IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CEPHALON, INC., MEMORIAL SLOAN-KETTERING CANCER CENTER, AND SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	C.A. No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

COMPLAINT

Plaintiffs Cephalon, Inc. ("Cephalon"), Memorial Sloan-Kettering Cancer Center ("MSKCC"), and Sloan-Kettering Institute for Cancer Research ("SKI"), bring this action for patent infringement against Defendant Fresenius Kabi USA, LLC ("Fresenius").

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 6,723,351 ("the '351 patent"); 6,855,339 ("the '339 patent"); 6,861,076 ("the '076 patent"); and 6,884,439 ("the '439 patent") (collectively, "patents-in-suit"), arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action arises from Fresenius' filing of Abbreviated New Drug Application ("ANDA") No. 208231 with the United States Food and Drug Administration ("FDA"), under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking approval to sell generic copies of Cephalon's TRISENOX® drug product prior to expiration of the patents-in-suit.

PARTIES

2. Cephalon is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, Pennsylvania 19355. Cephalon is engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

3. MSKCC is a not-for-profit corporation organized and existing under the laws of the State of New York, with its principal place of business at 1275 York Avenue, New York, New York 10065.

4. SKI is a not-for-profit corporation organized and existing under the laws of the State of New York, having its principal place of business at 1275 York Avenue, New York, New York 10065.

5. Upon information and belief, Fresenius is a limited liability company organized and existing under the laws of the State of Delaware, with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

6. Upon information and belief, Fresenius is in the business of, *inter alia*, developing, manufacturing, and selling pharmaceutical products, including generic copies of branded pharmaceutical products, for the U.S. market, directly or through its affiliates.

7. Upon information and belief, following FDA approval of ANDA No. 208231, Fresenius and/or its affiliates will make, use, offer to sell, and/or sell the generic arsenic trioxide injection product that is the subject of ANDA No. 208231 (hereinafter "Generic Arsenic Trioxide Product") throughout the United States, including this judicial district, and/or import such products into the United States, including this judicial district.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Fresenius.

11. Upon information and belief, Fresenius is a Delaware limited liability company, organized and existing under the laws of the State of Delaware and domiciled in Delaware.

12. Upon information and belief, Fresenius is registered to conduct business in Delaware, and maintains as a registered agent for service of process Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

13. Upon information and belief, Fresenius regularly and systematically conducts business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

14. Upon information and belief, Fresenius is registered pursuant to Del. Code Ann. tit. 24, § 2540 to distribute its pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy, under License Nos. DM-0006436 and A4-0000901, respectively.

15. Fresenius has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No.

208231, which has led to and/or will lead to foreseeable harm and injury to Plaintiffs, including Cephalon, a Delaware corporation.

16. Fresenius is subject to general jurisdiction in this court because it is domiciled in Delaware.

17. Fresenius is subject to personal jurisdiction in this Court because, *inter alia*, as a Delaware corporation Fresenius is subject to general jurisdiction in Delaware.

BACKGROUND

18. TRISENOX® was approved by the FDA on September 25, 2000 for the treatment of patients with acute promyelocytic leukemia ("APL").

19. Cephalon markets TRISENOX® in the U.S. as the holder of New Drug Application ("NDA") No. 021248 under 21 U.S.C. §355(b)(1).

PATENTS-IN-SUIT

20. SKI is the current owner of the patents-in-suit by virtue of an assignment from MSKCC and Cephalon is the exclusive licensee of the patents-in-suit with the right to sue for and obtain equitable relief and damages for infringement of the patents-in-suit.

21. The '351 patent, entitled "Process for Producing Arsenic Trioxide Formulations and Methods for Treating Cancer Using Arsenic Trioxide or Melarsoprol," was duly and legally issued by the U.S. Patent and Trademark Office on April 20, 2004. A true and correct copy of the '351 patent is attached hereto as Exhibit A.

