

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC.,  
a New Jersey corporation; and  
QUEEN'S UNIVERSITY AT  
KINGSTON, a Canadian academic  
organization,

Plaintiffs,

v.

NEW ENGLAND COMPOUNDING  
PHARMACY, INC., a Massachusetts  
corporation,

Defendant.

MAGISTRATE JUDGE RBC

04 12703 NMG  
Civil Action No.

[JURY TRIAL DEMANDED]

RECEIPT # 11039  
AMOUNT \$ 150.00  
SUMMONS ISSUED 1  
LOCAL RULE 4.1 -  
WAIVER FORM -  
MCF ISSUED -  
BY DPTY. CLK. MP  
DATE 12/27/04

**COMPLAINT**

Plaintiffs, DUSA Pharmaceuticals, Inc. ("DUSA") and Queen's University at Kingston ("Queen's University"), through their counsel, hereby allege the following for their Complaint against New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC"):

**JURISDICTION AND PARTIES**

1. This is a civil action for inducing patent infringement of United States Patent Nos. 6,710,066 ("the '066 patent"); and 5,955,490 ("the '490 patent"). This Court has jurisdiction under 28 U.S.C. § 1331 and § 1338(a). Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and §1400(b).

2. Plaintiff DUSA is a corporation organized under the laws of the State of New Jersey having its principal place of business at 25 Upton Drive, Wilmington, MA 01887.

3. Plaintiff Queen's University is a public university registered in the province of Ontario and located in Kingston, Ontario, Canada.

4. On information and belief, Defendant NECC is a for profit corporation incorporated under the laws of the Commonwealth of Massachusetts, having a principal place of business at 697 Waverly Street, Framingham, MA 01702.

5. Defendant NECC conducts business, has induced others to commit acts of infringement and resides in this Commonwealth and Judicial District, and a substantial part of the events giving rise to the claim occurred in this Judicial District.

### **COUNT I**

#### **CLAIM FOR INDUCEMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 6,710,066**

6. The '066 patent, entitled "Photochemotherapeutic Method Using 5-Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins," was duly and lawfully granted on March 23, 2004, by the United States Patent and Trademark Office. The '066 patent is owned by Plaintiff Queen's University and is exclusively licensed to Plaintiff DUSA.

7. Plaintiff DUSA, under its license from Plaintiff Queen's University, manufactures, offers for sale, and sells pharmaceutical compositions containing aminolevulinic acid under the trademark "Levulan®" for use in the treatment of actinic keratosis, as covered by the '066 patent.

8. Upon information and belief, Defendant NECC sells aminolevulinic acid solution, advertises the use of NECC's aminolevulinic acid solution for treatment of actinic keratosis, instructs others to use NECC's aminolevulinic acid solution for actinic keratosis treatment and thereby actively induces others to treat actinic keratosis with NECC's aminolevulinic acid solution by infringing the '066 patent under 35 U.S.C. § 271(b).

9. Upon information and belief, Defendant NECC is sending unsolicited facsimiles to physicians advertising aminolevulinic acid solution for the treatment of actinic keratosis. Copies of such facsimiles are attached as Exhibits A and B and are hereby incorporated by reference.

10. Defendant NECC's activities in inducing infringement of the '066 patent are knowing, willful and wanton under 35 U.S.C. § 284 and make this an exceptional case under 35 U.S.C. § 285.

## **COUNT II**

### **CLAIM FOR INDUCEMENT OF INFRINGEMENT OF UNITED STATES PATENT NO. 5,955,490**

11. The '490 patent, entitled "Photochemotherapeutic Method Using 5-Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins," was duly and lawfully granted on September 21, 1999, by the United States Patent and Trademark Office. The '490 patent is owned by Plaintiff Queen's University and is exclusively licensed to Plaintiff DUSA.

12. Upon information and belief, Defendant NECC sells aminolevulinic acid solution, advertises the use of NECC's aminolevulinic acid solution for treatment of acne using light therapy, instructs others to use NECC's aminolevulinic acid solution for acne treatment and thereby actively induces others to treat acne with NECC's aminolevulinic acid solution by infringing the '490 patent under 35 U.S.C. § 271(b).

13. Upon information and belief, Defendant NECC is sending unsolicited facsimiles to physicians advertising aminolevulinic acid solution for the treatment of acne. Copies of such facsimiles are attached as Exhibits A and B and are hereby incorporated by reference.

14. Defendant NECC's activities in inducing infringement of the '490 patent are knowing, willful and wanton under 35 U.S.C. § 284 and make this an exceptional case under 35 U.S.C. § 285.

