US008552025B2

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

(10) **Patent No.: US 8,552,025 B2**
(45) **Date of Patent: *Oct. 8, 2013**

(54) **STABLE METHYLNALTREXONE PREPARATION**

(75) Inventors: **Suketu P. Sanghvi**, Kendall Park, NJ (US); **Thomas A. Boyd**, Grandview, NY (US)

(73) Assignee: **Progenics Pharmaceuticals, Inc.**, Tarrytown, 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.: **12/639,862**

(22) Filed: **Dec. 16, 2009**

(65) **Prior Publication Data**

US 2010/0261744 A1 Oct. 14, 2010

Related U.S. Application Data

(63) Continuation of application No. 10/821,811, filed on Apr. 8, 2004, now abandoned.

(60) Provisional application No. 60/461,611, filed on Apr. 8, 2003.

(51) **Int. Cl.**
A01N 43/42 (2006.01)
A61K 31/44 (2006.01)

(52) **U.S. Cl.**
USPC **514/282**

(58) **Field of Classification Search**
USPC 514/282, 970
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,714,159	A	1/1973	Janssen et al.
3,723,440	A	3/1973	Freter et al.
3,854,480	A	12/1974	Zaffaroni
3,884,916	A	5/1975	Janssen et al.
3,937,801	A	2/1976	Lippmann
3,996,214	A	12/1976	Dajani et al.
4,012,393	A	3/1977	Markos et al.
4,013,668	A	3/1977	Adelstein et al.
4,025,652	A	5/1977	Diamond et al.
4,060,635	A	11/1977	Diamond et al.
4,066,654	A	1/1978	Adelstein et al.
4,069,223	A	1/1978	Adelstein
4,072,686	A	2/1978	Adelstein et al.
4,115,400	A	9/1978	Zimmerman
4,115,564	A	9/1978	Diamond et al.
4,116,963	A	9/1978	Adelstein
4,125,531	A	11/1978	Yen
4,176,186	A	11/1979	Goldberg et al.
4,194,045	A	3/1980	Adelstein
4,203,920	A	5/1980	Diamond et al.
4,241,066	A	12/1980	Kobylecki et al.
4,277,605	A	7/1981	Buyniski et al.
4,311,833	A	1/1982	Namikoshi et al.
4,322,426	A	3/1982	Hermann et al.
4,326,074	A	4/1982	Diamond et al.
4,326,075	A	4/1982	Diamond et al.
4,377,568	A	3/1983	Chopra et al.
4,385,078	A	5/1983	Onda et al.
4,427,676	A	1/1984	White et al.
4,430,327	A	2/1984	Frederickson et al.
4,452,775	A	6/1984	Kent
4,457,907	A	7/1984	Porter et al.
4,462,839	A	7/1984	McGinley et al.
4,466,968	A	8/1984	Bernstein
4,518,433	A	5/1985	McGinley et al.
4,533,739	A	8/1985	Pitzele et al.
4,556,552	A	12/1985	Porter et al.
4,606,909	A	8/1986	Bechgaard et al.
4,615,885	A	10/1986	Nakagame et al.
4,670,287	A	6/1987	Tsuji et al.
4,675,189	A	6/1987	Kent et al.
4,689,332	A	8/1987	McLaughlin et al.
4,719,215	A	1/1988	Goldberg
4,730,048	A	3/1988	Portoghese
4,765,978	A	8/1988	Abidi et al.
4,806,556	A	2/1989	Portoghese
4,824,853	A	4/1989	Wals et al.
4,836,212	A	6/1989	Schmitt et al.
4,837,214	A	6/1989	Tanaka et al.
4,857,533	A	8/1989	Sherman et al.
4,861,781	A	8/1989	Goldberg
4,863,928	A	9/1989	Atkinson et al.

(Continued)

FOREIGN PATENT DOCUMENTS

AU	610 561	8/1988
AU	99/13802	5/1999

(Continued)

OTHER PUBLICATIONS

Foss, Joseph F. A Review of the Potential Role of Methylnaltrexone in Opioid Bowel Dysfunction, The American Journal of Surgery vol. 182 (Suppl to Nov. 2001) 19S-26S.*

Remington's Pharmaceutical Sciences, Mack Publishing Co. 15th edition, 1975, pp. 278, 279, 283 and 284.*

Written Opinion for SG 200506463-9 mailed May 4, 2006.

International Search Report and Written Opinion for PCT/US2004/010997 mailed Aug. 31, 2004.

International Preliminary Report on Patentability for PCT/US2004/010997 mailed Oct. 27, 2005.

Office Action, mailed Oct. 2, 2008, for U.S. Appl. No. 10/821,811.

Office Action, mailed Mar. 12, 2009, for U.S. Appl. No. 10/821,811.

[No Author Listed] Endogenous opioids. http://opioids.com/opiates.html 3 pages.

(Continued)

Primary Examiner — Jeffrey S. Lundgren
Assistant Examiner — William Lee
(74) *Attorney, Agent, or Firm* — McCarter & English, LLP; Jonathan M. Sparks; Maneesh Gulati

(57) **ABSTRACT**

Stable pharmaceutical compositions useful for administering methylnaltrexone are described, as are methods for making the same. Kits, including these pharmaceutical compositions, also are provided.

23 Claims, 3 Drawing Sheets