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. 23-0879-GBW

DEFENDANT DEXCEL PHARMA TECHNOLOGIES LIMITED'S ANSWER TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Defendant Dexcel Pharma Technologies Limited ("Dexcel"), by and through its undersigned attorneys, hereby answers the Complaint for Patent Infringement (D.I. 1) ("Complaint") brought by Plaintiffs Pfizer Inc., FoldRx Pharmaceuticals, LLC, PF Prism IMB B.V., Wyeth LLC, and The Scripps Research Institute (collectively, "Plaintiffs") concerning U.S. Patent Nos. 7,214,695 ("the '695 patent"); 7,214,696 ("the '696 patent"); and 9,770,441 ("the '441 patent") (collectively, the "patents-in-suit").

GENERAL DENIAL

Dexcel denies all allegations in Plaintiffs' Complaint except for those specifically admitted below. With respect to the allegations made in the Complaint, upon knowledge with respect to Dexcel's own acts, and upon information and belief as to other matters, Dexcel responds and alleges as follows:

NATURE OF THE ACTION

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."

ANSWER: The allegations in Paragraph 1 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that the above-captioned action purports to be an action for patent infringement arising under the patent laws of the United States, in response to Dexcel's submission of ANDA No. 218365 ("Dexcel's ANDA") to the United States Food and Drug Administration ("FDA") to obtain approval for the commercial manufacture and sale in the United States of tafamidis 61 mg capsules prior to the expiry of the patents-in-suit ("Dexcel's ANDA Product"). Dexcel denies any remaining allegations contained in Paragraph 1.

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.

ANSWER: Admitted.

THE 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.

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3, and therefore denies them.

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.

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4, and therefore denies them.

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.

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5, and therefore denies them.

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.

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 6, and therefore denies them.

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.

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 7, and therefore denies them.

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.

ANSWER: The allegations in Paragraph 8 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that it is a corporation organized and existing under the laws of Israel, having a registered address at 21 Nahum Haftzadi Jerusalem, Israel 9123901. Dexcel denies any remaining allegations contained in Paragraph 8.

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.

ANSWER: The allegations in Paragraph 9 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that it does not contest personal jurisdiction in this case for the purposes of this action only. Dexcel admits that it filed Dexcel's ANDA with the FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis 61 mg capsules. Dexcel denies any remaining allegations contained in Paragraph 9.

JURISDICTION AND VENUE

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

ANSWER: The allegations in Paragraph 10 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits only that, insofar as this suit is properly brought, this Court has subject matter jurisdiction to adjudicate this action. Dexcel denies any remaining allegations contained in Paragraph 10.

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.

ANSWER: The allegations in Paragraph 11 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that it does not contest personal jurisdiction over it in this Court for the purposes of this action only. Dexcel denies any remaining allegations contained in Paragraph 11.

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.

ANSWER: The allegations in Paragraph 12 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that it does not contest personal jurisdiction over it in this Court for the purposes of this action only. Dexcel denies that the activities described in Paragraph 12 would infringe any valid claim of the patents-in-suit. Dexcel denies any remaining allegations contained in Paragraph 12.

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.

ANSWER: The allegations in Paragraph 13 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that it does not contest personal jurisdiction over it in this Court for the purposes of this action only. Dexcel denies any remaining allegations contained in Paragraph 13.

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.

ANSWER: The allegations in Paragraph 14 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that it does not contest

personal jurisdiction over it in this Court for the purposes of this action only. Dexcel denies any remaining allegations contained in Paragraph 14.

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.

ANSWER: The allegations in Paragraph 15 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that it does not contest venue over it in this Court for the purposes of this action only. Dexcel denies any remaining allegations contained in Paragraph 15.

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.

ANSWER: The allegations in Paragraph 16 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that the electronic version of FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") lists FoldRx Pharmaceuticals, LLC as the applicant holder of New Drug Application No. 212161. Dexcel lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 16, and therefore denies them.

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.

ANSWER: Admitted.

18. Vyndamax® contains tafamidis as its active ingredient.

ANSWER: Admitted.

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

ANSWER: The allegations in Paragraph 19 set forth legal conclusions to which no

response is required. To the extent a response is required, Dexcel admits that it filed Dexcel's ANDA with the FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis 61 mg capsules. Dexcel denies any remaining allegations contained in Paragraph 19.

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

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 20, and therefore denies them.

COUNT I – INFRINGEMENT OF THE '695 PATENT

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

ANSWER: Dexcel repeats, re-alleges, and incorporates by reference its responses to 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.

ANSWER: The allegations in Paragraph 22 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that on its face, the '695 patent titled "COMPOSITIONS AND METHODS FOR STABILIZING TRANSTHYRETIN AND INHIBITING TRANSTHYRETIN MISFOLDING" was issued on May 8, 2007. Dexcel denies any remaining allegations contained in Paragraph 22.

