IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE AURYXIA (FERRIC CITRATE) PATENT LITIGATION	MDL Docket No. 19-2896-LPS ***This document applies to C.A. No. 19-220***
KERYX BIOPHARMACEUTICALS, INC., PANION & BF BIOTECH, INC. and CHEN HSING HSU, Plaintiffs, v. CHEMO RESEARCH S.L. and INSUD PHARMA S.L.U., Defendants.	C.A. No. 19-220-LPS

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Keryx Biopharmaceuticals, Inc. ("Keryx"), Panion & BF Biotech, Inc. ("Panion") and Chen Hsing Hsu ("Dr. Hsu") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Chemo Research S.L. ("Chemo Research") and Insud Pharma S.L.U. ("Insud") (collectively "Chemo" or "Defendants"), allege as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, arising from Chemo's submission of Abbreviated New Drug Application ("ANDA") No. 212738 ("Chemo's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of Keryx's AURYXIA® (Ferric Citrate) Tablets

("Chemo's Proposed Product") prior to the expiration of United States Patent Nos. 5,753,706 (the "'706 patent"); 7,767,851 (the "'851 patent"); 8,093,423 (the "'423 patent"); 8,299,298 (the "'298 patent"); 8,338,642 (the "'642 patent"); 8,609,896 (the "'896 patent"); 8,754,257 (the "'257 patent"); 8,754,258 (the "'258 patent"); 8,846,976 (the "'976 patent"); 8,901,349 (the "'349 patent"); 9,050,316 (the "'316 patent"); 9,328,133 (the "'133 patent"); 9,387,191 (the "'191 patent"); 9,757,416 (the "'416 patent"); and 10,300,039 (the "'039 patent") (collectively, the "patents-in-suit"), owned by Plaintiffs.

The Parties

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

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

4. Plaintiff Dr. Hsu is an individual residing at 2244 Hot Oak Ridge Street, Las Vegas, Nevada 89134.

5. On information and belief, Insud is a corporation organized and existing under the laws of Spain, having its principal place of business at Manuel Pombo Angulo 28, 3rd Floor, 28050 Madrid, Spain.

6. On information and belief, Chemo Research is a corporation organized and existing under the laws of Spain, having its principal place of business at Manuel Pombo Angulo 28, 3rd Floor, 28050 Madrid, Spain. On information and belief, Chemo Research is a wholly-owned subsidiary of Insud.

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

8. On information and belief, Chemo Research, in conjunction with or under the direction of Insud, developed Chemo's Proposed Product and/or prepared ANDA No. 212738 for submission. On information and belief, upon receiving approval of ANDA No. 212738, Chemo Research, in conjunction with or under the direction of Insud, will manufacture, sell, offer to sell, and/or import Chemo's Proposed Product in the United States, including in this district.

The Patents-in-Suit

9. On May 19, 1998, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '706 patent, entitled, "Methods for Treating Renal Failure." The '706 patent is assigned to Dr. Hsu. Keryx is the exclusive licensee of all rights in the '706 patent that are relevant to this litigation. A copy of the '706 patent is attached hereto as Exhibit A.

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

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

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

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

14. On December 17, 2013, the USPTO duly and lawfully issued the '896 patent, entitled, "Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '896 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '896 patent that are relevant to this litigation. A copy of the '896 patent is attached hereto as Exhibit F.

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

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

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

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

19. On June 9, 2015, the USPTO duly and lawfully issued the '316 patent, entitled, "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '316 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the '316 patent that are relevant to this litigation. A copy of the '316 patent is attached hereto as Exhibit K.

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

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

22. On September 12, 2017, the USPTO duly and lawfully issued the '416 patent, entitled "Pharmaceutical-Grade Ferric Organic Compounds, Uses Thereof and Methods of Making Same." The '416 patent is assigned to Panion. Keryx is the exclusive licensee of all rights in the

'416 patent that are relevant to this litigation. A copy of the '416 patent is attached hereto as Exhibit N.

23. On May 28, 2019, the USPTO duly and lawfully issued the '039 patent, entitled "Ferric Citrate Dosage Forms." The '039 patent is assigned to Keryx. A copy of the '039 patent is attached hereto as Exhibit O.

The AURYXIA® (Ferric Citrate) Drug Product

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

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

Jurisdiction and Venue

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

27. On information and belief, Chemo has submitted, caused to be submitted, or aided and abetted in the preparation of Chemo's ANDA. On information and belief, upon FDA approval

of Chemo's ANDA, Chemo intends to commercially manufacture, import, market, offer for sale, and/or sell Chemo's Proposed Product throughout the United States including in this district.

28. This Court has personal jurisdiction over Chemo Research by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. On information and belief, Chemo Research purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, in this Judicial District, and this Judicial District is a likely destination of Chemo's Proposed Product.

