

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

|                                |                  |
|--------------------------------|------------------|
| PFIZER INC., FOLDRX            | )                |
| PHARMACEUTICALS, LLC, PF PRISM | )                |
| IMB B.V., and WYETH LLC,       | )                |
|                                | )                |
| Plaintiffs,                    | )                |
|                                | )                |
| v.                             | ) C.A. No. _____ |
|                                | )                |
| APOTEX INC. and APOTEX CORP.,  | )                |
|                                | )                |
| Defendants.                    | )                |

**COMPLAINT**

Plaintiffs Pfizer Inc.; FoldRx Pharmaceuticals, LLC; PF PRISM IMB B.V.; and Wyeth LLC (referred to collectively herein as “Plaintiffs”) file this Complaint for patent infringement against Apotex Inc. and Apotex Corp. (collectively, “Apotex”), 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 Apotex’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 No. 9,770,441 (“the ‘441 patent”) (attached as Exhibit A).

2. Apotex notified Pfizer by letter dated September 9, 2025 (“Apotex’s Notice Letter”) that it has submitted to the FDA ANDA No. 218905 (“Apotex’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 (“Apotex’s ANDA Product”) prior to the expiration of the ’441 patent.

### **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 limited liability company 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 IJssel, the Netherlands.

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

7. Upon information and belief, Defendant Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at Apotex Inc., 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada. Upon information and belief, Apotex Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Apotex Corp.

8. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. Upon information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

9. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc., and is controlled and/or dominated by Apotex Inc.

10. Upon information and belief, Apotex Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Apotex Inc., acting in concert with Apotex Corp., files ANDAs with FDA seeking approval to engage in, and engages 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.

11. Upon information and belief, Apotex Inc. and Apotex Corp. acted in concert to prepare and submit Apotex's ANDA for Apotex's ANDA Product, which was done at the direction of, under the control of, and for the direct benefit of Apotex Inc.

12. Upon information and belief, Apotex Inc. and Apotex Corp. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Apotex's ANDA Product at issue.

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

**JURISDICTION AND VENUE**

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

15. Apotex Inc. is subject to personal jurisdiction in Delaware because, among other things, Apotex Inc., itself and through its wholly-owned subsidiary Apotex Corp., 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, Apotex Inc., itself and through its agents, including its wholly-owned subsidiary Apotex Corp., 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. In addition, Apotex Inc. is subject to personal jurisdiction in Delaware because, upon information and belief, it controls Apotex Corp. and therefore the activities of Apotex Corp. in this jurisdiction are attributed to Apotex Inc.

16. This Court has personal jurisdiction over Apotex Corp. because, among other things, Apotex Corp. has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Apotex Corp. is a corporation formed under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent in Delaware (United Corporate Services, Inc., 800 North State Street, Suite 304, Dover, DE) to accept service of process. It therefore has

consented to general jurisdiction in Delaware. In addition, on information and belief, Apotex Corp. 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 systematic and continuous business contacts within the State of Delaware.

17. In addition, upon information and belief, Apotex Corp., acting as an agent of Apotex Inc., markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by Apotex Inc. or for which Apotex is the named applicant on approved ANDAs.

18. In addition, this Court has personal jurisdiction over Apotex Inc. and Apotex Corp. because, among other things, upon information and belief Apotex Inc. and Apotex Corp. acted in concert to file Apotex's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex's ANDA Product in the United States, including in Delaware.

19. Upon information and belief, if Apotex's ANDA is approved, Apotex Inc. and Apotex Corp., acting in concert and/or as agents of one another, will directly or indirectly manufacture, market, sell, and/or distribute Apotex's ANDA Product within the United States, including in Delaware, consistent with Apotex's practices for the marketing and distribution of other generic pharmaceutical products. Upon information and belief, Apotex Inc. and Apotex Corp. regularly do business in Delaware, and their 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, Apotex Inc.'s and Apotex Corp.'s generic pharmaceutical products are used and/or consumed within and throughout the United

States, including in Delaware. Upon information and belief, Apotex'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 '441 patent in the event that Apotex's ANDA Product is approved before the '441 patent expires.

20. Upon information and belief, Apotex Inc. and Apotex Corp. derive substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and that are manufactured by Apotex Inc. and Apotex Corp., either in concert and/or as agents of one another, and/or for which Apotex is the named applicant on approved ANDAs. Upon information and belief, various products for which Apotex is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

21. In addition, this Court has personal jurisdiction over Apotex because Apotex Corp., and Apotex Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Bayer Intellectual Property GmbH et al. v. Apotex Inc. et al.*, Case No. 23-327-RGA, D.I. 11 (D. Del. June 30, 2023); *Bayer Pharma AG et al. v. Apotex Inc. et al.*, Case No. 22-1596-RGA, D.I. 11 (D. Del. Mar. 7, 2023); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Case No. 21-1429-WCB, D.I. 14 (D. Del. Mar. 1, 2022); *Bial-Portela & CA S.A. v. Apotex Inc. et al.*, Case No. 21-187-CFC, D.I. 6 (D. Del. Mar. 3, 2021); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Case No. 20-749-RGA, D.I. 7 (D. Del. June 26, 2020).

