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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
15/685,257	08/24/2017	Sarah Rue	X20568A	1980

159715 7590 06/16/2020

Elanco US Inc.
Patent Division
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EXAMINER
SKELDING, ZACHARY S

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
06/16/2020	ELECTRONIC

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SARAH RUE, BRENDAN ECKELMAN,
QUINN L. DEVERAUX, and MARC NASOFF

Appeal 2019-005727
Application 15/685,257
Technology Center 1600

Before RICHARD M. LEBOVITZ, FRANCISCO C. PRATS, and JAMIE T. WISZ, *Administrative Patent Judges.*

WISZ, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

STATEMENT OF THE CASE

Appellant[1] has filed a Request for Rehearing ("Request") under 37 C.F.R. § 41.52(a)(1) for reconsideration of our Decision of March 10, 2020 ("Decision"). The Decision affirmed the Examiner's rejection of claims 21–23 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement.

DISCUSSION

Appellant raises two issues. First, Appellant asserts that the "Examiner misinterpreted the claims as to the number and type of variants being claimed, and claim misinterpretation cannot serve as a foundation for the stated rejection." Request 2. Specifically, Appellant cites to the Examiner's finding that the claims encompass millions of potential members while the Specification does not disclose what antibody structure of these potential variants is critical to the ability of the variant to bind canine CD20 with a Kd of at least 20 nM. *Id.* (citing Decision 6 (citing Final Act. 3)). Appellant asserts that the genus of potential antibodies encompassed by the claims instead involves 48,724 variants. *Id.* at 2–3.

Appellant further contends that the precise sequence of the claimed variants is known because the Examiner stated that one could enumerate the sequences potentially encompassed by the claims with the aid of a computer. *Id.* at 3 (citing Ans. 9). Appellant asks the Board to reconsider what support the Examiner "provides for the conclusion that knowing the number and individual sequences of the claimed antibody variants does 'not bring the

[1] We use the word "Appellant" to refer to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies the real party in interest as Elanco Tiergesundheit AG. Appeal Br. 2.

skilled artisan any closer to demonstrating possession of the subset of sequences that bind canine CD20 with an affinity (Kd) of at least 20 nM.'" *Id.* at 3.

Appellant further asserts that the Specification provides "blaze marks" because "[s]pecific amino acid positions within specific CDRs are identified and those specific positions may be substituted with specific other amino acids without affecting the function of the antibody." *Id.* at 4.

We are not persuaded by Appellant's arguments. As stated in our Decision, "the Specification does not disclose ***any*** members of the claimed genus because it does not disclose any 1G10 or 1G1 antibodies having any combination of variant amino acids that bind canine CD20 with an affinity of (Kd) at least 20 nM." Decision 9 (emphasis added). Regardless of whether the claims encompass millions or thousands of sequences, they still lack written description support because, in failing to disclose any member of the claimed genus, the Specification does not disclose 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 Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).

Furthermore, we are not persuaded by Appellant's citation to the Examiner's statement that one could enumerate the sequences potentially encompassed by the claim with the aid of a computer as evidence that there is written description support. Even though it may be possible to list out thousands of sequences, we agree with the Examiner that such a listing "would ***not*** bring the skilled artisan ***any*** closer to demonstrating possession of the subset of sequences that 'bind canine CD20 with an affinity (K_d) of at

least 20 nM.'" Ans. 9. As stated above and in the Decision, the Specification fails to disclose any member of the claimed genus and also does not provide a sufficient disclosure of a correlation between the claimed function — i.e., that it binds canine CD20 with an affinity (Kd) of at least 20 nM — and the structure of the antibodies that perform that function. Decision 9–10.

Second, Appellant asserts that the "Examiner misrepresented the teachings of the cited art and failed to provide substantial evidence - let alone a preponderance of evidence - that the Specification as filed lacked a written description supporting the rejected claims." Request 2. Specifically, Appellant requests that we re-examine the Examiner's citation to art, which was cited by the Examiner as evidence of the unpredictability associated with making mutations to multiple residues within a given CDR. Request 5–6 (citing Ans. 11). Appellant argues that "changes that may or may not alter an antibody's function do not provide substantial evidence the claimed variations *do* alter the function of the antibodies." *Id.* at 6.

We are not persuaded by Appellant's arguments. As Appellant acknowledges, the art cited by the Examiner shows that some, but not necessarily all, CDR mutations alter antibody function. *See* Request 6–7. For example, the paragraph in Brown[2] cited by Appellant discloses that 50% of T15 molecules with one to four mutations in the VH CDR2 region "had lost or had reduced capability to bind [antigen]." Request 6 (citing Brown 3285). While we agree with Appellant that this may mean that 50% of the

[2] Brown, McKay, et al. "Tolerance to Single, but Not Multiple, Amino Acid Replacements in Antibody V_H CDR2," The Journal of Immunology, 156:3285–3291 (1996).

mutants did not have reduced function, we disagree with Appellant that this fact is sufficient to provide written description support for the claims. We find that Brown and the other references cited by the Examiner demonstrate the unpredictability of antigen-binding when the CDR region of an antibody is mutated at one or more positions.

To satisfy the written description requirement under 35 U.S.C. § 112, first paragraph, the specification must "reasonably convey[] to those skilled in the art that the inventor had possession" of the claimed invention as of the filing date. *Ariad Pharms.*, 598 F.3d at 1351. The written description requirement for a claimed 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." *Id.* at 1350.

As explained in the Decision, the Specification fails to disclose any species falling within the scope of the genus and also fails to disclose structural features common to the members of the genus that bind canine CD20 with an affinity of (Kd) at least 20 nM. Decision 9–11. As the Decision further explained,

> the Specification's disclosure of a few 1 E4 antibody mutants, each with only a single mutation, is not sufficient to demonstrate possession of the claimed genus of structurally dissimilar 1G1 and 1G10 antibody mutants, with multiple mutations, that bind canine CD20 with an affinity (K_d) of at least 20 nM.

Id. at 10.

Appellant has not presented persuasive evidence that the Specification provides such disclosure.[3] Therefore, we find that one of ordinary skill in the art would not have understood that the inventors had possession of the claimed invention.

DECISION

We deny the requested relief with respect to making any changes to the Decision.

Outcome of Decision on Rehearing

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Denied	Granted
21–23	112, first paragraph	Written Description	21–23	

Final Outcome of Appeal after Rehearing

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
21–23	112, first paragraph	Written Description	21–23	

DENIED

[3] Although Appellant asserts that the inventors state that the specifically claimed antibody sequences result in antibody variants that bind CD20 with an affinity (Kd) of at least 20 nM, Appellant does not cite to a specific portion of the Specification which provides this evidence and we find no such support.