

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MITSUBISHI TANABE PHARMA)	
CORPORATION,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 24-549-JLH
)	
APOTEX INC. and APOTEX CORP.,)	
)	
Defendants.)	

**APOTEX INC. AND APOTEX CORP.’S ANSWER,
AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO COMPLAINT**

Defendants Apotex Inc. and Apotex Corp. (collectively, “Apotex”), by and through their counsel, hereby answer and respond to each of the allegations of the Complaint of Plaintiff Mitsubishi Tanabe Pharma Corporation (“Plaintiff” or “MTPC”) (D.I. 1), and assert their affirmative defenses as follows:

GENERAL DENIAL

Pursuant to Rule 8(b)(3) of the Federal Rules of Civil Procedure, Apotex denies all allegations in Plaintiff’s Complaint except those specifically admitted below. To the extent that any of the Complaint’s headings constitute factual allegations, Apotex specifically denies each and every such allegation.

NATURE OF THE CASE

1. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Plaintiff’s Complaint purports to set forth an action for infringement by Apotex of United States Patent Nos. 10,987,341 (“the ’341 patent”), 11,241,416 (“the ’416 patent”), 11,478,450 (“the ’450 patent”), and 11,826,352 (“the ’352 patent”) (collectively, the “Patents-in-Suit”) arising under the United States patent laws, title 35, United

States Code, §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

2. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it submitted Abbreviated New Drug Application (“ANDA”) No. 219256 to the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of an edaravone oral suspension prior to the expiration of the Patents-in-Suit which are listed in the FDA’s “Orange Book.” Apotex denies the remaining allegations of this Paragraph.

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3. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

4. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

5. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

6. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

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7. Apotex admits that information published by FDA identifies MTPC as the holder of New Drug Application (“NDA”) No. 215446. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

8. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

9. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

10. This Paragraph contains conclusions of law, for which no response is required. To the extent a response is required, Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

11. Admitted.

12. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

13. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

THE PARTIES

14. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations, aside from MTPC's address.

15. Admitted.

16. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Inc. markets and sells pharmaceutical products. Apotex denies the remaining allegations of this Paragraph.

17. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that "Apotex Inc. is the holder of ANDA No. 219256" seeking FDA approval. Apotex denies the remaining allegations of this Paragraph.

18. Admitted.

19. Admitted.

20. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, denied.

21. Apotex admits only that Apotex Corp. sells pharmaceutical products in the United States. Apotex denies the remaining allegations of this Paragraph.

22. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Inc. and Apotex Corp. are related entities. Apotex denies the remaining allegations of this Paragraph.

23. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that Apotex Inc. and Apotex Corp. are related entities. Apotex denies the remaining allegations of this Paragraph.

24. Admitted.

JURISDICTION AND VENUE

25. Apotex restates, realleges, and incorporates by reference each of the responses to Paragraphs 1 through 24 as if fully set forth herein.

26. Apotex admits this is an action for purported patent infringement arising under the “Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code.” Otherwise, denied.

27. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex is not contesting subject matter jurisdiction. Otherwise, denied.

28. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Inc. is not contesting personal jurisdiction or Plaintiff's choice of venue. Otherwise, denied.

29. Apotex admits that Apotex Inc. has been a party to the actions listed in this Paragraph. To the extent that a further answer is required, solely for the purposes of this action, Apotex Inc. is not contesting personal jurisdiction. Apotex denies the remaining allegations, to the extent that legal conclusions are required, of this Paragraph.

30. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Inc. is not contesting personal jurisdiction. Otherwise, denied.

31. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex Corp. is not contesting personal jurisdiction or venue. Otherwise, denied.

32. Apotex admits that Apotex Corp. has been a party to the actions listed in this Paragraph. To the extent that a further answer is required, solely for the purposes of this action, Apotex Corp. is not contesting personal jurisdiction. Apotex denies the remaining allegations, to the extent that legal conclusions are required, of this Paragraph.

33. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it submitted ANDA No. 219256 "to the FDA to seek FDA approval." Otherwise, denied.

34. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely for the purposes of this action, Apotex is not contesting personal jurisdiction. Otherwise, denied.

35. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely to conserve the resources of the parties and the Court, Apotex Inc. does not contest venue in this judicial district or personal jurisdiction for the limited purposes of this action only. Otherwise, denied.

36. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, solely to conserve the resources of the parties and the Court, Apotex Corp. does not contest venue in this judicial district for the limited purposes of this action only. Otherwise, denied.

THE PATENTS-IN-SUIT

37. Apotex admits only that the '341 patent is entitled "Edaravone Suspension for Oral Administration," issued on April 27, 2021, and a purported copy thereof was attached as Exhibit A to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

38. Apotex admits only that the '416 patent is entitled "Edaravone Suspension for Oral Administration," issued on February 8, 2022, and a purported copy thereof was attached as Exhibit B to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

39. Apotex admits only that the '450 patent is entitled "Edaravone Suspension for Oral Administration," issued on October 25, 2022, and a purported copy thereof was attached as Exhibit C to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

40. Apotex admits only that the '352 patent is entitled "Edaravone Suspension for Oral Administration," issued on November 28, 2023, and a purported copy thereof was attached as

Exhibit D to the Complaint. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this Paragraph and, therefore, denies those allegations.

DEFENDANTS' ANDA

41. Apotex admits that it submitted ANDA No. 219256 to the FDA and continues to maintain said ANDA. This Paragraph otherwise contains conclusions of law for which no response is required. To the extent a response is required beyond the foregoing admission, denied.

42. Admitted.

43. Admitted.

44. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it seeks FDA approval of ANDA No. 219256. Otherwise, denied.

45. Apotex admits that, as of the date of this Answer, “the FDA has not approved ANDA No. 219256.”

46. Apotex admits that it sent to MTPC Apotex’s Notice Letter which was dated March 22, 2024, stating that Apotex had submitted ANDA No. 219256 seeking FDA approval. This Paragraph otherwise contains conclusions of law for which no response is required. To the extent a response is required, denied.

47. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that its “Notice Letter” included an “Offer of Confidential Access” (“OCA”) to its ANDA. Otherwise, denied.

48. As of the date of this Answer, Plaintiff has not requested access to the ANDA under the terms offered in Apotex’s OCA. As such, Plaintiff’s allegations in this Paragraph are denied.

49. As of the date of this Answer, Plaintiff has not requested samples related to the ANDA under the terms offered in Apotex's OCA or otherwise. As such, Plaintiff's allegations in this Paragraph are denied.

50. Denied.

51. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex states that its non-infringement positions may be subject to discovery, Apotex's further factual investigation, and Plaintiff's prosecution of this action. Otherwise, denied.

52. Admitted.

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF THE '341 PATENT

53. Apotex restates, realleges, and incorporates by reference each of the responses to Paragraphs 1 through 52 as if fully set forth herein.

54. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it submitted its ANDA to the FDA prior to the expiration of the '341 patent. Otherwise, denied.

55. Denied.

56. Denied.

57. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

58. Denied.

59. Denied.

60. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '341 patent as of the date of the filing of its ANDA. Otherwise, denied.

61. Denied.

62. Denied.

63. Denied.

64. Denied.

COUNT 2: INFRINGEMENT OF THE '416 PATENT

65. Apotex restates, realleges, and incorporates by reference each of the responses to Paragraphs 1 through 64 as if fully set forth herein.

66. Denied.

67. Denied.

68. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

69. Denied.

70. Denied.

71. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '416 patent as of the date of the filing of its ANDA. Otherwise, denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

COUNT 3: INFRINGEMENT OF THE '450 PATENT

76. Apotex restates, realleges, and incorporates by reference each of the responses to Paragraphs 1 through 75 as if fully set forth herein.

77. Denied.

78. Denied.

79. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

80. Denied.

81. Denied.

82. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '450 patent as of the date of the filing of its ANDA. Otherwise, denied.

