IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KERYX BIOPHARMACEUTICALS, INC. and PANION & BF BIOTECH, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGMENT

Plaintiffs Keryx Biopharmaceuticals, Inc. ("Keryx") and Panion & BF Biotech, Inc. ("Panion") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceuticals Industries Limited ("Teva Ltd.") (collectively, "Teva" or "Defendants"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, arising from Teva's submission of Abbreviated New Drug Application ("ANDA") No. 212563 ("Teva's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Keryx's AURYXIA® (Ferric Citrate) Tablets ("Teva's Proposed Product") prior to the expiration of United States Patent Nos. 7,767,851 (the "'851 patent"); 8,093,423 (the "'423 patent"); 8,299,298 (the "'298 patent"); 8,338,642 (the "'642 patent"); 8,609,896 (the "'896 patent"); 8,754,257 (the "'257 patent"); 8,754,258 (the "'258 patent"); 8,846,976 (the "'976 patent"); 8,901,349 (the "'349 patent"); 9,050,316 (the "'316

patent"); 9,328,133 (the "'133 patent"); 9,387,191 (the "'191 patent"); and 9,757,416 (the "'416 patent") (collectively, the "patents-in-suit"), owned by Plaintiffs.

The Parties

2. Plaintiff Keryx is a corporation organized and existing under the laws of Delaware with a principal place of business at One Marina Park Drive, Twelfth Floor, Boston, Massachusetts 02210.

3. Plaintiff Panion is a corporation organized and existing under the laws of Taiwan, with its principal place of business at 16F No. 3, Yuanqu Street, Nangang District, Taipei, Taiwan.

4. On information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

5. On information and belief, Teva Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

6. On information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

7. On information and belief, Teva is in the business of marketing, distributing, and/or selling pharmaceutical drugs, including generic pharmaceutical drugs manufactured by Teva, throughout the United States, including in this Judicial District.

8. On information and belief, Teva USA, in conjunction with or under the direction of Teva Ltd., developed Teva's Proposed Product and/or prepared ANDA No. 212563 for submission. On information and belief, Teva Ltd. is the owner of DMF No. 29083 that covers the active pharmaceutical ingredient used in Teva's Proposed Product. On information and belief, upon receiving approval of ANDA No. 212563, Teva USA, in conjunction with or under

the direction of Teva Ltd., will manufacture, sell, offer to sell, and/or import Teva's Proposed Product in the United States, including in this district.

The Patents-in-Suit

9. On August 3, 2010, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '851 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '851 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '851 patent that are relevant to this litigation. A copy of the '851 patent is attached hereto as Exhibit A.

10. On January 10, 2012, the USPTO duly and lawfully issued the '423 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '423 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '423 patent that are relevant to this litigation. A copy of the '423 patent is attached hereto as Exhibit B.

11. On October 30, 2012, the USPTO duly and lawfully issued the '298 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Method of Making Same." The '298 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '298 patent that are relevant to this litigation. A copy of the '298 patent is attached hereto as Exhibit C.

12. On December 25, 2012, the USPTO duly and lawfully issued the '642 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '642 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '642 patent that are relevant to this litigation. A copy of the '642 patent is attached hereto as Exhibit D.

13. On December 17, 2013, the USPTO duly and lawfully issued the '896 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '896

patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '896 patent that are relevant to this litigation. A copy of the '896 patent is attached hereto as Exhibit E.

14. On June 17, 2014, the USPTO duly and lawfully issued the '257 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '257 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '257 patent that are relevant to this litigation. A copy of the '257 patent is attached hereto as Exhibit F.

15. On June 17, 2014, the USPTO duly and lawfully issued the '258 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '258 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '258 patent that are relevant to this litigation. A copy of the '258 patent is attached hereto as Exhibit G.

16. On September 30, 2014, the USPTO duly and lawfully issued the '976 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '976 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '976 patent that are relevant to this litigation. A copy of the '976 patent is attached hereto as Exhibit H.

17. On December 2, 2014, the USPTO duly and lawfully issued the '349 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '349 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '349 patent that are relevant to this litigation. A copy of the '349 patent is attached hereto as Exhibit I.

