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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JOHANNES ROTH and THOMAS VOGL[1]

Appeal 2020-000771
Application 14/423,751
Technology Center 1600

Before RICHARD M. LEBOVITZ, DEBORAH KATZ, and JOHN A. EVANS, *Administrative Patent Judges*.

EVANS, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

This is a decision on appeal under 35 U.S.C. § 134(a) from the Examiner's Final Rejection of Claims 11, 12, 54, and 56, which constitute all the claims pending in this application. Appeal Br. 5. Claims 5, 6, 9, 10, 35, and 36 are cancelled. *Id.* Claims 1–4, 7, 8, 13–34, 37–53, and 55 are withdrawn. *Id.* We have jurisdiction over the pending claims under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] We use the word "Appellant" to refer to "[A]pplicant[s]" as defined in 37 C.F.R. § 1.42(a). The Appeal Brief identifies Westfaelische Wilhelms-Universitaet Muenster, as the real party in interest. Appeal Br. 3.

CLAIMED SUBJECT MATTER

Invention[2]

The claims relate to an antibody with a specificity to an epitope that is a region corresponding to amino acid positions 63–79 or 73–85 of the human protein S100A9. *See* Abstract. Claim 11, the sole independent claim, is reproduced below with some formatting added.

> 11. A method of reducing TLR4 signaling induced by homodimeric Sl00A9 or heterodimeric Sl00A8/A9 and release of TNFα in a subject suffering from rheumatoid arthritis, the method comprising administering to the subject at least one immunoglobulin that binds to a peptide of a vertebrate S100A9 protein or a portion thereof, wherein the peptide has an mino[3] acid sequence selected from
>
> MEDLDTNADKQLSFEEF (SEQ ID NO: 1),
> MEDLDTNEDKQLSFEEF (SEQ ID NO: 14),
> MEDLDTNVDKQLSFEEF (SEQ ID NO: 15),
> MEDLDTNLDKQLSFEEF (SEQ ID NO: 16),
> MEDLDTNGDKQLNFEEF (SEQ ID NO: 17),
> LEDLDTNADKQLTFEEF (SEQ ID NO: 18),
> LEDLDTNVDKQLS FEEF (SEQ ID NO: 19),
> LEDLDTNEDKQLSFEEF (SEQ ID NO: 20),
>
> MEDLDTN GDKELNFEEF (SEQ ID NO: 21),
> MEDLDTNEDKELSFEEY (SEQ ID NO: 22),

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[2] Throughout this Decision, we refer to the Appeal Brief ("Appeal Br.") filed April 15, 2019, the Reply Brief ("Reply Br.") none of Record, the Final Office Action ("Final Act.") mailed November 16, 2018, the Second or Subsequent Examiner's Answer mailed August 9, 2019, and the Specification ("Spec.") filed February 25, 2015.

[3] We find "mino" is a typographic error. In the event of further prosecution, the recitation should be corrected to read amino."

LEDLDTNGDKQLNFEEF (SEQ ID NO: 23),
MEDLDTNQDNQLSFEEC (SEQ ID NO: 24),
MEDLDTNLDQQLSFEEL (SEQ ID NO: 25),
MQDLDTNQDQQLSFEEV (SEQ ID NO: 26),
MEDLDTNQDKQLSFEEF (SEQ ID NO: 27),

MQELDTNQ NGQVDFKEF (SEQ ID NO: 28),

FEETDLNKDKELTFEEF (SEQ ID NO: 29),
QLSFEEFIMLMAR (SEQ ID NO: 3),

QLSFEEFIVLMAR (SEQ ID NO: 30),
QLSFEEFIML VAR (SEQ ID NO: 31),
QLTFEEFIMLMGR (SEQ ID NO: 32),
QLSFEEFIML VIR (SEQ ID NO: 33),
QLSFEEFIIL VAR (SEQ ID NO: 34),
QLSFEELTMLLAR (SEQ ID NO: 35),
QLSFEEVIMLFAR (SEQ ID NO: 36),
QLSFEEFSILMAK (SEQ ID NO: 37),
QLSFEEFSMLV AK (SEQ ID NO: 38),
QLSFEECMMLMAK (SEQ ID NO: 39),
QLSFEECMMLMGK (SEQ ID NO: 40),
ELSFEEYIVLVAK (SEQ IDNO: 41),
QLSFEEFVILMAR (SEQ ID NO: 42),
QLNFEEFSIL VGR (SEQ ID NO: 43), and
QVDFKEFSMMMAR (SEQ ID NO: 44).

Rejection[4]

Claims 11, 12, 54, and 56 stand rejected under 35 U.S.C. U.S.C. § 112 (1st ¶), as failing to comply with the written description requirement.

[4] The present application is being examined under the pre-AIA first to invent provisions. Final Act 2.

ANALYSIS

We have reviewed the rejections of Claims 11, 12, 54, and 56 in light of Appellant's arguments that the Examiner erred. We have considered in this decision only those arguments Appellant actually raised in the Briefs. Any other arguments which Appellant could have made but chose not to make in the Briefs are deemed to be waived. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2018). We adopt as our own the findings and reasons set forth in the rejection from which this appeal is taken and in the Examiner's Answer, to the extent consistent with our analysis below. We provide the following explanation to highlight and address specific arguments and findings primarily for emphasis.

CLAIMS 11, 12, 54, AND 56: WRITTEN DESCRIPTION.