83. Denied.

84. Denied.

85. Denied.

86. Denied.

COUNT 4: INFRINGEMENT OF THE '352 PATENT

87. Apotex restates, realleges, and incorporates by reference each of the responses to Paragraphs 1 through 86 as if fully set forth herein.

88. Denied.

89. Denied.

90. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this Paragraph and, therefore, denies those allegations.

91. Denied.

92. Denied.

93. This Paragraph states a legal conclusion that does not require an answer. To the extent that an answer is required, Apotex admits that it was aware of the '352 patent as of the date of filing its ANDA. Otherwise, denied.

94. Denied.

95. Denied.

96. Denied.

97. Denied.

PRAYER FOR RELIEF

All remaining allegations not specifically admitted herein are denied. It is further denied that Plaintiff is entitled to the relief requested in the Complaint or to any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Apotex asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST AFFIRMATIVE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the Patents-in-Suit are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE

Apotex has not and will not directly or indirectly infringe any valid or enforceable claim of the Patents-in-Suit. The manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of the Apotex ANDA does not and will not infringe any valid or enforceable claim of the Patents-in-Suit, either literally or under the doctrine of equivalents.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff is barred from asserting infringement based on the doctrine of equivalents in view of prosecution history estoppel, disclaimer, the disclosure-dedication rule, vitiation, and/or ensnarement.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for exceptional case or willful infringement.

SIXTH AFFIRMATIVE DEFENSE

35 U.S.C. § 288 prevents Plaintiff from recovering any costs associated with this case.

SEVENTH AFFIRMATIVE DEFENSE

Apotex reserves all defenses, in law or equity, which may now exist or, in the future, be available during discovery and further factual investigation in this case.

COUNTERCLAIMS

Counterclaim-Plaintiffs Apotex Inc. and Apotex Corp. (collectively, “Apotex”) for their counterclaims against Plaintiff/Counterclaim-Defendant Mitsubishi Tanabe Pharma Corporation (“Plaintiff/Counterclaim-Defendant” or “MTPC”), allege as follows:

1. This is a counterclaim action for declaratory judgment that United States Patent Nos. 10,987,341 (“the ’341 patent”), 11,241,416 (“the ’416 patent”), 11,478,450 (“the ’450 patent”), and 11,826,352 (“the ’352 patent”) (collectively, the “Patents-in-Suit”) are invalid and not infringed pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and for such other relief as the Court deems just and proper.

THE PARTIES

2. Apotex Inc. is a Canadian corporation, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. On information and belief, and based on the allegations in the Complaint, MTPC is a corporation organized and existing under the laws of Japan having its corporate headquarters at 3-2-10, Dosho-machi, Chuo-ku, Osaka, 541-8505, Japan.

JURISDICTION AND VENUE

5. The Court has jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*

6. This is an action based on an actual controversy between Apotex and Plaintiff/Counterclaim-Defendant concerning the noninfringement and invalidity of the Patents-in-Suit arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, and Apotex's right to continue to seek approval by the Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 219256 (the "Apotex ANDA") and, upon FDA approval, to manufacture, use, sell, and offer to sell within, and/or import into, the United States the products that are the subject of the Apotex ANDA ("Apotex's ANDA Product(s)") should Apotex decide to do so.

7. The Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant because MTPC has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Apotex in this District and, on information and belief, because MTPC transacts business within the State of Delaware and/or has engaged in systematic and continuous business contacts—directly or indirectly through a subsidiary—within the State of Delaware.

8. Venue is proper in this District under 28 U.S.C. § 1391, § 1400(b), 21 U.S.C. § 355(j)(5)(C)(i)(II), and/or by Plaintiff/Counterclaim-Defendant's choice of forum.

BACKGROUND

9. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 8 of the Counterclaims, as if fully set forth herein.

