizumab in 2002. *See, e.g.*, Adis International Limited. Eculizumab: 5G1.1, h5G1.1, long-acting anti-C5 monoclonal antibody 5G1-1, long-acting anti-C5 monoclonal antibody 5G1.1. *Drugs R D.* 2007;8:61–8.22; Kaplan M. Eculizumab (Alexion). *Curr Opin Invest Drugs* 2002;3:1017–23.23; and Zuber J. et. al. Use of eculizumab for atypical haemolytic uraemic syndrome and C3 glomerulopathies. *Nat Rev Neph* 2012; 8:643–57.

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").

Here, the exhibits cited in Appellant's Opening Brief, as well as Dr. Dahiyat's Declaration, confirm that much was known about anti-C5 antibodies at the time of the invention. The prior art included numerous specific examples of the antibodies—far more than the limited number known in *Juno*—and the technology is mature. Br. at 14-18. Facts matter, and unlike the claims in *Juno*, the evidence here demonstrates that anti-C5 antibodies are well-known and already possessed by skilled artisans. The specification says relatively little about anti-C5 antibodies because they are so well-known in the art and already in the possession of skilled artisans. The inventors did not invent anti-C5 antibodies (which are well-known) but merely invented the improvement of their half-life through amino acid substitutions. The claims are thus perfectly suited to the *Jepson* format, which allows the inventors clearly to distinguish what is already conventional and known (administering an anti-C5 antibody with an Fc domain), 37 C.F.R. § 1.75(e), from the novel improvement (the claimed amino acid substitutions).

* * * *

At bottom, the record provides ample written description support: (i) claim 8 has no functional limitations aside from the increased half-life deriving from the specifically claimed amino acid substitutions in the Fc region, (ii) anti-C5 antibodies were well-known (and the scientific literature detailed numerous amino acid structures for them), and (iii) the specification describes the invention comprising M428L/N434S substitutions in the Fc region. Br. at 10-21. The Board should withdraw its written description rejection of claim 8.

3. Even if the "Method of treating a patient" Preamble Language is Limiting, Claim 8 Still has Written Description Support

In the alternative, even if the Board were to determine the preamble should be construed in its entirety as limiting, claim 8 would still have written description support. The phrase "method of treating a patient" requires nothing more than the claimed step of "administering" the anti-C5 antibody with the recited Fc domain substitutions. "Treating" does not connote any effectiveness or require any particular result. It merely refers to providing care (i.e., administering). And the remainder of the claim likewise lacks any required efficacy or result deriving from the sole claimed step of "administering."

Claim 8 is highly analogous 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 et al. 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 in the patient, but instead only requires 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") (emphasis original).

Accordingly, if the Board were to determine "method of treating a patient" is limiting, "treating" still would not require any functional result—it only requires administering the anti-C5 antibody with the claimed Fc domain substitutions. Thus, regardless of whether the preamble is construed as limiting, the "invention" here is the claimed Fc domain substitutions, which the Board did not dispute the specification supports. Decision at 6. Nor did the Board dispute that (i) anti-

C5 antibodies were well-known in the art, and (ii) the specification describes a specific example of an anti-C5 antibody (5G1.1). *See* Section II.A.2.

B. The Board Erred by Rejecting Claim 9

1. Claim 9 Invokes 35 U.S.C. § 112, paragraph 6[7]

Claim 9 includes the means-plus-function limitation "means for binding human C5 protein":

> 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.

The parties agree that by incorporating the limitation "means for binding human C5 protein," claim 9 invokes 35 U.S.C. § 112, paragraph 6. Decision at 28; Br. at 22-23. When analyzing a claim that invokes § 112, paragraph 6 one must "first identify[ ] the claimed function(s) of the phrase and second determin[e] what structure disclosed in the specification performs that function." *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1351 (Fed. Cir. 2015) (en banc).

Appellant and the Board agree that the claimed function is "binding human C5 protein." Br. at 26; Decision at 28-29. "After identifying the claimed function, the court must then determine what structure, if any, disclosed in the specification corresponds to the claimed function." *Cardiac Pacemakers, Inc. v. St. Jude Med., Inc.*, 296 F.3d 1106, 1113 (Fed. Cir. 2002). Whether the specification describes sufficient structure "must be considered from the perspective of a person skilled in the art," and the "question is not whether one of skill in the art would be capable of implementing a structure to perform the function, but whether that person would understand the

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[7] Appellant notes that because this is a pre-AIA application, 35 U.S.C. § 112, paragraph 6 applies, not the AIA version of § 112(f).

written description itself to disclose such a structure." *Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1338 (Fed. Cir. 2008).

A person of skill in the art reviewing the specification for corresponding structure would have identified the phrase "anti-complement (C5) antibodies such as 5G1.1" as relevant to the analysis and, specifically, would have identified the 5G1.1 antibody as the structure performing the claimed function. Specification at [133]. In a means-plus-function claim, "structure disclosed in the specification 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 first part of the specification phrase reciting the genus of "anti-complement (C5) antibodies" cannot be considered corresponding structure for purposes of 35 U.S.C. § 112, paragraph 6. As the Board noted, this language "is generic." Decision at 29. It thus fails to provide sufficiently defined structure, as required under § 112, paragraph 6, that is clearly linked to the function of binding human C5 protein. Not only does this language encompass a broader genus of C5 antibodies than those that bind human C5 protein, but it also fails to provide details as to the specific structure of the antibody performing this very specifically claimed function.

