IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., WYETH LLC, PFIZER PHARMACEUTICALS LLC, PF PRISM C.V., PFIZER MANUFACTURING HOLDINGS LLC, WYETH HOLDINGS LLC, and WYETH HOLDINGS CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, LLC,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Wyeth LLC, Pfizer Pharmaceuticals LLC, PF PRISM C.V., Pfizer Manufacturing Holdings LLC, Wyeth Holdings LLC, and Wyeth Holdings Corporation, (collectively, "Pfizer"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Fresenius Kabi USA, LLC (hereinafter "Fresenius") of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's TYGACIL® tigecycline injectable IV infusion, ("TYGACIL®") prior to the expiration of U.S. Patent No. RE 40,183 ("the '183 patent"), U.S. Patent No. 7,879,828 ("the '828 patent"), and U.S. Patent No. 8,372,995 ("the '995 patent").

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of Delaware and having a place of business at 5 Giralda Farms, Madison, New Jersey 07940. Wyeth LLC's sole member is Pfizer Inc.

4. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having a place of business at Bo. Carmelitas, Road 689, Km 1.9, Vega Baja, Puerto Rico 00693. Pfizer Pharmaceuticals LLC is a wholly-owned subsidiary of PF PRISM C.V.

5. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized and existing under the laws of the Netherlands, and registered at the trade register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456, with offices at Blaak 40 basement, 3011 TA, Rotterdam, Netherlands. PF PRISM C.V. is the holder of New Drug Application No. 21821, which has been approved by the FDA.

6. Plaintiff Pfizer Manufacturing Holdings LLC is a limited liability company organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Manufacturing Holdings LLC is a general partner of PF PRISM C.V.

7. Wyeth Holdings LLC, formerly known as Wyeth Holdings Corporation, is a limited liability company organized and existing under the laws of Maine and having a place of business at 235 East 42nd Street, New York, New York 10017.

8. Upon information and belief, defendant Fresenius Kabi USA, LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 3 Corporate Drive, Lake Zurich, Illinois 60047.

9. Upon information and belief, Fresenius is in the business of manufacturing, marketing, and selling generic drug products. As a part of this business, upon information and belief, Fresenius, directly or through agents, regularly files NDAs and abbreviated new drug applications ("ANDAs") with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as a part of these NDAs and ANDAs, Fresenius, directly or through agents, regularly files certifications of the type described in Sections 505(b)(2)(A)(iv) and 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of U.S. patents that cover them. Upon information and belief, Fresenius's ordinary business operations include litigating and filing claims in the courts of the United States, including the United States District Court for the District of Delaware, regarding the infringement, validity, and/or enforceability of United States patents that cover or are alleged to cover generic drug products that are the subject of NDAs and ANDAs filed by Fresenius.

10. Upon information and belief, Fresenius manufactures drug products for the purpose of sale within the United States, including in Delaware.

11. Upon information and belief, Fresenius derives substantial revenue from services or things used or consumed in the state of Delaware.

JURISDICTION AND VENUE

12. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 1391, and 1400(b).

13. Fresenius is subject to personal jurisdiction in Delaware because, among other things, upon information and belief, Fresenius is a limited liability company formed under the laws of the state of Delaware.

14. Upon information and belief, Fresenius has a registered agent in Delaware (Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808); it is registered with the Delaware Board of Pharmacy as a "Distributor/Manufacturer CSR" and "Pharmacy - Wholesale" pursuant to 24 Del. C. § 2540; it is in the business of manufacturing drug products, which it manufactures, distributes, sells, or offers to sell throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA and NDA cases without contesting jurisdiction in this District; it has, directly or through an agent, filed an NDA, and/or been actively involved in the preparation and submission of an NDA, for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in NDA No. 205645 in the United States, including in Delaware; and, upon receiving FDA approval, it intends to offer to sell and sell the generic product described in NDA No. 205645 in the United States, including in Delaware.

15. Upon information and belief, Fresenius has availed itself of the legal protections of the state of Delaware by filing claims or counterclaims affirmatively seeking relief

in other prior actions in this Court, including in *Millennium Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC, et al.*, 1:13-cv-00467-GMS (D. Del.); *Fresenius Kabi USA, LLC v. Dr. Reddy's Laboratories Ltd., et al.*, 1:13-cv-00925-SLR (D. Del.), and *Fresenius Kabi USA, LLC v. Watson Laboratories Inc., et al.*, 1:13-cv-01015-SLR (D. Del.).