10. On or about April 27, 2021, according to the electronic records of the U.S. Patent and Trademark Office (the "USPTO"), the '341 patent, entitled "EDARAVONE SUSPENSION FOR ORAL ADMINISTRATION," issued, on its face, to Tetsuo Hayama, Tomohiro Takahashi, Tomoyuki Omura, Kouji Hayashi, Munetomo Matsuda, and Tadashi Miyazawa.

Plaintiff/Counterclaim-Defendant represented that a copy of the '341 patent was attached as Exhibit A to the Complaint.

11. On or about February 8, 2022, according to the electronic records of the USPTO, the '416 patent, entitled "EDARAVONE SUSPENSION FOR ORAL ADMINISTRATION," issued, on its face, to Tetsuo Hayama, Tomohiro Takahashi, Tomoyuki Omura, Kouji Hayashi, Munetomo Matsuda, and Tadashi Miyazawa. Plaintiff/Counterclaim-Defendant represented that a copy of the '416 patent was attached as Exhibit B to the Complaint. The '416 patent is subject to a terminal disclaimer.

12. On or about October 25, 2022, according to the electronic records of the USPTO, the '450 patent, entitled "EDARAVONE SUSPENSION FOR ORAL ADMINISTRATION," issued, on its face, to Tetsuo Hayama, Tomohiro Takahashi, Tomoyuki Omura, Kouji Hayashi, Munetomo Matsuda, and Tadashi Miyazawa. Plaintiff/Counterclaim-Defendant represented that a copy of the '450 patent was attached as Exhibit C to the Complaint. The '450 patent is also subject to a terminal disclaimer.

13. On or about November 8, 2023, according to the electronic records of the USPTO, the '352 patent, entitled "EDARAVONE SUSPENSION FOR ORAL ADMINISTRATION," issued, on its face, to Tetsuo Hayama, Tomohiro Takahashi, Tomoyuki Omura, Kouji Hayashi, Munetomo Matsuda, and Tadashi Miyazawa. Plaintiff/Counterclaim-Defendant represented that a copy of the '352 patent was attached as Exhibit D to the Complaint. The '352 patent is also subject to a terminal disclaimer.

14. On information and belief, Plaintiff/Counterclaim-Defendant purports to own, and/or to have the right to enforce, the Patents-in-Suit.

15. On information and belief, Plaintiff/Counterclaim-Defendant caused the FDA to list the Patents-in-Suit in the FDA's Orange Book publication in connection with New Drug Application ("NDA") No. 215446 for RADICAVA ORS®.

16. On information and belief, Plaintiff/Counterclaim-Defendant has not caused the FDA to remove the Patents-in-Suit from the Orange Book in connection with RADICAVA ORS®.

17. By maintaining that listing of the Patents-in-Suit in the Orange Book, Plaintiff/Counterclaim-Defendant represents that the claims of infringement of the Patents-in-Suit "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1)(A)(viii).

18. By letter dated March 22, 2024, Apotex timely notified Plaintiff/Counterclaim-Defendant that Apotex had submitted ANDA No. 219256 to the FDA with a Paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-in-Suit ("Notice Letter"). Apotex's Notice Letter met the statutory and regulatory requirements for such notice letters and included a detailed statement of the factual and legal bases for Apotex's opinion that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products. Apotex incorporates by reference the positions set forth in its Notice Letter but reserves the right to amend them.

19. Apotex's Notice Letter included an Offer of Confidential Access ("OCA"), provided pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Despite providing this OCA, on information and belief, counsel for Apotex is unaware of any attempt by Plaintiff/Counterclaim-Defendant to negotiate the terms of the OCA or otherwise seek access to Apotex's ANDA in order to make a determination as to whether an infringement action should be brought.

20. On May 3, 2024, without reviewing any portions of Apotex's ANDA, Plaintiff/Counterclaim-Defendant sued Apotex in this District for purported infringement of the Patents-in-Suit.

21. In view of the foregoing, there has been, and is now, a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between Apotex and Plaintiff/Counterclaim-Defendant having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court with respect to noninfringement and invalidity of the Patents-in-Suit, and as to Apotex's right to obtain FDA approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products.

