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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex Parte WENDY RYAN GORDON and
KLAUS NORMAN LOVENDAHL

Appeal 2019-004893
Application 15/159,381
Technology Center 1600

Before ERIC B. GRIMES, RYAN H. FLAX, and
CYNTHIA M. HARDMAN, *Administrative Patent Judges*.

CYNTHIA M. HARDMAN, *Administrative Patent Judge*.

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant¹ submits this appeal from the Examiner's decision to reject claims directed to certain fusion polypeptides. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

¹ We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as "Regents of the University of Minnesota." Appeal Br. 2.

STATEMENT OF THE CASE

The claims are directed to fusion polypeptides comprising at least a portion of a polypeptide of interest and at least a functional portion of an HUH polypeptide Rep/relaxase domain. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A fusion polypeptide comprising:
 - at least a portion of a polypeptide of interest; and
 - at least a functional portion of an HUH polypeptide Rep/relaxase domain, wherein the HUH polypeptide Rep/relaxase domain comprises:
 - a catalytic tyrosine residue;
 - at least one and no more than two metal-coordinating histidine residues; and
 - endonuclease nicking activity.

Appeal Br. 9 (Claims Appendix).

Claims 1 and 2 are on appeal. The claims stand rejected under 35 U.S.C. § 112(a) for failure to comply with the written description requirement.² Ans. 3.

OPINION

The Examiner asserts that claims 1 and 2 lack written description support because “the specification does not clearly describe the correlation between the genus of claimed HUH polypeptides structures or portions thereof and the genus of target [polynucleotide] sequences that can be cleaved/nicked by said endonuclease nicking action (function).” Ans. 4. The Examiner acknowledges that the Specification and the art teach some

² This rejection was presented as a new ground of rejection in the Examiner’s Answer. *See* Ans. 3.

polypeptides with a catalytic tyrosine and a HUH polypeptide with endonuclease nicking activity towards specific nucleotide sequences (Ans. 4, citing Spec. Table 1), but asserts that “as broadly claimed, one of skill in the art cannot predict the structure of the HUH endonucleases with specific cleavage/nicking activities.” Ans. 4.

“[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). We determine that the Examiner has not carried the burden of presenting a *prima facie* case of unpatentability.

The Examiner focuses on the lack of disclosure of a way to correlate the structure of the HUH endonucleases with the specific oligonucleotide sequences that they will cleave or nick. *See, e.g.*, Ans. 10–11. Such a correlation, however, is divorced from the claims. The claims do not recite any limitations relating to specific oligonucleotide sequences, nor do they require the ability to cleave or nick any specific oligonucleotide sequence. Rather, the claims are drawn to fusion polypeptides comprising at least a portion of a polypeptide of interest and any functional portion of any HUH domain that comprises a catalytic tyrosine residue, one or two metal-coordinating histidine residues, and endonuclease nicking activity. Appeal Br. 9 (Claims Appendix). A fusion polypeptide falling within the scope of the claims would have nicking activity against the specific oligonucleotide sequence that is the target of the HUH domain that is incorporated into the fusion polypeptide, but the target oligonucleotide sequence is not itself part of the claims. Accordingly, we do not agree with the Examiner that the Specification must disclose a way to correlate the structure of HUH

endonucleases with the specific target oligonucleotide sequence it will cleave or nick.

The Examiner additionally asserts that Appellant “ha[s] not reduced into practice the claimed genus of fusion proteins with functional portions of HUH polypeptide domains with enormous number of specificities.” Ans. 5. This statement demonstrates at least two errors. First, as discussed above, specificity against particular oligonucleotide sequences is not recited in the claims, and thus there is no basis to require reduction to practice of HUH endonucleases with the specific oligonucleotide sequences they will cleave or nick. Second, and more importantly, compliance with the written description requirement does not require reduction to practice of the entire claimed genus. *See Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1352 (Fed. Cir. 2010) (en banc) (“The written description requirement does not demand . . . an actual reduction to practice.”); *see also id.* at 1350 (“[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.”) (citation omitted). The Examiner acknowledges that the Specification provides examples of known HUH domains and their target oligonucleotide sequences, and indicates that others are known. *See* Ans. 4 (citing Spec. Table 1, 5:15–17); *see also* Spec. 13:1–10, Table 2. The Examiner has not asserted, let alone demonstrated, that the number of examples in the Specification is insufficient to support the claimed genus.

For the reasons discussed above, we determine that the Examiner has not established a *prima facie* case of unpatentability based on lack of written

description support. Our analysis of the patentability of the rejected claims is limited to the Examiner's written description rejection. We do not consider whether the claims are unpatentable under any other statutory ground.

CONCLUSION

We reverse the rejection of claims 1 and 2 under 35 U.S.C. § 112(a) as failing to comply with the written description requirement.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 2	112(a)	Written Description		1, 2

REVERSED