BACKGROUND

16. TYGACIL® is a tetracycline class antibacterial indicated for the treatment of complicated skin and skin structure infections, complicated intra-abdominal infections, and community-acquired bacterial pneumonia, in adults. Each TYGACIL® vial contains 50 mg tigecycline lyophilized powder for reconstitution for intravenous infusion and 100 mg of lactose monohydrate.

17. The '183 patent, entitled "7-Substituted-9-Substituted Amino-6-Demethyl-6-Deoxytetracyclines" (Exhibit A hereto), was duly and legally issued on March 25, 2008 to Wyeth Holdings Corporation, now known as Wyeth Holdings LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the '183 patent, which has been listed in connection with TYGACIL® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

18. The '828 patent, entitled "Tigecycline Compositions and Methods of Preparation" (Exhibit B hereto), was duly and legally issued on February 1, 2011 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the '828 patent, which has been listed in connection with TYGACIL® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

19. In 2011, PF PRISM C.V. took an exclusive license to the '183 patent, the '828 patent, and application no. 11/440,032 (which later issued as the '995 patent). Thereafter, PF PRISM C.V. contributed its rights under the exclusive license to Pfizer Pharmaceuticals LLC.

20. The '995 patent, entitled "Crystalline Solid Forms of Tigecycline and Methods of Preparing Same" (Exhibit C hereto), was duly and legally issued on February 12, 2013 to Wyeth LLC, as assignee, and subject to the exclusive license referenced herein. TYGACIL® and the use thereof are covered by one or more claims of the '995 patent, which has been listed in connection with TYGACIL® in the FDA's publication Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

21. Pfizer has all right, title, and interest in the '183 patent, the '828 patent, and the '995 patent, including the right to sue for infringement thereof.

22. By letter dated October 1, 2013 (the "Notice Letter"), Fresenius notified Pfizer that Fresenius had submitted to the FDA NDA No. 205645 for Tigecycline for Injection, 50 mg/vial ("Fresenius's NDA Product"). Fresenius's NDA Product is a drug product that is a generic version of TYGACIL®.

23. The purpose of Fresenius's submission of NDA No. 205645 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's NDA Product prior to the expiration of the '183 patent, the '828 patent, and the '995 patent.

24. In the Notice Letter, Fresenius also notified Pfizer that, as part of its NDA No. 205645, Fresenius had filed certifications of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), with respect to the '183 patent, the '828 patent, and the '995 patent. Upon information and belief, Fresenius submitted NDA No. 205645 to the FDA

containing a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) asserting that the '183 patent, the '828 patent, and the '995 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Fresenius's NDA Product, or alternatively, that these patents are invalid.

25. The parties, while reserving all rights, ultimately negotiated terms under which Pfizer could review the Fresenius NDA, but Fresenius refused to produce other Fresenius internal documents and data relevant to infringement.

26. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. RE 40,183 UNDER 35 U.S.C. § 271(e)(2)

27. Pfizer incorporates each of the preceding paragraphs 1–26 as if fully set forth herein.

28. Fresenius's submission of NDA No. 205645 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's NDA Product prior to the expiration of the '183 patent was an act of infringement of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

29. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product would infringe one or more claims of the '183 patent, either literally or under the doctrine of equivalents.

30. Upon information and belief, Fresenius will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product with its proposed labeling upon approval of NDA No. 205645.

31. Upon information and belief, the use of Fresenius's NDA Product in accordance with and as directed by Fresenius's proposed labeling for that product would infringe one or more claims of the '183 patent.

32. Upon information and belief, Fresenius plans and intends to, and will, actively induce infringement of the '183 patent when NDA No. 205645 is approved, and plans and intends to, and will, do so after approval.

33. Upon information and belief, Fresenius knows that Fresenius's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '183 patent, and that Fresenius's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '183 patent after approval of NDA No. 205645.

34. Upon information and belief, after approval of NDA No. 205645, Fresenius will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '183 patent prior to the expiration of the patent.

35. The foregoing actions by Fresenius constitute and/or will constitute infringement of the '183 patent, active inducement of infringement of the '183 patent, and contribution to the infringement by others of the '183 patent.

36. Upon information and belief, Fresenius has acted with full knowledge of the '183 patent and without a reasonable basis for believing that it would not be liable for infringing the '183 patent, actively inducing infringement of the '183 patent, and contributing to the infringement by others of the '183 patent.

37. Unless Fresenius is enjoined from infringing the '183 patent, actively inducing infringement of the '183 patent, and contributing to the infringement by others of the '183 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 7,879,828 UNDER 35 U.S.C. § 271(e)(2)

38. Pfizer incorporates each of the preceding paragraphs 1–37 as if fully set forth herein.

39. Fresenius's submission of NDA No. 205645 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's NDA Product prior to the expiration of the '828 patent was an act of infringement of the '828 patent under 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product would infringe one or more claims of the '828 patent, either literally or under the doctrine of equivalents.