A person of skill in the art, however, would have understood that the latter portion of the specification phrase "anti-complement (C5) antibodies such as 5G1.1" 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. Indeed, the Board admitted that it "consider[ed] the term '5G1.1' disclosed in the Specification to be a specific antibody that binds to human C5." Decision at 7. That 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 C5 protein." In a means-plus-function claim,

a "claim is valid even if only one embodiment discloses corresponding structure." *Cardiac Pacemakers*, 296 F.3d at 1113 (describing "corresponding structure" as structure that performs the claimed function). *See also Creo Products, Inc. v. Presstek, Inc.*, 305 F.3d 1337, 1346 (Fed. Cir. 2002) ("where the specification discloses different alternative embodiments, the claim is valid even if only one embodiment discloses corresponding structure.").

Therefore, when properly analyzed under 35 U.S.C. § 112, paragraph 6, claim 9 should be construed to cover the corresponding structure for the "means for binding human C5 protein"—5G1.1 and "equivalents thereof." *See* 35 U.S.C. § 112, paragraph 6.

C. The Board Erred by Rejecting Claim 9 Under 35 U.S.C. § 112 (a) and 35 U.S.C. § 112(b)

Because the specification identifies corresponding structure (5G1.1) performing the claimed function to satisfy the requirements under 35 U.S.C. § 112, paragraph 6 the Board erred by rejecting the claim under 35 U.S.C. § 112(a) and § 112(b).[8]

Under the proper analysis for claim 9's 35 U.S.C. § 112, paragraph 6 limitation, corresponding structure exists in the specification (i.e., 5G1.1) such that the claim cannot be indefinite. Thus, the Board's indefiniteness rejection should be reversed.

The Board also rejected the claim as invalid for lack of written description but provided no independent analysis of claim 9's written description besides asserting there was insufficient corresponding structure. Decision at 29-30. Because, as described above, sufficient corresponding structure exists, the Board erred in rejecting claim 9 for lack of written description.[9]

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[8] Appellant notes that the same argument applies when referencing the pre-AIA section of § 112, first and second paragraphs, which is the applicable statute to this pre-AIA application.

[9] The Board also makes a passing reference to "reasons discussed above for claim 8" without explaining what portion of its written description analysis of claim 8 ostensibly applies to claim 9. Decision at 30. As discussed, claim 8 has adequate written description support.

As a final point, because claim 9 when properly construed under 35 U.S.C. § 112, paragraph 6, encompasses only 5G1.1 and its equivalents having the claimed Fc modification, there is undoubtedly adequate written description support.[10] As the Board recognizes, "5G1.1 was known in the prior art before the effective filing date of the application" and is a "specific antibody." Decision at 7.

As such, the Board should withdraw its rejection of claim 9 for indefiniteness and lack of written description.

D. The Board Erred by Affirming the Examiner's Nonstatutory Obviousness Type Double Patenting Rejection of Claims 8-9

The Board overlooked the Examiner's failure to provide a *prima facie* case of unpatentability for his nonstatutory obviousness-type double patenting rejection relying on the combination of the claims of the '818 Patent with Schwaeble. 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. The Examiner also failed to present a *prima facie* case of unpatentability.

Because the Board overlooked these deficiencies in the Examiner's rationale, the nonstatutory obviousness-type double patenting rejection of claims 8-9 should be reversed.

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[10] The Board should afford Claim 9's recitation of "[a] method of treating a patient" in the preamble no patentable weight. This language is nothing more than a statement of intended purpose and is therefore not limiting. *See Bristol-Myers*, 246 F.3d at 1375. The proper scope of claim 9 thus requires only the specific 5G1.1 antibody and its equivalents having the claimed Fc modification.

III. CONCLUSION

Appellant respectfully requests that the Board withdraw each of its new grounds of rejection under 35 U.S.C. § 112(a) and § 112(b) and reverse the Examiner's nonstatutory obviousness-type double patenting rejection such that this application may be allowed to issue as a patent with pending claims 8-9.

Respectfully submitted,

Date: March 10, 2023

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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.

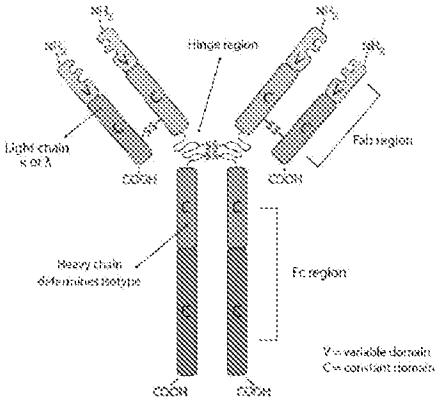
NEW GROUNDS OF REJECTION

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)