IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

DUCHESNAY INC. Plaintiff, v. ACTAVIS LABORATORIES FL, INC. and TEVA PHARMACEUTICALS USA, INC., Defendants.	)	C.A. No. 18-1895-RGA

DEFENDANTS ACTAVIS LABORATORIES FL, INC. AND TEVA PHARMACEUTICALS USA, INC.'S ANSWER, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS

Defendants Actavis Laboratories FL, Inc. ("Actavis") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Defendants"), through their attorneys, hereby submit this Answer, Affirmative Defenses, and Counterclaims to the Complaint filed by Plaintiff Duchesnay, Inc. ("Duchesnay").

ANSWER TO COMPLAINT

Each of the Paragraphs below corresponds to the same-numbered Paragraphs in the Complaint. Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. Defendants deny that Plaintiff is entitled to the relief requested or any other relief.

Defendants, through their attorneys, respond to the Complaint as follows:

NATURE OF THE ACTION

1. Defendants state that the allegations set forth in Paragraph 1 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants admit that the Complaint purports to state an action for patent infringement arising under the patent laws of the United States, Titles 35, United States Code, concerning an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Bonjesta® prior to the expiration of U.S. Patent Nos. 9,089,489 ("the '489 patent"), 9,375,404 ("the '404 patent"), 9,526,703 ("the '703 patent"), and 9,937,132 ("the '132 patent"). Defendants admit that the '489, '404, '703, and '132 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for Bonjesta®. Defendants deny the remaining allegations of Paragraph 1.

THE PARTIES

2. Defendants repeat and incorporate here by reference its responses to Paragraph 1.

3. Defendants admit upon information and belief, based on the facts alleged in the Complaint, that Plaintiff Duchesnay is a Canadian corporation having its corporate office at 950 Boulevard Michèle-Bohec, Blainville, Québec, Canada J7C 5E2. Defendants are without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 3 of the Complaint and therefore deny the same.

4. Defendants admit that Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1090 Horsham Road, North Wales, PA 19454. Defendants admit that Teva USA is in the business of developing and manufacturing pharmaceutical products. Defendants deny the remaining allegations of Paragraph 4.

5. Defendants admit that Teva USA is a wholly-owned subsidiary of Teva Pharmaceutical Industries Ltd. ("Teva Ltd."). Defendants admit that Teva Ltd. has United States subsidiaries, some of which are incorporated in Delaware. Defendants are without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 5 of the Complaint and therefore deny the same.

6. Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action, and therefore no further answer is required. To the extent an answer is required, Defendants admit that Teva Ltd. is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tikva, 49131, Israel. Defendants admit that Teva Ltd. is in the business of developing and manufacturing pharmaceutical products. Defendants deny the remaining allegations of Paragraph 6.

7. Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action, and therefore no further answer is required. To the extent an answer is required, Defendants admit that Teva Ltd. has United States subsidiaries, some of which are incorporated in Delaware. Defendants are without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 7 of the Complaint and therefore deny the same.

8. Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action, and therefore no further answer is required as to Teva Ltd. To the extent an answer is required, Defendants admit that Teva USA acquired Actavis in August of 2016. Defendants deny the remaining allegations of Paragraph 8.

9. Defendants admit that Actavis is a corporation organized and existing under the laws of the State of Florida. Defendants admit that Actavis is in the business of developing, and

manufacturing pharmaceutical products. Defendants deny the remaining allegations of Paragraph 9.

10. Defendants admit that Actavis is a subsidiary of Teva Ltd. Defendants admit that Teva Ltd. has United States subsidiaries, some of which are incorporated in Delaware. Defendants are without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 10 of the Complaint and therefore deny the same.

11. Defendants admit that Actavis and Teva USA are indirect wholly-owned subsidiaries of Teva Ltd. Defendants further respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action, and therefore no further answer is required as to Teva Ltd. Defendants deny the remaining allegations of Paragraph 11.

12. Defendants admit that Teva USA prepared and submitted ANDA No. 212472. Defendants further respond that Teva Ltd. is no longer a party to this action. Defendants deny the remaining allegations of Paragraph 12.

