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

(10) **Patent No.:** **US 9,066,980 B2**  
(45) **Date of Patent:** **\*Jun. 30, 2015**

- (54) **LIQUID PHARMACEUTICAL FORMULATIONS OF PALONOSETRON**
- (71) Applicants: **Helsinn Healthcare SA**, Lugano (CH); **Roche Palo Alto LLC**, Palo Alto, CA (US); **Simone Macciocchi**, Melide (CH); **Giulio Macciocchi**, Breganzona (CH)
- (72) Inventors: **Giorgio Calderari**, Rancate (CH); **Daniele Bonadeo**, Casalzuigno (IT); **Roberta Cannella**, Varese (IT); **Alberto Macciocchi**, Melide (CH); **Andrew Miksztal**, Palo Alto, CA (US); **Thomas Malefyt**, Carmel Valley, CA (US); **Kathleen M Lee**, Palo Alto, CA (US)
- (73) Assignees: **Helsinn Healthcare SA**, Lugano/Pazzallo (CH); **Roche Palo Alto LLC**, Palo Alto, CA (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.: **13/902,299**
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- (65) **Prior Publication Data**

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**Related U.S. Application Data**

- (63) Continuation of application No. 13/901,437, filed on May 23, 2013, now Pat. No. 8,598,219, which is a continuation-in-part of application No. 13/087,012, filed on Apr. 14, 2011, now Pat. No. 8,518,981, which is a continuation of application No. 11/186,311, filed on Jul. 21, 2005, now Pat. No. 7,947,724, which is a continuation of application No. PCT/EP2004/000888, filed on Jan. 30, 2004.
- (60) Provisional application No. 60/444,351, filed on Jan. 30, 2003.
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*A61K 47/26* (2006.01)  
*A61K 31/473* (2006.01)  
*A61K 47/18* (2006.01)  
*A61K 47/12* (2006.01)  
*A61K 47/00* (2006.01)  
*A61K 47/02* (2006.01)  
*A61K 9/00* (2006.01)
- (52) **U.S. Cl.**  
CPC ..... *A61K 47/26* (2013.01); *A61K 47/183* (2013.01); *A61K 47/12* (2013.01); *A61K 47/00* (2013.01); *A61K 31/473* (2013.01); *A61K 47/02* (2013.01); *A61K 9/0019* (2013.01); *A61K 9/0095* (2013.01)
- (58) **Field of Classification Search**

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(57) **ABSTRACT**

The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis. The liquid formulations are particularly useful for oral administration.

Dr. Reddy's Laboratories, Ltd., et al.  
v.



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- (58) **Field of Classification Search**  
USPC ..... 514/296, 397  
See application file for complete search history.

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(57) **ABSTRACT**  
The present invention relates to shelf-stable liquid formulations of palonosetron for reducing chemotherapy and radiotherapy induced emesis with palonosetron. The formulations are particularly useful in the preparation of intravenous and oral liquid medicaments.

**16 Claims, No Drawings**

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- Sep. 4, 2012 Reddy's brief in opposition to Plaintiffs' cross-motion for partial summary judgment and reply memorandum of law in further support of Reddy's motion to dismiss or for summary judgment of non-infringement (D. N.J. Case No. 12-2867)(Including Exhibits 1-4).
- DeLuca Declaration (D. N.J. Case No. 12-2867)(Including exhibits A-J), dated Sep. 3, 2012.
- Sep. 10, 2012 Plaintiffs' letter to Judge Cooper in response to Reddy's combined opposition to Plaintiffs' cross-motion for partial summary judgment and reply in support of Reddy's motion to dismiss or for summary judgment of noninfringement (D. N.J. Case No. 12-2867)(including exhibits A and B).
- Sep. 14, 2012 Dr. Reddy's letter in response to Plaintiffs' Sep. 10, 2012 letter (D. N.J. Case No. 12-2867).
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