41. Upon information and belief, Fresenius will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product with its proposed labeling upon approval of NDA No. 205645.

42. Upon information and belief, the use of Fresenius's NDA Product in accordance with and as directed by Fresenius's proposed labeling for that product would infringe one or more claims of the '828 patent.

43. Upon information and belief, Fresenius plans and intends to, and will, actively induce infringement of the '828 patent when NDA No. 205645 is approved, and plans and intends to, and will, do so after approval.

44. Upon information and belief, Fresenius knows that Fresenius's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that Fresenius's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '828 patent after approval of NDA No. 205645.

45. Upon information and belief, after approval of NDA No. 205645, Fresenius will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '828 patent prior to the expiration of the patent.

46. The foregoing actions by Fresenius constitute and/or will constitute infringement of the '828 patent, active inducement of infringement of the '828 patent, and contribution to the infringement by others of the '828 patent.

47. Upon information and belief, Fresenius has acted with full knowledge of the '828 patent and without a reasonable basis for believing that it would not be liable for infringing the '828 patent, actively inducing infringement of the '828 patent, and contributing to the infringement by others of the '828 patent.

48. Unless Fresenius is enjoined from infringing the '828 patent, actively inducing infringement of the '828 patent, and contributing to the infringement by others of the '828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 8,372,995 UNDER 35 U.S.C. § 271(e)(2)

49. Pfizer incorporates each of the preceding paragraphs 1–48 as if fully set forth herein.

50. Fresenius's submission of NDA No. 205645 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Fresenius's NDA Product prior to the expiration of the '995 patent was an act of infringement of the '995 patent under 35 U.S.C. § 271(e)(2)(A).

51. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product would infringe one or more claims of the '995 patent, either literally or under the doctrine of equivalents.

52. Upon information and belief, Fresenius will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product with its proposed labeling upon approval of NDA No. 205645.

53. Upon information and belief, the use of Fresenius's NDA Product in accordance with and as directed by Fresenius's proposed labeling for that product would infringe one or more claims of the '995 patent.

54. Upon information and belief, Fresenius plans and intends to, and will, actively induce infringement of the '995 patent when NDA No. 205645 is approved, and plans and intends to, and will, do so after approval.

55. Upon information and belief, Fresenius knows that Fresenius's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that Fresenius's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '995 patent after approval of NDA No. 205645.

56. Upon information and belief, after approval of NDA No. 205645, Fresenius will, without authority, import into the United States and/or offer to sell, sell, and/or

use within the United States, a product which is made by a process that infringes one or more claims of the '995 patent prior to the expiration of the patent.

57. The foregoing actions by Fresenius constitute and/or will constitute infringement of the '995 patent, active inducement of infringement of the '995 patent, and contribution to the infringement by others of the '995 patent.

58. Upon information and belief, Fresenius has acted with full knowledge of the '995 patent and without a reasonable basis for believing that it would not be liable for infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent.

59. Unless Fresenius is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. RE 40,183

60. Pfizer incorporates each of the preceding paragraphs 1–59 as if fully set forth herein.

61. Fresenius has knowledge of the '183 patent.

62. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product would infringe one or more claims of the '183 patent.

63. Upon information and belief, Fresenius will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product with its proposed labeling after approval of NDA No. 205645.

64. Upon information and belief, the use of Fresenius's NDA Product in accordance with and as directed by Fresenius's proposed labeling for that product would infringe one or more claims of the '183 patent.

65. Upon information and belief, Fresenius plans and intends to, and will, actively induce infringement of the '183 patent when NDA No. 205645 is approved, and plans and intends to, and will, do so after approval.

66. Upon information and belief, Fresenius knows that Fresenius's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '183 patent, and that Fresenius's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '183 patent after approval of NDA No. 205645.

67. Upon information and belief, after approval of NDA No. 205645, Fresenius will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '183 patent prior to the expiration of the patent.

68. The foregoing actions by Fresenius constitute and/or will constitute infringement of the '183 patent, active inducement of infringement of the '183 patent, and contribution to the infringement by others of the '183 patent.

69. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '183 patent, actively inducing infringement of the '183 patent, and contributing to the infringement by others of the '183 patent.