JURISDICTION AND VENUE

13. Defendants repeat and incorporate here by reference its responses to Paragraphs 1–12.

14. Defendants state that the allegations set forth in Paragraph 14 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants admit that the Complaint purports to state claims arising under the patent laws of the United States and the Declaratory Judgment Act, and that this Court has subject matter jurisdiction over the action; Defendants deny the remaining allegations of Paragraph 14.

15. Defendants state that the allegations set forth in Paragraph 15 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Defendants for purposes of this

action only. Defendants further respond that Teva Ltd. is no longer a party to this action pursuant to D.I. 9. Defendants deny the remaining allegations of Paragraph 15.

16. Defendants state that the allegations set forth in Paragraph 16 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Teva USA for purposes of this action only. Defendants admit that Teva USA is incorporated in Delaware. Defendants deny the remaining allegations of Paragraph 16.

17. Defendants state that the allegations set forth in Paragraph 17 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Teva USA for purposes of this action only; Defendants deny the remaining allegations of Paragraph 17.

18. Defendants state that the allegations set forth in Paragraph 18 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Teva USA for purposes of this action only; Defendants deny the remaining allegations of Paragraph 18.

19. Defendants state that the allegations set forth in Paragraph 19 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Teva USA for purposes of this action only. Defendants admit that Teva USA was involved in the preparation and submission of ANDA No. 212472 with a Paragraph IV Certification regarding the ’489, ’404, ’703, and ’132 patents. Defendants deny the remaining allegations of Paragraph 19.

20. Defendants state that the allegations set forth in Paragraph 20 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is

required, Defendants do not contest personal jurisdiction over Teva USA for purposes of this action only. Defendants admit that Teva USA was named as a party in *Teva Pharmaceuticals USA, Inc. et al. v. Biocon Ltd. et al.*, Civ. Action No. 1:16-cv-00278 (D. Del. 2016); *Teva Pharmaceuticals USA, Inc. v. Dr. Reddy's Laboratories, Ltd.*, Civ. Action No. 1:16-cv-01267 (D. Del. 2016); *Novartis Pharmaceuticals Corp. v. Teva Pharmaceuticals USA, Inc., et al*, Civ. Action No. 1:18-cv-01039 (D. Del. 2018); *Galderma Laboratories LP et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. Action No. 1:17-cv-01783 (D. Del. 2017); *Adverio Pharma GmbH et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. Action No. 1:18-cv-00112 (D. Del. 2018). Defendants deny the remaining allegations of Paragraph 20.

21. Defendants state that the allegations set forth in Paragraph 21 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Teva USA for purposes of this action only; Defendants deny the remaining allegations of Paragraph 21.

22. Defendants state that the allegations set forth in Paragraph 22 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action, and therefore no further answer is required. To the extent an answer is required, Defendants refer to the language of D.I. 9 regarding Teva Ltd.'s agreement to be bound and agreement not to contest personal jurisdiction or venue in this Court for purposes of enforcing any such judgment or order against it. Defendants deny the remainder of paragraph 22.

23. Defendants state that the allegations set forth in Paragraph 23 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this

action is no longer a party to this action, and therefore no further answer is required. To the extent an answer is required, Defendants refer to the language of D.I. 9 regarding Teva Ltd.'s agreement to be bound and agreement not to contest personal jurisdiction or venue in this Court for purposes of enforcing any such judgment or order against it. Defendants deny the remainder of paragraph 23.

24. Defendants state that the allegations set forth in Paragraph 24 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action and no further answer is required. To the extent an answer is required, Defendants refer to the language of D.I. 9 regarding Teva Ltd.'s agreement to be bound and agreement not to contest personal jurisdiction or venue in this Court for purposes of enforcing any such judgment or order against it. Defendants deny the remainder of paragraph 24.

25. Defendants state that the allegations set forth in Paragraph 25 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action and no further answer is required. To the extent an answer is required, Defendants refer to the language of D.I. 9 regarding Teva Ltd.'s agreement to be bound and agreement not to contest personal jurisdiction or venue in this Court for purposes of enforcing any such judgment or order against it. Defendants deny the remainder of paragraph 25.

26. Defendants state that the allegations set forth in Paragraph 26 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action and no further answer is required. To the extent an answer is required, Defendants refer to

the language of D.I. 9 regarding Teva Ltd.'s agreement to be bound and agreement not to contest personal jurisdiction or venue in this Court for purposes of enforcing any such judgment or order against it. Defendants admit that Teva Ltd. has been a named party in the cases listed in Paragraph 26. Defendants deny the remainder of paragraph 26.

