IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., FOLDRX PHARMACEUTICALS, LLC, PF PRISM IMB B.V., WYETH LLC, and THE SCRIPPS RESEARCH INSTITUTE, Plaintiffs, v. DEXCEL PHARMA TECHNOLOGIES LIMITED, Defendant.	C.A. No. _____

COMPLAINT

Plaintiffs Pfizer Inc.; FoldRx Pharmaceuticals, LLC; PF PRISM IMB B.V.; Wyeth LLC; and The Scripps Research Institute (referred to collectively herein as "Plaintiffs") file this Complaint for patent infringement against Dexcel Pharma Technologies Limited ("Dexcel"), and by their attorneys, hereby allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Dexcel's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Vyndamax® (tafamidis) 61 mg capsules prior to the expiration of U.S. Patent Nos. 7,214,695 ("the '695 patent") (attached as Exhibit A), 7,214,696 ("the '696 patent") (attached as Exhibit B), and 9,770,441 ("the '441 patent") (attached as Exhibit C). These three patents are referred to collectively as "the patents-in-suit."

2. Dexcel notified Pfizer by letter dated June 26, 2023 ("Dexcel's Notice Letter") that it has submitted to the FDA ANDA No. 218365 ("Dexcel's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic tafamidis 61 mg capsules ("Dexcel's ANDA Product") prior to the expiration of the patents-in-suit.

PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

4. Plaintiff FoldRx Pharmaceuticals, LLC is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 66 Hudson Boulevard East, New York, NY 10001. FoldRx Pharmaceuticals, LLC is the holder of New Drug Application ("NDA") No. 212161 for the manufacture and sale of tafamidis 61 mg capsules, which has been approved by the FDA. FoldRx Pharmaceuticals, LLC is a wholly owned subsidiary of Pfizer Inc.

5. Plaintiff PF PRISM IMB B.V. is a private limited company (*besloten venootschap*) organized under the law of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and having its business address at Rivium Westlaan 142, 2909 LD, Cepelle aan den IJessel, the Netherlands.

6. Plaintiff Wyeth LLC is a limited liability company organized and existing under the laws of the States of Delaware with offices at 66 Hudson Boulevard East, New York, NY 10001.

7. Plaintiff The Scripps Research Institute is a nonprofit public benefit corporation organized and existing under the laws of the State of California, with a registered address at 10550 North Torrey Pines Road, La Jolla, CA 92037.

8. Upon information and belief, defendant Dexcel is a corporation organized and existing under the laws of Israel, having a registered address at 1 Dexcel Street Or-Akiva, Israel 3060000.

9. Upon information and belief, Dexcel knows and intends that upon approval of Dexcel's ANDA, Dexcel will manufacture and directly or indirectly market, sell, and distribute Dexcel's ANDA Product throughout the United States, including in Delaware.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

11. Dexcel is subject to personal jurisdiction in Delaware because, among other things, Dexcel has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Dexcel, itself and through its agents develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Plaintiffs' claims, and/or has engaged in continuous and systematic business contacts within the State of Delaware.

12. Upon information and belief, if Dexcel's ANDA is approved, Dexcel will directly or indirectly manufacture, market, sell, and/or distribute Dexcel's ANDA Product within the United States, including in Delaware, consistent with Dexcel's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Dexcel

regularly does business in Delaware, and its practices with other generic products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. Upon information and belief, Dexcel's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. Upon information and belief, Dexcel's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of the activities would have a substantial effect within Delaware and would constitute infringement of the patents-in-suit in the event that Dexcel's ANDA Product is approved before the patents-in-suit expire.

13. Upon information and belief, Dexcel derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Dexcel and/or for which Dexcel is the named applicant on approved ANDAs. Upon information and belief, various products for which Dexcel is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

14. Alternatively, the Court may exercise personal jurisdiction over Dexcel pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Dexcel would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Dexcel has sufficient contacts with the United States as a whole, including but not limited to filing an ANDA with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that the Court's exercise of jurisdiction over Dexcel satisfies due process.

15. Venue is proper in this district as to Dexcel pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Dexcel is a corporation organized and existing under the laws of Israel and is subject to personal jurisdiction in this judicial district.

FACTUAL BACKGROUND

16. Plaintiff FoldRx Pharmaceuticals, LLC is the holder of New Drug Application No. 212161 for Vyndamax®, which has been approved by the FDA.