22. The '351 patent is listed in the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") with respect to TRISENOX®.

23. The '339 patent, entitled "Process for Producing Arsenic Trioxide Formulations and Methods for Treating Cancer Using Arsenic Trioxide or Melarsoprol," was

duly and legally issued by the U.S. Patent and Trademark Office on February 15, 2005. A true and correct copy of the '339 patent is attached hereto as Exhibit B.

24. The '339 patent is listed in the FDA's Orange Book with respect to TRISENOX®.

25. The '076 patent, entitled "Process for Producing Arsenic Trioxide Formulations and Methods for Treating Cancer Using Arsenic Trioxide or Melarsoprol," was duly and legally issued by the U.S. Patent and Trademark Office on March 1, 2005. A true and correct copy of the '076 patent is attached hereto as Exhibit C.

26. The '076 patent is listed in the FDA's Orange Book with respect to TRISENOX®.

27. The '439 patent, entitled "Process for Producing Arsenic Trioxide Formulations and Methods for Treating Cancer Using Arsenic Trioxide or Melarsoprol," was duly and legally issued by the U.S. Patent and Trademark Office on April 26, 2005. A true and correct copy of the '439 patent is attached hereto as Exhibit D.

28. The '439 patent is listed in the FDA's Orange Book with respect to TRISENOX®.

INFRINGEMENT BY FRESENIUS

29. By letter dated October 7, 2015 ("the Notice Letter"), Fresenius notified MSKCC and Cephalon that it had submitted ANDA No. 208231 to the FDA under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, and sale of its Generic Arsenic Trioxide Product before the expiration of the patents-in-suit.

30. Upon information and belief, Fresenius intends to engage in commercial manufacture, use, and sale of its Generic Arsenic Trioxide Product promptly upon receiving FDA approval to do so.

31. Upon information and belief, by filing ANDA No. 208231, Fresenius has represented to the FDA that its Generic Arsenic Trioxide Product has the same active ingredient as TRISENOX®, requires the same route and schedule of administration, dosage form, and strength as TRISENOX®, and is bioequivalent to TRISENOX®.

32. The label for Cephalon's TRISENOX® includes the following language:

> ----------INDICATIONS AND USAGE----------
> TRISENOX is an arsenical indicated for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.
> ----------DOSAGE AND ADMINISTRATION----------
> - For induction therapy, administer intravenously at a dose of 0.15 mg/kg daily until bone marrow remission. Do not exceed 60 doses for total induction. (2.1)
> - Begin consolidation treatment 3 to 6 weeks after completion of induction therapy. Administer intravenously at a dose of 0.15 mg/kg daily for 25 doses over a period up to 5 weeks. (2.1)
> - Delay treatment for severe non-hematologic adverse reactions. (2.2)
> - Dilute prior to use. (2.3)
> - Administer intravenously over 1-2 hours. The infusion duration may be extended up to 4 hours if acute vasomotor reactions are observed. (2.3)

33. Upon information and belief, Fresenius' proposed label for ANDA No. 208231 will include the same or similar language.

34. Upon information and belief, Fresenius intends for doctors to prescribe, and for patients suffering from APL to use, its Generic Arsenic Trioxide Product in accordance with and as directed by Fresenius' proposed labeling.

35. Upon information and belief, Fresenius included in ANDA No. 208231 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) identifying each of the patents-in-suit.

COUNT I

INFRINGEMENT OF THE '351 PATENT

36. Each of the preceding paragraphs 1 to 35 is incorporated as if fully set forth herein.

37. Upon information and belief, Fresenius had actual and constructive knowledge of the '351 patent prior to filing ANDA No. 208231. *Inter alia*, Fresenius included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) identifying the '351 patent in ANDA No. 208231 when it was filed.