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

ANSWER: The allegations in Paragraph 23 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that on its face, the inventors named on the '695 patent are Jeffrey W. Kelly, Evan T. Powers, and Hossein Razavi.

Dexcel denies any remaining allegations contained in Paragraph 23.

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

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 24, and therefore denies them.

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

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 25, and therefore denies them.

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®.

ANSWER: The allegations in Paragraph 26 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations contained in Paragraph 26.

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®.

ANSWER: The allegations in Paragraph 27 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that claim 3 of the '695 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 27.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted

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.

ANSWER: The allegations in Paragraph 30 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations contained in Paragraph 30.

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®.

ANSWER: The allegations in Paragraph 31 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel states that claim 3 of the '695 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 31.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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.

ANSWER: The allegations in Paragraph 34 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations contained in Paragraph 34.

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).

ANSWER: Denied.

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.

ANSWER: Dexcel admits that it filed Dexcel's ANDA with the FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis 61 mg capsules. Dexcel denies any remaining allegations contained in Paragraph 36.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Dexcel repeats, re-alleges, and incorporates by reference its responses to 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.

ANSWER: The allegations in Paragraph 47 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits Plaintiffs brought a patent infringement suit against Dexcel, in response to which Dexcel denies any infringement. Dexcel denies any remaining allegations contained in Paragraph 47.

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

ANSWER: The allegations in Paragraph 48 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits Plaintiffs brought a patent infringement suit against Dexcel, in response to which Dexcel denies any infringement. Dexcel denies any remaining allegations contained in Paragraph 48.

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.

ANSWER: Denied.

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.

ANSWER: Dexcel repeats, re-alleges, and incorporates by reference its responses to 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.

ANSWER: The allegations in Paragraph 51 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that on its face, the inventors named on the '696 patent are Jeffrey W. Kelly and Yoshiki Sekijima. Dexcel denies any remaining allegations contained in Paragraph 51.

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

ANSWER: The allegations in Paragraph 52 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that on its face, the '696 patent titled "COMPOSITIONS AND METHODS FOR STABILIZING TRANSTHYRETIN AND INHIBITING TRANSTHYRETIN MISFOLDING" was issued on May 8, 2007. Dexcel

denies any remaining allegations contained in Paragraph 52.

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

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53, and therefore denies them.

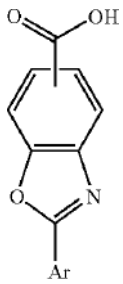
54. Plaintiffs together own all substantial rights in the ’696 patent.

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 54, and therefore denies them.

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®.

ANSWER: The allegations in Paragraph 55 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations contained in Paragraph 55.

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.

ANSWER: Dexcel states that claim 1 of the ’696 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 56.

57. Claim 3 of the '696 patent recites:

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

ANSWER: Dexcel states that claim 3 of the '696 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 57.

58. Claim 9 of the '696 patent recites:

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

ANSWER: Dexcel states that claim 9 of the '696 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 58.

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.

ANSWER: Admitted.

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.

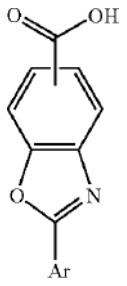
ANSWER: Admitted.

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.

ANSWER: Denied.

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.

ANSWER: Dexcel states that claim 1 of the '696 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 62.

63. Claim 3 of the '696 patent recites:

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

ANSWER: Dexcel states that claim 3 of the '696 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 63.

64. Claim 9 of the '696 patent recites:

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

ANSWER: Dexcel states that claim 9 of the '696 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 64.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in Paragraph 68 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations in Paragraph 68.

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).

ANSWER: Denied.

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.

ANSWER: Dexcel admits that it filed Dexcel's ANDA with the FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis 61 mg capsules. Dexcel denies any remaining allegations contained in Paragraph 70.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Dexcel repeats, re-alleges, and incorporates by reference its responses to 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.

ANSWER: The allegations in Paragraph 81 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits Plaintiffs brought a patent infringement suit against Dexcel, in response to which Dexcel denies any infringement. Dexcel denies any remaining allegations contained in Paragraph 81.

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

ANSWER: The allegations in Paragraph 82 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits Plaintiffs brought a patent infringement suit against Dexcel, in response to which Dexcel denies any infringement. Dexcel denies any remaining allegations contained in Paragraph 82.

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.

ANSWER: Denied.

COUNT V – INFRINGEMENT OF THE '441 PATENT

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

ANSWER: Dexcel repeats, re-alleges, and incorporates by reference its responses to 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.

ANSWER: The allegations in Paragraph 85 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that on its face, the '441 patent titled "CRYSTALLINE SOLID FORMS OF 6-CARBOXY-2(3,5- DICHLOROPHENYL)-BENZOXAZOLE" was issued on September 26, 2017. Dexcel denies any remaining allegations contained in Paragraph 85.

