

US008114833B2

(12) United States Patent

Pedersen et al.

(10) Patent No.: US 8,114,833 B2

(45) **Date of Patent:** *Feb. 14, 2012

(54) PROPYLENE GLYCOL-CONTAINING PEPTIDE FORMULATIONS WHICH ARE OPTIMAL FOR PRODUCTION AND FOR USE IN INJECTION DEVICES

(75) Inventors: Tina Bjeldskov Pedersen, Smørum

(DK); Claude Bonde, Lyngby (DK); Dorthe Kot Engelund, Holte (DK)

- (73) Assignee: Novo Nordisk A/S, Bagsvaerd (DK)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35

U.S.C. 154(b) by 663 days.

This patent is subject to a terminal dis-

claimer.

- (21) Appl. No.: 11/435,977
- (22) Filed: May 17, 2006

(65) **Prior Publication Data**

US 2007/0010424 A1 Jan. 11, 2007

Related U.S. Application Data

- (63) Continuation of application No. PCT/DK2004/000792, filed on Nov. 18, 2004.
- (60) Provisional application No. 60/524,653, filed on Nov. 24, 2003.

(30) Foreign Application Priority Data

Nov. 20, 2003 (DK) 2003 01719

- (51) **Int. Cl.**
 - **A61K 38/26** (2006.01)
- (52) **U.S. Cl.** 514/2; 530/308

(56) References Cited

U.S. PATENT DOCUMENTS

| | 0.0. | 11111111 | DOCOMENT |
|-----------|------|----------|-----------------|
| 4,468,346 | A | 8/1984 | Paul et al. |
| 5,206,219 | A | 4/1993 | Desai |
| 5,272,135 | A | 12/1993 | Takruri |
| 5,455,331 | A | 10/1995 | Pearce |
| 5,652,216 | A | 7/1997 | Kornfelt et al. |
| 5,705,483 | A | 1/1998 | Galloway |
| 6,133,229 | A | 10/2000 | Gibson et al. |
| 6,184,201 | B1 | 2/2001 | Drucker et al. |
| 6,268,343 | B1 | 7/2001 | Knudsen et al. |
| 6,274,553 | B1 | 8/2001 | Furuya |
| 6,284,727 | B1 | 9/2001 | Kim et al. |
| 6,380,357 | B2 | 4/2002 | Hermeling |
| 6,384,016 | B1 | 5/2002 | Kaarsholm |
| 6,444,788 | B1 | 9/2002 | Staby |
| 6,586,399 | B1 | 7/2003 | Drucker et al. |
| 6,844,321 | B2 | 1/2005 | Arentsen |
| | | | |

| 7,022,674 | B2 | 4/2006 | DeFelippis et al. |
|--------------|-----|---------|-----------------------|
| 7,049,284 | B2 | 5/2006 | Drucker et al. |
| 7,056,886 | B2 | 6/2006 | Isaacs |
| 7,238,663 | B2 | 7/2007 | DeFelippis et al. |
| 2001/0014666 | A1 | 8/2001 | Hermeling et al. |
| 2001/0027180 | A1 | 10/2001 | Isaacs |
| 2002/0151467 | A1 | 10/2002 | Leung |
| 2003/0060412 | A1 | 3/2003 | Prouty, et al. |
| 2003/0069182 | A1 | 4/2003 | Rinella |
| 2003/0119734 | A1 | 6/2003 | Flink et al. |
| 2003/0158101 | A1 | 8/2003 | Drucker |
| 2003/0207802 | A1 | 11/2003 | DeFelippis |
| 2003/0220243 | A1 | 11/2003 | Glaesner et al. |
| 2003/0220255 | A1 | 11/2003 | Knudsen et al. |
| 2004/0156835 | A1 | 8/2004 | Imoto et al. |
| 2004/0248782 | A1 | 12/2004 | Bridon et al. |
| 2006/0084605 | A1* | 4/2006 | Engelund et al 514/12 |
| 2006/0287221 | A1* | 12/2006 | Knudsen et al 514/3 |

FOREIGN PATENT DOCUMENTS

| CA | 2306024 | 4/1999 |
|----|-------------|----------|
| CA | 2527743 | 12/2004 |
| EP | 0431679 | 11/1990 |
| EP | 0438767 | 12/1990 |
| EP | 699687 | 8/1995 |
| EP | 708179 | 4/1996 |
| EP | 747390 | 12/1996 |
| EP | 0926159 | 6/1999 |
| EP | 1329462 | 10/2001 |
| EP | 1424077 | 5/2002 |
| EP | 1344533 | 9/2003 |
| EP | 1396499 | 3/2004 |
| EP | 722492 | 3/2005 |
| JP | 10101696 | 4/1998 |
| JP | 2000-510813 | 8/2000 |
| JP | 2001-525371 | 12/2001 |
| JP | 2002-504908 | 2/2002 |
| JP | 2002-508332 | 3/2002 |
| JP | 2002-524514 | 8/2002 |
| JP | 2002-532557 | 10/2002 |
| JP | 2003-519195 | 6/2003 |
| JP | 2003519195 | 6/2003 |
| | (Cor | ntinued) |

(Continued)

OTHER PUBLICATIONS

Singh, S et al—Aaps Pharmscitech—2003—vol. 4—Part 3-pp. 334-342

(Continued)

Primary Examiner — Christina Bradley (74) Attorney, Agent, or Firm — Michael J. Brignati

(57) ABSTRACT

The present invention relates to pharmaceutical formulations comprising a peptide and propylene glycol, to methods of preparing such formulations, and to uses of such formulations in the treatment of diseases and conditions for which use of the peptide contained in such formulations is indicated. The present invention further relates to methods for reducing the clogging of injection devices by a peptide formulation and for reducing deposits on production equipment during production of a peptide formulation.

31 Claims, 7 Drawing Sheets