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12 UNITED STATES DISTRICT COURT
13 DISTRICT OF ARIZONA

14 DUSA PHARMACEUTICALS, INC., a
15 New Jersey corporation; and QUEEN'S
UNIVERSITY AT KINGSTON, a
16 Canadian academic Organization,

17 Plaintiffs,

18 v.

19 SPECTRUM PHARMACY PRODUCTS, a
20 division of SPECTRUM CHEMICAL AND
MANUFACTURING CORPORATION,
21 INC. a California corporation d/b/a
SPECTRUM LABORATORY
22 PRODUCTS, INC., a California
corporation and a subsidiary of
23 SPECTRUM CHEMICAL AND
LABORATORY PRODUCTS, INC., a
24 California corporation and subsidiary of
SPECTRUM CHEMICAL
25 MANUFACTURING CORPORATION, a
California corporation,

26 Defendant.

No.

COMPLAINT

JURY TRIAL DEMANDED

Snell & Wilmer

L.L.P.
LAW OFFICES
One Arizona Center, 400 E. Van Buren
Phoenix, Arizona 85004-2202
(602) 382-6000

1 Plaintiffs DUSA Pharmaceuticals, Inc. ® (“DUSA®”) and Queen’s
2 University at Kingston (“Queen’s University”) (collectively “Plaintiffs”), through their
3 counsel, hereby allege the following for their Complaint against Spectrum Pharmacy
4 Products, a division of Spectrum Chemical Manufacturing Corporation a California
5 corporation d/b/a Spectrum Laboratory Products, Inc., a subsidiary of Spectrum Chemical
6 and Laboratory Products, Inc., a subsidiary of Spectrum Chemical Manufacturing
7 Corporation (“Spectrum”) as follows:

8 **JURISDICTION AND PARTIES**

9
10 1. This is a civil action for patent infringement of United States Patent Nos.
11 6,710,066 (“the ‘066 patent”) and 5,955,490 (“the ‘490 patent”) under 35 U.S.C. § 271(b),
12 and for unfair competition in violation of § 1125 of the Trademark Act (§43(a) of the
13 Lanham Act).

14 2. This Court has jurisdiction under 28 U.S.C. § 1331 and § 1338(a).

15 3. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and
16 §1400(b).

17
18 4. DUSA® is a corporation organized under the laws of the State of New Jersey
19 having its principal place of business at 25 Upton Drive, Wilmington, MA 01887.

20
21 5. Queen’s University is a public university registered in the province of
22 Ontario and located in Kingston, Ontario, Canada.

23 6. Defendant Spectrum Pharmacy Products, with a regular and established
24 place of business at 7400 North Oracle Road, Tucson, AZ 85704, is a division of
25 Spectrum Chemical and Manufacturing Corporation, a private California corporation with
26 a principal place of business at 14422 South San Pedro Street, Gardena, CA 90248.
27 Spectrum Chemical and Manufacturing Corporation does business as Spectrum
28

1 Laboratory Products, Inc., a California corporation with a principal place of business at
2 14422 South San Pedro Street, Gardena, CA 90248, and is a subsidiary of Spectrum
3 Chemical and Laboratory Products, Inc., with a principal place of business at 14422 South
4 San Pedro Street, Gardena, CA 90248. Spectrum Chemical and Laboratory Products, inc.
5 is a subsidiary of Spectrum Chemical Manufacturing Corporation, with a principal place
6 of business at 14422 South San Pedro Street, Gardena, CA 90248.

7
8 7. Defendant Spectrum conducts business and has induced others to commit
9 acts of infringement in this Judicial District. Spectrum resides in this State and Judicial
10 District, and a substantial part of the events giving rise to the claim occurred in this
11 Judicial District.

12 **COUNT I**
13 **CLAIM FOR INDUCEMENT OF INFRINGEMENT**
14 **OF UNITED STATES PATENT NO. 6,710,066**

15 8. Plaintiffs repeat and re-allege each and every allegation in the foregoing
16 paragraphs as though fully set forth herein.