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

ANSWER: The allegations in Paragraph 86 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits that on its face, the inventors named on the '441 patent are Kevin Paul Girard, Andrew J. Jensen, and Kris Nicole Jones. Dexcel denies any remaining allegations contained in Paragraph 86.

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

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 87, and therefore denies them.

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

ANSWER: Dexcel lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 88, and therefore denies them.

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®.

ANSWER: The allegations in Paragraph 89 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations contained in Paragraph 89.

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.

ANSWER: Dexcel states that claim 1 of the '441 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 90.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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.

ANSWER: Denied.

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.

ANSWER: Dexcel states that claim 1 of the '441 patent speaks for itself. Except as otherwise expressly admitted, Dexcel denies any remaining allegations contained in Paragraph 94.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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.

ANSWER: Denied.

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.

ANSWER: The allegations in Paragraph 98 set forth legal conclusions to which no response is required. Dexcel denies any remaining allegations contained in Paragraph 98.

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).

ANSWER: Denied.

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.

ANSWER: Dexcel admits that it filed Dexcel's ANDA with the FDA to obtain approval for the commercial manufacture and sale in the United States of tafamidis 61 mg capsules. Dexcel denies any remaining allegations contained in Paragraph 100.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Dexcel repeats, re-alleges, and incorporates by reference its responses to 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.

ANSWER: The allegations in Paragraph 111 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits Plaintiffs brought a patent infringement suit against Dexcel, in response to which Dexcel denies any infringement. Dexcel denies any remaining allegations contained in Paragraph 111.

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

ANSWER: The allegations in Paragraph 112 set forth legal conclusions to which no response is required. To the extent a response is required, Dexcel admits Plaintiffs brought a patent infringement suit against Dexcel, in response to which Dexcel denies any infringement. Dexcel denies any remaining allegations contained in Paragraph 112.

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.

ANSWER: Denied.

PRAYER FOR RELIEF

Dexcel denies that Plaintiffs are entitled to any judgment, any of the requested relief, or any other relief against Dexcel and, therefore, specifically denies Paragraphs (a)-(g) of the Complaint's Prayer for Relief. Each averment and/or allegation contained in Plaintiffs' Complaint that is not specifically admitted herein is hereby denied. Dexcel requests that judgment be entered in its favor, dismissing Plaintiffs' Complaint with prejudice, awarding Dexcel its attorneys' fees, interest, and costs incurred in this litigation under 35 U.S.C. § 285, and granting such other or further relief as the Court may deem just and proper.

AFFIRMATIVE AND OTHER DEFENSES

Without prejudice to the denials set forth in this Answer, and without admitting any averments of Plaintiffs' Complaint not otherwise specifically admitted, and without assuming the burden of proof on any such defenses that would otherwise rest on the Plaintiffs, and without regard to and without any prejudice regarding the applicable burden of proof, Dexcel avers and asserts the following Affirmative Defenses to the Complaint. Dexcel expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST DEFENSE
NON-INFRINGEMENT OF THE '695 PATENT

Dexcel has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '695 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid enforceable, and properly construed claim of the '695 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND DEFENSE
INVALIDITY OF THE '695 PATENT

Each claim of the '695 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidation.

THIRD DEFENSE
NON-INFRINGEMENT OF THE '696 PATENT

Dexcel has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '696 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid enforceable, and properly construed claim of the '696 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

FOURTH DEFENSE
INVALIDITY OF THE '696 PATENT

Each claim of the '696 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidation.

FIFTH DEFENSE
NON-INFRINGEMENT OF THE '441 PATENT

Dexcel has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, enforceable, and properly construed claim of the '441 patent, either directly, indirectly, contributorily, by inducement, or in any other manner. The manufacture, use, offer for sale, sale, and/or importation of Dexcel's ANDA Product has not, does not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid

enforceable, and properly construed claim of the '441 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

SIXTH DEFENSE
INVALIDITY OF THE '441 PATENT

Each claim of the '441 patent is invalid for failing to satisfy one or more of the conditions for patentability set forth in Title 35 of the United States Code §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidation.

SEVENTH DEFENSE
FAILURE TO STATE A CLAIM

Plaintiffs fail to state a claim upon which relief can be granted.

EIGHTH DEFENSE
NO EXCEPTIONAL CASE

Dexcel's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

NINTH DEFENSE
NO WILLFUL INFRINGEMENT

Dexcel has not willfully infringed any valid and enforceable claim of the patents-in-suit.

TENTH DEFENSE

Any defense asserted in any other action in which the patents-in-suit are asserted, may be asserted in this action.

RESERVATION OF DEFENSES

Dexcel reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

Dated: October 5, 2023

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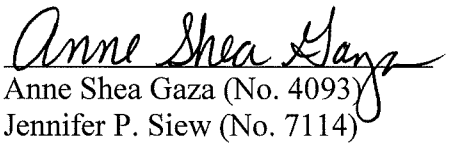

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on October 5, 2023 a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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