US009636318B2

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

(10) **Patent No.: US 9,636,318 B2**
(45) **Date of Patent: *May 2, 2017**

(54) **FUMARATE ESTER DOSAGE FORMS**

(71) Applicant: **BANNER LIFE SCIENCES LLC**, High Point, NC (US)

(72) Inventors: **Jason M. Vaughn**, Browns Summit, NC (US); **Justin R. Hughey**, Asheboro, NC (US); **Tanesha Roberts**, Greensboro, NC (US); **Tatyana Dyakonov**, Greensboro, NC (US); **Sunil Agnihotri**, Scarborough, ME (US); **Aqeel A. Fatmi**, High Point, NC (US)

(73) Assignee: **BANNER LIFE SCIENCES LLC**, High Point, NC (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 7 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/248,506**

(22) Filed: **Aug. 26, 2016**

(65) **Prior Publication Data**

US 2017/0056359 A1 Mar. 2, 2017

Related U.S. Application Data

(63) Continuation-in-part of application No. 14/840,072, filed on Aug. 31, 2015, now Pat. No. 9,326,947, and a continuation-in-part of application No. PCT/US2015/047636, filed on Aug. 31, 2015.

(60) Provisional application No. 62/300,941, filed on Feb. 29, 2016, provisional application No. 62/356,872, filed on Jun. 30, 2016.

(51) **Int. Cl.**

A61K 8/04	(2006.01)
A61K 9/48	(2006.01)
A61K 47/44	(2006.01)
A61K 8/37	(2006.01)
A61K 31/225	(2006.01)
A61K 9/00	(2006.01)
A61K 9/10	(2006.01)

(52) **U.S. Cl.**

CPC ***A61K 31/225*** (2013.01); ***A61K 9/0053*** (2013.01); ***A61K 9/10*** (2013.01); ***A61K 9/4858*** (2013.01); ***A61K 9/4866*** (2013.01); ***A61K 9/4891*** (2013.01)

(58) **Field of Classification Search**

None

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,146,730	A	9/1992	Dietel
5,424,332	A	6/1995	Speiser
5,459,983	A	10/1995	Sadek
6,355,676	B1	3/2002	Joshi
6,436,992	B1	8/2002	Joshi
6,482,516	B1	11/2002	Sadek
6,509,376	B1	1/2003	Joshi
7,157,423	B2	1/2007	Joshi
7,320,999	B2	1/2008	Joshi
7,432,240	B2	10/2008	Joshi
7,612,110	B2	11/2009	Joshi
7,619,001	B2	11/2009	Joshi
7,803,840	B2	9/2010	Joshi
7,915,310	B2	3/2011	Joshi
8,293,270	B2	10/2012	Sukuru
8,333,989	B2	12/2012	Sukuru
8,399,514	B2	3/2013	O Neill
8,524,773	B2	9/2013	Joshi
8,669,281	B1	3/2014	Sanrame
8,669,282	B2	3/2014	Zicker
8,685,445	B2	4/2014	Hassan
8,759,393	B2	6/2014	Joshi
9,090,558	B2	7/2015	Sanrame
2003/0018072	A1	1/2003	Joshi
2004/0054001	A1	3/2004	Petzelbauer
2006/0051345	A1	3/2006	Frohna
2006/0115527	A1	6/2006	Chidambaram
2006/0165778	A1	7/2006	Hassan
2007/0104778	A1	5/2007	Ketsela
2008/0004344	A1	1/2008	Nilsson
2008/0233185	A1	9/2008	Joshi
2008/0299196	A1	12/2008	Nilsson
2008/0300217	A1	12/2008	Nilsson
2009/0304790	A1	12/2009	Nilsson
2010/0034274	A1	2/2010	Li
2010/0130607	A1	5/2010	Gold
2010/0259906	A1	10/2010	Chang
2010/0324327	A1	12/2010	Lee
2011/0112196	A1	5/2011	Lukashev
2012/0034274	A1	2/2012	Rupp
2012/0165404	A1	6/2012	Lukashev
2012/0259012	A1	10/2012	Lukashev
2013/0216615	A1	8/2013	Goldman
2013/0259906	A1	10/2013	Rupp
2013/0295169	A1	11/2013	Goldman
2013/0302410	A1	11/2013	Gold
2013/0303613	A1	11/2013	Lukashev
2013/0315993	A1	11/2013	Nilsson
2013/0316003	A1	11/2013	Nilsson

(Continued)

FOREIGN PATENT DOCUMENTS

EP	0312697	A2	4/1989
WO	0030622	A2	6/2000

(Continued)

OTHER PUBLICATIONS

TECFIDERAÂ® Prescribing Information Mar. 2013 (BIOGEN IDEC).

(Continued)

Primary Examiner — Abigail Fisher

(74) *Attorney, Agent, or Firm* — Brinks Gilson & Lione

(57) **ABSTRACT**

Described herein are pharmaceutical compositions comprising fumarate esters, methods for making the same, and methods for treating subjects in need thereof. In particular, oral controlled release pharmaceutical compositions comprising fumarate esters suspended in liquid matrices are described. One embodiment described herein is a pharmaceutical composition comprising fumarate esters suspended in a lipid or lipophilic liquid with enhanced bioavailability.

22 Claims, 25 Drawing Sheets