27. Defendants state that the allegations set forth in Paragraph 27 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants respond that in accordance with D.I. 9, Teva Ltd. is no longer a party to this action and no further answer is required. To the extent an answer is required, Defendants refer to the language of D.I. 9 regarding Teva Ltd.'s agreement to be bound and agreement not to contest personal jurisdiction or venue in this Court for purposes of enforcing any such judgment or order against it. Defendants deny the remainder of paragraph 27.

28. Defendants state that the allegations set forth in Paragraph 28 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Actavis for purposes of this action only; Defendants deny the remaining allegations of Paragraph 28.

29. Defendants state that the allegations set forth in Paragraph 29 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Actavis for purposes of this action only; Defendants deny the remaining allegations of Paragraph 29.

30. Defendants state that the allegations set forth in Paragraph 30 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Actavis for purposes of this action only. Defendants admit that Actavis was involved in the preparation and submission of ANDA

No. 212472 with a Paragraph IV Certification regarding the '489, '404, '703, and '132 patents. Defendants further respond that the remainder of the allegations of Paragraph 30 require speculation as to future events, and therefore Defendants deny the same.

31. Defendants state that the allegations set forth in Paragraph 31 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Actavis for purposes of this action only. Defendants admit that Actavis was named as a party in *Cosmo Technologies Ltd. v. Actavis Laboratories FL, Inc. et al.,* Civ. Action No. 1:18-cv-01006 (D. Del. 2018); *Valeant Pharmaceuticals Intl. et al. v. Actavis Laboratories FL, Inc. et al.*, Civ. Action No. 1:18-cv-01288 (D. Del. 2018); *Shire Development LLC et al. v. Teva Pharmaceuticals USA, Inc. et al.*, Civ. Action No. 1:17-cv-01696 (D. Del. 2017). Defendants deny the remainder of the allegations set forth in Paragraph 31.

32. Defendants state that the allegations set forth in Paragraph 32 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Actavis for purposes of this action only; Defendants deny the remaining allegations of Paragraph 32.

33. Defendants state that the allegations set forth in Paragraph 33 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest personal jurisdiction over Teva USA and Actavis for purposes of this action only. Defendants further respond that Teva Ltd. is no longer a party to this action and no further answer is required. Defendants deny the remaining allegations of Paragraph 33.

34. Defendants state that the allegations set forth in Paragraph 34 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants do not contest venue in this Court for purposes of this action only.

THE PATENTS-IN-SUIT

35. Defendants repeat and incorporate here by reference its responses to Paragraphs 1–34.

36. Defendants admit that the ’489 patent states on its face that it is titled “Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof,” and that it further states that it issued on July 28, 2015 to Manon Vranderick, Jean-Luc St-Onge, Christelle Gedeon, Michele Gallo, and Éric Gervais. Defendants also admit that Exhibit A purports to be a copy of the ’489 patent. The remaining allegations set forth in Paragraph 36 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

37. Defendants admit that the ’404 patent states on its face that it is titled “Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof,” and that it further states that it issued on June 28, 2016 to Manon Vranderick, Jean-Luc St-Onge, Christelle Gedeon, Michele Gallo, and Éric Gervais. Defendants also admit that Exhibit B purports to be a copy of the ’404 patent. The remaining allegations set forth in Paragraph 37 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

38. Defendants admit that the ’703 patent states on its face that it is titled “Plurimodal Release Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof,” and that it further states that it issued on December 27, 2016 to Manon Vranderick, Jean-Luc St-Onge, Michele Gallo, and Éric Gervais. Defendants also admit that Exhibit C purports to be a

copy of the ’703 patent. The remaining allegations set forth in Paragraph 38 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

39. Defendants admit that the ’132 patent states on its face that it is titled “Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof,” and that it further states that it issued on April 10, 2018 to Manon Vranderick, Jean-Luc St-Onge, Christelle Gedeon, Michele Gallo, and Éric Gervais. Defendants also admit that Exhibit D purports to be a copy of the ’132 patent. The remaining allegations set forth in Paragraph 39 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

40. Defendants admit that the ’489, ’404, ’703, and ’132 patents appear to be listed in the Orange Book corresponding to NDA No. 209661. Defendants are without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 40 of the Complaint and therefore deny the same.

INFRINGEMENT BY DEFENDANTS

41. Defendants repeat and incorporate here by reference its responses to Paragraphs 1–40.

42. Defendants admit that Teva USA notified Plaintiff Duchesnay in a letter dated October 16, 2018 (“Teva’s Notice Letter”) that Teva USA had submitted to the FDA Teva USA’s ANDA No. 212472 (“the Teva ANDA”). Defendants deny the remaining allegations of Paragraph 42.

43. Defendants admit that Teva’s Notice Letter stated that Teva USA is seeking the FDA’s approval to engage in the commercial manufacture, use, or sale of Teva USA’s ANDA

Product ("Teva's ANDA Product") prior to the expiration of the patents-in-suit. Defendants deny the remaining allegations of Paragraph 43.

44. Defendants admit that Defendants Teva USA and Actavis were involved in the preparation and submission of ANDA No. 212472. Defendants respond that Teva Ltd. is no longer a party to this case, and as such no further answer is required as to Teva Ltd. Defendants deny the remaining allegations of Paragraph 44.

45. Defendants state that the allegations set forth in Paragraph 45 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

46. Defendants respond that the allegations of Paragraph 46 require speculation as to future events, and therefore Defendants deny the same.

47. Defendants admit that Teva's Notice Letter states that Teva's ANDA contains a Paragraph IV Certification stating Teva USA's opinion that the patents-in-suit are not valid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product.

48. Defendants state that the allegations set forth in Paragraph 48 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants admit that the Complaint was filed before expiration of the forty-five days from the date Duchesnay received Teva's Notice Letter.

COUNT I (INFRINGEMENT OF THE '489 PATENT)

49. Defendants repeat and incorporate here by reference its responses to Paragraphs 1–48.

50. Defendants admit that 35 U.S.C. §271(e)(2)(A) states that it shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and

Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent. Defendants admit to submission of ANDA No. 212472 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '489 patent. Defendants deny the remainder of the allegations in Paragraph 50.

51. Defendants state that the allegations set forth in Paragraph 51 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny that claims 1–26 and 29–30 of the '489 patent are infringed at least because said claims are invalid. The remainder of the allegations in Paragraph 51 is denied.

52. Denied.

53. Defendants admit that as of the filing of the Complaint, they had knowledge of the '489 patent and have filed the Teva ANDA seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product. Defendants state that the remaining allegations set forth in Paragraph 53 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

54. Denied.

55. Denied.

56. Defendants state that the allegations set forth in Paragraph 56 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

COUNT II (INFRINGEMENT OF THE '404 PATENT)

57. Defendants repeat and incorporate here by reference their responses to Paragraphs 1–56.

58. Defendants admit that 35 U.S.C. §271(e)(2)(A) states that it shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent. Defendants admit to submission of ANDA No. 212472 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '404 patent. Defendants deny the remainder of the allegations in Paragraph 58.

59. Defendants state that the allegations set forth in Paragraph 59 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny that claims 1–4, 16, and 18–19 of the '404 patent are infringed at least because said claims are invalid. The remainder of the allegations in Paragraph 59 is denied.

60. Denied.

61. Defendants admit that as of the filing of the Complaint, they had knowledge of the '404 patent and have filed the Teva ANDA seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product. Defendants state that the remaining allegations set forth in Paragraph 61 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

62. Denied.

63. Denied.

64. Defendants state that the allegations set forth in Paragraph 64 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

COUNT III (INFRINGEMENT OF THE '703 PATENT)

65. Defendants repeat and incorporate here by reference their responses to Paragraphs 1–64.

66. Defendants admit that 35 U.S.C. §271(e)(2)(A) states that it shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent. Defendants admit to submission of ANDA No. 212472 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '703 patent. Defendants deny the remainder of the allegations in Paragraph 66.

67. Defendants state that the allegations set forth in Paragraph 67 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny that claims 1–24, 28, and 30 of the '703 patent are infringed at least because said claims are invalid. The remainder of the allegations in Paragraph 67 is denied.