17. Vyndamax® is approved for the treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.

18. Vyndamax® contains tafamidis as its active ingredient.

19. Dexcel's ANDA Product is a generic version of Vyndamax®.

20. Plaintiffs are filing this Complaint within forty-five days of receipt of Dexcel's Notice Letter.

COUNT I – INFRINGEMENT OF THE '695 PATENT

21. Plaintiffs incorporate each of the preceding paragraphs 1–20 as if fully set forth herein.

22. The '695 patent, titled "COMPOSITIONS AND METHODS FOR STABILIZING TRANSTHYRETIN AND INHIBITING TRANSTHYRETIN MISFOLDING" (attached as Exhibit A), was duly and legally issued on May 8, 2007.

23. The inventors named on the '695 patent are Jeffrey W. Kelly, Evan T. Powers, and Hossein Razavi.

24. The Scripps Research Institute is the assignee of the '695 patent.

25. Plaintiffs together own all substantial rights in the '695 patent.

26. Vyndamax® is covered by one or more claims of the '695 patent, including claims 1–9, and the '695 patent has been listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Vyndamax®.

27. For example, claim 3 of the'695 patent recites "[t]he compound of claim 1 that is 2-(3,5-Dicholoro-phenyl)-benzoxazole-6-carboxylic acid," which covers tafamidis and Vyndamax®.

28. In Dexcel's Notice Letter, Dexcel notified Plaintiffs of the submission of Dexcel's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Dexcel's ANDA Product prior to the expiration of the '695 patent.

29. In Dexcel's Notice Letter, Dexcel also notified Plaintiffs that, as part of its ANDA, Dexcel had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '695 patent. Dexcel submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '695 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product.

30. Dexcel's ANDA Product and the use of Dexcel's ANDA Product (including in accordance with and as directed by Dexcel's proposed labeling for Dexcel's ANDA Product) are covered by at least claims 1–9 of the '695 patent.

31. For example, claim 3 of the'695 patent recites "[t]he compound of claim 1 that is 2-(3,5-Dicholoro-phenyl)-benzoxazole-6-carboxylic acid," which covers tafamidis and Vyndamax®.

32. In Dexcel's Notice Letter, Dexcel states that its ANDA Product contains tafamidis, i.e., the compound 2-(3,5-Dicholoro-phenyl)-benzoxazole-6-carboxylic acid.

33. In Dexcel's Notice Letter, Dexcel states that "DEXCEL'S ANDA Product will be marketed for the same indications currently approved for VYNDAMAX®."

34. In Dexcel's Notice Letter, Dexcel did not contest the infringement of claims 1–9 of the '695 patent on any basis other than the alleged invalidity of those claims.

35. Dexcel's submission of Dexcel's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product before the expiration of the '695 patent was an act of infringement of the '695 patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon information and belief, Dexcel will engage, directly or indirectly, in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dexcel's ANDA Product immediately and imminently upon approval of Dexcel's ANDA.

37. The manufacture, use, sale, offer for sale, or importation of Dexcel's ANDA Product would infringe one or more claims of the '695 patent, including claims 1–9 of the '695 patent.

38. The manufacture, use, sale, offer for sale, or importation of Dexcel's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '695 patent, including claims 1–9 of the '695 patent.

39. Upon information and belief, Dexcel plans and intends to, and will, actively induce infringement of the '695 patent when Dexcel's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Dexcel's activities will be done with knowledge of the '695 patent and specific intent to infringe that patent.

40. Upon information and belief, Dexcel knows that Dexcel's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '695 patent, that Dexcel's ANDA Product is not a staple article or commodity of commerce, and that Dexcel's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Dexcel plans and intends to, and will, contribute to infringement of the '695 patent immediately and imminently upon approval of Dexcel's ANDA.

41. Notwithstanding Dexcel's knowledge of the claims of the '695 patent, Dexcel has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Dexcel's ANDA Product with their product labeling following FDA approval of Dexcel's ANDA prior to the expiration of the '695 patent.

42. The foregoing actions by Dexcel constitute and/or will constitute infringement of the '695 patent; active inducement of infringement of the '695 patent; and contribution to the infringement by others of the '695 patent.

43. Upon information and belief, Dexcel has acted with full knowledge of the '695 patent and without a reasonable basis for believing that it would not be liable for infringement of the '695 patent; active inducement of infringement of the '695 patent; and/or contribution to the infringement by others of the '695 patent.

44. Plaintiffs will be substantially and irreparably damaged by infringement of the '695 patent.

45. Unless Dexcel is enjoined from infringing the '695 patent, actively inducing infringement of the '695 patent, and contributing to the infringement by other of the '695 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '695 PATENT

46. Plaintiffs incorporate by reference each of the preceding paragraphs 1–45 as if fully set forth herein.

47. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on one hand and Dexcel on the other regarding Dexcel's infringement, active inducement of infringement, and contribution to the infringement by others of the '695 patent, and/or the validity of the '695 patent.

