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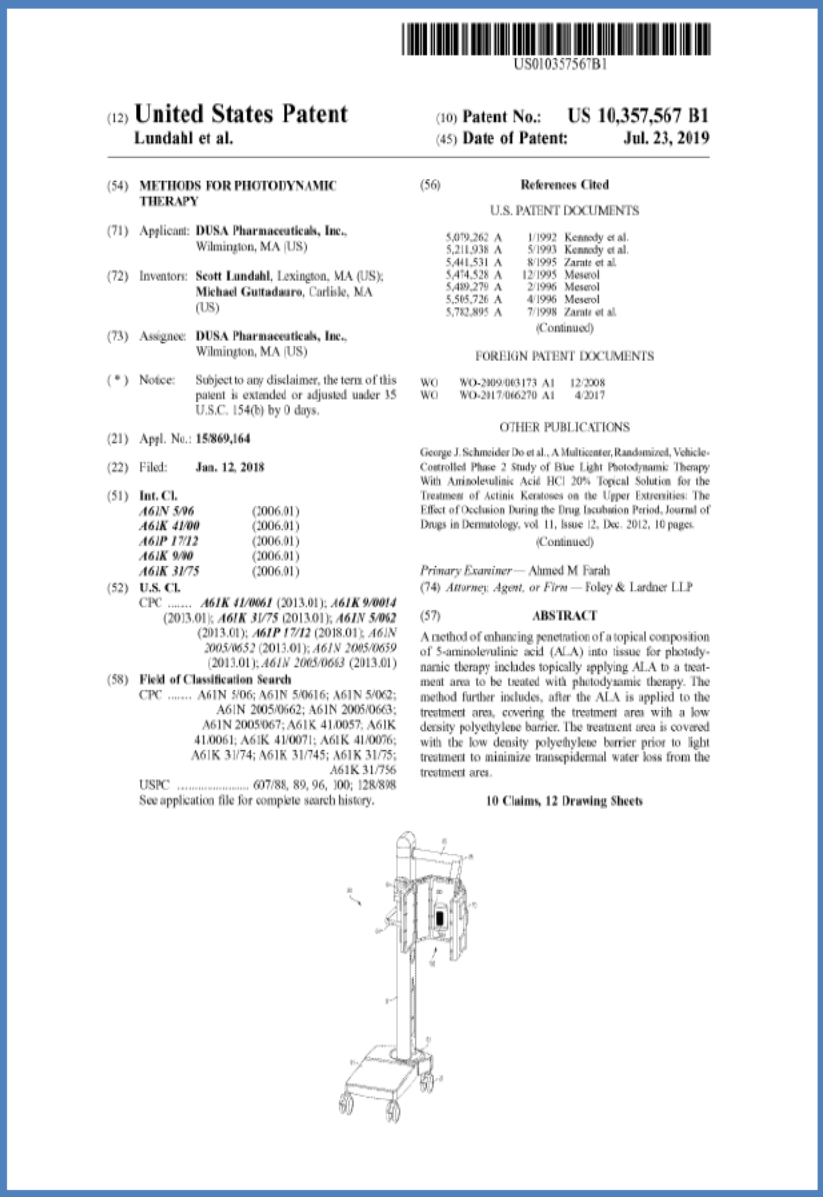

US010357567B1

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

(10) **Patent No.: US 10,357,567 B1**
(45) **Date of Patent: Jul. 23, 2019**

(54) **METHODS FOR PHOTODYNAMIC THERAPY**

(71) Applicant: **DUSA Pharmaceuticals, Inc.**, Wilmington, MA (US)

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(*) 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.: **15/869,164**

(22) Filed: **Jan. 12, 2018**

(51) **Int. Cl.**

A61N 5/06	(2006.01)
A61K 41/00	(2006.01)
A61P 17/12	(2006.01)
A61K 9/00	(2006.01)
A61K 31/75	(2006.01)

(52) **U.S. Cl.**
CPC ***A61K 41/0061*** (2013.01); ***A61K 9/0014*** (2013.01); ***A61K 31/75*** (2013.01); ***A61N 5/062*** (2013.01); ***A61P 17/12*** (2018.01); *A61N 2005/0652* (2013.01); *A61N 2005/0659* (2013.01); *A61N 2005/0663* (2013.01)

(58) **Field of Classification Search**
CPC A61N 5/06; A61N 5/0616; A61N 5/062; A61N 2005/0662; A61N 2005/0663; A61N 2005/067; A61K 41.0057, A61K 41.0061; A61K 41/0071; A61K 41/0076; A61K 31/74; A61K 31/745; A61K 31/75; A61K 31/756
USPC 607/88, 89, 96, 100; 128/898
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

5,079,262	A	1/1992	Kennedy et al.
5,211,938	A	5/1993	Kennedy et al.
5,441,531	A	8/1995	Zarate et al.
5,474,528	A	12/1995	Meserol
5,489,279	A	2/1996	Meserol
5,505,726	A	4/1996	Meserol
5,782,895	A	7/1998	Zarate et al.

