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# (54) METHODS OF MAKING BEMPEDOIC ACID AND COMPOSITIONS OF THE SAME

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- (60) Provisional application No. 62/864,873, filed on Jun. 21, 2019.
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#### (56) References Cited

#### U.S. PATENT DOCUMENTS

3,152,148 A	10/1964	Easterly et al.
3,441,605 A	4/1969	Blake
3,773,946 A	11/1973	Greger
3,930,024 A	12/1975	Greger
4,281,200 A	7/1981	Snoble
4,287,200 A	9/1981	Kawamatsu et al.
4,584,321 A	4/1986	Manghisi et al.
4,613,593 A	9/1986	Yamatsu et al.

4,634,119 A	1/1987	Pesthy
4,634,719 A	1/1987	Takaishi et al.
4,639,344 A	1/1987	Ueno et al.
4,689,344 A	8/1987	Bar-Tana
4,711,896 A	12/1987	Bar-Tana et al.
4,714,762 A	12/1987	Hoefle et al.
4,896,344 A	1/1990	Grady et al.
5,166,174 A	11/1992	Ueno et al.
5,225,439 A	7/1993	Ueno et al.
5,284,858 A	2/1994	Ueno et al.
5,380,709 A	1/1995	Ueno et al.
5,428,062 A	6/1995	Ueno et al.
5,502,198 A	3/1996	Picard et al.
5,504,073 A	4/1996	Homan
5,570,569 A	11/1996	Masuda
5,578,639 A	11/1996	Homan
5,633,287 A	5/1997	Lee et al.
5,648,387 A	7/1997	Bisgaier et al.
5,750,569 A	5/1998	Bisgaier et al.
5,756,344 A	5/1998	Onda et al.
5,756,544 A	5/1998	Bisgaier et al.
5,783,600 A	7/1998	Bisgaier et al.
5,834,596 A	11/1998	Ageland et al.
5,886,034 A	3/1999	Ueno et al.
5,968,963 A	10/1999	Homan
5,981,595 A	11/1999	Picard et al.
6,004,925 A	12/1999	Dasseux et al.
6,017,905 A	1/2000	Roark et al.
6,037,323 A	3/2000	Dasseux et al.
	(Con	tinued)
	(0011	

#### FOREIGN PATENT DOCUMENTS

CN 109721486 A 5/2019 EP 0284108 A2 9/1988 (Continued)

## OTHER PUBLICATIONS

Hunyadi et al. IP.com Journal (2018), 18(7A), 1-9 (No. IPCOM000254434D), Jun. 27, 2018.\*

AbMole Bioscience, ETC-1002 (Bempedoic acid), 2 pages, retrieved on Mar. 10, 2021 from <a href="http://www.abmole.com/products/etc-1002.html">http://www.abmole.com/products/etc-1002.html</a>

Ackerly, et al., 1995, "A novel approach to dual-acting thromboxane receptor antagonist/synthase inhibitors based on the link of 1.3-dioxane-thromboxane receptor antagonists and -thromboxane synthase inhibitors", J. Med. Chem. 38:1608-1628.

Acton, et al., 1996, "Identification of scavenger receptor SR-B1 as high density lipoprotein receptor", Science. 271 (5248):518-20. Ahrens, et al., 1967, "A direct method for preparing pyridoxal and 4-pyridoxic acid (1)", J. Heterocyl. Chem. 4:625-26.

(Continued)

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#### (57) ABSTRACT

The invention provides methods of preparing 8-hydroxy-2, 2,14,14-tetramethylpentadecanedioic acid and methods of making a pharmaceutical material comprising a purified amount of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid. Also provided are compositions and pharmaceutical materials including a purified amount of 8-hydroxy-2, 2,14,14-tetramethylpentadecanedioic acid as well as methods of treating various diseases and conditions using the compositions and pharmaceutical materials.

#### 17 Claims, 6 Drawing Sheets