US009149533B2

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

(10) **Patent No.: US 9,149,533 B2**
(45) **Date of Patent: Oct. 6, 2015**

(54) **TAMPER RESISTANT PHARMACEUTICAL FORMULATIONS**

(71) Applicant: **Purdue Pharma L.P.**, Stamford, CT (US)

(72) Inventors: **Debora Guido**, Bordentown, NJ (US); **Haiyong Hugh Huang**, Princeton Junction, NJ (US)

(73) Assignee: **Purdue Pharma L.P.**, Stamford, CT (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.

(21) Appl. No.: **14/172,447**

(22) Filed: **Feb. 4, 2014**

(65) **Prior Publication Data**

US 2014/0221416 A1 Aug. 7, 2014

Related U.S. Application Data

(60) Provisional application No. 61/761,055, filed on Feb. 5, 2013.

(51) **Int. Cl.**

A61K 9/26	(2006.01)
A61K 31/44	(2006.01)
A61K 47/36	(2006.01)
A61K 9/20	(2006.01)
A61K 31/485	(2006.01)
A61K 31/165	(2006.01)
A61K 31/167	(2006.01)
A61K 47/02	(2006.01)
A61K 47/32	(2006.01)

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

CPC ***A61K 47/36*** (2013.01); ***A61K 9/205*** (2013.01); ***A61K 9/2009*** (2013.01); ***A61K 9/2013*** (2013.01); ***A61K 9/2027*** (2013.01); ***A61K 9/2031*** (2013.01); ***A61K 31/165*** (2013.01); ***A61K 31/167*** (2013.01); ***A61K 31/485*** (2013.01); ***A61K 47/02*** (2013.01); ***A61K 47/32*** (2013.01)

(58) **Field of Classification Search**

CPC A61K 31/5375; A61K 31/715; A61K 31/717; A61K 31/74; A61K 31/78; A61K 31/485

USPC 424/472; 514/282, 812

See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,065,143	A	11/1962	Christenson et al.
3,133,132	A	5/1964	Loeb et al.
3,173,876	A	3/1965	Zobrist et al.
3,260,646	A	7/1966	Paulsen et al.
3,276,586	A	10/1966	Rosaen
3,541,005	A	11/1970	Strathmann et al.
3,541,006	A	11/1970	Bixler et al.
3,546,876	A	12/1970	Fokker et al.
3,845,770	A	11/1974	Theeuwes et al.
3,916,889	A	11/1975	Russell
3,965,256	A	6/1976	Leslie
3,980,766	A	9/1976	Shaw et al.
4,063,064	A	12/1977	Saunders et al.
4,070,494	A	1/1978	Hoffmeister et al.
4,088,864	A	5/1978	Theeuwes et al.
4,160,020	A	7/1979	Ayer et al.
4,175,119	A	11/1979	Porter
4,200,098	A	4/1980	Ayer et al.
4,235,870	A	11/1980	Leslie
4,285,987	A	8/1981	Ayer et al.
4,293,539	A	10/1981	Ludwig et al.
4,366,310	A	12/1982	Leslie
4,385,057	A	5/1983	Bjork et al.
4,389,393	A	6/1983	Schor et al.
4,424,205	A	1/1984	LaHann et al.
4,443,428	A	4/1984	Oshlack et al.
4,457,933	A	7/1984	Gordon et al.
4,459,278	A	7/1984	Porter
4,588,580	A	5/1986	Gale et al.
4,599,342	A	7/1986	LaHann
4,610,870	A	9/1986	Jain et al.
4,612,008	A	9/1986	Wong et al.
4,666,705	A	5/1987	DeCrosta et al.
4,764,378	A	8/1988	Keith et al.
4,765,989	A	8/1988	Wong et al.
4,769,372	A	9/1988	Kreek
4,785,000	A	11/1988	Kreek et al.
4,806,341	A	2/1989	Chien et al.
4,812,446	A	3/1989	Brand
4,834,984	A	5/1989	Goldie et al.
4,844,909	A	7/1989	Goldie et al.
4,861,598	A	8/1989	Oshlack
4,957,681	A	9/1990	Klimesch et al.

(Continued)

FOREIGN PATENT DOCUMENTS

CA	2569743	12/2005
CA	2 746 888	6/2010

(Continued)

OTHER PUBLICATIONS

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (2010). Prescribing Information for Concerta Extended-Release Tablets.

International Search Report for International Application No. PCT/US14/14665 filed on Feb. 4, 2014, mailed May 5, 2014, 10 pgs.

Written Opinion of International Searching Authority for International Application No. PCT/US14/14665 filed on Feb. 4, 2014, mailed May 5, 2014, 42 pgs.

(Continued)

Primary Examiner — Kevin E Weddington

(74) *Attorney, Agent, or Firm* — Lowenstein Sandler LLP

(57) **ABSTRACT**

Disclosed in certain embodiments is a solid oral dosage form comprising a heat-labile gelling agent; a thermal stabilizer; and a drug susceptible to abuse.

54 Claims, No Drawings