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MORGAN, LEWIS & BOCKIUS LLP (SP)
ONE MARKET, SPEAR STREET TOWER, SUITE 2800
SAN FRANCISCO, CA 94105

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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.

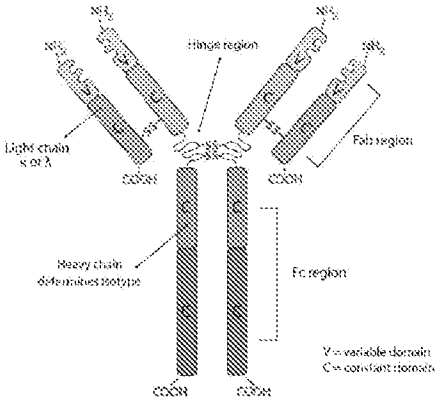
NEW GROUNDS OF REJECTION

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)