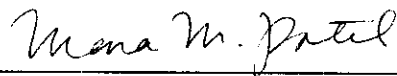
WHEREFORE, Plaintiffs pray that:

- (a) Defendant NECC be preliminarily and permanently enjoined from actively inducing others to infringe United States Patent No. 6,710,066;
- (b) Defendant NECC be preliminarily and permanently enjoined from actively inducing others to infringe United States Patent No. 5,955,490;
- (c) Defendant NECC be ordered to pay compensatory damages as a result of its actively inducing infringement of United States Patent No. 6,710,066, including all damages suffered by Plaintiffs as a result of the infringement, increased by three times for willful behavior;
- (d) Defendant NECC be ordered to pay compensatory damages as a result of its actively inducing infringement of United States Patent No. 5,955,490, including all damages suffered by Plaintiffs as a result of the infringement, increased by three times for willful behavior;
- (e) Plaintiffs be awarded their costs of this action including reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- (f) Plaintiffs be awarded such other further relief as the Court shall deem appropriate.

Respectfully submitted this 27th day of December 2004.

DUSA PHARMACEUTICALS, INC. and  
QUEEN'S UNIVERSITY AT KINGSTON

By their attorneys,



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## New England Compounding Center

*Customized Pharmacy Services*

697 Waverly Street, Framingham, MA 01702

Tel: 800.994.6322 or 508.820.0606

Fax: 888.820.0583 or 508.820.1616

[www.neccrx.com](http://www.neccrx.com) [mail@neccrx.com](mailto:mail@neccrx.com)

Are you treating acne patients with Blue Light Therapy?

**We may be able to help!**

New England Compounding Center can provide you with, on a prescription basis, 20% aminolevulinic acid solution in a convenient 2ml screw top vial.

### Advantages:

- Easy to apply
- Great for larger surface areas
- Reconstitute on site

New England Compounding Center has earned a national reputation as a provider of compounded pharmaceuticals and excellent service to patients and prescribers.

**Please call today to discuss your needs 800-994-6322.**

*We would appreciate the opportunity to serve you and your patients.*

## Directions for Reconstitution Aminolevulinic Acid 20% (ALA)

- 1) Aminolevulinic Acid (ALA) is stored in the refrigerator
- 2) When ready to use, open the silver packet which contains 2 vials:
  - a. ALA (Solvent) Solution, (1.5 ml)
  - b. ALA 20% 354mg Powder
- 3) Open the vial labeled "ALA (Solvent) Solution" and pour the contents into the vial labeled "ALA 20% 354mg Powder", creating a 2 ml volume of a 20% ALA Solution.
- 4) Screw cap on the vial tightly and shake well; may take 4 to 5 minutes for the powder to dissolve.
- 5) The ALA solution expires in 2 hours once reconstituted.
- 6) The ALA solution is for external use and can be applied with the enclosed brush or any other suitable swab.



# Patient Advisory Leaflet

## Aminolevulinic Acid 20% (ALA)

Aminolevulinic Acid 20% (ALA) is a naturally occurring photosensitizing compound which has been approved by the FDA to treat pre-cancerous skin lesions called actinic keratosis. ALA is applied to the skin and subsequently "activated" by specific wavelengths of light. This process of activating ALA with light is termed Photodynamic Therapy. The purpose of activating the ALA is to improve the appearance and reduce acne rosacea, acne vulgaris, sebaceous hyperplasia, decrease oiliness of the skin and improve texture and smoothness by minimizing pore size. Any pre-cancerous lesions are also simultaneously treated. The improvement of these skin conditions (other than actinic keratosis) is considered an "off-label" use of ALA.

ALA is normally applied to the skin for 30 – 90 minutes. Subsequently, the area will be treated with a specific wavelength of light to activate the ALA. Following treatment, the ALA is washed from the skin. The patient should avoid direct sunlight for 24 hours following the treatment due to photosensitivity.

Anticipated side effects of ALA treatment include discomfort, burning, swelling, redness and possible skin peeling, especially in any areas of sun damaged skin and pre-cancers of the skin, as well as lightening or darkening of skin tone and spots, and possible hair removal. The peeling may last many days and the redness for several weeks if you have an exuberant response to treatment.





**New England Compounding Center**  
*Customized Pharmacy Services*  
697 Waverly Street Framingham, MA 01702  
(508) 820-0606, (800) 994 - NECC  
Fax (508) 820-1616 or (888) 820 0583  
[www.neccrx.com](http://www.neccrx.com)

**Dr. Mark Nestor**

Fax# 305-933-6720

From: Pat Hill  
Phone: 508-820-0606 ext. 609

Date: 10/29/2004

3 PAGES

Thank you for your interest in our prescription compounding services.  
Our **20 % Aminolevulinic Acid (ALA)** solution is dispensed  
in a 1ml and 2 ml volume.

Price per vial is \$xx.00 @ quantity 6 vials @ 2 ml volume  
Price per vial is \$xx.00 @ quantity 6 vials @ 1 ml volume

A number of physicians have come to our pharmacy looking for a  
better way to apply this topical medication to larger treatment areas.

It has a 6 month beyond use date (unmixed)  
**We supply a convenient applicator brush with each vial.**  
**Medication is shipped cold.**

To order:

- Please fax in a script from the doctor with his DEA# and address.
- Fax to # 888-820-0583
- List 1 patient name for every 3 vials. (i.e. 6 vials = 2 patient names)
- Include your Credit Card information.

Pat Hill

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