48. An actual case or controversy exists between Plaintiffs and Dexcel with respect to Dexcel's liability for infringement of the '695 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Dexcel's ANDA Product will infringe, induce infringement, and actively contribute to the infringement of the '695 patent.

COUNT III – INFRINGEMENT OF THE '696 PATENT

50. Plaintiffs incorporate by reference each of the preceding paragraphs 1–49 as if fully set forth herein.

51. The inventors named on the '696 patent are Jeffrey W. Kelly and Yoshiki Sekijima.

52. The '696 patent, titled "COMPOSITIONS AND METHODS FOR STABILIZING TRANSTHYRETIN AND INHIBITING TRANSTHYRETIN MISFOLDING," was duly and legally issued on May 8, 2007.

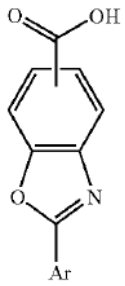
53. The Scripps Research Institute is the assignee of the '696 patent.

54. Plaintiffs together own all substantial rights in the '696 patent.

55. Vyndamax® and its use (including in accordance with and as directed by Dexcel's proposed labeling for Dexcel's ANDA Product) are covered by one or more claims of the '696 patent, including claims 1–3 and 7–9, and the '696 patent has been listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Vyndamax®.

56. For example, claim 1 of the'696 patent recites:

> A method of treating a transthyretin amyloid disease, comprising administering to a subject in need thereof, a therapeutically effective amount of a compound of formula



> or a pharmaceutically acceptable salt thereof, wherein Ar is phenyl, 3,5-difluorophenyl, 2,6-difluorophenyl, 3,5-dichlorophenyl, 2,6-dichlorophenyl, 2-(trifluoromethyl)phenyl, or 3-(trifluoromethyl)phenyl.

57. Claim 3 of the '696 patent recites:

> The method of claim 1, wherein the compound is 6-Carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

58. Claim 9 of the '696 patent recites:

> The method of claim 3, wherein the transthyretin amyloid disease is familial amyloid cardiomyopathy.

59. In Dexcel's Notice Letter, Dexcel notified Plaintiffs of the submission of Dexcel's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the

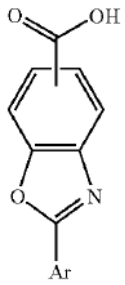
FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Dexcel's ANDA Product prior to the expiration of the '696 patent.

60. In Dexcel's Notice Letter, Dexcel also notified Plaintiffs that, as part of its ANDA, Dexcel had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '696 patent. Dexcel submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '696 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product.

61. Dexcel's ANDA Product and the use of Dexcel's ANDA Product (including in accordance with and as directed by Dexcel's proposed labeling for Dexcel's ANDA Product) are covered by at least claims 1–3 and 7–9 of the '696 patent.

62. For example, claim 1 of the'696 patent recites:

> A method of treating a transthyretin amyloid disease, comprising administering to a subject in need thereof, a therapeutically effective amount of a compound of formula



> or a pharmaceutically acceptable salt thereof, wherein Ar is phenyl, 3,5-difluorophenyl, 2,6-difluorophenyl, 3,5-dichlorophenyl, 2,6-dichlorophenyl, 2-(trifluoromethyl)phenyl, or 3-(trifluoromethyl)phenyl.

63. Claim 3 of the '696 patent recites:

> The method of claim 1, wherein the compound is 6-Carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

64. Claim 9 of the ’696 patent recites:

> The method of claim 3, wherein the transthyretin amyloid disease is familial amyloid cardiomyopathy.

65. In Dexcel’s Notice Letter, Dexcel states that its ANDA Product contains tafamidis, i.e., the compound 6-Carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

66. In Dexcel’s Notice Letter, Dexcel states that “DEXCEL’S ANDA Product will be marketed for the same indications currently approved for VYNDAMAX®.”

67. Upon information and belief, the proposed labeling for Dexcel’s ANDA Product directs and encourages a method of treating a transthyretin amyloid disease, wherein the transthyretin amyloid disease is familial amyloid cardiomyopathy using Dexcel’s ANDA Product.

68. In Dexcel’s Notice Letter, Dexcel did not contest that the use by third parties of Dexcel’s ANDA Product in accordance with the proposed labeling would infringe claims 1–3 and 7–9 of the ’696 patent on any basis other than the alleged invalidity of those claims.