18. On June 9, 2015, the USPTO duly and lawfully issued the '316 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '316 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the

'316 patent that are relevant to this litigation. A copy of the '316 patent is attached hereto as Exhibit J.

19. On May 3, 2016, the USPTO duly and lawfully issued the '133 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '133 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '133 patent that are relevant to this litigation. A copy of the '133 patent is attached hereto as Exhibit K.

20. On July 12, 2016, the USPTO duly and lawfully issued the '191 patent, entitled, "Ferric Citrate Dosage Forms." The '191 patent is assigned to Keryx. A copy of the '191 patent is attached hereto as Exhibit L.

21. On September 12, 2017, the USPTO duly and lawfully issued the '416 patent, entitled "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '416 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '416 patent that are relevant to this litigation. A copy of the '416 patent is attached hereto as Exhibit M.

The AURYXIA® (Ferric Citrate) Drug Product

22. Keryx holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for ferric citrate, 210 mg tablets (NDA No. 205874), which it sells under the trade name AURYXIA®. AURYXIA® is an orally available, absorbable, iron-based medicine. AURYXIA® is FDA-approved for the control of serum phosphorus levels in adult patients with chronic kidney disease ("CKD") on dialysis, and for the treatment of iron deficiency anemia in adult patients with CKD not on dialysis. The claims of the patents-in-suit cover, *inter alia*, novel forms of ferric citrate, methods of controlling phosphate retention, methods of decreasing serum calcium levels, and methods of treating hyperphosphatemia.

23. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to AURYXIA®.

Jurisdiction and Venue

24. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

25. On information and belief, Teva USA, with the participation of Teva Ltd., has submitted, caused to be submitted, or aided and abetted in the preparation of Teva's ANDA. On information and belief, upon FDA approval of Teva's ANDA, Teva USA, with the participation of Teva Ltd., intends to commercially manufacture, import, market, offer for sale, and/or sell Teva's Proposed Product throughout the United States including in this District.

26. This Court has personal jurisdiction over Teva USA for the reason that, *inter alia*, Teva USA is incorporated in this State. On information and belief, Teva USA's registered agent in the State of Delaware is Corporate Creations Network Inc. located at 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810. On information and belief, Teva USA holds Pharmacy Wholesale Licenses from the State of Delaware under License Nos. A4-0001447 and -0001468 and Distributor/Manufacturer Licenses for Controlled Substances from the State of Delaware under License Nos. DM-0007115 and -0006546. On information and belief, Teva USA purposefully has conducted and continues to conduct business in this Judicial District.

27. On information and belief, Teva USA is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug product

described in Teva's ANDA. On information and belief, Teva USA also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

28. This Court has personal jurisdiction over Teva Ltd. because, inter alia, it: (1) has purposefully availed itself of the privilege of doing business in Delaware, including directly or indirectly through its subsidiary, agent, and/or alter ego, Teva USA, a company that is incorporated in the State of Delaware and holds licenses with the State of Delaware as pharmacy wholesaler and distributor/manufacturer of controlled substances; and (2) maintains extensive and systematic contacts with the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in Delaware including through, directly or indirectly, Teva USA.

29. Teva Ltd.'s Securities and Exchange Commission Form 10-K filing states that it is "the leading generic drug company in the United States" and that it markets "over 500 generic prescription and OTC products in more than 1,800 dosage strengths and packaging sizes, including oral solid dosage forms, injectable products, inhaled products, liquids, ointments and creams." Teva Ltd. Securities and Exchange Commission Form 10-K (for the fiscal year ended December 31, 2017) ("Teva Ltd. Form 10-K") at 6. The Teva Ltd. Form 10-K further states that its annual "[r]evenues of generic medicines in the United States, [its] largest generics market, were $5.0 billion . . . ." *Id*. at 61. It further states that Teva Ltd.'s "generic medicines pipeline in the United States includes, as of December 31, 2017, 343 product applications awaiting FDA approval, including 84 tentative approvals." *Id*. at 64.