17 9. The '066 patent, entitled "Photochemotherapeutic Method Using 5-
18 Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins," was duly and
19 lawfully granted on March 23, 2004, by the United States Patent and Trademark Office.
20 The '066 patent is owned by Plaintiff Queen's University and is exclusively licensed to
21 Plaintiff DUSA[®]. *See* Exhibit A (a true and correct copy of United States Patent No.
22 6,710,066).

23 10. DUSA[®], under its license from Queen's University, manufactures, offers for
24 sale, and sells pharmaceutical compositions containing aminolevulinic acid under the
25 trademark, LEVULAN[®], for use in the treatment of actinic keratosis, a nonmalignant
26 hyperproliferative skin lesions, as covered by the '066 patent.
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1 11. Upon information and belief, Defendant Spectrum sells aminolevulinic acid,
2 advertises the use of Spectrum’s aminolevulinic acid for treatment of actinic keratosis,
3 instructs others to use Spectrum’s aminolevulinic acid for actinic keratosis treatment and
4 thereby actively induces others to treat actinic keratosis with Spectrum’s aminolevulinic
5 acid by infringing the ’066 patent under 35 U.S.C. § 271(b).

6 12. Defendant Spectrum advertises the use of Spectrum’s aminolevulinic acid
7 on its website, and sells and instructs the use of its aminolevulinic acid through its
8 website. *See* <http://www.spectrumrx.com/SpectrumRx/> (Exhibit B) (a true and correct
9 copy of Defendant’s website).

10 13. Defendant Spectrum has been employing searchable metatags on its
11 website’s source code that direct internet users to Spectrum’s website by indicating that
12 Spectrum’s aminolevulinic acid products are intended for use in dermatologic
13 compounding that includes the treatment of actinic keratosis. *See* Exhibit C (a true and
14 correct copy of source code for Defendant’s website).

15 14. By way of further inducement, Defendant Spectrum advertises, sells, and
16 instructs physicians in the use of a misleading National Drug Code (“NDC”) in
17 connection with Spectrum’s aminolevulinic acid so that physicians and/or patients may
18 submit insurance claims for the use of Spectrum’s aminolevulinic acid in the treatment of
19 actinic keratosis. *See* Exhibit B.

20 15. Every drug product sold in the United States must be listed with the Food
21 and Drug Administration (“FDA”) and assigned an NDC number. This number must be
22 provided to obtain insurance reimbursement.

23 16. Spectrum’s aminolevulinic acid is advertised and sold on its website with
24 the NDC numbers: 49452-0425-2 and 49452-0425-3. *See* Exhibit B.

1 17. The NDC numbers advertised by Defendant Spectrum are not registered
2 with or recognized by the FDA as identifying an aminolevulinic acid drug product. *See*
3 Exhibit D (a true and correct copy of the results of a “Search by Firm Name” performed
4 on the FDA’s National Drug Code directory website,
5 <http://www.fda.gov/cder/ndc/database/default.htm>).

6 18. The NDC numbers that Defendants Spectrum provides in conjunction with
7 its aminolevulinic acid are not NDC numbers registered with or recognized by the FDA as
8 applying to any drug product. *See* Exhibit E (a true and correct copy of the results of a
9 “Search by NDC Number by Labeler Code” performed on the FDA’s National Drug Code
10 directory website, <http://www.fda.gov/cder/ndc/database/default.htm>).

11 19. Defendant Spectrum’s association of a NDC number with its aminolevulinic
12 acid falsely suggests to physicians and patients that Spectrum’s aminolevulinic acid is an
13 FDA-approved drug product. Unlike Plaintiff DUSA[®]’s aminolevulinic acid solution
14 LEVULAN[®], Spectrum’s aminolevulinic acid is not FDA-approved as a drug product.
15 *See* Exhibits D and E.

16 20. The mischaracterization of Defendant Spectrum’s aminolevulinic acid as an
17 FDA-approved drug product has the effect of misleading physicians and patients that
18 Spectrum’s product is manufactured under the same standards and regulatory controls
19 with respect to the safety and efficacy as Plaintiff DUSA[®]’s aminolevulinic acid solution
20 LEVULAN[®].