69. Dexcel’s submission of Dexcel’s ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dexcel’s ANDA Product before the expiration of the ’696 patent was an act of infringement of the ’696 patent under 35 U.S.C. § 271(e)(2)(A).

70. Upon information and belief, Dexcel will engage, directly or indirectly, in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dexcel’s ANDA Product immediately and imminently upon approval of Dexcel’s ANDA.

71. The manufacture, use, sale, offer for sale, or importation of Dexcel’s ANDA Product would infringe one or more claims of the ’696 patent, including claims 1–3 and 7–9 of the ’696 patent.

72. The manufacture, use, sale, offer for sale, or importation of Dexcel's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '696 patent, including claims 1–3 and 7–9 of the '696 patent.

73. Upon information and belief, Dexcel plans and intends to, and will, actively induce infringement of the '696 patent when Dexcel's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Dexcel's activities will be done with knowledge of the '696 patent and specific intent to infringe that patent.

74. Upon information and belief, Dexcel knows that Dexcel's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '696 patent, that Dexcel's ANDA Product is not a staple article or commodity of commerce, and that Dexcel's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Dexcel plans and intends to, and will, contribute to infringement of the '696 patent immediately and imminently upon approval of Dexcel's ANDA.

75. Notwithstanding Dexcel's knowledge of the claims of the '696 patent, Dexcel has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Dexcel's ANDA Product with their product labeling following FDA approval of Dexcel's ANDA prior to the expiration of the '696 patent.

76. The foregoing actions by Dexcel constitute and/or will constitute infringement of the '696 patent; active inducement of infringement of the '696 patent; and contribution to the infringement by others of the '696 patent.

77. Upon information and belief, Dexcel has acted with full knowledge of the '696 patent and without a reasonable basis for believing that it would not be liable for infringement of

the ’696 patent; active inducement of infringement of the ’696 patent; and/or contribution to the infringement by others of the ’696 patent.

78. Plaintiffs will be substantially and irreparably damaged by infringement of the ’696 patent.

79. Unless Dexcel is enjoined from infringing the ’696 patent, actively inducing infringement of the ’696 patent, and contributing to the infringement by others of the ’696 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’696 PATENT

80. Plaintiffs incorporate by reference each of the preceding paragraphs 1–79 as if fully set forth herein.

81. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on one hand and Dexcel on the other regarding Dexcel’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’696 patent, and/or the validity of the ’696 patent.

82. An actual case or controversy exists between Plaintiffs and Dexcel with respect to Dexcel’s liability for infringement of the ’696 patent.

83. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Dexcel’s ANDA Product will infringe, induce infringement, and actively contribute to the infringement of the ’696 patent.

COUNT V – INFRINGEMENT OF THE ’441 PATENT

84. Plaintiffs incorporate each of the preceding paragraphs 1–83 as if fully set forth herein.

85. The '441 patent, titled "CRYSTALLINE SOLID FORMS OF 6-CARBOXY-2(3,5-DICHLOROPHENYL)-BENZOXAZOLE" (attached as Exhibit C), was duly and legally issued on September 26, 2017.

86. The inventors named on the '441 patent are Kevin Paul Girard, Andrew J. Jensen, and Kris Nicole Jones.

87. Pfizer Inc. is the assignee of the '441 patent.

88. Plaintiffs together own all substantial rights in the '441 patent.

89. Vyndamax® and its use are covered by one or more of claims 1–16 of the '441 patent, and the '441 patent has been listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") in connection with Vyndamax®.

90. For example, claim 1 of the '441 patent recites:

> A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
> a solid state NMR spectrum comprising 13C chemical shifts (ppm) at 120.8±0.2 and 127.7±0.2,
> a powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6±0.2, and
> a Raman spectrum comprising a Raman shift peak (cm-1) at 1292±2.

91. In Dexcel's Notice Letter, Dexcel notified Plaintiffs of the submission of Dexcel's ANDA to the FDA. The purpose of this submission was to obtain, *inter alia*, approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Dexcel's ANDA Product prior to the expiration of the '441 patent.

92. In Dexcel's Notice Letter, Dexcel also notified Plaintiffs that, as part of its ANDA, Dexcel had filed certifications of the type described in Section 505(j)(2)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(iv), with respect to the '441 patent. Dexcel submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '441

patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product.

93. Upon information and belief, Dexcel's ANDA Product and the use of Dexcel's ANDA Product (including in accordance with and as directed by Dexcel's proposed labeling for Dexcel's ANDA Product) are covered by one or more of claims 1–16 of the '441 patent.