68. Denied.

69. Defendants admit that as of the filing of the Complaint, they had knowledge of the '703 patent and have filed the Teva ANDA seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product. Defendants state that the remaining allegations set forth in Paragraph 69 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

70. Denied.

71. Denied.

72. Defendants state that the allegations set forth in Paragraph 72 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

COUNT IV (INFRINGEMENT OF THE '132 PATENT)

73. Defendants repeat and incorporate here by reference their responses to Paragraphs 1–72.

74. Defendants admit that 35 U.S.C. §271(e)(2)(A) states that it shall be an act of infringement to submit an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent. Defendants admit to submission of ANDA No. 212472 seeking FDA approval to engage in the commercial manufacture, use, offer to sell, or sale of generic doxylamine succinate and pyridoxine hydrochloride extended-release tablets before expiration of the '132 patent. Defendants deny the remainder of the allegations in Paragraph 74.

75. Defendants state that the allegations set forth in Paragraph 75 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny that claims 1–12, 14, and 16–21 of the '132 patent are infringed at least because said claims are invalid. The remainder of the allegations in Paragraph 75 is denied.

76. Denied.

77. Defendants admit that as of the filing of the Complaint, they had knowledge of the '132 patent and have filed the Teva ANDA seeking approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product. Defendants state that the remaining allegations set forth in Paragraph 77 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

78. Denied.

79. Denied.

80. Defendants state that the allegations set forth in Paragraph 80 of the Complaint are legal conclusions to which no responsive pleading is necessary, but to the extent a response is required, Defendants deny the same.

PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to any of the relief sought in the prayer for relief or to any relief whatsoever.

AFFIRMATIVE AND SEPARATE DEFENSES

FIRST AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, and/or importation into the United States of the drug products described in ANDA No. 212472 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’489 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

THIRD AFFIRMATIVE DEFENSE

Each and every claim of the ’489 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

FOURTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, and/or importation into the United States of the drug products described in ANDA No. 212472 has not infringed, does not infringe, and will not

infringe any valid and enforceable claim of the ’404 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

FIFTH AFFIRMATIVE DEFENSE

Each and every claim of the ’404 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

SIXTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, and/or importation into the United States of the drug products described in ANDA No. 212472 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’703 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

SEVENTH AFFIRMATIVE DEFENSE

Each and every claim of the ’703 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

EIGHTH AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale, and/or importation into the United States of the drug products described in ANDA No. 212472 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the ’132 patent directly, indirectly, by inducement, contributorily, literally, under the doctrine of equivalents, or in any other manner.

NINTH AFFIRMATIVE DEFENSE

Each and every claim of the ’132 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103, and 112, and/or is invalid under the doctrine of obviousness-type double patenting.

TENTH AFFIRMATIVE DEFENSE

Plaintiff is barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

ELEVENTH AFFIRMATIVE DEFENSE

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

TWELFTH AFFIRMATIVE DEFENSE

Defendants reserve the right to allege additional affirmative defenses, as they become known through the course of discovery.

COUNTERCLAIMS

Without admitting any of the allegations of Duchesnay Inc. ("Duchesnay" or "Counterclaim Defendant") other than those expressly admitted herein, and without prejudice of the rights of Defendants to plead additional Counterclaims as the facts of the matter warrant, Actavis Laboratories FL, Inc. ("Actavis") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Defendants" or "Counterclaim Plaintiffs") hereby assert the following Counterclaims against Counterclaim Defendant.

INTRODUCTION

These Counterclaims seek a declaratory judgment that the Doxylamine Succinate and Pyridoxine Hydrochloride Extended-Release tablets ("Teva's ANDA Product") described in Teva's ANDA No. 212472 ("the Teva ANDA") do not infringe any valid and enforceable claim of U.S. Patent Nos. 9,089,489 ("the '489 patent"), 9,375,404 ("the '404 patent"), 9,526,703 ("the '703 patent"), and 9,937,132 ("the '132 patent"), and that each and every claim of the patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103 and 112.

THE PARTIES

1. Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454.

2. Actavis is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at 4955 Orange Drive, Davie, Florida 33314.

3. Upon information and belief, based on the facts alleged in the Complaint, Duchesnay is a Canadian corporation having its corporate office at 950 Boulevard Michèle-Bohec, Blainville, Québec, Canada J7C 5E2.