38. Fresenius' submission of ANDA No. 208231 with a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its Generic Arsenic Trioxide Product prior to the expiration of the '351 patent constitutes infringement of the '351 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon FDA approval of Fresenius' ANDA No. 208231, Fresenius will further infringe the '351 patent by making, using, offering to sell, and selling its Generic Arsenic Trioxide Product in the United States and/or importing such products into the United States, and by actively inducing and contributing to infringement by others, including a doctor treating a patient with APL, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

40. Upon information and belief, Fresenius was aware that its filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '351 patent.

41. Upon information and belief, Fresenius was aware that its Generic Arsenic Trioxide Product is especially made or adapted for use in infringing the '351 patent and that Fresenius' Generic Arsenic Trioxide Product is not suitable for any substantial non-infringing

uses. Upon information and belief, Fresenius plans and intends to, and will, contribute to the infringement of the '351 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Fresenius' ANDA.

42. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '351 patent, actively inducing infringement of the '351 patent and/or contributing to the infringement by others of the '351 patent.

43. Fresenius' activities render this case an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

44. If Fresenius' infringement of the '351 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II

INFRINGEMENT OF THE '339 PATENT

45. Each of the preceding paragraphs 1 to 35 is incorporated as if fully set forth herein.

46. Upon information and belief, Fresenius had actual and constructive knowledge of the '339 patent prior to filing ANDA No. 208231. *Inter alia*, Fresenius included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) identifying the '339 patent in ANDA No. 208231 when it was filed.

47. Fresenius' submission of ANDA No. 208231 with a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its Generic Arsenic Trioxide Product prior to the expiration of the '339 patent constitutes infringement of the '339 patent under 35 U.S.C. § 271(e)(2)(A).

48. Upon FDA approval of Fresenius' ANDA No. 208231, Fresenius will further infringe the '339 patent by making, using, offering to sell, and selling its Generic Arsenic Trioxide Product in the United States and/or importing such products into the United States, and by actively inducing and contributing to infringement by others, including a doctor treating a patient with APL, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

49. Upon information and belief, Fresenius was aware that its filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '339 patent.

50. Upon information and belief, Fresenius was aware that its Generic Arsenic Trioxide Product is especially made or adapted for use in infringing the '339 patent and that Fresenius' Generic Arsenic Trioxide Product is not suitable for any substantial non-infringing uses. Upon information and belief, Fresenius plans and intends to, and will, contribute to the infringement of the '339 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Fresenius' ANDA.

51. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '339 patent, actively inducing infringement of the '339 patent and/or contributing to the infringement by others of the '339 patent.

52. Fresenius' activities render this case an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

53. If Fresenius' infringement of the '339 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III

INFRINGEMENT OF THE '076 PATENT

54. Each of the preceding paragraphs 1 to 35 is incorporated as if fully set forth herein.

55. Upon information and belief, Fresenius had actual and constructive knowledge of the '076 patent prior to filing ANDA No. 208231. *Inter alia*, Fresenius included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) identifying the '076 patent in ANDA No. 208231 when it was filed.

56. Fresenius' submission of ANDA No. 208231 with a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its Generic Arsenic Trioxide Product prior to the expiration of the '076 patent constitutes infringement of the '076 patent under 35 U.S.C. § 271(e)(2)(A).

57. Upon FDA approval of Fresenius' ANDA No. 208231, Fresenius will further infringe the '076 patent by making, using, offering to sell, and selling its Generic Arsenic Trioxide Product in the United States and/or importing such products into the United States, and by actively inducing and contributing to infringement by others, including a doctor treating a patient with APL, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

58. Upon information and belief, Fresenius was aware that its filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '076 patent.

59. Upon information and belief, Fresenius was aware that its Generic Arsenic Trioxide Product is especially made or adapted for use in infringing the '076 patent and that Fresenius' Generic Arsenic Trioxide Product is not suitable for any substantial non-infringing uses. Upon information and belief, Fresenius plans and intends to, and will, contribute to the

infringement of the ’076 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Fresenius’ ANDA.

60. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the ’076 patent, actively inducing infringement of the ’076 patent and/or contributing to the infringement by others of the ’076 patent.

61. Fresenius’ activities render this case an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

62. If Fresenius’ infringement of the ’076 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV

INFRINGEMENT OF THE ’439 PATENT

63. Each of the preceding paragraphs 1 to 35 is incorporated as if fully set forth herein.

64. Upon information and belief, Fresenius had actual and constructive knowledge of the ’439 patent prior to filing ANDA No. 208231. *Inter alia*, Fresenius included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) identifying the '439 patent in ANDA No. 208231 when it was filed.

65. Fresenius’ submission of ANDA No. 208231 with a Paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of its Generic Arsenic Trioxide Product prior to the expiration of the ’439 patent constitutes infringement of the ’439 patent under 35 U.S.C. § 271(e)(2)(A).

66. Upon FDA approval of Fresenius' ANDA No. 208231, Fresenius will further infringe the '439 patent by making, using, offering to sell, and selling its Generic Arsenic Trioxide Product in the United States and/or importing such products into the United States, and by actively inducing and contributing to infringement by others, including a doctor treating a patient with APL, in violation of 35 U.S.C. § 271(a)-(c), unless enjoined by this Court.

67. Upon information and belief, Fresenius was aware that its filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '439 patent.

68. Upon information and belief, Fresenius was aware that its Generic Arsenic Trioxide Product is especially made or adapted for use in infringing the '439 patent and that Fresenius' Generic Arsenic Trioxide Product is not suitable for any substantial non-infringing uses. Upon information and belief, Fresenius plans and intends to, and will, contribute to the infringement of the '439 patent under 35 U.S.C. § 271(c) immediately and imminently upon approval of Fresenius' ANDA.

69. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '439 patent, actively inducing infringement of the '439 patent and/or contributing to the infringement by others of the '439 patent.

70. Fresenius' activities render this case an exceptional one, and Plaintiffs are entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

71. If Fresenius' infringement of the '439 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

a) A judgment that, under 35 U.S.C. § 271(e)(2)(A), Fresenius' submission to the FDA of ANDA No. 208231 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Fresenius' Generic Arsenic Trioxide Product before the expiration of the '351 patent was an act of infringement;

b) A judgment that Fresenius would infringe one or more claims of the ’351 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Fresenius' Generic Arsenic Trioxide Product prior to expiration of said ’351 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

c) Damages or other monetary relief to Plaintiffs should Fresenius or its affiliates, subsidiaries, and each of its officers, agents, servants and employees, or those acting in privity or concert with them, engage in the commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Fresenius' Generic Arsenic Trioxide Product prior to the latest expiration date of the ’351 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

d) A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Fresenius, and all officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the patents-in-suit with Fresenius' Generic Arsenic Trioxide Product prior to the expiration date of the ’351 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

e) A permanent injunction enjoining Fresenius and all persons acting in concert with Fresenius from seeking, obtaining, or maintaining approval of Fresenius’ ANDA

No. 208231 until the expiration date of the ’351 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

f) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Fresenius' ANDA No. 208231 seeking approval to manufacture, use, offer for sale, sell in and import into the United States the Generic Arsenic Trioxide Product, or any product or compound the use of which infringes the ’351 patent, shall be a date that is not earlier than the expiration of the ’351 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

g) A judgment that, under 35 U.S.C. § 271(e)(2)(A), Fresenius' submission to the FDA of ANDA No. 208231 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Fresenius' Generic Arsenic Trioxide Product before the expiration of the ’339 patent was an act of infringement;

h) A judgment that Fresenius would infringe one or more claims of the ’339 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Fresenius' Generic Arsenic Trioxide Product prior to expiration of said ’339 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

i) Damages or other monetary relief to Plaintiffs should Fresenius or its affiliates, subsidiaries, and each of its officers, agents, servants and employees, or those acting in privity or concert with them, engages in the commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Fresenius’ Generic Arsenic Trioxide Product prior to the latest expiration date of the ’339 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