COUNT I

Declaratory Judgment of Noninfringement of the '341 Patent

22. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 21 of the Counterclaims, as if fully set forth herein.

23. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiff/Counterclaim-Defendant regarding whether the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products will infringe any claim of the '341 patent.

24. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '341 patent and alleges that Apotex has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '341 patent.

25. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either

literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '341 patent.

26. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '341 patent.

COUNT II
Declaratory Judgment of Invalidity of the '341 Patent

27. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 26 of the Counterclaims, as if fully set forth herein.

28. Plaintiff/Counterclaim-Defendant has accused Apotex of infringing claims of the '341 patent in connection with ANDA No. 219256.

29. Apotex denies infringement of any claim of the '341 patent because all claims of the '341 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '341 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

30. The alleged inventions of the '341 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '341 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions of the '341 patent and would have had a reasonable expectation of success in doing so.

31. The claims of the '341 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '341 patent and

the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

32. The claims of the '341 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

33. Unless Plaintiff/Counterclaim-Defendant is enjoined, Apotex believes that Plaintiff/Counterclaim-Defendant will continue to assert that Apotex infringes the claims of the '341 patent and will continue to interfere with Apotex's business.

34. Apotex will be irreparably harmed if Plaintiff/Counterclaim-Defendant is not enjoined from continuing to assert the claims of the '341 patent and from interfering with Apotex's business.

35. Apotex is entitled to a declaratory judgment that the asserted claims of the '341 patent are invalid.

COUNT III
Declaratory Judgment of Noninfringement of the '416 Patent

36. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 35 of the Counterclaims, as if fully set forth herein.

37. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiff/Counterclaim-Defendant regarding whether the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Products will infringe any claim of the '416 patent.

38. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '416 patent and alleges that Apotex has not, does not, and will not infringe (either literally

or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '416 patent.

39. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '416 patent.

40. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '416 patent.

COUNT IV
Declaratory Judgment of Invalidity of the '416 Patent

41. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 40 of the Counterclaims, as if fully set forth herein.

42. Plaintiff/Counterclaim-Defendant has accused Apotex of infringing claims of the '416 patent in connection with ANDA No. 219256.

43. Apotex denies infringement of any claim of the '416 patent because all claims of the '416 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '416 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

44. The alleged inventions of the '416 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '416 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to

achieve the alleged inventions of the '416 patent and would have had a reasonable expectation of success in doing so.

45. The claims of the '416 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art, including but not limited to the '341 patent. The differences between the subject matter claimed in the '416 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

46. The claims of the '416 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

47. Unless Plaintiff/Counterclaim-Defendant is enjoined, Apotex believes that Plaintiff/Counterclaim-Defendant will continue to assert that Apotex infringes the claims of the '416 patent and will continue to interfere with Apotex's business.

48. Apotex will be irreparably harmed if Plaintiff/Counterclaim-Defendant is not enjoined from continuing to assert the claims of the '416 patent and from interfering with Apotex's business.

49. Apotex is entitled to a declaratory judgment that the asserted claims of the '416 patent are invalid.

COUNT V
Declaratory Judgment of Noninfringement of the '450 Patent

50. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 49 of the Counterclaims, as if fully set forth herein.

51. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiff/Counterclaim-Defendant regarding whether the manufacture, use,

offer for sale, sale, or importation of Apotex's ANDA Product will infringe any claim of the '450 patent.

52. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '450 patent and alleges that Apotex has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '450 patent.

53. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '450 patent.

54. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '450 patent.

COUNT VI
Declaratory Judgment of Invalidity of the '450 Patent

55. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 54 of the Counterclaims, as if fully set forth herein.

56. Plaintiff/Counterclaim-Defendant has accused Apotex of infringing claims of the '450 patent in connection with ANDA No. 219256.