The Examiner finds Claim 11, the sole independent claim, claims a method, including administering an immunoglobulin, that binds to a peptide of a vertebrate S100A9 protein, or a portion thereof, wherein the S100A9 protein has an epitope amino acid sequence selected from SEQ ID NO: 1 (elected species). Final Act. 3. The Examiner finds the specification defines the term antibody to encompass camelid antibodies, a domain, and aptamers and therefore, the claims encompass many genera of chemical and biological molecules. Final Act. 4. The Examiner finds, however, the specification provides no guidance regarding the corresponding structure that is required for the molecule to perform the required functions. *Id.*

Appellant points to no evidence of Record that any species of the claimed antibody genus has actually been made. Appellant proffers extensive evidence of Record to show their invention is enabled, i.e., that the

specification enables a person of skill to make and use the invention.

Appeal Br. 10. Appellant argues:

> In determining the sufficiency of support in a disclosure with respect to the written description requirement, "it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him."

Appeal Br. 10 (citing *In re Edwards*, 196 USPQ 465, 467 (C.C.P.A. 1978) (*citing In re Lukach*, 169 USPQ 795 (C.C.P.A. 1971); *In re Driscoll*, 195 USPQ 434 (C.C.P.A. 1977)).

The Examiner finds:

> the instant specification provides no description of a single immunoglobulin that binds to the claimed S100A9 peptides. Rather, Applicant has provided the structural information for the peptide (i.e. SEQ ID NO: 1) to which the immunoglobulin must bind. In *Amgen v. Sanofi*,[5] the Court held that when an antibody is claimed, 35 U.S.C. 112(a) requires adequate description of the antibody itself. *Amgen*, 872 F.3d at 1378-79. The Court expressly stated that the so-called "newly characterized antigen" test, should not be used in determining whether there is adequate written description under 35 U.S.C. 112(a) for a claim drawn to an antibody.

Ans. 11–12.

There is no Reply Brief of Record. In *Amgen*, our reviewing court held:

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[5] Citing *Amgen Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017).

> Our en banc decision in Ariad,[6] reflecting earlier decisions such as *Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 56–57, 59 S.Ct. 8, 83 L.Ed. 34 (1938), and *In re Ruschig*, 379 F.2d 990, 991–95 (CCPA 1967), made clear that, to satisfy the statutory requirement of a description of the invention, it is not enough for the specification to show how to make and use the invention, i.e., to enable it. *Ariad*, 598 F.3d at 1345–46, 1347–48.

Amgen, at 1377. The holding of *Amgen* precludes the decision Appellant seeks:

> We cannot say that this particular context, involving a "newly characterized antigen" and a functional genus claim to corresponding antibodies, is one in which the underlying science establishes that a finding of "make and use" (routine or conventional production) actually does equate to the required description of the claimed products. For us to draw such a conclusion, and transform a factual issue into a legally required inference, we would have to declare a contested scientific proposition to be so settled as to be entitled to judicial notice. That we cannot do.

Amgen, at 1378.

"When [an application for] 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 Deutschland GmbH & Co., KG v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1300 (2014) (internal quotations omitted). "We have held that "a sufficient description of a genus . . . requires the disclosure of either a representative number of

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[6] *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.*

Appellant claims, by functional language, a genus of antibodies that: (1) bind to a peptide having a claimed amino acid sequence, (2) reduce TLR4 signaling induced by a claimed S100 protein, and (3) inhibit the release of TNFα in rheumatoid arthritis. We find a person of ordinary skill in the immunologic arts, upon reading the Specification, would find written description for a genus of antibodies that (1) bound to a peptide having a claimed amino acid sequence. However, in the absence of evidence that all members of the claimed genus of antibodies (2) reduce TLR4 signaling induced by a claimed S100 protein, and (3) inhibit the release of TNFα in rheumatoid arthritis, we do not find the Record demonstrates that where an antibody binds to the claimed peptide, it inherently must also achieve these functions. Thus, Appellant's argument that the identification of immunoglobins that bind to specific S100A9 epitopes provides written description support for the claimed method is unpersuasive. (*See* Appeal Br. 12.)

Appellant argues that "[t]he instant specification teaches that immunoglobulins binding against a peptide of a vertebrate S100A9 protein or a portion thereof, are expected to have the function of reducing TLR4 signaling induced by homodimeric S100A9 or heterodimeric S100A8/ A9 and release of TNFα" (Appeal Br. 11), but an expectation of function is not sufficient to demonstrate possession of that function in an unpredictable art. *See AbbVie*, 759 F.3d at 1300. Appellant also points to one antibody clone, "I12-8-6," which is asserted to "clearly reduce[] TNFα secretion induced by

homodimeric S100A9" and to support a structure-function relationship of the immunoglobulin. Appeal Br. 12, citing Exhibit B, at 2. We are not persuaded that one clone, without further evidence, is necessarily representative of all of the immunoglobulins encompassed by Appellant's claims. Accordingly, Appellant's arguments in support of written description support do not persuade us that one of ordinary skill in the art would have considered the Specification to have described the claimed method.

In view of the foregoing, we sustain the rejection of Claims 11, 12, 54, and 56 under 35 U.S.C. U.S.C. 112 (1st ¶).

CONCLUSION

Claims Rejected	35 U.S.C. §	Basis	Affirmed	Reversed
11, 12, 54, 56	112(1st ¶)	Written Description	11, 12, 54, 56	--

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). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED