IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, and TAKEDA PHARMACEUTICALS U.S.A., INC.	)	
Plaintiffs,	)	C.A. No. ____
v.	)	
NORWICH PHARMACEUTICALS, INC., ALVOGEN PB RESEARCH AND DEVELOPMENT LLC, ALVOGEN PHARMA US, INC., and ALVOGEN GROUP, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Takeda Pharmaceutical Company Limited and Takeda Pharmaceuticals U.S.A., Inc. (collectively, "Takeda"), by its undersigned attorneys, for its Complaint against defendants Norwich Pharmaceuticals, Inc. ("Norwich"), Alvogen PB Research and Development LLC ("Alvogen PB"), Alvogen Pharma US, Inc. ("Alvogen US"), and Alvogen Group, Inc. ("Alvogen Group") (collectively, "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,105,486 ("the '486 patent") (attached as Exhibit A hereto); United States Patent No. 7,223,735 ("the '735 patent") (attached as Exhibit B hereto); United States Patent No. 7,655,630 ("the '630 patent") (attached as Exhibit C hereto); United States Patent No. 7,659,253 ("the '253 patent") (attached as Exhibit D hereto); United States Patent No. 7,659,254 ("the '254 patent") (attached as Exhibit E hereto); United States Patent No. 7,662,787 ("the '787 patent")

(attached as Exhibit F hereto); United States Patent No. 7,662,788 ("the '788 patent") (attached as Exhibit G hereto); United States Patent No. 7,671,030 ("the '030 patent") (attached as Exhibit H hereto); United States Patent No. 7,671,031 ("the '031 patent") (attached as Exhibit I hereto); United States Patent No. 7,674,774 ("the '774 patent") (attached as Exhibit J hereto); United States Patent No. 7,678,770 ("the '770 patent") (attached as Exhibit K hereto); United States Patent No. 7,678,771 ("the '771 patent") (attached as Exhibit L hereto); United States Patent No. 7,687,466 ("the '466 patent") (attached as Exhibit M hereto); United States Patent No. 7,687,467 ("the '467 patent") (attached as Exhibit N hereto); United States Patent No. 7,700,561 ("the '561 patent") (attached as Exhibit O hereto); United States Patent No. 7,713,936 ("the '936 patent") (attached as Exhibit P hereto); United States Patent No. 7,718,619 ("the '619 patent") (attached as Exhibit Q hereto); and United States Patent No. 7,723,305 ("the '305 patent") (attached as Exhibit R hereto) (collectively, "the Patents-in-Suit").

2. This action is related to the following case which was previously litigated in the District of New Jersey: *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:11-03781-SRC-CLW.

3. *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:11-03781-SRC-CLW (consolidated) concerned the same brand product—Vyvanse®—and the same 18 patents asserted in this action.

4. Judge Chesler, in *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:11-03781-SRC-CLW (consolidated), granted summary judgment against the generic defendants. J. Chesler's summary judgment ruling was that (a) claims 1–4 of the '630 patent, claim 3 of the '787 patent and claims 1–12 of the '253 patent (collectively, the

"Compound Claims") and claim 4 of the '486 patent are not invalid as anticipated or obvious, and (b) there was infringement of the Compound Claims and inducement of infringement of claim 4 of the '486 patent.

5. The Federal Circuit affirmed Judge Chesler's judgment with respect to all ANDA holders. *See Shire LLC v. Amneal Pharm., LLC*, 802 F.3d 1301 (Fed. Cir. 2015).

6. Upon information and belief, certain Norwich, Alvogen PB, Alvogen US, and Alvogen Group executives were previously employed by Actavis, one of the defendants in *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:11-03781-SRC-CLW (consolidated), and were responsible for Actavis's failed challenge of the same Patents-in-Suit in *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al*, Civil Action No. 2:11-03781-SRC-CLW.

THE PARTIES

7. Plaintiff Takeda Pharmaceutical Company Limited is a corporation organized and existing under the laws of Japan and having a place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka-shi, Osaka, Japan.