70. Unless Fresenius is enjoined from infringing the '183 patent, actively inducing infringement of the '183 patent, and contributing to the infringement by others of the '183 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT V – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,879,828

71. Pfizer incorporates each of the preceding paragraphs 1–70 as if fully set forth herein.

72. Fresenius has knowledge of the '828 patent.

73. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product would infringe one or more claims of the '828 patent, either literally or under the doctrine of equivalents.

74. Upon information and belief, Fresenius will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product with its proposed labeling after approval of NDA No. 205645.

75. Upon information and belief, the use of Fresenius's NDA Product in accordance with and as directed by Fresenius's proposed labeling for that product would infringe one or more claims of the '828 patent.

76. Upon information and belief, Fresenius plans and intends to, and will, actively induce infringement of the '828 patent when NDA No. 205645 is approved, and plans and intends to, and will, do so after approval.

77. Upon information and belief, Fresenius knows that Fresenius's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '828 patent, and that Fresenius's NDA Product and its proposed labeling are not suitable for

substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '828 patent after approval of NDA No. 205645.

78. Upon information and belief, after approval of NDA No. 205645, Fresenius will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '828 patent prior to the expiration of the patent.

79. The foregoing actions by Fresenius constitute and/or will constitute infringement of the '828 patent, active inducement of infringement of the '828 patent, and contribution to the infringement by others of the '828 patent.

80. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '828 patent, actively inducing infringement of the '828 patent, and contributing to the infringement by others of the '828 patent.

81. Unless Fresenius is enjoined from infringing the '828 patent, actively inducing infringement of the '828 patent, and contributing to the infringement by others of the '828 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,372,995

82. Pfizer incorporates each of the preceding paragraphs 1–81 as if fully set forth herein.

83. Fresenius has knowledge of the '995 patent.

84. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product would infringe one or more claims of the '995 patent, either literally or under the doctrine of equivalents.

85. Upon information and belief, Fresenius will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Fresenius's NDA Product with its proposed labeling after approval of NDA No. 205645.

86. Upon information and belief, the use of Fresenius's NDA Product in accordance with and as directed by Fresenius's proposed labeling for that product would infringe one or more claims of the '995 patent.

87. Upon information and belief, Fresenius plans and intends to, and will, actively induce infringement of the '995 patent when NDA No. 205645 is approved, and plans and intends to, and will, do so after approval.

88. Upon information and belief, Fresenius knows that Fresenius's NDA Product and its proposed labeling are especially made or adapted for use in infringing the '995 patent, and that Fresenius's NDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Fresenius plans and intends to, and will, contribute to infringement of the '995 patent after approval of NDA No. 205645.

89. Upon information and belief, after approval of NDA No. 205645, Fresenius will, without authority, import into the United States and/or offer to sell, sell, and/or use within the United States, a product which is made by a process that infringes one or more claims of the '995 patent prior to the expiration of the patent.

90. The foregoing actions by Fresenius constitute and/or will constitute infringement of the '995 patent, active inducement of infringement of the '995 patent, and contribution to the infringement by others of the '995 patent.

91. Upon information and belief, Fresenius acted without a reasonable basis for believing that it would not be liable for infringing the '995 patent, actively inducing

infringement of the '995 patent, and contributing to the infringement by others of the '995 patent.

92. Unless Fresenius is enjoined from infringing the '995 patent, actively inducing infringement of the '995 patent, and contributing to the infringement by others of the '995 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law.

WHEREFORE, Pfizer requests the following relief:

(a) A judgment that Fresenius has infringed the '183 patent, the '828 patent, and the '995 patent;

(b) A judgment ordering that the effective date of any FDA approval for Fresenius to make, use, offer for sale, sell, market, distribute, or import Fresenius's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '183 patent, the '828 patent, or the '995 patent be not earlier than the expiration date of the '183 patent, the '828 patent, or the '995 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Fresenius, and all persons acting in concert with Fresenius, from making, using, selling, offering for sale, marketing, distributing, or importing Fresenius's NDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '183 patent, the '828 patent, or the '995 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '183 patent, the '828 patent, or the '995 patent, respectively, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Fresenius's NDA Product, or any product or compound the

making, using, offering for sale, sale, marketing, distributing, or importation of which infringes the '183 patent, the '828 patent, or the '995 patent, prior to the expiration date of the '183 patent, the '828 patent, or the '995 patent, respectively, will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '183 patent, the '828 patent, or the '995 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Pfizer's costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Maryellen Noreika (#3208)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
mnoreika@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Thomas H.L. Selby
David I. Berl
Stanley E. Fisher
Adam D. Harber
Jonathan L. Williams
Martha C. Kidd
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, N.W.
Washington, DC 20005
(202) 434-5000

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