21 21. The mischaracterization of Defendant Spectrum’s aminolevulinic acid as an
22 FDA-approved drug product has the effect of misleading physicians and patients that
23 Spectrum’s product has proven safety and efficacy.

24 22. The misleading NDC numbers that Defendants Spectrum provides in
25 conjunction with its aminolevulinic acid also has the effect of misleading physicians and
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1 patients that, because it is an FDA approved drug product and carries an NDC number like
2 other drug products, insurance reimbursement is available for use of Spectrum's
3 aminolevulinic acid in the treatment of actinic keratosis, just as it is with Plaintiff
4 DUSA[®]'s aminolevulinic acid solution LEVULAN[®].

5
6 23. Defendant Spectrum's activities in inducing infringement of the '066 patent
7 are knowing, willful and wanton under 35 U.S.C. § 284 and make this an exceptional case
8 under 35 U.S.C. § 285.

9
10 **COUNT II**
CLAIM FOR INDUCEMENT OF INFRINGEMENT
OF UNITED STATES PATENT NO. 5,955,490

11 24. Plaintiffs repeat and re-allege each and every allegation in the foregoing
12 paragraphs as though fully set forth herein.

13
14 25. The '490 patent, entitled "Photochemotherapeutic Method Using 5-
15 Aminolevulinic Acid and Other Precursors of Endogenous Porphyrins," was duly and
16 lawfully granted on September 21, 1999, by the United States Patent and Trademark
17 Office. The '490 patent is owned by Plaintiff Queen's University and is exclusively
18 licensed to Plaintiff DUSA[®]. See Exhibit F (a true and correct copy of United States
19 Patent No. 5,955,490).

20 26. DUSA[®], under its license from Queen's University, manufactures, offers for
21 sale, and sells pharmaceutical compositions containing aminolevulinic acid under the
22 trademark, LEVULAN[®], for use in the treatment of acne, as covered by the '490 patent.

23
24 27. Upon information and belief, Defendant Spectrum sells aminolevulinic acid,
25 advertises the use of Spectrum's aminolevulinic acid for treatment of acne, instructs
26 others to use Spectrum's aminolevulinic acid for acne treatment and thereby actively
27 induces others to treat acne with Spectrum's aminolevulinic acid by infringing the '066
28 patent under 35 U.S.C. § 271(b).

1 28. Defendant Spectrum advertises the use of Spectrum's aminolevulinic acid
2 on its website, and sells and instructs the use of its aminolevulinic acid through its
3 website. *See* Exhibit B.

4 29. Defendant Spectrum has been employing searchable metatags on its
5 website's source code that direct internet users to Spectrum's website by indicating that
6 Spectrum's aminolevulinic acid products are intended for use in dermatologic
7 compounding that includes the treatment of acne. *See* Exhibit C.

8 30. By way of further inducement, Defendant Spectrum advertises, sells, and
9 instructs the use of a misleading NDC Number in connection with Spectrum's
10 aminolevulinic acid so that physicians and/or patients may submit insurance claims for the
11 use of Spectrum's aminolevulinic acid in the treatment of acne. *See* Exhibit B.

12 31. Every drug product sold in the United States must be listed with the FDA
13 and assigned an NDC number. This number must be provided to obtain insurance
14 reimbursement.

15 32. Spectrum's aminolevulinic acid is advertised and sold on its website with
16 the NDC numbers: 49452-0425-2 and 49452-0425-3. *See* Exhibit B.

17 33. The NDC numbers advertised by Defendant Spectrum are not registered
18 with or recognized by the FDA as identifying an aminolevulinic acid drug product. *See*
19 Exhibit D (a true and correct copy of the results of a "Search by Firm Name" performed
20 on the FDA's National Drug Code directory website,
21 <http://www.fda.gov/cder/ndc/database/default.htm>).