(Continued)

FOREIGN PATENT DOCUMENTS

WO	WO-2009/063173 A1	12/2008
WO	WO-2017/066270 A1	4/2017

OTHER PUBLICATIONS

George J. Schmeider Do et al., A Multicenter, Randomized, Vehicle-Controlled Phase 2 Study of Blue Light Photodynamic Therapy With Aminolevulinic Acid HCl 20% Topical Solution for the Treatment of Actinic Keratoses on the Upper Extremities: The Effect of Occlusion During the Drug Incubation Period, Journal of Drugs in Dermatology, vol. 11, Issue 12, Dec. 2012, 10 pages.

(Continued)

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(57) **ABSTRACT**

A method of enhancing penetration of a topical composition of 5-aminolevulinic acid (ALA) into tissue for photodynamic therapy includes topically applying ALA to a treatment area to be treated with photodynamic therapy. The method further includes, after the ALA is applied to the treatment area, covering the treatment area with a low density polyethylene barrier. The treatment area is covered with the low density polyethylene barrier prior to light treatment to minimize transepidermal water loss from the treatment area.

10 Claims, 12 Drawing Sheets

Methods for Photodynamic Therapy
Critical Date: January 12, 2018
Expiration Date: January 12, 2038

Initial Patent Review
U.S. 10357567

Biofrontera Exhibit 1036
Biofrontera Inc. et al. v. DUSA Pharmaceuticals, Inc.
IPR2022-00056

International Patent Reviews

IPR Initial Review

Patent information

URL	Priority	Expiration	RC*	FC**
https://patents.google.com/patent/US10357567	Jan 12 2018	Jan 12 2038	55	99

*patent and non-patent literature citations ** citing patents

Technology Description & Application Area

Patent Number	Title	Description/Application Area
10357567	Methods for photodynamic therapy	A method of enhancing penetration of a topical composition of 5-aminolevulinic acid (ALA) into tissue for photodynamic therapy is disclosed. The method includes topically applying ALA to a treatment area to be treated with photodynamic therapy. The method further includes, after the ALA is applied to the treatment area, covering the treatment area with a polymeric barrier ...

Prosecution History

U.S. 10357567	Date	Action/Outcome
Original Filing	Jan 12 2018	Originally filed with claims 1-23.
Request for Restriction/Election	Apr 3 2018	I. Claims 1-8 and 16-23, drawn to alternative methods of enhancing penetration of a topical composition into a tissue for photodynamic therapy, classified in A61 K41 /0061. This application contains claims directed a patentably distinct specie. The invention of Group I contains claims directed to the following patentably distinct species: Species A (claims directed to a method of enhancing penetration of a topical composition into tissue characterized by applying 5-aminolevulinic acid (molecular formula C5H9NQ3) to a body tissue to be treated, see Par. 0007 and 0010 of the specification), and Specie B (claims directed to method of enhancing penetration of a topical composition to a skin tissue characterized by applying 5-aminolevulinic acid hydrochloride (molecular formula: C5H10CINO3) to a body tissue to be treated, see Par. 0011).

		II. Claims 9-15, drawn to a method of photodynamic treatment of a body/skin tissue, classified in A61 N 5/062.
Response to Request for Restriction/Election	Apr 13 2018	Applicant elected Group I, claims 1-8 and 16-23, without traverse and Species A, claims directed to a method of enhancing penetration of a topical composition into a tissue, characterized by applying 5-aminolevulinic acid (molecular formula C5H9N03), with traverse.
Non-Final Rejection	Aug 9 2018	Claims 9-15 and 21-23 withdrawn from consideration. Claims 1-8 and 16-20 rejected. Claims 1-8 and 16-20 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the inventor or a joint inventor, or for pre-AIA the applicant regards as the invention. The term "low" in claim 1 line 5 and claim 16 line 6 is a relative term which renders the claim indefinite. Claim 8 recites the limitation "the maximum plasma" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claims 1, 2, 5 and 16 rejected under 35 U.S.C. 102(a)(1) as being anticipated by Foguet Roca, Pub. No. U.S. 2009/0324727. **Note**: in the Background section of the instant application, the applicant describes the use of ALA compositions for photodynamic therapy as well known in the art. The applicant further indicates that the inventors found 'coving [sic] polyethylene for a period of time over a treatment area is effective to minimize trans-epidermal water loss from the treatment area' (see Par. 006 of the specification). The examiner further notes that the use of surfactants such as polyethylene for coating on a surface to minimize water loss for a period of time, or on a surface of a medical capsule to minimize water absorption is well known in the art (see Pars. 0004 and 0208 of Parent et al., Pub. No. U.S. 2014/0010761; and Pars. 0090 and 0106 of Bonasera et al., Pub. No. U.S 2005/0090429). Claims 1 and 16 rejected under 35 U.S.C. 102(a)(1) as being anticipated by Trigiante, Pub. No. U.S. 2011 /0053965.
Applicant Arguments	Nov 2 1018	Claim 1 amended to include allowable subject matter relating to claim 4. Claims 2, 4, 9-15, 17, 18 and 21-233 were cancelled without prejudice or disclaimer. Claim 5 was rewritten into independent form and revised to include subject matter supported at least by paras. [0022], [0059], [0066] and [0073] of the specification as filed. New claims 24 and 25 include subject matter also supported by at least these portions of the disclosure. Claim 8 was amended for antecedent basis purposes. Claim 16 was amended to include allowable subject matter relating to claim 17. Claim 20 is amended for consistency with the amendments to claim 16. Claim 1 was amended by adding the phrase "removing the low density polyethylene barrier within 3 hours and then applying light to

