



US009764003B2

(12) **United States Patent**
Jensen

(10) **Patent No.:** **US 9,764,003 B2**
(45) **Date of Patent:** **Sep. 19, 2017**

- (54) **USE OF LONG-ACTING GLP-1 PEPTIDES**
- (71) Applicant: **Novo Nordisk A/S**, Bagsvaerd (DK)
- (72) Inventor: **Christine B. Jensen**, Charlottenlund (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 0 days.

DK	WO 2006097537	A2 *	9/2006	C07K 14/605
RU	2409349	C2	1/2011		
RU	2413530	C2	3/2011		
WO	2010/092163	A2	8/2010		
WO	2011/080103	A1	7/2011		
WO	2011138421	A1	11/2011		
WO	2012/016419	A1	2/2012		
WO	2012080471	A1	6/2012		
WO	2012107476	A1	8/2012		
WO	2012/130136	A1	10/2012		
WO	2012/136790	A1	10/2012		
WO	2012177929	A2	12/2012		

- (21) Appl. No.: **14/409,493**
- (22) PCT Filed: **Jun. 21, 2013**
- (86) PCT No.: **PCT/EP2013/063004**
§ 371 (c)(1),
(2) Date: **Dec. 19, 2014**
- (87) PCT Pub. No.: **WO2014/005858**
PCT Pub. Date: **Jan. 9, 2014**

- (65) **Prior Publication Data**
US 2015/0190474 A1 Jul. 9, 2015

- Related U.S. Application Data**
- (60) Provisional application No. 61/694,837, filed on Aug. 30, 2012, provisional application No. 61/708,162, filed on Oct. 1, 2012.

- (30) **Foreign Application Priority Data**
Jul. 1, 2012 (EP) 12174535
Oct. 1, 2012 (EP) 12186781

- (51) **Int. Cl.**
A61K 38/26 (2006.01)
A61P 5/50 (2006.01)
A61P 3/04 (2006.01)
A61P 3/10 (2006.01)

- (52) **U.S. Cl.**
CPC *A61K 38/26* (2013.01)

- (58) **Field of Classification Search**
None
See application file for complete search history.

- (56) **References Cited**
U.S. PATENT DOCUMENTS
8,129,343 B2 3/2012 Lau et al.
8,536,122 B2 9/2013 Lau et al.
2010/0047762 A1 2/2010 Button et al.
2010/0292133 A1 11/2010 Spetzler et al.
2011/0301080 A1 12/2011 Bush et al.

- FOREIGN PATENT DOCUMENTS**
CN 102229668 11/2011
CN 102229668 A 11/2011

OTHER PUBLICATIONS

Kim et al., "Effects of once-weekly dosing of a long-acting release formulation of exenatide on glucose control and body weight in subjects with type 2 diabetes," *Diabetes Care* 30:1487-1493 (2007).*

Bydureon NDA 022200/S-008 package information, pp. 1-179 (Feb. 2014).*

Clinical Trial NCT00696657, entitled "A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide," pp. 1-5 (Mar. 11, 2015)—accessed Sep. 24, 2015 at URL clinicaltrials.gov/archive/NCT00696657/2011_03_25.*

Lau et al., "Discovery of the once-weekly glucagon-like peptide-1 (GLP-1) analogue semaglutide," *J. Med. Chem.* 58:7370-7380 (2015).*

Eperzan assessment report, Euro. Med. Agency, pp. 1-124 (2014)—accessed Sep. 24, 2015 at URL: ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002735/WC500165119.pdf.*

Trulicity assessment report, Euro. Med. Agency, pp. 1-172 (2014)—accessed Sep. 24, 2015 at URL: ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002825/WC500179473.pdf.*

CDC, "Nathional Health and Nutrition Examination Survey: Healthy weight, overweight, and obesity among U.S. adults," 03-0260, pp. 1-2 (Jul. 2003) accessed May 10, 2016 at URL cdc.gov/nchs/data/nhanes/databriefs/adultweight.pdf.*

Madsbad S et al. An Overview of once-weekly glucagon-like peptide-1 receptor agonists available efficacy and safety data and perspectives for the future, *Diabetes, Obesity and Metabolism Year* 2011, vol. 13, No. 5, pp. 394-407.