22 34. The NDC numbers that Defendants Spectrum provides in conjunction with
23 its aminolevulinic acid are not NDC numbers registered with or recognized by the FDA as
24 applying to any drug product. *See* Exhibit E (a true and correct copy of the results of a
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1 “Search by NDC Number by Labeler Code” performed on the FDA’s National Drug Code
2 directory website, <http://www.fda.gov/cder/ndc/database/default.htm>).

3 35. Defendant Spectrum’s association of a NDC number with its aminolevulinic
4 acid suggests to physicians and patients that Spectrum’s aminolevulinic acid is an FDA-
5 approved drug product. Unlike Plaintiff DUSA[®]’s aminolevulinic acid solution
6 LEVULAN[®], Spectrum’s aminolevulinic acid is not FDA-approved drug product. *See*
7 Exhibits D and E.
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9 36. The misleading characterization of Defendant Spectrum’s aminolevulinic
10 acid as an FDA-approved drug product has the effect of misleading physicians and
11 patients that Spectrum’s product is manufactured under the same standards and regulatory
12 controls with respect to the safety and efficacy as Plaintiff DUSA[®]’s aminolevulinic acid
13 solution LEVULAN[®].

14 37. The mischaracterization of Defendant Spectrum’s aminolevulinic acid as an
15 FDA-approved drug product has the effect of misleading physicians and patients that
16 Spectrum’s product has proven safety and efficacy.
17

18 38. The misleading NDC numbers that Defendants Spectrum provides in
19 conjunction with its aminolevulinic acid also has the effect of misleading physicians and
20 patients that, because it is an FDA approved drug and carries an NDC number like other
21 drug products, insurance reimbursement is available for use of Spectrum’s aminolevulinic
22 acid in the treatment of actinic keratosis, just as it is with Plaintiff DUSA[®]’s
23 aminolevulinic acid solution LEVULAN[®].

24 39. Defendant Spectrum’s activities in inducing infringement of the ‘490 patent
25 are knowing, willful and wanton under 35 U.S.C. § 284 and make this an exceptional case
26 under 35 U.S.C. § 285.
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COUNT III
UNFAIR COMPETITION UNDER § 43(A) OF THE LANHAM ACT

1
2 40. Plaintiffs repeat and re-allege each and every allegation in the foregoing
3 paragraphs as though fully set forth herein.
4

5 41. Defendant Spectrum, in connection with its aminolevulinic acid, uses in
6 commerce symbols and/or false or misleading descriptions of fact and/or false or
7 misleading representations of fact which are likely to cause confusion, or to cause
8 mistake, or to deceive as to the sponsorship or approval of Spectrum's aminolevulinic acid
9 by the FDA, in violation of § 1125 of the Trademark Act (§43(a) of the Lanham Act).

10 42. Defendant Spectrum, in connection with its aminolevulinic acid, uses in
11 commerce symbols and/or false or misleading descriptions of fact and/or false or
12 misleading representations of fact which, in commercial advertising or promotion,
13 misrepresents the nature, characteristics, and/or qualities of Spectrum's aminolevulinic
14 acid, in violation of § 1125 of the Trademark Act (§43(a) of the Lanham Act).

15 43. Defendant Spectrum advertises, sells, and instructs the use of a misleading
16 NDC in connection with Spectrum's aminolevulinic acid. *See* Exhibit B.
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18 44. Every drug product sold in the United States must be listed with the FDA
19 and assigned an NDC number. This number must be provided to obtain insurance
20 reimbursement.
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22 45. Spectrum's aminolevulinic acid is advertised and sold on its website with
23 the NDC numbers: 49452-0425-2 and 49452-0425-3. *See* Exhibit B.

24 46. The NDC numbers advertised by Defendant Spectrum are not registered
25 with or recognized by the FDA as identifying an aminolevulinic acid drug product. *See*
26 Exhibit D (a true and correct copy of the results of a "Search by Firm Name" performed
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1 on the FDA's National Drug Code directory website,
2 <http://www.fda.gov/cder/ndc/database/default.htm>).