		the treatment area." Claim 16 was amended by adding the phrase "removing the low density polyethylene barrier so as to expose the treatment site; and illuminating the exposed treatment site with an illuminator so as to deliver a 10 J/cm2 dose of blue light." Upon entry of the amendments, claims 1, 3, 5-8, 16, 19, 20, 24 and 25 will be pending.
Final Rejection	Feb 25 2019	Claims 1, 5-8, 16, 19, 20, 24 and 25 were allowed. Claim 3 was rejected under 35 U.S.C. 112(d) or pre-AIA 35 U.S.C. 112, 4th paragraph, as being of improper dependent form for failing to further limit the subject matter of the claim upon which it depends, or for failing to include all the limitations of the claim upon which it depends.
Applicant Response	Apr 12 2019	Accepted cancellation of claim 3.
Notice of Allowance	Jun 3 2019	The allowed claim(s) were 1,5-8, 16, 19-20 and 24-25.
Issue Notification	Jul 2 2019	Issue date specified as Jul 23 2019 for US Patent 10357567
Notice of Publication	Jul 18 2019	US-2019-0216927-A 1 published on Jul 18 2019

Litigation History

U.S. Patent 10357567: none

Current Orange Book Patent Data

Active Ingredient: AMINOLEVULINIC ACID HYDROCHLORIDE
Proprietary Name: LEVULAN
Dosage Form; Route of Administration: SOLUTION; TOPICAL
Strength: 20%
Reference Listed Drug: Yes
Reference Standard: Yes
TE Code:
Application Number: N020965
Product Number: 001
Approval Date: Dec 3, 1999
Applicant Holder Full Name: DUSA PHARMACEUTICALS INC
Marketing Status: Prescription

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
001	10357567	01/12/2038			U-804		08/02/2019

Exclusivity Data

Product No	Exclusivity Code	Exclusivity Expiration
001	I-766	03/09/2021

Best Potential Prior Art

Relevant Patent or Publication	Publication Date
Dragieva, G., et al. "A randomized controlled clinical trial of topical photodynamic therapy with methyl aminolaevulinate in the treatment of actinic keratoses in transplant recipients." British Journal of Dermatology 151.1 (2004): 196-200.	July 2004
Kurwa, Habib A., et al. "A randomized paired comparison of photodynamic therapy and topical 5-fluorouracil in the treatment of actinic keratoses." Journal of the American Academy of Dermatology 41.3 (1999): 414-418.	September 1999
Braathen, Lasse R., et al. "Guidelines on the use of photodynamic therapy for nonmelanoma skin cancer: an international consensus." *Journal of the American Academy of Dermatology* 56.1 (2007): 125-143.	January 2007
MacCormack, Mollie A. "Photodynamic therapy in dermatology: an update on applications and outcomes." Seminars in cutaneous medicine and surgery. Vol. 27. No. 1. WB Saunders, 2008.	March 2008
Wolf, Peter, Edgar Rieger, and Helmut Kerl. "Topical photodynamic therapy with endogenous porphyrins after application of 5-aminolevulinic acid: an alternative treatment modality for solar keratoses, superficial squamous cell carcinomas, and basal cell carcinomas?" Journal of the American Academy of Dermatology 28.1 (1993): 17-21.	January 1993
Ozog, David M., et al. "Photodynamic therapy: a clinical consensus guide." Dermatologic Surgery 42.7 (2016): 804-827.	July 2016
Schmieder, George J., Eugene Y. Huang, and Michael Jarratt. "A multicenter, randomized, vehicle-controlled phase 2 study of blue light photodynamic therapy with aminolevulinic acid HCl 20% topical solution for the treatment of actinic keratoses on the upper extremities: the effect of occlusion during the drug incubation period." Journal of drugs in dermatology: JDD 11.12 (2012): 1483-1489.*	November 2012

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