Buse B. J. et al., Exenatide once weekly versus liraglutide once daily in patients with type 2 diabetes (DURATION-6): a randomised, open-label study, *Lancet*, 2013, vol. 381, pp. 117-124.

Mizuta et al. "The Role for GLP-1 in Regulation of Body Weight." *Progress in Medicine* 2008 vol. 28 No. 8 pp. 1909-1912.

* cited by examiner

Primary Examiner — Julie Ha
Assistant Examiner — Kristina M Hellman
(74) *Attorney, Agent, or Firm* — Leon Y. Lum

(57) **ABSTRACT**

The invention relates to use of long-acting GLP-1 peptides in certain dosage regimes for the treatment of type 2 diabetes, obesity, etc.

6 Claims, 6 Drawing Sheets

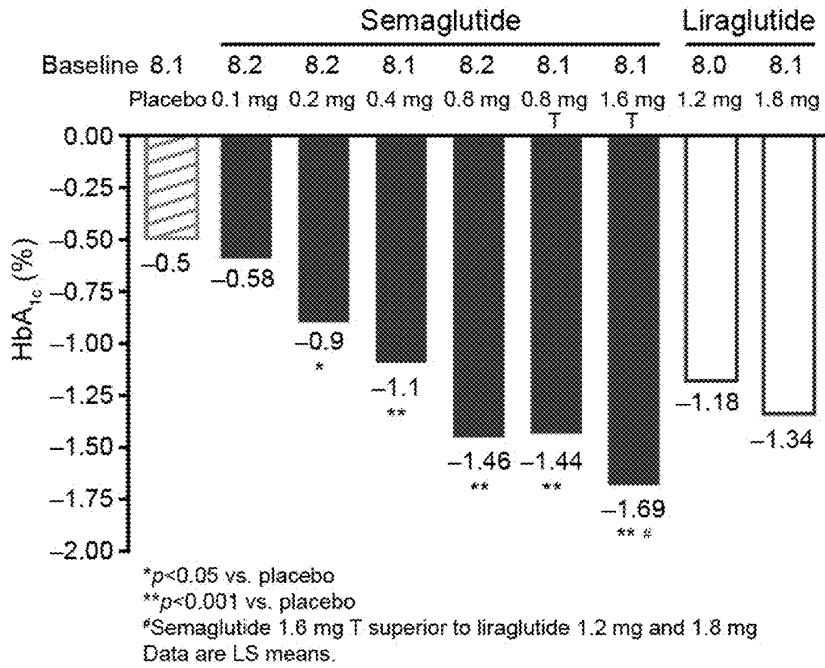


Fig. 1

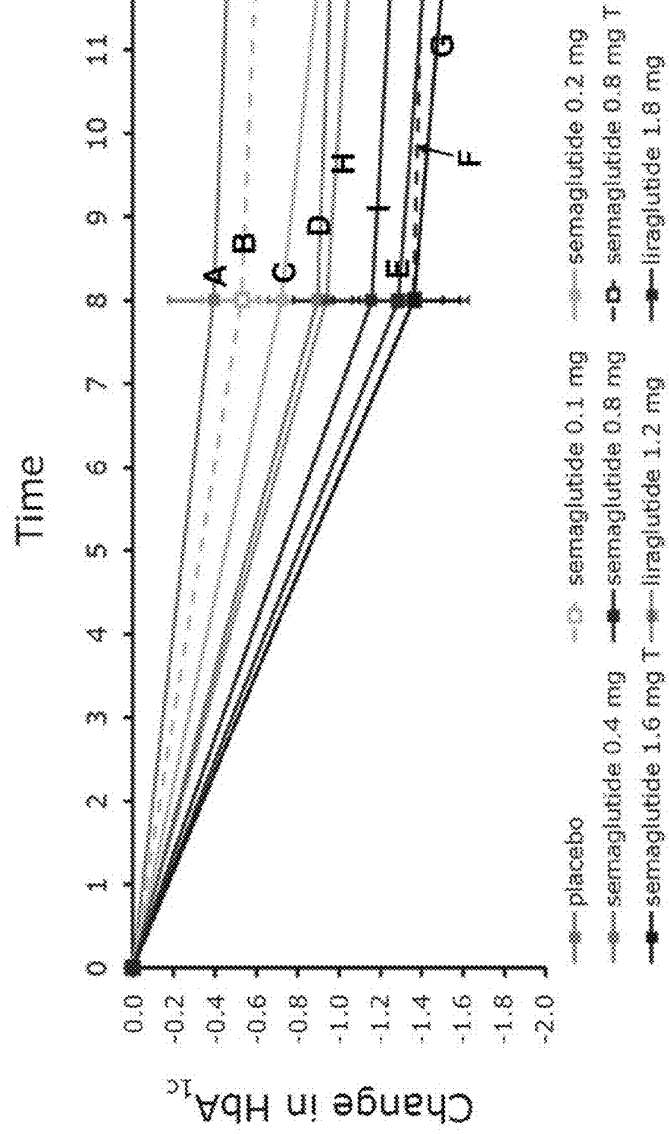


Fig. 2

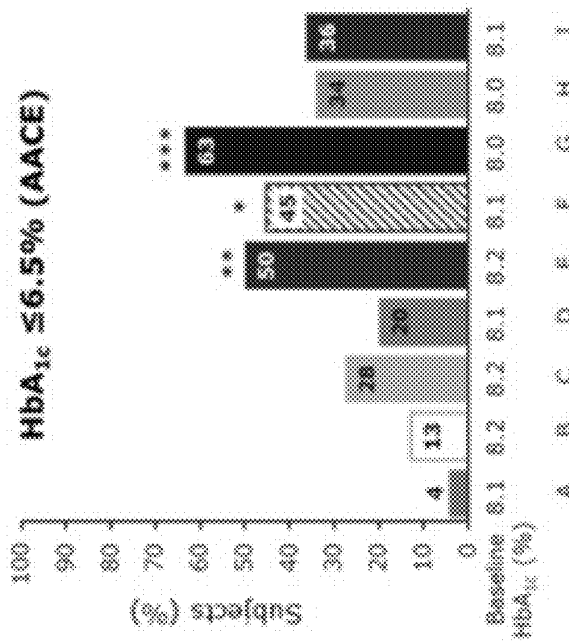


Fig. 3A

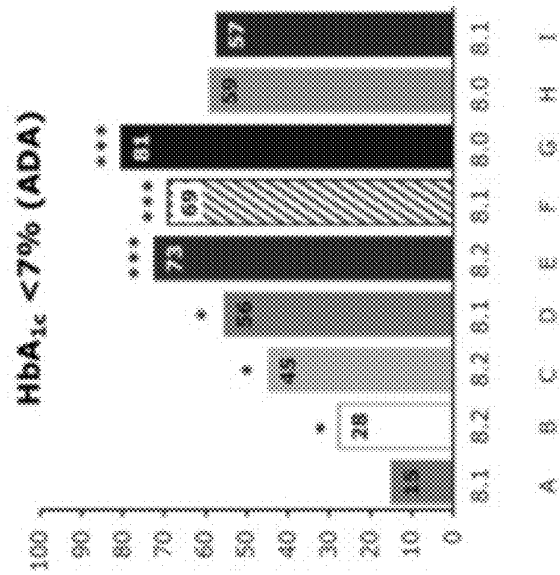


Fig. 3 B

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.