j) A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Fresenius, and all officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the patents-in-suit with Fresenius' Generic Arsenic Trioxide Product prior to the expiration date of the ’339 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

k) A permanent injunction enjoining Fresenius and all persons acting in concert with Fresenius from seeking, obtaining, or maintaining approval of Fresenius’ ANDA No. 208231 until the expiration date of the ’339 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

l) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Fresenius’ ANDA No. 208231 seeking approval to manufacture, use, offer for sale, sell in and import into the United States the Generic Arsenic Trioxide Product, or any product or compound the use of which infringes the ’339 patent, shall be a date that is not earlier than the expiration of the ’339 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

m) A judgment that, under 35 U.S.C. § 271(e)(2)(A), Fresenius' submission to the FDA of ANDA No. 208231 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Fresenius' Generic Arsenic Trioxide Product before the expiration of the ’076 patent was an act of infringement;

n) A judgment that Fresenius would infringe one or more claims of the ’076 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Fresenius’ Generic Arsenic Trioxide Product

prior to expiration of said ’076 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

o) Damages or other monetary relief to Plaintiffs should Fresenius or its affiliates, subsidiaries, and each of its officers, agents, servants and employees, or those acting in privity or concert with them, engages in the commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Fresenius' Generic Arsenic Trioxide Product prior to the latest expiration date of the ’076 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

p) A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Fresenius, and all officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the patents-in-suit with Fresenius' Generic Arsenic Trioxide Product prior to the expiration date of the ’076 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

q) A permanent injunction enjoining Fresenius and all persons acting in concert with Fresenius from seeking, obtaining, or maintaining approval of Fresenius’ ANDA No. 208231 until the expiration date of the ’076 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

r) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Fresenius’ ANDA No. 208231 seeking approval to manufacture, use, offer for sale, sell in and import into the United States the Generic Arsenic Trioxide Product, or any product or compound the use of which infringes the ’076 patent, shall be a date that is not

earlier than the expiration of the ’076 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

s) A judgment that, under 35 U.S.C. § 271(e)(2)(A), Fresenius’ submission to the FDA of ANDA No. 208231 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Fresenius' Generic Arsenic Trioxide Product before the expiration of the ’439 patent was an act of infringement;

t) A judgment that Fresenius would infringe one or more claims of the ’439 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offering to sell, and sale in, and importation into the United States of Fresenius' Generic Arsenic Trioxide Product prior to expiration of said ’439 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

u) Damages or other monetary relief to Plaintiffs should Fresenius or its affiliates, subsidiaries, and each of its officers, agents, servants and employees, or those acting in privity or concert with them, engages in the commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Fresenius’ Generic Arsenic Trioxide Product prior to the latest expiration date of the ’439 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

v) A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283, enjoining Fresenius, and all officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them from infringing any claims of the patents-in-suit with Fresenius' Generic Arsenic Trioxide Product prior to the expiration date of the ’439 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

w) A permanent injunction enjoining Fresenius and all persons acting in concert with Fresenius from seeking, obtaining, or maintaining approval of Fresenius' ANDA No. 208231 until the expiration date of the '439 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

x) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Fresenius' ANDA No. 208231 seeking approval to manufacture, use, offer for sale, sell in and import into the United States the Generic Arsenic Trioxide Product, or any product or compound the use of which infringes the '439 patent, shall be a date that is not earlier than the expiration of the '439 patent including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

y) A declaration that Fresenius has no legal or equitable defense to Cephalon's allegations of infringement;

z) A judgment that this is an exceptional case and awarding Plaintiffs attorneys' fees under 35 U.S.C. § 285;

aa) An award of Plaintiffs' reasonable costs and expenses in this action; and

bb) An award of any further and additional relief to Plaintiffs as this Court deems just and proper.

BAYARD, P.A.

Dated: November 19, 2015

/s/ Stephen B. Brauerman (No. 4952)
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