3 47. The NDC numbers that Defendants Spectrum provides in conjunction with
4 its aminolevulinic acid are not NDC numbers registered with or recognized by the FDA as
5 applying to any drug product. *See* Exhibit E (a true and correct copy of the results of a
6 "Search by NDC Number by Labeler Code" performed on the FDA's National Drug Code
7 directory website, <http://www.fda.gov/cder/ndc/database/default.htm>).

8 48. Defendant Spectrum's association of a NDC number with its aminolevulinic
9 acid falsely suggests to physicians and patients that Spectrum's aminolevulinic acid is an
10 FDA-approved drug product. Unlike Plaintiff DUSA[®]'s aminolevulinic acid solution
11 LEVULAN[®], Spectrum's aminolevulinic acid is not FDA-approved as a drug product.
12 *See* Exhibits D and E.

13 49. The mischaracterization of Defendant Spectrum's aminolevulinic acid as an
14 FDA-approved drug product has the effect of misleading physicians and patients that
15 Spectrum's product is manufactured under the same standards and regulatory controls as
16 Plaintiff DUSA[®]'s aminolevulinic acid solution LEVULAN[®].

17 50. The mischaracterization of Defendant Spectrum's aminolevulinic acid as an
18 FDA-approved drug product has the effect of misleading physicians and patients that
19 Spectrum's product exhibits the same safety and efficacy as Plaintiff DUSA[®]'s
20 aminolevulinic acid solution LEVULAN[®].

21 51. The misleading NDC numbers that Defendants Spectrum provides in
22 conjunction with its aminolevulinic acid also has the effect of misleading physicians and
23 patients that, because it is an FDA approved drug product and carries an NDC number like
24 other drug products, insurance reimbursement is available for use of Spectrum's
25 aminolevulinic acid in the treatment of actinic keratosis, just as it is with Plaintiff
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1 DUSA[®]'s aminolevulinic acid solution LEVULAN[®]. The NDC numbers that Defendants
2 Spectrum provides in connection with its aminolevulinic acid also is likely to cause
3 confusion, or to cause mistake, or to deceive physicians and patients that insurance
4 reimbursement is available for use of Spectrum's aminolevulinic acid, just as it is with
5 Plaintiff DUSA[®]'s aminolevulinic acid solution LEVULAN[®].

6 WHEREFORE, Plaintiffs pray that:
7

8 (a) Defendant Spectrum be preliminarily and permanently enjoined from
9 actively inducing others to infringe United States Patent No. 6,710,066;

10 (b) Defendant Spectrum be preliminarily and permanently enjoined from
11 actively inducing others to infringe United States Patent No. 5,955,490;

12 (c) Defendant Spectrum be preliminarily and permanently enjoined from
13 engaging in unfair competition in violation of § 1125 of the Trademark Act (§43(a) of the
14 Lanham Act);
15

16 (d) Defendant Spectrum be ordered to pay compensatory damages as a result of
17 its actively inducing infringement of United States Patent No. 6,710,066, including all
18 damages suffered by Plaintiffs as a result of the infringement, increased by three times for
19 willful behavior;

20 (f) Defendant Spectrum be ordered to pay compensatory damages as a result of
21 its actively inducing infringement of United States Patent No. 5,955,490, including all
22 damages suffered by Plaintiffs as a result of the infringement, increased by three times for
23 willful behavior;

24 (g) Defendant Spectrum be ordered to pay compensatory damages as a result of
25 its violation of § 1125 of the Trademark Act (§43(a) of the Lanham Act), including all
26 damages suffered by Plaintiffs as a result of the violations, increased by three times for
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1 willful behavior;

2 (h) that Plaintiffs be awarded their costs of this action including reasonable
3 attorneys' fees pursuant to 35 U.S.C. § 285; and
4

5 (i) Plaintiffs be awarded such other further relief as the Court shall deem
6 appropriate.

7 Respectfully submitted this 10th day of July, 2006.

8 SNELL & WILMER L.L.P.

9
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15 -and-

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