30. On information and belief, Teva USA and Teva Ltd. work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

31. On information and belief, Teva USA acts at the direction, and for the benefit, of Teva Ltd., and is controlled and/or dominated by Teva Ltd.

32. On information and belief, Teva USA and Teva Ltd. operate as a single integrated business.

33. On information and belief, both Teva USA and Teva Ltd. have previously been sued in this Judicial District and have not challenged personal jurisdiction. *See*, *e.g.*, *Insys Therapeutics, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 18-1308-CFC (D.Del.).

34. Teva USA and Teva Ltd. have further availed themselves of the jurisdiction of this Court by previously initiating litigation in this Judicial District. *See*, *e.g.*, *Teva Pharmaceuticals USA, Inc., et al. v. Mylan Pharmaceuticals Inc.*, No. 17-0249-GMS (D. Del.), and *Teva Pharmaceuticals USA, Inc. v. Doctor Reddy's Labs., Ltd.*, No. 16-1267-GMS (D. Del.).

35. In the alternative, this Court has personal jurisdiction over Teva Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting ANDAs to the FDA and/or manufacturing, importing, offering to sell, and/or selling pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

36. Venue is proper for Teva Ltd. pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) including because, *inter alia*, Teva Ltd. is a foreign corporation.

37. Venue is proper for Teva USA in this Judicial District pursuant to 28 U.S.C. § 1400(b) because Teva USA is incorporated in this district.

38. On information and belief, both Teva USA and Teva Ltd. have been previously sued in this Judicial District and have not challenged venue. *See*, *e.g.*, *Insys Therapeutics, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 18-1308-CFC (D.Del.).

Acts Giving Rise to This Suit

39. Pursuant to Section 505 of the FFDCA, Teva USA filed Teva's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product before the patents-in-suit expire.

40. On information and belief, following FDA approval of Teva's ANDA, Teva will manufacture, use, offer to sell, or sell Teva's Proposed Product throughout the United States, or import such generic products into the United States.

41. On information and belief, in connection with the filing of its ANDA as described above, Teva provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), ("Teva's Paragraph IV Certification") alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Teva's ANDA.

42. No earlier than November 5, 2018, Teva sent written notice of its Paragraph IV Certification to Plaintiffs ("Teva's Notice Letter"). Teva's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Teva's ANDA. Teva's Notice Letter also informed Plaintiffs that Teva seeks approval to market Teva's Proposed Product before the patents-in-suit expire.

43. In Teva's Notice Letter, Teva offered to provide access to certain confidential information and materials within Teva's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

Teva's offer of confidential access was conditioned on terms identified in Teva's Notice Letter. The terms and conditions of Teva's offer of confidential access were unreasonable and beyond those that would apply under a protective order. The restrictions Teva has placed on access to its ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III). The parties did not reach an agreement on the terms of such confidential access. To date, Teva has not provided any portion of its ANDA to Plaintiffs.

44. This Complaint is being filed before expiration of the forty-five days from the date Plaintiffs received Teva's Notice Letter.

Count I: Infringement of the '851 Patent

45. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

46. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '851 patent, constitutes infringement of one or more of the claims of the '851 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

47. A justiciable controversy exists between the parties hereto as to the infringement of the '851 patent.

48. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '851 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

49. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '851 patent is not enjoined.

50. Plaintiffs do not have an adequate remedy at law.

51. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '423 Patent

52. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

53. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '423 patent, constitutes infringement of one or more of the claims of the '423 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1-7.

54. A justiciable controversy exists between the parties hereto as to the infringement of the '423 patent.

55. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '423 patent under 35 U.S.C. § 271(b), including at least claims 1-7, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '423 patent and with knowledge that its acts are encouraging infringement.

56. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '423 patent under 35 U.S.C. § 271(c), including at least claims 1-7, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '423 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

57. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '423 patent is not enjoined.

58. Plaintiffs do not have an adequate remedy at law.

59. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '298 Patent

60. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

61. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '298 patent, constitutes infringement of one or more of the claims of the '298 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

62. A justiciable controversy exists between the parties hereto as to the infringement of the '298 patent.

63. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '298 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

64. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '298 patent is not enjoined.