JURISDICTION AND VENUE

4. This is a declaratory judgment action arising under the patent laws of the United States, Title 35, United States Code. This Court has jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a), the patent laws of the United States set forth at 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. Personal jurisdiction over Duchesnay is proper because, *inter alia*, Duchesnay has consented to the personal jurisdiction of this Court by commencing its action for patent infringement in this Judicial District, as set forth in its Complaint and because, on information and belief, either directly or through agents, it transacts business in, and derives substantial revenue from, Delaware.

6. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400.

7. There is an actual justiciable controversy between the parties concerning non-infringement and invalidity of the ’489, ’404, ’703, and ’132 patents.

FACTUAL BACKGROUND

8. Upon information and belief, based on the facts alleged in the Complaint, Duchesnay is the apparent holder of the approved New Drug Application ("NDA") No. 209661 for Bonjesta®.

9. Upon information and belief, based on the facts alleged in the Complaint, the FDA lists the '489, '404, '703, and '132 patents in the Orange Book corresponding to NDA No. 209661 for Bonjesta®.

10. The '489 patent is entitled on its face "Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," and states that it was issued on July 28, 2015. **Exhibit A** of the Complaint is a true and correct copy of the '489 patent.

11. The '404 patent is entitled on its face "Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," and states that it was issued on June 28, 2016. **Exhibit B** of the Complaint is a true and correct copy of the '404 patent.

12. The '703 patent is entitled on its face "Plurimodal Release Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," and states that it was issued on December 27, 2016. **Exhibit C** of the Complaint is a true and correct copy of the '703 patent.

13. The '132 patent is entitled on its face "Formulation of Doxylamine and Pyridoxine and/or Metabolites or Salts Thereof," and states that it was issued on April 10, 2018. **Exhibit D** of the Complaint is a true and correct copy of the '132 patent.

14. Upon information and belief, based on the facts alleged in the Complaint, the '489, '404, '703, and '132 patents are each wholly assigned to and owned by Counterclaim Defendant Duchesnay.

15. Upon information and belief, Counterclaim Defendant caused the ’489, ’404, ’703, and ’132 patents to be listed in the Orange Book corresponding to NDA No. 209661 for Bonjesta®.

16. The Teva ANDA was filed by Teva USA seeking FDA approval to engage in the commercial manufacture, use or sale of Teva’s ANDA Product.

17. The Teva ANDA contained “paragraph IV certifications” under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the ’489, ’404, ’703, and ’132 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Teva’s ANDA Product.

18. On November 29, 2018, Counterclaim Defendant filed this lawsuit alleging infringement of the ’489, ’404, ’703, and ’132 patents.

COUNT I
DECLARATORY JUDGMENT OF INVALIDITY
OF THE ’489 PATENT

19. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–18 of these Counterclaims.

20. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the ’489 patent, based on Counterclaim Defendant’s allegations in its Complaint that Counterclaim Plaintiffs have infringed or will infringe the ’489 patent.

21. Each and every claim of the ’489 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the bases for which include, but are not limited to, one or more of the following:

(a) The alleged invention of the ’489 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the ’489 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

(c) The ’489 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the ’489 patent does 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 ’489 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’489 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the ’489 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the 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 the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The ’489 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(g) The claims of the ’489 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

22. Teva USA notified Counterclaim Defendant in a letter dated October 16, 2018 (“Teva’s Notice Letter”) that it had submitted ANDA No. 212472 (“the Teva ANDA”) to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Teva’s ANDA Product prior to the expiration of the ’489 patent. Teva’s Notice Letter included a detailed statement of factual and legal bases for the allegation that the claims of the ’489 patent are invalid. Teva USA incorporates by reference the factual and legal bases provided in Teva’s Notice Letter for the allegation that the claims of the ’489 patent are invalid.

23. Counterclaim Plaintiffs are entitled to a judicial declaration that all claims of the ’489 patent are invalid.

COUNT II
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’489 PATENT

24. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–23 of these Counterclaims.

25. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the Teva ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva’s ANDA Product infringes, has infringed,

or will infringe any valid and enforceable claim of the ’489 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

26. Counterclaim Plaintiffs have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’489 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

27. Counterclaim Plaintiffs have not infringed, is not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the ’489 patent. For example, the claims of the ’489 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112. Because one cannot infringe an invalid claim, the claims of the ’489 patent are not infringed, directly, indirectly, literally or under the doctrine of equivalents.

