

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

**BIOFRONTERA INCORPORATED,
BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH,**

AND

BIOFRONTERA AG

Petitioner

v.

DUSA PHARMACEUTICALS, INC.

Patent Owner

***Inter Partes* Review No. IPR2022-00056**

Patent 10,357,567

PETITION FOR *INTER PARTES* REVIEW UNDER 35 U.S.C. 312

Table of Contents

I.	INTRODUCTION	1
II.	MANDATORY NOTICES	3
	A. Real Party in Interest (37 C.F.R. § 42.8(b)(1))	3
	B. Related Matters (37 C.F.R. § 42.8(b)(2)).....	3
	C. Lead and Back-Up Counsel (37 C.F.R. § 42.8(b)(3)).....	4
	D. Service Information (37 C.F.R. § 42.8(b)(4)).....	4
	E. Payment of Fees (37 C.F.R. §§ 42.15(a) and 42.103(a)).....	4
III.	GROUND FOR STANDING (37 C.F.R. § 42.104(a)).....	4
IV.	STATEMENT OF PRECISE RELIEF REQUESTED FOR EACH CLAIM CHALLENGED	5
	A. Claims for Which Review Is Requested (37 C.F.R. § 42.104(b)(1))	5
	B. Statutory Grounds of Challenge (37 C.F.R. § 42.104(b)(2))	5
V.	FIELD OF TECHNOLOGY	8
	A. Photodynamic Therapy	9
	B. 5-Aminolevulinic Acid (ALA).....	10
	C. Photodynamic Therapy Light Sources	11
	D. Photodynamic Therapy Treatment of Actinic Keratosis.....	14
	E. Use of Occlusion to Minimize Transepidermal Water Loss and Enhance Penetration of ALA Was Well-Known in the Art.....	16
VI.	THE '567 PATENT.....	18
	A. Claims and Specification of the '567 Patent	18
	B. Prosecution History of the '567 Patent	21
	C. Claim Construction	22
	1. “dorsal surface of the hand” (claim 6) / “dorsal surface of the forearm” (claim 7).....	22
VII.	REASONS FOR THE RELIEF REQUESTED UNDER 37 C.F.R. §§ 42.22(A)(2) AND 42.104(B)(4)	24
	A. The Scope and Content of the Prior Art.....	24

1.	The Prior Art Teaches that Occlusive Barriers Like LDPE Minimize Transepidermal Water Loss	24
2.	The Prior Art Teaches Removal of Occlusive Coverings for Photodynamic Therapy Prior to Illumination	26
3.	The Prior Art Teaches PDT Treatment using LDPE Occlusive Barriers on the Hands and Forearms.....	27
B.	Level of Ordinary Skill in the Art.....	28
C.	Ground 1 – Claims 1-4 and 6-10 Are Unpatentable as Anticipated by Willey	28
1.	Claim 1pre: “A method of enhancing penetration of a topical composition of 5-aminolevulinic acid (ALA) into tissue for photodynamic therapy, the method comprising:”	28
2.	Claim 1a: “topically applying ALA to a treatment area to be treated with photodynamic therapy”	29
3.	Claim 1b: “after the ALA is applied to the treatment area, covering the treatment area with a low density polyethylene barrier prior to light treatment to minimize transepidermal water loss from the treatment area; and”	29
4.	Claim 1c: “removing the low density polyethylene barrier within 3 hours and then applying light to the treatment area.”	31
5.	Claim 2: “A method as set forth in claim 1, wherein the low density polyethylene barrier is removed from the treatment area within 3 hours and then blue light is applied to the treatment area for a 10 J/cm ² light dose.”	32
6.	Claim 3: “The method of claim 1, wherein a maximum plasma concentration of ALA following application of the ALA is less than about 110 ng/mL.”	33
7.	Claim 4pre: “A method of enhancing penetration of a topical composition of 5-aminolevulinic acid (ALA) into tissue for photodynamic therapy, the method comprising:”	34
8.	Claim 4a: “topically applying ALA to a treatment area to be treated with photodynamic therapy; and”	34
9.	Claim 4b: “after the ALA is applied to the treatment area, covering the treatment area with a low density	

	polyethylene barrier prior to light treatment to minimize transepidermal water loss from the treatment area,”	35
10.	Claim 4c: “wherein the treatment area is located on a hand or a forearm.”	35
11.	Claim 6: “The method as set forth in claim 4, wherein the treatment area is a dorsal surface of the hand.” / Claim 7: “The method as set forth in claim 4, wherein the treatment area is a dorsal surface of the forearm.”	35
12.	Claim 8pre: “A method of using 5-aminolevulinic acid (ALA) and a low density polyethylene barrier, comprising:”	36
13.	Claim 8a: “contacting a treatment site with a composition comprising the ALA so as to wet the treatment site;”	36
14.	Claim 8b: “following wetting of the treatment site, covering the wetted treatment site with the low density polyethylene barrier;”	37
15.	Claim 8c: “removing the low density polyethylene barrier so as to expose the treatment site; and”	38
16.	Claim 8d: “illuminating the exposed treatment site with an illuminator so as to deliver a 10 J/cm ² dose of blue light.”	38
17.	Claim 9: “The method of claim 8, wherein the low density polyethylene barrier is removed no later than three hours after the treatment site is covered.”	38
18.	Claim 10: “The method of claim 8, further comprising: positioning the treatment site between two inches and four inches from a surface of the illuminator.”	39
D.	Ground 2 – Claim 3 Is Unpatentable as Obvious Over Willey Combined with Ameluz	39
1.	Claim 3: “The method of Claim 1, wherein a maximum plasma concentration of ALA following application of the ALA is less than about 110 ng/mL.”	39
E.	Ground 3 – Claim 5 Is Unpatentable as Obvious Over Willey Combined with Sotiriou	43
1.	Claim 5: “A method as set forth in claim 4, wherein the low density polyethylene barrier is removed from the	

treatment area and then red light is applied to the treatment area for a 10 to 75 J/cm² light dose.”43

F. Ground 4 – Claims 1-9 Are Unpatentable as Anticipated by Noven Pharma45

1. Claim 1pre: “A method of enhancing penetration of a topical composition of 5-aminolevulinic acid (ALA) into tissue for photodynamic therapy, the method comprising:”45

2. Claim 1a: “topically applying ALA to a treatment area to be treated with photodynamic therapy”46

3. Claim 1b: “after the ALA is applied to the treatment area, covering the treatment area with a low density polyethylene barrier prior to light treatment to minimize transepidermal water loss from the treatment area; and”46

4. Claim 1c: “removing the low density polyethylene barrier within 3 hours and then applying light to the treatment area.”47

5. Claim 2: “A method as set forth in claim 1, wherein the low density polyethylene barrier is removed from the treatment area within 3 hours and then blue light is applied to the treatment area for a 10 J/cm² light dose.”49

6. Claim 3: “The method of claim 1, wherein a maximum plasma concentration of ALA following application of the ALA is less than about 110 ng/mL.”51

7. Claim 4pre: “A method of enhancing penetration of a topical composition of 5-aminolevulinic acid (ALA) into tissue for photodynamic therapy, the method comprising:”52

8. Claim 4a: “topically applying ALA to a treatment area to be treated with photodynamic therapy; and”53

9. Claim 4b: “after the ALA is applied to the treatment area, covering the treatment area with a low density polyethylene barrier prior to light treatment to minimize transepidermal water loss from the treatment area,”53

10. Claim 4c: “wherein the treatment area is located on a hand or a forearm.”53

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