29. This Court has personal jurisdiction over Insud by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. On information and belief, Insud purposefully has conducted and continues to conduct business, directly or through its parent, subsidiaries, affiliates and/or agents, including Chemo Research and Exeltis USA, Inc., in this Judicial District, and this Judicial District is a likely destination of Chemo's Proposed Product.

30. This Court has personal jurisdiction over Chemo because Chemo has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with the State of Delaware. On information and belief, Chemo regularly and continuously transacts business within Delaware, including by making pharmaceutical products for sale in Delaware and selling pharmaceutical products in Delaware. On information and belief, Chemo derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. On information and belief, Chemo derives substantial revenue from selling pharmaceutical products throughout the United States, including in this Judicial District.

31. On information and belief, Chemo intends to engage in a future course of conduct that includes acts of patent infringement in Delaware. These acts will lead to foreseeable harm

and injury to Plaintiffs in Delaware and in this Judicial District. For example, on information and belief, Chemo will work towards the regulatory approval, manufacturing, use, importation, marketing, offer for sale, sale, and distribution of pharmaceutical products, including Chemo's Proposed Product, throughout the United States, including in Delaware and in this Judicial District, prior to the expiration of the patents-in-suit.

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

33. Venue is proper for Insud and Chemo Research pursuant to 28 U.S.C. §§ 1391(c)(3) and 1400(b) including because, *inter alia*, Insud and Chemo Research are foreign corporations.

Acts Giving Rise to This Suit

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

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

36. In connection with the filing of its ANDA as described above, Chemo provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the patents-in-suit, excluding the '039 patent, are invalid, unenforceable, and/or will not be infringed by the activities described in Chemo's ANDA ("Chemo's Paragraph IV Certification").

37. No earlier than December 21, 2018, Chemo sent written notice of its Paragraph IV Certification to Plaintiffs ("Chemo's First Notice Letter"). Chemo's First Notice Letter alleged that the claims of the patents-in-suit, except for the '039 patent, are invalid and/or will not be infringed by the activities described in Chemo's ANDA. Chemo's First Notice Letter also informed Plaintiffs that Chemo seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Chemo's Proposed Product before the patents-in-suit, except for the '039 patent, expire.

38. On information and belief, during the pendency of Chemo's ANDA, Chemo provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the '039 patent are invalid, unenforceable, and/or will not be infringed by the activities described in Chemo's ANDA ("Chemo's '039 Patent Paragraph IV Certification").

39. No earlier than May 14, 2020, Chemo sent written notice of its '039 Patent Paragraph IV Certification to Plaintiffs ("Chemo's Second Notice Letter"). Chemo's Second Notice Letter alleged that the claims of the '039 patent, are invalid and/or will not be infringed by the activities described in Chemo's ANDA. Chemo's Second Notice Letter also informed Plaintiffs that Chemo seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of Chemo's Proposed Product before the '039 patent expires.

40. The original complaint in this action was filed before expiration of the forty-five days from the date Plaintiffs received Chemo's First Notice Letter.

41. Plaintiffs sought leave to file this First Amended Complaint, alleging infringement of the '039 patent, before expiration of the forty-five days from the date Plaintiffs received Chemo's Second Notice Letter.

Count I: Infringement of the '706 Patent

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

43. Chemo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Chemo's Proposed Product, prior to the expiration of the '706 patent, constitutes infringement of one or more of the claims of the '706 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 6, and 9.

44. A justiciable controversy exists between the parties hereto as to the infringement of the '706 patent.

45. Unless enjoined by this Court, upon FDA approval of Chemo's ANDA, Chemo will infringe one or more claims of the '706 patent under 35 U.S.C. § 271(a), including at least claim 6, by making, using, offering to sell, selling, and/or importing Chemo's Proposed Product in the United States.

46. Unless enjoined by this Court, upon FDA approval of Chemo's ANDA, Chemo will induce infringement of one or more claims of the '706 patent under 35 U.S.C. § 271(b), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Chemo's Proposed Product in the United States. On information and belief, upon FDA approval

of Chemo's ANDA, Chemo will intentionally encourage acts of direct infringement with knowledge of the '706 patent and with knowledge that its acts are encouraging infringement.

47. Unless enjoined by this Court, upon FDA approval of Chemo's ANDA, Chemo will contributorily infringe one or more claims of the '706 patent under 35 U.S.C. § 271(c), including at least claims 1 and 9, by making, using, offering to sell, selling, and/or importing Chemo's Proposed Product in the United States. On information and belief, Chemo knew and knows that Chemo's Proposed Product is designed for a use that infringes one or more claims of the '706 patent, and Chemo's Proposed Product lacks a substantial non-infringing use.

48. Plaintiffs will be substantially and irreparably damaged and harmed if Chemo's infringement of the '706 patent is not enjoined.

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

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

Count II: Infringement of the '851 Patent

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

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

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

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

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

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

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

Count III: Infringement of the '423 Patent

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

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

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

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

ANDA, Chemo will intentionally encourage acts of direct infringement with knowledge of the '423 patent and with knowledge that its acts are encouraging infringement.

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

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

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

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

Count IV: Infringement of the '298 Patent

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

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

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

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

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

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

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

Count V: Infringement of the '642 Patent

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

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

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

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

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

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

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

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

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

Count VI: Infringement of the '896 Patent

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

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

the expiration of the '896 patent, constitutes infringement of one or more of the claims of the '896 patent under 35 U.S.C. § 271(e)(2)(A), including at least claim 1.

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

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

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

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

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

Count VII: Infringement of the '257 Patent

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

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

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

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

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

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

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

Count VIII: Infringement of the '258 Patent

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

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

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

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

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

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

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

Count IX: Infringement of the '976 Patent

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

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

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

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

107. Unless enjoined by this Court, upon FDA approval of Chemo's ANDA, Chemo will contributorily infringe one or more claims of the '976 patent under 35 U.S.C. § 271(c), including at least claim 1, by making, using, offering to sell, selling, and/or importing Chemo's

Proposed Product in the United States. On information and belief, Chemo knew and knows that Chemo's Proposed Product is designed for a use that infringes one or more claims of the '976 patent, and Chemo's Proposed Product lacks a substantial non-infringing use.

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

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

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

Count X: Infringement of the '349 Patent

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

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

113. A justiciable controversy exists between the parties hereto as to the infringement of the '349 patent.

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

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

116. Plaintiffs will be substantially and irreparably damaged and harmed if Chemo's infringement of the '349 patent is not enjoined.

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

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

Count XI: Infringement of the '316 Patent

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

120. Chemo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Chemo's Proposed Product, prior to the expiration of the '316 patent, constitutes infringement of one or more of the claims of the '316 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1 and 12.

121. A justiciable controversy exists between the parties hereto as to the infringement of the '316 patent.

122. Unless enjoined by this Court, upon FDA approval of Chemo's ANDA, Chemo will induce infringement of one or more claims of the '316 patent under 35 U.S.C. § 271(b), including at least claims 1 and 12, by making, using, offering to sell, selling, and/or importing

Chemo's Proposed Product in the United States. On information and belief, upon FDA approval of Chemo's ANDA, Chemo will intentionally encourage acts of direct infringement with knowledge of the '316 patent and with knowledge that its acts are encouraging infringement.

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

124. Plaintiffs will be substantially and irreparably damaged and harmed if Chemo's infringement of the '316 patent is not enjoined.

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

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

Count XII: Infringement of the '133 Patent

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

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

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

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

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

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

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

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

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

Count XIII: Infringement of the '191 Patent

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

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

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

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

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

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

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

Count XIV: Infringement of the '416 Patent

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

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

the expiration of the '416 patent, constitutes infringement of one or more of the claims of the '416 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 12, 23, and 30.

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

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

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

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

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

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

Count XV: Infringement of the '039 Patent

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

152. Chemo's submission of its ANDA to engage in the commercial manufacture, use, offer for sale, sale, or importation into the United States of Chemo's Proposed Product, prior to the expiration of the '039 patent, constitutes infringement of one or more of the claims of the '039 patent under 35 U.S.C. § 271(e)(2)(A), including at least claims 1, 5, 8, 11, and 15.

153. A justiciable controversy exists between the parties hereto as to the infringement of the '039 patent.

154. Unless enjoined by this Court, upon FDA approval of Chemo's ANDA, Chemo will induce infringement of one or more claims of the '039 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b), including at least claims 1, 5, 8, 11, and 15, by making, using, offering to sell, selling, and/or importing Chemo's Proposed Product in the United States. On information and belief, upon FDA approval of Chemo's ANDA, Chemo will intentionally encourage acts of direct infringement with knowledge of the '039 patent and with knowledge that its acts are encouraging infringement.

155. Plaintiffs will be substantially and irreparably damaged and harmed if Chemo's infringement of the '039 patent is not enjoined.

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Chemo has infringed the patents-in-suit by submitting ANDA No. 212738 to the FDA;

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

C. An Order that the effective date of FDA approval of ANDA No. 212738 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiffs are or become entitled;

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

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

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

G. To the extent that Chemo has committed any acts with respect to the devices, compositions, formulations, and methods of use and administration claimed in the patents-in-

suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Plaintiffs damages for such acts;

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

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

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

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

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

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Dated: June 26, 2020

CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2020, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on June 26, 2020, upon the following in the manner indicated:

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