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PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CONJUCHEM, LLC
Requester and Cross-Appellant

v.

AMYLIN PHARMACEUTICALS, INC.
Patent Owner and Appellant

Appeal 2013-004331
Inter Partes Reexamination Control 95/000,276
U.S. Patent 6,924,264 B1
Technology Center 3900

Before TONI R. SCHEINER, RICHARD M. LEBOVITZ, and
JEFFREY B. ROBERTSON, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on the appeal by the Patent Owner from the Patent Examiner's decision to reject pending claims 24 and 26-36 in the above-identified *inter partes* reexamination of U.S. Patent No. 6,924,264 B1. The

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Board's jurisdiction for this appeal is under 35 U.S.C. §§ 6(b), 134, and 315.
We affirm-in-part.

I. BACKGROUND

The patent in dispute in this appeal is U.S. Patent No. 6,924,264 B1, issued August 2, 2005 ("the '264 patent"). The Patent Owner ("PO") and Real Party in Interest is Amylin Pharmaceuticals, Inc. (PO Appeal Br. 1, dated February 15, 2012). A request for *inter parte* reexamination of the '264 patent was made on July 9, 2007 by third party requester ConjuChem Biotechnologies Inc.

Claims 24 and 26-36 are pending and stand rejected by the Examiner. Claims 24 and 26-36 are not original claims but were added by amendment during the reexamination proceeding. Patent Owner appealed all the rejections.

A Respondent Brief (March 15, 2012) and Cross-Appeal (February 15, 2012) were filed on behalf of ConjuChem, LLC, located at 11755 Wilshire Blvd., Suite 2000, Los Angeles, CA 92005 who was listed as the Third Party Requestor and real party in interest in the respective briefs. However, the Third Party Requestor that filed the original Request for Reexamination leading to this appeal is ConjuChem Biotechnologies Inc., located at 225, President-Kennedy Avenue, Montreal, QC H2X3Y8. The parties therefore appear to be different. There does not appear to be any documentation in the record before us to indicate how, when, and why the real party in interest, or a person in privity thereto, may have changed since the filing of the Request. There also does not appear to be a change in

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correspondence or an appointment of power attorney to the attorney who filed the Respondent and Cross-Appeal briefs.

An Order To Show Cause was mailed on October 18, 2013 giving the Requester two weeks to clarify the discrepancy between the real party in interest identified in the request for *inter partes* reexamination and the real party in interest set forth in Requester's Respondent brief. Otherwise, the cross-appeal would be dismissed. The attorney who filed the Respondent Brief and Cross-Appeal was contacted by the PTAB on October 31, 2013, but she informed the PTAB that she has not been involved with the case for over a year. No response to the Order To Show Cause was received. Accordingly, as the party filing the Respondent Brief and Cross-Appeal is unauthorized, the Cross-Appeal is dismissed and consideration will not be given to the Respondent Brief to Patent Owner's Appeal. See 37 C.F.R. §§ 41.60, 1.915(b)(8), and 1.957(a).

Claimed subject matter

The claimed subject matter relates to exendin-4 conjugated to albumin or PEG. Exendin-4 is a known peptide found in the salivary secretions of the Gila monster ('264 patent, col. 1, ll. 34-48). Exendin-4 is related to members of the glucagon-like peptide (GLP) family (*id.* at col. 1, ll. 49-54), such as GLP-1. Exendin-4 was known to have an insulinotropic effect in stimulating insulin secretion from pancreas cells (*id.* at col. 1, ll. 54-56) and to be useful for treating diabetes (*id.* at col. 2, ll. 53-56). Exendin-4 was also reported to have a longer duration of action than GLP-1 (*id.* at col. 2, ll. 47-51). Exendin-4 and its analogs were known prior to the filing date of the

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'264 patent (*id.* at col. 3, ll. 13-28). The patent describes conjugating Exendin-4 to PEG or albumin (*id.* at col. 4, ll. 36-57; col. 24, ll. 58-65). Such conjugates are described by the '264 patent as having a kidney clearance less than unmodified exendin-4 (*id.* at col. 4, ll. 65-67; col. 24, ll. 58-65; col. 31).

Claims 24 and 26 are representative of the appealed claims and read as follows:

24. A pharmaceutical composition for use in humans comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of exendin-4 or an agonist analog of exendin-4 linked through the C-terminal amino acid to one polymer selected from the group consisting of polyethylene glycol and albumin.

26. The pharmaceutical composition of claim 24, wherein the polymer is albumin.

Rejections

The claims stand rejected by the Examiner as follows (PO Appeal Br.):¹

A. Claims 24 and 26-36 under 35 U.S.C. § 103(a) as obvious in view of Eng² in combination with Drucker III,³ Davis,⁴ Poznansky I (1984),⁵ Gombotz,⁶ Shearwater,⁷ or Poznansky II (1988).⁸

¹ Rejections A through D were listed by Patent Owner as rejecting claim 25. However, claim 25 is canceled.

² Eng, US 5,424,286, issued June 13, 1995.

³ Drucker, WO 98/52600, published November 26, 1998.

⁴ Davis et al, *Reductions of Immunogenicity and Extension of Circulating Half-Life of Peptides and Proteins, in Peptide and Protein Drug Delivery* 831-864 (Vincent H. L. Lee ed., 1991).

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