8. Plaintiff Takeda Pharmaceuticals U.S.A., Inc. is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 95 Hayden Ave., Lexington, Massachusetts 02421.

9. Upon information and belief, Norwich is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 6826 State Highway 12, Norwich, New York 13815.

10. Upon information and belief, Norwich has a place of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058.

11. Upon information and belief, Norwich has a place of business at 44

Whippany Road, Suite 300, Morristown, New Jersey 07960.

12. Upon information and belief, Norwich is in the business of, among other things, manufacturing and packaging pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

13. Upon information and belief, Alvogen PB is a corporation organized and existing under the laws of the State of Delaware, having places of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058 and 44 Whippany Road, Suite 300, Morristown, New Jersey 07960.

14. Upon information and belief, Alvogen US is a corporation organized and existing under the laws of the State of Delaware, having places of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058 and 44 Whippany Road, Suite 300, Morristown, New Jersey 07960.

15. Upon information and belief, Alvogen Group is a corporation organized and existing under the laws of the State of Delaware, having places of business at 10 Bloomfield Avenue, Building B, Pine Brook, New Jersey 07058 and 44 Whippany Road, Suite 300, Morristown, New Jersey 07960.

16. Upon information and belief, Defendants are in the business of, among other things, developing, manufacturing, and selling generic pharmaceutical products that they distribute in the State of Delaware and throughout the United States.

17. Upon information and belief, Alvogen PB is the regulatory agent for Norwich.

18. Upon information and belief, Norwich provides Alvogen PB, Alvogen US, and Alvogen Group, among other things, manufacturing and packaging services.

19. Upon information and belief, Norwich is a wholly owned subsidiary of Alvogen US.

20. Upon information and belief, Alvogen PB is a wholly owned subsidiary of Alvogen US.

21. Upon information and belief, Alvogen US is a wholly owned subsidiary of Alvogen Group.

JURISDICTION AND VENUE

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

23. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that they have committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Takeda in the State of Delaware and throughout the United States.

24. This Court also has personal jurisdiction over Norwich by virtue of the fact that Norwich is at home in Delaware as reflected by the fact that it is incorporated in Delaware, regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by distributing its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, upon information and belief, Norwich conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and/or sales of pharmaceutical products to Delaware residents that are continuous and systematic. Additionally, upon information and belief, Norwich intends to distribute, market, and/or sell the proposed product described in ANDA No. 214547 in the State of Delaware.

25. This Court also has personal jurisdiction over Alvogen PB by virtue of the fact that Alvogen PB is at home in Delaware as reflected by the fact that it is incorporated in Delaware, regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including the sale of its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, upon information and belief, Alvogen PB conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and/or sales of pharmaceutical products to Delaware residents that are continuous and systematic. Additionally, upon information and belief, Alvogen PB intends to distribute, market, and/or sell the proposed product described in ANDA No. 214547 in the State of Delaware.

26. This Court also has personal jurisdiction over Alvogen US by virtue of the fact that Alvogen US is at home in Delaware as reflected by the fact that it is incorporated in Delaware, regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including the sale of its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, upon information and belief, Alvogen US conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and/or sales of pharmaceutical products to Delaware residents that are continuous and systematic. Additionally, upon information and belief, Alvogen US intends to distribute, market, and/or sell the proposed product described in ANDA No. 214547 in the State of Delaware.

27. This Court also has personal jurisdiction over Alvogen Group by virtue of

the fact that Alvogen Group is at home in Delaware as reflected by the fact that it is incorporated in Delaware, regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including the sale of its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, upon information and belief, Alvogen Group conducts marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and/or sales of pharmaceutical products to Delaware residents that are continuous and systematic. Additionally, upon information and belief, Alvogen Group intends to distribute, market, and/or sell the proposed product described in ANDA No. 214547 in the State of Delaware.

28. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

29. Takeda Pharmaceuticals U.S.A., Inc. is the owner of New Drug Application ("NDA") No. 021977, which was approved by the FDA for the manufacture and sale of Vyvanse®. Vyvanse® is the trade name for lisdexamfetamine dimesylate, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg capsules for oral administration and is approved for the treatment of Attention Deficit Hyperactivity Disorder ("ADHD") and moderate to severe binge-eating disorder in adults.

30. NDA 021977 was previously owned by Shire Development LLC.

31. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-in-Suit are listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "*Orange Book*") as covering the Vyvanse® product.

32. Takeda Pharmaceutical Company Limited has been assigned, and currently holds all rights, title and interest in and to the Patents-in-Suit.

33. The Patents-in-Suit were previously assigned to Shire LLC.

34. The ’486 patent, titled “Abuse-Resistant Amphetamine Compounds,” was duly and legally issued on September 12, 2006. The ’486 patent is generally directed to methods of treatment using L-lysine-d-amphetamine.

35. The ’735 patent, titled “Abuse Resistant Lysine Amphetamine Compounds,” was duly and legally issued on May 29, 2007. The ’735 patent is generally directed to pharmaceutical compositions comprising L-lysine-d-amphetamine.

36. The ’630 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on February 2, 2010. The ’630 patent is generally directed to the compound, L-lysine-d-amphetamine dimesylate.

37. The ’253 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on February 9, 2010. The ’253 patent is generally directed to crystalline lisdexamphetamine dimesylate.

38. The ’254 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on February 9, 2010. The ’254 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

39. The ’787 patent, titled “Abuse Resistant Lysine Amphetamine Compounds,” was duly and legally issued on February 16, 2010. The ’787 patent is generally directed to L-lysine-d-amphetamine compounds.

40. The ’788 patent, titled “Abuse Resistant Amphetamine Prodrugs,” was duly and legally issued on February 16, 2010. The ’788 patent is generally directed to

methods of treatment comprising L-lysine-d-amphetamine.

41. The ’030 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 2, 2010. The ’030 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

42. The ’031 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 2, 2010. The ’031 patent is generally directed to methods of delivering amphetamines.

43. The ’774 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 9, 2010. The ’774 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

44. The ’770 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 16, 2010. The ’770 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

45. The ’771 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 16, 2010. The ’771 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

46. The ’466 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 30, 2010. The ’466 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

47. The ’467 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was duly and legally issued on March 30, 2010. The ’467 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

48. The ’561 patent, titled “Abuse-Resistant Amphetamine Prodrugs,” was

duly and legally issued on April 20, 2010. The '561 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

49. The '936 patent, titled "Abuse-Resistant Amphetamine Products," was duly and legally issued on May 11, 2010. The '936 patent is generally directed to methods of treatment comprising L-lysine-d-amphetamine.

50. The '619 patent, titled "Abuse-Resistant Amphetamine Prodrugs," was duly and legally issued on May 18, 2010. The '619 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

51. The '305 patent, titled "Abuse-Resistant Amphetamine Prodrugs," was duly and legally issued on May 25, 2010. The '305 patent is generally directed to compositions comprising L-lysine-d-amphetamine.

52. Defendants jointly prepared Abbreviated New Drug Application ("ANDA") No. 214547 ("the Norwich ANDA") and submitted it to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of generic lisdexamfetamine dimesylate capsules, 10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, and 70 mg, for oral administration ("the Norwich Proposed Product").

53. The Norwich ANDA identifies Vyvanse® (NDA No. 021977) as the Reference Listed Drug.

54. Takeda's counsel received the Norwich ANDA pursuant to an Offer of Confidential Access and Confidentiality Agreement.

55. Upon information and belief, the Norwich ANDA supports Takeda's infringement allegations.

56. Upon information and belief, Defendants will market and distribute the Norwich Proposed Product throughout the United States, if approved.

57. Upon information and belief, executives from Norwich are responsible for overseeing Alvogen PB's, Alvogen US's, and Alvogen Group's generic drug program.

58. Upon information and belief, executives from Alvogen PB, Alvogen US, and Alvogen Group are responsible for overseeing the Norwich Proposed Product.

59. Upon information and belief, Lisa Graver is and has been the President and Director of Norwich.

60. Upon information and belief, Lisa Graver is and has been the President of Alvogen PB and Alvogen US.

61. Upon information and belief, Lisa Graver is and has been an Executive-Vice President of Alvogen Group.

62. Upon information and belief, Lisa Graver has overseen global research and development, regulatory affairs, portfolio selection, and legal for Alvogen Group, Alvogen US, and Alvogen PB. Upon information and belief, under Lisa Graver's leadership, Alvogen US has built a pipeline of at least 28 potential first-to-file/first-to-market drugs for the U.S. market and a total pipeline of over 60 ANDAs.

63. Upon information and belief, Lisa Graver helped prepare, file, and submit the Norwich ANDA.

64. Upon information and belief, Lisa Graver was formerly at least partly responsible for challenging the Patents-in-Suit while at Actavis.

65. Upon information and belief, Andrea Sweet is and has been the Secretary of Norwich.

66. Upon information and belief, Andrea Sweet is and has been the head of U.S. Legal for Alvogen US and Alvogen PB.

67. Upon information and belief, Andrea Sweet is responsible for leading intellectual property strategy and patent litigation at Alvogen US and Alvogen PB.

68. Upon information and belief, Andrea Sweet leads Alvogen US's and Alvogen PB's Hatch-Waxman litigation strategy, including for Vyvanse®.

69. Upon information and belief, Andrea Sweet helped prepare, file, and submit the Norwich ANDA.

70. Upon information and belief, Andrea Sweet was formerly at least partly responsible for challenging the Patents-in-Suit while at Actavis.

71. Norwich sent a letter to Shire Development LLC and Shire LLC purporting to provide notification that the Norwich ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the Patents-In-Suit ("the Norwich Notice Letter").

72. The same counsel identified in the Norwich Notice Letter—Axinn, Veltrop & Harkrider—is the same counsel that represented Actavis, in *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:11-03781-SRC-CLW. Upon information and belief, counsel for Norwich is aware of Judge Chesler's summary judgment ruling in *Shire LLC et al. v. Amneal Pharmaceuticals, LLC et al.*, Civil Action No. 2:11-03781-SRC-CLW and is also aware of the Federal Circuit's affirmance.

73. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid

or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(7)(i)–(ii).

74. The Norwich Notice Letter does not assert non-infringement for each and every claim of each and every patent for which Norwich has made a paragraph IV certification.

75. The Norwich Notice Letter does not provide a full and detailed explanation of Norwich's factual and legal basis of invalidity and/or unenforceability for each and every claim of each and every patent for which Norwich has made a paragraph IV certification.

FIRST COUNT
(Infringement of the '486 Patent by Defendants)

76. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

77. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

78. Upon information and belief, Defendants included a paragraph IV certification to the '486 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '486 patent.

79. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

80. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

81. The inclusion of a paragraph IV certification to the '486 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '486 patent is an act of infringement by Defendants of one or more claims of the '486 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

82. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '486 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

83. Upon information and belief, Defendants are aware of the existence of the '486 patent, and are aware of the previous litigations relating to the '486 patent resulting in a summary judgment holding that claim 4 of the '486 patent was not invalid and was infringed and that the judgment was upheld on appeal. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the '486 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

84. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and

permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '735 Patent by Defendants)

85. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

86. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

87. Upon information and belief, Defendants included a paragraph IV certification to the '735 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '735 patent.

88. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

89. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

90. The inclusion of a paragraph IV certification to the '735 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '735 patent is an act of infringement by Norwich of one or more claims of the '735 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

91. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product

that is the subject of ANDA No. 214547 will infringe one or more claims of the '735 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

92. Upon information and belief, Defendants are aware of the existence of the '735 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '735 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

93. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

THIRD COUNT

(Infringement of the '630 Patent by Defendants)

94. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

95. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

96. Upon information and belief, Defendants included a paragraph IV certification to the '630 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '630 patent.

97. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

98. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

99. The inclusion of a paragraph IV certification to the '630 patent in ANDA

No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the ’630 patent is an act of infringement by Norwich of one or more claims of the ’630 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

100. Upon information and belief, Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the ’630 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

101. Upon information and belief, Defendants are aware of the existence of the ’630 patent and are aware of the previous litigations relating to the ’630 patent resulting in a summary judgment holding that claims 1–4 of the ’630 patent were not invalid and were infringed and that the judgment was upheld on appeal. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the ’630 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

102. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FOURTH COUNT

(Infringement of the ’253 Patent by Defendants)

103. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

104. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

105. Upon information and belief, Defendants included a paragraph IV certification to the ’253 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the ’253 patent.

106. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

107. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

108. The inclusion of a paragraph IV certification to the ’253 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the ’253 patent is an act of infringement by Defendants of one or more claims of the ’253 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

109. Upon information and belief, Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the ’253 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

110. Upon information and belief, Defendants are aware of the existence of the ’253 patent, and are aware of the previous litigations relating to the ’253 patent resulting in a summary judgment holding that claims 1–12 of the ’253 patent were not invalid and were infringed and that the judgment was upheld on appeal. Upon information and belief,

Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the '253 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

111. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FIFTH COUNT

(Infringement of the '254 Patent by Defendants)

112. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

113. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

114. Upon information and belief, Defendants included a paragraph IV certification to the '254 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '254 patent.

115. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

116. Upon information and belief, as of the dates of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

117. The inclusion of a paragraph IV certification to the '254 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '254 patent is an act of infringement by Defendants of one or more claims of

the '254 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

118. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '254 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

119. Upon information and belief, Defendants are aware of the existence of the '254 patent and acted without a reasonable basis for believing that they would not be liable for infringement of the '254 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

120. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SIXTH COUNT

(Infringement of the '787 Patent by Defendants)

121. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

122. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

123. Upon information and belief, Defendants included a paragraph IV certification to the '787 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '787 patent.

124. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

125. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

126. The inclusion of a paragraph IV certification to the '787 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '787 patent is an act of infringement by Defendants of one or more claims of the '787 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

127. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '787 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

128. Upon information and belief, Defendants are aware of the existence of the '787 patent, and are aware of the previous litigations relating to the '787 patent resulting in a summary judgment holding that claim 3 of the '787 patent was not invalid and was infringed and that the judgment was upheld on appeal. Upon information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the '787 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

129. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SEVENTH COUNT
(Infringement of the '788 Patent by Defendants)

130. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

131. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

132. Upon information and belief, Defendants included a paragraph IV certification to the '788 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '788 patent.

133. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

134. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

135. The inclusion of a paragraph IV certification to the '788 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Defendants Proposed Product before the expiration of the '788 patent is an act of infringement by Defendants of one or more claims of the '788 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

136. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '788 patent,

under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

137. Upon information and belief, Defendants are aware of the existence of the '788 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '788 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

138. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

EIGHTH COUNT
(Infringement of the '030 Patent by Defendants)

139. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

140. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

141. Upon information and belief, Defendants included a paragraph IV certification to the '030 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '030 patent.

142. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

143. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

144. The inclusion of a paragraph IV certification to the '030 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture,

use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '030 patent is an act of infringement by Norwich of one or more claims of the '030 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

145. Upon information and belief, Norwich's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '030 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

146. Upon information and belief, Defendants are aware of the existence of the '030 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '030 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

147. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

NINTH COUNT
(Infringement of the '031 Patent by Defendants)

148. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

149. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

150. Upon information and belief, Defendants included a paragraph IV certification to the '031 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '031 patent.

151. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

152. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

153. The inclusion of a paragraph IV certification to the '031 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '031 patent is an act of infringement by Norwich of one or more claims of the '031 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

154. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '031 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

155. Upon information and belief, Defendants are aware of the existence of the '031 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '031 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

156. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

TENTH COUNT
(Infringement of the '774 Patent by Defendants)

157. Takeda repeats and realleges each of the foregoing paragraphs as if fully

set forth herein.

158. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

159. Upon information and belief, Defendants included a paragraph IV certification to the '774 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '774 patent.

160. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

161. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

162. The inclusion of a paragraph IV certification to the '774 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '774 patent is an act of infringement by Defendants of one or more claims of the '774 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

163. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '774 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

164. Upon information and belief, Defendants are aware of the existence of the

'774 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '774 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

165. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

ELEVENTH COUNT
(Infringement of the '770 Patent by Defendants)

166. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

167. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

168. Upon information and belief, Defendants included a paragraph IV certification to the '770 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '770 patent.

169. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

170. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

171. The inclusion of a paragraph IV certification to the '770 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '770 patent is an act of infringement by Defendants of one or more claims of

the ’770 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

172. Upon information and belief, Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the ’770 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

173. Upon information and belief, Defendants are aware of the existence of the ’770 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’770 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

174. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

TWELFTH COUNT

(Infringement of the ’771 Patent by Defendants)

175. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

176. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

177. Upon information and belief, Defendants included a paragraph IV certification to the ’771 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the ’771 patent.

178. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

179. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

180. The inclusion of a paragraph IV certification to the '771 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '771 patent is an act of infringement by Defendants of one or more claims of the '771 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

181. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '771 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

182. Upon information and belief, Defendants are aware of the existence of the '771 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '771 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

183. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

THIRTEENTH COUNT
(Infringement of the '466 Patent by Defendants)

184. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

185. Upon information and belief, Defendants seek FDA approval for the

manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

186. Upon information and belief, Defendants included a paragraph IV certification to the '466 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '466 patent.

187. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

188. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

189. The inclusion of a paragraph IV certification to the '466 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '466 patent is an act of infringement by Defendants of one or more claims of the '466 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

190. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '466 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

191. Upon information and belief, Defendants are aware of the existence of the '466 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '466 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

192. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FOURTEENTH COUNT
(Infringement of the '467 Patent by Defendants)

193. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

194. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

195. Upon information and belief, Defendants included a paragraph IV certification to the '467 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '467 patent.

196. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

197. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

198. The inclusion of a paragraph IV certification to the '467 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '467 patent is an act of infringement by Defendants of one or more claims of the '467 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

199. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '467 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

200. Upon information and belief, Defendants are aware of the existence of the '467 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '467 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

201. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

FIFTEENTH COUNT
(Infringement of the '561 Patent by Defendants)

202. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

203. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

204. Upon information and belief, Defendants included a paragraph IV certification to the '561 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '561 patent.

205. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

206. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in

21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

207. The inclusion of a paragraph IV certification to the '561 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '561 patent is an act of infringement by Defendants of one or more claims of the '561 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

208. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '561 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

209. Upon information and belief, Defendants are aware of the existence of the '561 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '561 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

210. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SIXTEENTH COUNT
(Infringement of the '936 Patent by Defendants)

211. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

212. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

213. Upon information and belief, Defendants included a paragraph IV

certification to the ’936 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the ’936 patent.

214. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

215. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

216. The inclusion of a paragraph IV certification to the ’936 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the ’936 patent is an act of infringement by Defendants of one or more claims of the ’936 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

217. Upon information and belief, Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the ’936 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

218. Upon information and belief, Defendants are aware of the existence of the ’936 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’936 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

219. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and

permanently enjoined by this Court.

SEVENTEENTH COUNT
(Infringement of the '619 Patent by Defendants)

220. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

221. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

222. Upon information and belief, Defendants included a paragraph IV certification to the '619 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '619 patent.

223. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

224. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

225. The inclusion of a paragraph IV certification to the '619 patent in ANDA No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '619 patent is an act of infringement by Defendants of one or more claims of the '619 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

226. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product

that is the subject of ANDA No. 214547 will infringe one or more claims of the '619 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

227. Upon information and belief, Defendants are aware of the existence of the '619 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '619 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

228. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

EIGHTEENTH COUNT
(Infringement of the '305 Patent by Defendants)

229. Takeda repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

230. Upon information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of the Norwich Proposed Product.

231. Upon information and belief, Defendants included a paragraph IV certification to the '305 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '305 patent.

232. Upon information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import the Norwich Proposed Product upon FDA approval.

233. Upon information and belief, as of the date of the Norwich Notice Letter, Norwich was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

234. The inclusion of a paragraph IV certification to the '305 patent in ANDA

No. 214547 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Norwich Proposed Product before the expiration of the '305 patent is an act of infringement by Defendants of one or more claims of the '305 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

235. Upon information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Norwich Proposed Product that is the subject of ANDA No. 214547 will infringe one or more claims of the '305 patent, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

236. Upon information and belief, Defendants are aware of the existence of the '305 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '305 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

237. The acts of infringement set forth above will cause Takeda irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

STATEMENT REGARDING PRIOR-FILED SUIT

238. Takeda previously filed an action in the District of New Jersey on July 15, 2020 asserting infringement of the same Patents-in-Suit based on the same ANDA No. 214547 in the instant action. That action has been assigned Civil Action No. 2:20-cv-08966-SRC-CLW ("the D.N.J. Action").

239. The D.N.J. Action is assigned to Judge Chesler. In the D.N.J. Action, Takeda alleged that venue was proper over the Defendants.

240. Judicial economy would be promoted, and Takeda's choice of forum

respected, if the claims related to Takeda's action for infringement of the Patents-in-Suit are addressed by Judge Chesler in the District of New Jersey.

241. Takeda brought this second-filed case in Delaware to ensure that if the D.N.J. Action were dismissed, Takeda would retain the Hatch-Waxman statutory stay of FDA approval.

PRAYER FOR RELIEF

WHEREFORE, Takeda respectfully requests the following relief:

i. A judgment declaring that the '486 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '486 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '486 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '486 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '486 patent including any regulatory extensions;

vi. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '486 patent;

vii. A judgment declaring that infringement of the '486 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '486 patent;

viii. A judgment declaring that the '735 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '735 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to

the expiration of the ’735 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the ’735 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the ’735 patent including any regulatory extensions;

xiii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’735 patent;

xiv. A judgment declaring that infringement of the ’735 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’735 patent;

xv. A judgment declaring that the ’630 patent is valid and enforceable;

xvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in

the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '630 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '630 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '630 patent expires including any regulatory extensions;

xix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '630 patent including any regulatory extensions;

xx. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '630 patent;

xxi. A judgment declaring that infringement of the '630 patent is willful if

Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '630 patent;

xxii. A judgment declaring that the '253 patent is valid and enforceable;

xxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '253 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxiv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '253 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '253 patent expires including any regulatory extensions;

xxvi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '253

patent including any regulatory extensions;

xxvii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '253 patent;

xxviii. A judgment declaring that infringement of the '253 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '253 patent;

xxix. A judgment declaring that the '254 patent is valid and enforceable;

xxx. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '254 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxi. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '254 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date

on which the ’254 patent expires including any regulatory extensions;

xxxiii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the ’254 patent including any regulatory extensions;

xxxiv. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’254 patent;

xxxv. A judgment declaring that infringement of the ’254 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’254 patent;

xxxvi. A judgment declaring that the ’787 patent is valid and enforceable;

xxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the ’787 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or

importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '787 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xxxix. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '787 patent expires including any regulatory extensions;

xl. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '787 patent including any regulatory extensions;

xli. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '787 patent;

xlii. A judgment declaring that infringement of the '787 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '787 patent;

xliii. A judgment declaring that the '788 patent is valid and enforceable;

xliv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to

obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '788 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xlv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '788 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xlvi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '788 patent expires including any regulatory extensions;

xlvii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '788 patent including any regulatory extensions;

xlviii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '788 patent;

xlix. A judgment declaring that infringement of the ’788 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’788 patent;

l. A judgment declaring that the ’030 patent is valid and enforceable;

li. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the ’030 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the ’030 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

liii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the ’030 patent expires including any regulatory extensions;

liv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United

States of the product that is the subject of ANDA No. 214547 until the expiration of the '030 patent including any regulatory extensions;

lv. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '030 patent;

lvi. A judgment declaring that infringement of the '030 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '030 patent;

lvii. A judgment declaring that the '031 patent is valid and enforceable;

lviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '031 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lix. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '031 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lx. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any

approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '031 patent expires including any regulatory extensions;

lxi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '031 patent including any regulatory extensions;

lxii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '031 patent;

lxiii. A judgment declaring that infringement of the '031 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '031 patent;

lxiv. A judgment declaring that the '774 patent is valid and enforceable;

lxv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '774 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. §

271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '774 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxvii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '774 patent expires including any regulatory extensions;

lxviii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '774 patent including any regulatory extensions;

lxix. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '774 patent;

lxx. A judgment declaring that infringement of the '774 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '774 patent;

lxxi. A judgment declaring that the '770 patent is valid and enforceable;

lxxii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the

submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '770 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxiii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '770 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxiv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '770 patent expires including any regulatory extensions;

lxxv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '770 patent including any regulatory extensions;

lxxvi. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '770

patent;

lxxvii. A judgment declaring that infringement of the '770 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '770 patent;

lxxviii. A judgment declaring that the '771 patent is valid and enforceable;

lxxix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '771 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxx. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '771 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '771 patent expires including any regulatory extensions;

lxxxii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from

engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '771 patent including any regulatory extensions;

lxxxiii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '771 patent;

lxxxiv. A judgment declaring that infringement of the '771 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '771 patent;

lxxxv. A judgment declaring that the '466 patent is valid and enforceable;

lxxxvi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '466 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '466 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

lxxxviii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '466 patent expires including any regulatory extensions;

lxxxix. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '466 patent including any regulatory extensions;

xc. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '466 patent;

xci. A judgment declaring that infringement of the '466 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '466 patent;

xcii. A judgment declaring that the '467 patent is valid and enforceable;

xciii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '467 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xciv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '467 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xcv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '467 patent expires including any regulatory extensions;

xcvi. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '467 patent including any regulatory extensions;

xcvii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '467 patent;

xcviii. A judgment declaring that infringement of the '467 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '467 patent;

xcix. A judgment declaring that the '561 patent is valid and enforceable;

c. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '561 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

ci. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '561 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

cii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '561 patent expires including any regulatory extensions;

ciii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '561 patent including any regulatory extensions;

civ. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to

sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '561 patent;

cv. A judgment declaring that infringement of the '561 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '561 patent;

cvi. A judgment declaring that the '936 patent is valid and enforceable;

cvii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '936 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

cviii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '936 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

cix. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '936 patent expires including any regulatory extensions;

cx. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys,

and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '936 patent including any regulatory extensions;

cxi. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '936 patent;

cxii. A judgment declaring that infringement of the '936 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '936 patent;

cxiii. A judgment declaring that the '619 patent is valid and enforceable;

cxiv. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '619 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

cxv. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the '619 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or

contributory infringement;

cxvi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the '619 patent expires including any regulatory extensions;

cxvii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the '619 patent including any regulatory extensions;

cxviii. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '619 patent;

cxix. A judgment declaring that infringement of the '619 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the '619 patent;

cxx. A judgment declaring that the '305 patent is valid and enforceable;

cxxi. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 214547 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 was an act of infringement of the '305 patent by Defendants directly and/or indirectly, including by

inducement and/or contributory infringement;

cxxii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 prior to the expiration of the ’305 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

cxxiii. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 214547 shall be no earlier than the date on which the ’305 patent expires including any regulatory extensions;

cxxiv. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of ANDA No. 214547 until the expiration of the ’305 patent including any regulatory extensions;

cxxv. A judgment awarding Takeda damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’305 patent;

cxxvi. A judgment declaring that infringement of the ’305 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 214547 that infringes the ’305 patent;

cxxvii. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Takeda its attorneys' fees and costs;

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

Respectfully submitted,

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