65. Plaintiffs do not have an adequate remedy at law.

66. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '642 Patent

67. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

68. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '642 patent, constitutes infringement of one or more of the claims of the '642 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 8-10, and 17-18.

69. A justiciable controversy exists between the parties hereto as to the infringement of the '642 patent.

70. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '642 patent under 35 U.S.C. § 271(a), including at least claims 1 and 10, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

71. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '642 patent under 35 U.S.C. § 271(b), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '642 patent and with knowledge that its acts are encouraging infringement.

72. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '642 patent under 35 U.S.C. § 271(c), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that

Teva's Proposed Product is designed for a use that infringes one or more claims of the '642 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

73. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '642 patent is not enjoined.

74. Plaintiffs do not have an adequate remedy at law.

75. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '896 Patent

76. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

77. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '896 patent, constitutes infringement of one or more of the claims of the '896 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

78. A justiciable controversy exists between the parties hereto as to the infringement of the '896 patent.

79. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '896 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

80. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '896 patent is not enjoined.

81. Plaintiffs do not have an adequate remedy at law.

82. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '257 Patent

83. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

84. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '257 patent, constitutes infringement of one or more of the claims of the '257 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

85. A justiciable controversy exists between the parties hereto as to the infringement of the '257 patent.

86. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '257 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

87. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '257 patent is not enjoined.

88. Plaintiffs do not have an adequate remedy at law.

89. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count VII: Infringement of the '258 Patent

90. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

91. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '258 patent, constitutes infringement of one or more of the claims of the '258 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

92. A justiciable controversy exists between the parties hereto as to the infringement of the '258 patent.

93. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '258 patent under 35 U.S.C. § 271(a), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

94. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '258 patent is not enjoined.

95. Plaintiffs do not have an adequate remedy at law.

96. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count VIII: Infringement of the '976 Patent

97. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

98. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '976 patent, constitutes infringement of one or more of the claims of the '976 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

99. A justiciable controversy exists between the parties hereto as to the infringement of the '976 patent.

100. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '976 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '976 patent and with knowledge that its acts are encouraging infringement.

101. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '976 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

102. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '976 patent is not enjoined.

103. Plaintiffs do not have an adequate remedy at law.

104. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count IX: Infringement of the '349 Patent

105. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

106. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '349 patent, constitutes infringement of one or more of the claims of the '349 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

107. A justiciable controversy exists between the parties hereto as to the infringement of the ’349 patent.

108. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will induce infringement of one or more claims of the ’349 patent under 35 U.S.C. § 271(b), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva’s Proposed Product in the United States. On information and belief, upon FDA approval of Teva’s ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the ’349 patent and with knowledge that its acts are encouraging infringement.

109. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will contributorily infringe one or more claims of the ’349 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Teva’s Proposed Product in the United States. On information and belief, Teva knew and knows that Teva’s Proposed Product is designed for a use that infringes one or more claims of the ’349 patent, and Teva’s Proposed Product lacks a substantial non-infringing use.

110. Plaintiffs will be substantially and irreparably damaged and harmed if Teva’s infringement of the ’349 patent is not enjoined.

111. Plaintiffs do not have an adequate remedy at law.

112. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

Count X: Infringement of the ’316 Patent

113. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

114. Teva’s submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva’s Proposed Product, prior to the

expiration of the ’316 patent, constitutes infringement of one or more of the claims of the ’316 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1 and 12.

115. A justiciable controversy exists between the parties hereto as to the infringement of the ’316 patent.

116. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will induce infringement of one or more claims of the ’316 patent under 35 U.S.C. § 271(b), including at least claims 1 and 12, by making, using, offering to sell, selling, and/or importing Teva’s Proposed Product in the United States. On information and belief, upon FDA approval of Teva’s ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the ’316 patent and with knowledge that its acts are encouraging infringement.

117. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will contributorily infringe one or more claims of the ’316 patent under 35 U.S.C. § 271(c), including at least claims 1 and 12, by making, using, offering to sell, selling, and/or importing Teva’s Proposed Product in the United States. On information and belief, Teva knew and knows that Teva’s Proposed Product is designed for a use that infringes one or more claims of the ’316 patent, and Teva’s Proposed Product lacks a substantial non-infringing use.

118. Plaintiffs will be substantially and irreparably damaged and harmed if Teva’s infringement of the ’316 patent is not enjoined.

119. Plaintiffs do not have an adequate remedy at law.

120. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

Count XI: Infringement of the ’133 Patent

121. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

122. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '133 patent, constitutes infringement of one or more of the claims of the '133 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 8-10, and 17-18.

123. A justiciable controversy exists between the parties hereto as to the infringement of the '133 patent.

124. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '133 patent under 35 U.S.C. § 271(a), including at least claims 1 and 10, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

125. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '133 patent under 35 U.S.C. § 271(b), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '133 patent and with knowledge that its acts are encouraging infringement.

126. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '133 patent under 35 U.S.C. § 271(c), including at least claims 8-9 and 17-18, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '133 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

127. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '133 patent is not enjoined.

128. Plaintiffs do not have an adequate remedy at law.

129. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XII: Infringement of the '191 Patent

130. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

131. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '191 patent, constitutes infringement of one or more of the claims of the '191 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 6, 11 and 16.

132. A justiciable controversy exists between the parties hereto as to the infringement of the '191 patent.

133. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '191 patent under 35 U.S.C. § 271(a), including at least claims 1, 6, 11 and 16, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States.

134. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '191 patent is not enjoined.

135. Plaintiffs do not have an adequate remedy at law.

This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

Count XIII: Infringement of the '416 Patent

136. Plaintiffs repeat and reallege the allegations of the preceding paragraphs as if fully set forth herein.

137. Teva's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Teva's Proposed Product, prior to the expiration of the '416 patent, constitutes infringement of one or more of the claims of the '416 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 12, 23, and 30.

138. A justiciable controversy exists between the parties hereto as to the infringement of the '416 patent.

139. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '416 patent under 35 U.S.C. § 271(b), including at least claims 1, 12, 23, and 30, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '416 patent and with knowledge that its acts are encouraging infringement.

140. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '416 patent under 35 U.S.C. § 271(c), including at least claims 1, 12, 23 and 30, by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in the United States. On information and belief, Teva knew and knows that Teva's Proposed Product is designed for a use that infringes one or more claims of the '416 patent, and Teva's Proposed Product lacks a substantial non-infringing use.

141. Plaintiffs will be substantially and irreparably damaged and harmed if Teva's infringement of the '416 patent is not enjoined.

142. Plaintiffs do not have an adequate remedy at law.

143. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Teva has infringed the patents-in-suit by submitting ANDA No. 212563 to the FDA;

B. A Judgment that Teva has infringed, and that Teva's commercial manufacture, use, offer to sell, sale, or importation of Teva's Proposed Product will infringe one or more claims of the patents-in-suit;

C. An Order that the effective date of FDA approval of ANDA No. 212563 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

D. Preliminary and permanent injunctions enjoining Teva and its officers, agents, attorneys and employees, and those acting in concert with them, from making, using, offering to sell, selling, or importing Teva's Proposed Product until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

E. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, its officers, agents, attorneys and employees, and those acting in privity or concert with them, from practicing the devices, compositions, formulations, and methods of use and administration claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of claims of the patents-in-suit, until after the expiration of the patents-in-suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

F. A Judgment that the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva's Proposed Product will directly infringe, induce, and/or contribute to infringement of the patents-in-suit;

G. To the extent that Teva has committed any acts with respect to the devices, compositions, formulations, and methods of use and administration claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

H. If Teva engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiffs resulting from such infringement, together with interest;

I. A Judgment declaring that the patents-in-suit remain valid and enforceable;

J. A Judgment finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Plaintiffs their attorneys' fees incurred in this action;

K. A Judgment awarding Plaintiffs their costs and expenses incurred in this action; and

L. Such further and other relief as this Court may deem just and proper.

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