57. Apotex denies infringement of any claim of the '450 patent because all claims of the '450 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '450 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

58. The alleged inventions of the '450 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '450 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions of the '450 patent and would have had a reasonable expectation of success in doing so.

59. The claims of the '450 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art, including but not limited to the '341 and '416 patents. The differences between the subject matter claimed in the '450 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

60. The claims of the '450 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

61. Unless Plaintiff/Counterclaim-Defendant is enjoined, Apotex believes that Plaintiff/Counterclaim-Defendant will continue to assert that Apotex infringes the claims of the '450 patent and will continue to interfere with Apotex's business.

62. Apotex will be irreparably harmed if Plaintiff/Counterclaim-Defendant is not enjoined from continuing to assert the claims of the '450 patent and from interfering with Apotex's business.

63. Apotex is entitled to a declaratory judgment that the asserted claims of the '450 patent are invalid.

COUNT VII
Declaratory Judgment of Noninfringement of the '352 Patent

64. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 63 of the Counterclaims, as if fully set forth herein.

65. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Plaintiff/Counterclaim-Defendant regarding whether the manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product will infringe any claim of the '352 patent.

66. Apotex denies infringement of any valid, enforceable, and properly construed claim of the '352 patent and alleges that Apotex has not, does not, and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, and properly construed claim of the '352 patent.

67. The manufacture, use, sale, or offer for sale within, and/or importation into the United States of Apotex's ANDA Products does not and will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, and properly construed claim of the '352 patent.

68. Apotex is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Apotex's ANDA Products does not and will not infringe any valid and/or enforceable claim of the '352 patent.

COUNT VIII
Declaratory Judgment of Invalidity of the '352 Patent

69. Apotex incorporates each of its responses to each Paragraph of the Complaint, as well as the foregoing paragraphs 1 through 68 of the Counterclaims, as if fully set forth herein.

70. Plaintiff/Counterclaim-Defendant has accused Apotex of infringing claims of the '352 patent in connection with ANDA No. 219256.

71. Apotex denies infringement of any claim of the '352 patent because all claims of the '352 patent are invalid for failure to meet one or more of the conditions of patentability specified in Title 35 of the United States Code. Given their invalidity, Apotex cannot infringe any claims of the '352 patent, including for at least the reasons set forth in the detailed statements included with Apotex's Notice Letter.

72. The alleged inventions of the '352 patent do no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '352 patent is no more than the predictable use of prior art elements. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged inventions of the '352 patent and would have had a reasonable expectation of success in doing so.

73. The claims of the '352 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art, including but not limited to the '341, '416, and '450 patents. The differences between the subject matter claimed in the '352 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious, at the time that the alleged inventions were made, to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

74. The claims of the '352 patent are further invalid for failure to satisfy the requirements of 35 U.S.C. § 112.

75. Unless Plaintiff/Counterclaim-Defendant is enjoined, Apotex believes that Plaintiff/Counterclaim-Defendant will continue to assert that Apotex infringes the claims of the '352 patent and will continue to interfere with Apotex's business.

76. Apotex will be irreparably harmed if Plaintiff/Counterclaim-Defendant is not enjoined from continuing to assert the claims of the '352 patent and from interfering with Apotex's business.

77. Apotex is entitled to a declaratory judgment that the asserted claims of the '352 patent are invalid.

EXCEPTIONAL CASE

This case is an exceptional one and Apotex is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Apotex prays that the Court enter judgment in its favor and against Plaintiff/Counterclaim-Defendant as follows:

- a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiff/Counterclaim-Defendant therein;
- b) Declaring that the claims of the Patents-in-Suit are not and will not be infringed;
- c) Declaring that the claims of the Patents-in-Suit are invalid or unenforceable;
- d) Entering judgment in Apotex's favor;
- e) Finding that this case is exceptional pursuant to 35 U.S.C. § 285 and granting an award of Apotex's attorneys' fees and costs to the extent permitted by law; and
- f) Granting Apotex any and all other relief to which Apotex may be justly entitled.

Dated: May 24, 2024

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