28. Teva’s Notice Letter included a detailed statement of factual and legal bases for the allegation that Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally or under the doctrine of equivalents, of the ’489 patent. Counterclaim Plaintiffs incorporate by reference the factual and legal bases provided in Teva’s Notice Letter for that allegation.

29. Counterclaim Plaintiffs are entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’489 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, and/or importation of Teva’s ANDA Product that is the subject of the Teva ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’489 patent either literally or under the doctrine of equivalents.

COUNT III
DECLARATORY JUDGMENT OF INVALIDITY OF THE '404 PATENT

30. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–29 of these Counterclaims.

31. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '404 patent, based on Counterclaim Defendant's allegations in its Complaint that Counterclaim Plaintiffs have infringed or will infringe the '404 patent.

32. Each and every claim of the '404 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the bases for which include, but are not limited to, one or more of the following:

(a) The alleged invention of the '404 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '404 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

(c) The '404 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '404 patent does 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 '404 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '404 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '404 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the 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 the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The '404 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(g) The claims of the '404 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

33. Teva USA notified Counterclaim Defendant in Teva's Notice Letter that it had submitted ANDA No. 212472 to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Teva's ANDA Product prior to the expiration of the '404 patent. Teva's Notice Letter included a detailed statement of factual and legal bases for the allegation that the claims of the '404 patent are invalid. Teva USA incorporates by reference the factual

and legal bases provided in Teva's Notice Letter for the allegation that the claims of the '404 patent are invalid.

34. Counterclaim Plaintiffs are entitled to a judicial declaration that all claims of the '404 patent are invalid.

COUNT IV
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '404 PATENT

35. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–34 of these Counterclaims.

36. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the Teva ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '404 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

37. Counterclaim Plaintiffs have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '404 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

38. Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '404 patent. For example, the claims of the '404 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112. Because one cannot infringe an invalid claim, the claims of the '404 patent are not infringed, directly, indirectly, literally or under the doctrine of equivalents.

39. Teva's Notice Letter included a detailed statement of factual and legal bases for the allegation that Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally or under the doctrine of equivalents, of the '404 patent. Counterclaim Plaintiffs incorporate by reference the factual and legal bases provided in Teva's Notice Letter for that allegation.

40. Counterclaim Plaintiffs are entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '404 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Product that is the subject of the Teva ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '404 patent either literally or under the doctrine of equivalents.

COUNT V
DECLARATORY JUDGMENT OF INVALIDITY OF THE '703 PATENT

41. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–40 of these Counterclaims.

42. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '703 patent, based on Counterclaim Defendant's allegations in its Complaint that Counterclaim Plaintiffs have infringed or will infringe the '703 patent.

43. Each and every claim of the '703 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the bases for which include, but are not limited to, one or more of the following:

(a) The alleged invention of the ’703 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the ’703 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

(c) The ’703 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the ’703 patent does 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 ’703 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’703 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the ’703 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the 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 the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The ’703 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(g) The claims of the ’703 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

44. Teva USA notified Counterclaim Defendant in Teva’s Notice Letter that it had submitted ANDA No. 212472 (“the Teva ANDA”) to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Teva’s ANDA Product prior to the expiration of the ’703 patent. Teva’s Notice Letter included a detailed statement of factual and legal bases for the allegation that the claims of the ’703 patent are invalid. Teva USA incorporates by reference the factual and legal bases provided in Teva’s Notice Letter for the allegation that the claims of the ’703 patent are invalid.

45. Counterclaim Plaintiffs are entitled to a judicial declaration that all claims of the ’703 patent are invalid.

COUNT VI
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’703 PATENT

46. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–45 of these Counterclaims.

47. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the Teva ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva’s ANDA Product infringes, has infringed,

or will infringe any valid and enforceable claim of the ’703 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

48. Counterclaim Plaintiffs have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’703 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

49. Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the ’703 patent. For example, the claims of the ’703 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112. Because one cannot infringe an invalid claim, the claims of the ’703 patent are not infringed, directly, indirectly, literally or under the doctrine of equivalents.

