



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-----------------------|------------------|
| 14/774,109 | 09/09/2015 | Michael A. Weiss | 200512.00297 | 3261 |
| 21324 | 7590 | 11/27/2019 | EXAMINER | |
| HAHN LOESER & PARKS, LLP 200 Public Square, Suite 2800 Cleveland, OH 44114 | | | HEARD, THOMAS SWEENEY | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |
| | | | NOTIFICATION DATE | DELIVERY MODE |
| | | | 11/27/2019 | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@hahnlaw.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex Parte MICHAEL A. WEISS

Appeal 2018-008648
Application 14/774,109
Technology Center 1600

Before FRANCISCO C. PRATS, RACHEL H. TOWNSEND, 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 insulin analogues. 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 Case Western Reserve University. Appeal Br. 3.

STATEMENT OF THE CASE

The claims are directed to insulin analogues containing one or more substitutions relative to wild type insulin. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. An insulin analogue containing at least one substitution relative to wild type insulin comprising a substitution at a position selected from the group consisting of:
an Asp, His, or Leu substitution at B13,
a His, Trp or Tyr substitution at B17,
a Thr, Asp, Asn, Glu, Gln, His or Tyr substitution at A12,
a Glu, His, Tyr, Phe or Trp substitution at A13, and
a His, Trp, or Tyr substitution at A17;

with the proviso that when a Trp substitution or a Glu substitution is present at A13, a substitution is additionally present at position B24 wherein the substitution at position B24 is selected from the group consisting of *para*-chloro Phenylalanine, *ortho*-fluoro Phenylalanine and Cyclohexanylanine, or a Gln substitution is present at position A8.

Appeal Br. 10 (Claims Appendix).

Claims 1–3 and 21 are on appeal, and stand rejected as follows:

Claims 1–3 and 21 are rejected under 35 U.S.C. § 102(a)(2) as anticipated by Weiss '516.² Non-Final Rejection, dated Sept. 27, 2017 (“Non-Final Act.”) at 3.

Claim 1 is rejected under 35 U.S.C. 102(a)(1) as anticipated by Weiss '896.³ Non-Final Act. 6.

² Weiss, US 8,993,516 B2, issued Mar. 31, 2015 (“Weiss '516”).

³ Weiss et al., US 2011/0195896 A1, published Aug. 11, 2011 (“Weiss '896”).

In response to a species election requirement, Appellant elected an insulin analogue having an A-chain sequence of SEQ ID NO: 20 and a B-chain sequence of SEQ ID NO: 16. *See* Response dated June 10, 2016 at 2. The Examiner found that neither this species, nor the then-claimed genus (to the extent searched), were free of the prior art. *See* Non-Final Rejection dated Sept. 15, 2016 at 3.

In response, Appellant amended the claims, and requested examination of a different species, i.e., an insulin analogue having an A-chain sequence of SEQ ID NO: 22 and a B-chain sequence of SEQ ID NO: 16. *See* Response dated Feb. 15, 2017 at 6; *see also* Final Rejection dated Apr. 27, 2017 at 3 (acknowledging Appellant's request for a search of SEQ ID NO: 16 and 22).

Accordingly, as to the appealed rejections, we limit our analysis to the patentability of the analogues having SEQ ID NO: 16 and 20 and SEQ ID NO: 16 and 22, and take no position regarding the patentability of the broader generic claims or the remaining species. *See Ex parte Ohsaka*, 2 USPQ2d 1460, 1461 (BPAI 1987).

OPINION

Anticipation by Weiss '516

The Examiner rejected claims 1–3 and 21 as anticipated by Weiss '516. The Examiner found that Weiss '516 discloses an insulin analogue comprising a wild type A chain together with a B chain having “SEQ ID NO: 4,” where Weiss' SEQ ID NO: 4 is identical to Appellant's SEQ ID NO: 16. Non-Final Act. 4–5. The Examiner concluded that this analogue anticipates the claims. *Id.*

Having carefully considered the arguments and evidence advanced by Appellant and the Examiner, we determine that the preponderance of the evidence does not support the Examiner's conclusion of anticipation.

As Appellant correctly pointed out, “[c]laim 1 does not recite merely any substitution relative to wild type, but recites selection of at least one substitution from a specific Markush group consisting of substitutions at positions B13, B17, A12, A13 and A17.” Reply Br. 3. SEQ ID NO: 4 in Weiss '516, although being identical to SEQ ID NO: 16 disclosed in the Specification, does not contain any of the specific B chain substitutions recited in claim 1. And wild-type A-chain, by virtue of its being wild type, does not have a substitution anywhere, so it does not have the sequence of SEQ ID NO: 20 or 22. Thus, an analogue comprised of a wild type A-chain and SEQ ID NO: 4 does not fall within the scope of claim 1. Accordingly, we reverse the rejection over Weiss '516.

Anticipation by Weiss '896

The Examiner also rejected claim 1 as anticipated by Weiss '896. The Examiner found that Weiss '896 discloses an insulin analogue comprising a wild type B chain together with an A-chain having “SEQ ID NO: 32,” where Weiss' SEQ ID NO: 32 is identical to Appellant's SEQ ID NO: 20. Non-Final Act. 6. The Examiner found that Weiss's SEQ ID NO: 32 has a tryptophan (W) substitution at position A13, and thus concluded that this analogue anticipates claim 1. *Id.*

We again determine that the preponderance of the evidence does not support the Examiner's conclusion of anticipation. First, we presume that the Examiner intended to cite SEQ ID NO: 31 in Weiss '896, rather than SEQ ID NO: 32, because the former (SEQ ID NO: 31) has a tryptophan (W)

substitution at position A13, but the latter does not. *See* Weiss '896 at 17. In any event, the Examiner overlooks that in accordance with the “proviso” recited in claim 1, when the insulin analogue has a tryptophan (W) substitution at position A13, it must also have a specific substitution at either position B24 or A8. *See* Appeal Br. 10 (Claims Appendix). The Examiner has not established that Weiss '896 discloses the required additional substitution at either position B24 or A8, and thus has not established anticipation. Accordingly, we reverse the rejection over Weiss '896.

CONCLUSION

We reverse the rejection of claims 1–3 and 21 under 35 U.S.C. § 102(a)(2) as anticipated by Weiss '516.

We reverse the rejection of claim 1 under 35 U.S.C. 102(a)(1) as anticipated by Weiss '896.

DECISION SUMMARY

In summary:

| Claims Rejected | 35 U.S.C. § | Reference(s)/Basis | Affirmed | Reversed |
|------------------------|--------------------|---------------------------|-----------------|-----------------|
| 1–3 and 21 | 102 | Weiss '516 | | 1–3 and 21 |
| 1 | 102 | Weiss '896 | | 1 |
| Overall Outcome | | | | 1–3 and 21 |

REVERSED