



US009375478B1

(12) **United States Patent**
Kenney et al.

(10) **Patent No.:** **US 9,375,478 B1**
(45) **Date of Patent:** ***Jun. 28, 2016**

(54) **VASOPRESSIN FORMULATIONS FOR USE IN TREATMENT OF HYPOTENSION**

(71) Applicant: **Par Pharmaceutical, Inc.**, Spring Valley, NY (US)

(72) Inventors: **Matthew Kenney**, New Haven, MI (US); **Vinayagam Kannan**, Rochester, MI (US); **Sunil Vandse**, Basking Ridge, NJ (US); **Suketu Sanghvi**, Kendall Park, NJ (US)

(73) Assignee: **PAR PHARMACEUTICAL, INC.**, Chestnut Ridge, NY (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **14/717,882**

(22) Filed: **May 20, 2015**

Related U.S. Application Data

(63) Continuation of application No. 14/610,499, filed on Jan. 30, 2015.

(51) **Int. Cl.**
A61K 38/11 (2006.01)
A61K 47/10 (2006.01)

(52) **U.S. Cl.**
CPC **A61K 47/10** (2013.01); **A61K 38/11** (2013.01)

(58) **Field of Classification Search**
CPC C07K 7/16; A61K 38/11
See application file for complete search history.

(56) References Cited

U.S. PATENT DOCUMENTS

4,542,124	A	9/1985	Huffman et al.
4,604,378	A	8/1986	Callahan et al.
4,684,622	A	8/1987	Ali et al.
4,746,508	A	5/1988	Carey et al.
4,762,820	A	8/1988	Gavras
4,764,378	A	8/1988	Keith et al.
4,767,628	A	8/1988	Hutchinson
4,781,871	A	11/1988	West, III et al.
5,042,975	A	8/1991	Chien et al.
5,124,315	A	6/1992	Ceschel et al.
5,192,741	A	3/1993	Orsolini et al.
5,204,112	A	4/1993	Hope et al.
5,225,212	A	7/1993	Martin et al.
5,250,022	A	10/1993	Chien et al.
5,252,263	A	10/1993	Hope et al.
5,288,497	A	2/1994	Stanley et al.
5,288,498	A	2/1994	Stanley et al.
5,359,030	A	10/1994	Ekwuribe
5,424,068	A	6/1995	Filip
5,482,931	A *	1/1996	Harris A61K 9/0019 514/10.3
5,698,516	A	12/1997	Nilsson et al.
5,702,717	A	12/1997	Cha et al.
5,770,559	A	6/1998	Manning et al.

5,776,885	A	7/1998	Orsolini et al.
5,785,989	A	7/1998	Stanley et al.
5,811,399	A	9/1998	Khavinson et al.
5,889,110	A	3/1999	Hutchison
5,902,790	A	5/1999	Green et al.
5,972,894	A	10/1999	Sinackevich et al.
5,981,474	A	11/1999	Manning et al.
5,989,857	A	11/1999	Mundschenk
6,004,573	A	12/1999	Rathi et al.
6,034,175	A	3/2000	Hutchison
6,086,918	A	7/2000	Stern et al.
6,117,949	A	9/2000	Rathi et al.
6,143,722	A	11/2000	Melin et al.
6,174,547	B1	1/2001	Dong et al.
6,180,608	B1	1/2001	Gefter et al.
6,187,756	B1	2/2001	Lee et al.
6,201,072	B1	3/2001	Rathi et al.
6,264,981	B1	7/2001	Zhang et al.
6,287,588	B1	9/2001	Shih et al.
6,589,549	B2	7/2003	Shih et al.
6,592,894	B1	7/2003	Zarif et al.
6,630,486	B1	10/2003	Royer
6,720,001	B2	4/2004	Chen et al.
6,740,333	B2	5/2004	Beckett et al.
6,811,689	B2	11/2004	Zhang et al.
6,814,870	B2	11/2004	Zhang et al.
6,821,249	B2	11/2004	Casscells, III et al.
6,841,617	B2	1/2005	Jeong et al.
6,949,509	B2	9/2005	Woodrow
6,967,028	B2	11/2005	Dulieu et al.
6,991,798	B1	1/2006	Gschneider et al.
6,998,137	B2	2/2006	Shih et al.
7,074,775	B2	7/2006	Miller
7,087,244	B2	8/2006	Jeong et al.
7,135,190	B2	11/2006	Piao et al.
7,151,084	B2	12/2006	Miller
7,157,421	B2	1/2007	Miller
7,186,414	B2	3/2007	Gschneider et al.
7,402,652	B2	7/2008	Miller

(Continued)

OTHER PUBLICATIONS

U.S. Appl. No. 14/610,488, filed Jan. 30, 2015, Kenney et al.
U.S. Appl. No. 14/610,499, filed Jan. 30, 2015, Kenney et al.
U.S. Appl. No. 14/610,579, filed Jan. 30, 2015, Kenney et al.
U.S. Appl. No. 14/610,594, filed Jan. 30, 2015, Kenney et al.
U.S. Appl. No. 14/717,877, filed May 20, 2015, Kenney et al.
Office action dated Mar. 18, 2015 for U.S. Appl. No. 14/610,488.
Office action dated Mar. 23, 2015 for U.S. Appl. No. 14/610,499.
Office action dated Mar. 24, 2015 for U.S. Appl. No. 14/610,594.
Office action dated Mar. 25, 2015 for U.S. Appl. No. 14/610,579.
Pharmaceutical Partners of Canada, Inc. "Vasopressin Injection, USP" Jun. 2009.
Rodriguez-Nunez, et al. Terlipressin continuous infusion: please mind the solvent! Current Drug Targets. 2009; 10(6):577.

(Continued)

Primary Examiner — Christina Bradley

(74) *Attorney, Agent, or Firm* — Wilson Sonsini Goodrich & Rosati

(57) ABSTRACT

Provided herein are peptide formulations comprising polymers as stabilizing agents. The peptide formulations can be more stable for prolonged periods of time at temperatures higher than room temperature when formulated with the polymers. The polymers used in the present invention can decrease the degradation of the constituent peptides of the peptide formulations.

11 Claims, 10 Drawing Sheets