50. Teva’s Notice Letter included a detailed statement of factual and legal bases for the allegation that Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally or under the doctrine of equivalents, of the ’703 patent. Counterclaim Plaintiffs incorporate by reference the factual and legal bases provided in Teva’s Notice Letter for that allegation.

51. Counterclaim Plaintiffs are entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’703 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, and/or importation of Teva’s ANDA Product that is the subject of the Teva ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’703 patent either literally or under the doctrine of equivalents.

COUNT VII
DECLARATORY JUDGMENT OF INVALIDITY OF THE '132 PATENT

52. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–51 of these Counterclaims.

53. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding the invalidity of the '132 patent, based on Counterclaim Defendant's allegations in its Complaint that Counterclaim Plaintiffs have infringed or will infringe the '132 patent.

54. Each and every claim of the '132 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112, the bases for which include, but are not limited to, one or more of the following:

(a) The alleged invention of the '132 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

(b) The alleged invention of the '132 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

(c) The '132 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

(d) The alleged invention of the '132 patent does 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 '132 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '132 patent and would have had a reasonable expectation of success in doing so.

(e) The subject matter claimed in the '132 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the 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 the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

(f) The '132 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

(g) The claims of the '132 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

55. Teva USA notified Counterclaim Defendant in Teva's Notice Letter that it had submitted ANDA No. 212472 to the FDA seeking approval to engage in the commercial manufacture, use and/or sale of Teva's ANDA Product prior to the expiration of the '132 patent. Teva's Notice Letter included a detailed statement of factual and legal bases for the allegation that the claims of the '132 patent are invalid. Teva USA incorporates by reference the factual

and legal bases provided in Teva's Notice Letter for the allegation that the claims of the '132 patent are invalid.

56. Counterclaim Plaintiffs are entitled to a judicial declaration that all claims of the '132 patent are invalid.

COUNT VIII
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '132 PATENT

57. Counterclaim Plaintiffs re-allege and incorporate by reference the allegations in paragraphs 1–56 of these Counterclaims.

58. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of the Teva ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '132 patent either directly or indirectly, and either literally or under the doctrine of equivalents.

59. Counterclaim Plaintiffs have not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '132 patent either literally or under the doctrine of equivalents and are not liable for such infringement.

60. Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally, or under the doctrine of equivalents, of the '132 patent. For example, the claims of the '132 patent are invalid for at least failure to comply with one or more conditions for patentability set forth in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, and 112. Because one cannot infringe an invalid claim, the claims of the '132 patent are not infringed, directly, indirectly, literally or under the doctrine of equivalents.

61. Teva's Notice Letter included a detailed statement of factual and legal bases for the allegation that Counterclaim Plaintiffs have not infringed, are not infringing, and will not infringe any valid and enforceable claim, directly, indirectly, literally or under the doctrine of equivalents, of the '132 patent. Counterclaim Plaintiffs incorporate by reference the factual and legal bases provided in Teva's Notice Letter for that allegation.

62. Counterclaim Plaintiffs are entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '132 patent either literally or under the doctrine of equivalents; and that the manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Product that is the subject of the Teva ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '132 patent either literally or under the doctrine of equivalents.

COUNTERCLAIM PLAINTIFF'S PRAYER FOR RELIEF

Wherefore, Counterclaim Plaintiffs respectfully requests that this Court enter judgment in its favor and against Counterclaim Defendant, and issue an order:

A. Dismissing Counterclaim Defendants' Complaint with prejudice;

B. Declaring all claims of the '489, '404, '703, and '132 patents invalid;

C. Declaring that the filing of the Teva ANDA has not infringed and does not infringe any valid and enforceable claim, if any, of the '489, '404, '703, and '132 patents;

D. Declaring that Counterclaim Plaintiffs have not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, of the '489, '404, '703, and '132 patents;

E. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Product does not, and would not, if marketed,

directly or indirectly infringe any valid and enforceable claim, if any, of the '489, '404, '703, and '132 patents;

F. Declaring this case is an exceptional case in favor of Counterclaim Plaintiffs pursuant to 35 U.S.C. § 285;

G. Awarding costs and attorneys' fees to Counterclaim Plaintiffs;

H. Awarding Counterclaim Plaintiffs such other and further relief as the Court deems just and equitable.

/s/ Karen E. Keller

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