94. For example, claim 1 of the '441 patent recites:

> A crystalline form of 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole, wherein said crystalline form has an analytical parameter selected from the group consisting of
> a solid state NMR spectrum comprising 13C chemical shifts (ppm) at 120.8±0.2 and 127.7±0.2,
> a powder X-ray diffraction pattern comprising a peak at a diffraction angle (2θ) of 28.6±0.2, and
> a Raman spectrum comprising a Raman shift peak (cm-1) at 1292±2.

95. In Dexcel's Notice Letter, Dexcel states that its ANDA Product contains tafamidis, i.e., 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

96. In Dexcel's Notice Letter, Dexcel states that "DEXCEL'S ANDA Product will be marketed for the same indications currently approved for VYNDAMAX®."

97. Upon information and belief, the proposed labeling for Dexcel's ANDA Product directs and encourages a method of treating a transthyretin amyloid disease, wherein the transthyretin amyloid disease is familial amyloid cardiomyopathy using Dexcel's ANDA Product.

98. In Dexcel's Notice Letter, Dexcel did not contest the infringement of claims 1–16 of the '441 patent on any basis other than the alleged invalidity of those claims.

99. Dexcel's submission of Dexcel's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product before the expiration of the '441 patent was an act of infringement of the '441 patent under 35 U.S.C. § 271(e)(2)(A).

100. Upon information and belief, Dexcel will engage, directly or indirectly, in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Dexcel's ANDA Product immediately and imminently upon approval of Dexcel's ANDA.

101. The manufacture, use, sale, offer for sale, or importation of Dexcel's ANDA Product would infringe one or more of claims 1–16 of the '441 patent.

102. The manufacture, use, sale, offer for sale, or importation of Dexcel's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more of claims 1–16 of the '441 patent.

103. Upon information and belief, Dexcel plans and intends to, and will, actively induce infringement of the '441 patent when Dexcel's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Dexcel's activities will be done with knowledge of the '441 patent and specific intent to infringe that patent.

104. Upon information and belief, Dexcel knows that Dexcel's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '441 patent, that Dexcel's ANDA Product is not a staple article or commodity of commerce, and that Dexcel's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Dexcel plans and intends to, and will, contribute to infringement of the '695 patent immediately and imminently upon approval of Dexcel's ANDA.

105. Notwithstanding Dexcel's knowledge of the claims of the '441 patent, Dexcel has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Dexcel's ANDA Product with their product labeling following FDA approval of Dexcel's ANDA prior to the expiration of the '441 patent.

106. The foregoing actions by Dexcel constitute and/or will constitute infringement of the ’441 patent; active inducement of infringement of the ’441 patent; and contribution to the infringement by others of the ’441 patent.

107. Upon information and belief, Dexcel has acted with full knowledge of the ’441 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’441 patent; active inducement of infringement of the ’441 patent; and/or contribution to the infringement by others of the ’441 patent.

108. Plaintiffs will be substantially and irreparably damaged by infringement of the ’441 patent.

109. Unless Dexcel is enjoined from infringing the ’441 patent, actively inducing infringement of the ’695 patent, and contributing to the infringement by other of the ’441 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’441 PATENT

110. Plaintiffs incorporate by reference each of the preceding paragraphs 1–109 as if fully set forth herein.

111. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on one hand and Dexcel on the other regarding Dexcel’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’441 patent, and/or the validity of the ’441 patent.

112. An actual case or controversy exists between Plaintiffs and Dexcel with respect to Dexcel’s liability for infringement of the ’441 patent.

113. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Dexcel's ANDA Product will infringe, induce infringement, and actively contribute to the infringement of the '441 patent.

* * *

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that each of the patents-in-suit has been infringed under 35 U.S.C. § 271(e)(2) by Dexcel's submission to the FDA of Dexcel's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of commercial manufacture, use, offer for sale, sale or importation of Dexcel's ANDA Product, or any other drug product that infringement or the use of which infringes one or more of the patents-in-suit, be not earlier than the expiration dates of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Dexcel, and all persons acting in concert with Dexcel, from the commercial manufacture, use, sale, offer for sale, or importation in the United States of Dexcel's ANDA Product, or any other drug product covered by or whose use is covered by one or more of the patents-in-suit prior to the expiration of said patents, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale, or importation of Dexcel's ANDA Product, or any other drug product which is covered by or whose use is covered by one or more of the patents-in-suit, prior to the expiration of said patents, will infringe, induce the infringement of, and contribute to the infringement by others of said patents;

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

(f) Costs and expenses in this action; and

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

Dated: August 10, 2023

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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