22. Alternatively, the Court may exercise personal jurisdiction over Apotex Inc. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law;

(b) Apotex Inc. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Apotex Inc. 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 Apotex Inc. satisfies due process.

23. Venue is proper in this district as to Apotex Inc. pursuant to 28 U.S.C. § 1391 because, *inter alia*, Apotex is a corporation organized and existing under the laws of Canada and is subject to personal jurisdiction in this judicial district.

24. Venue is proper in this district for Apotex Corp. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

#### **FACTUAL BACKGROUND**

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

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

27. Vyndamax® contains tafamidis as its active ingredient.

28. Apotex's ANDA Product is a generic version of Vyndamax®.

29. Apotex's Notice Letter purported to include an "Offer of Confidential Access" to Plaintiffs to portions of Apotex's ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

30. In an exchange of correspondence, counsel for Pfizer and counsel for Apotex negotiated the terms of Apotex's Offer of Confidential Access. The parties did not agree on terms under which Pfizer could review, among other things, the Drug Master File referenced in Apotex's ANDA or relevant characterization data. Apotex further refused to produce samples of Apotex's ANDA Product.

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

#### **COUNT I – INFRINGEMENT OF THE '441 PATENT**

32. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

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

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

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

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

37. 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®.

38. In Apotex's Notice Letter, Apotex notified Plaintiffs of the submission of Apotex'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 Apotex's ANDA Product prior to the expiration of the '441 patent.

39. In Apotex's Notice Letter, Apotex also notified Plaintiffs that, as part of its ANDA, Apotex 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. Apotex 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 Apotex's ANDA Product.

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

41. 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  $^{13}\text{C}$  chemical shifts (ppm) at  $120.8\pm0.2$  and  $127.7\pm0.2$ ,  
 a powder X-ray diffraction pattern comprising a peak at a diffraction angle ( $2\theta$ ) of  $28.6\pm0.2$ , and  
 a Raman spectrum comprising a Raman shift peak ( $\text{cm}^{-1}$ ) at  $1292\pm2$ .

42. Apotex's ANDA Product contains tafamidis, i.e., 6-carboxy-2-(3,5-dichlorophenyl)-benzoxazole.

43. On information and belief, Apotex's ANDA product contains a crystalline form of tafamidis that has a solid state NMR spectrum comprising  $^{13}\text{C}$  chemical shifts (ppm) at  $120.8\pm0.2$  and  $127.7\pm0.2$ , a powder X-ray diffraction pattern comprising a peak at a diffraction angle ( $2\theta$ ) of  $28.6\pm0.2$ , or a Raman spectrum comprising a Raman shift peak ( $\text{cm}^{-1}$ ) at  $1292\pm2$ .

44. As another example, claim 15 of the '441 patent recites “[a] pharmaceutical composition comprising the crystalline form of claim 1 in a therapeutically effective amount in admixture with at least one pharmaceutically acceptable excipient.”

45. On information and belief, Apotex's ANDA Product is a pharmaceutical composition comprising the crystalline form of claim 1 in a therapeutically effective amount in admixture with at least one pharmaceutically acceptable excipient.

46. As a further example, claim 16 of the '441 patent recites “[a] method of treating transthyretin amyloid disease in a mammal, the method comprising administering to the mammal a therapeutically effective amount of the crystalline form claim 1.”

47. On information and belief, the proposed labeling for Apotex's ANDA Product directs and encourages a method of treating a transthyretin amyloid disease in a mammal, the method comprising administering to the mammal a therapeutically effective amount of the crystalline form claim 1.

48. Apotex's submission of Apotex's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Apotex'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).

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

50. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product would infringe one or more of claims 1–16 of the '441 patent.

51. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of Apotex'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.

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

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

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

55. The foregoing actions by Apotex 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.

56. Upon information and belief, Apotex 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.

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

58. Unless Apotex is enjoined from infringing the '441 patent, actively inducing infringement of the '441 patent, and contributing to the infringement by others of the '441 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**COUNT II – DECLARATORY JUDGMENT  
OF INFRINGEMENT OF THE '441 PATENT**

59. Plaintiffs incorporate by reference each of the preceding paragraphs as if fully set forth herein.

60. 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 Apotex on the other regarding Apotex'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.

61. An actual case or controversy exists between Plaintiffs and Apotex with respect to Apotex's liability for infringement of the '441 patent.

62. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Apotex'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 the '441 patent has been infringed under 35 U.S.C. § 271(e)(2) by Apotex's submission to the FDA of Apotex'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 Apotex's ANDA Product, or any other drug product that infringes or the use of which infringes the '441 patent, be not earlier than the

expiration dates of said patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Apotex, and all persons acting in concert with Apotex, from the commercial manufacture, use, sale, offer for sale, or importation in the United States of Apotex's ANDA Product, or any other drug product covered by or whose use is covered by the '441 patent prior to the expiration of said patent, 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 Apotex's ANDA Product, or any other drug product covered by or whose use is covered by the '441 patent, prior to the expiration of said patent, will infringe, induce the infringement of, and contribute to the infringement by others of said patent;

(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.

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October 24, 2025

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*/s/ Megan E. Dellinger*

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