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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INCYTE CORP. and INCYTE HOLDINGS CORP., **Plaintiffs,** **v.** **PADAGIS ISRAEL PHARMACEUTICALS LTD.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiffs Incyte Corporation and Incyte Holdings Corporation (together, "Incyte"), by their undersigned attorneys, for their Complaint against Defendant Padagis Israel Pharmaceuticals Ltd. ("Padagis"), 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*., arising from Padagis's submission of Abbreviated New Drug Application ("ANDA") No. 218657 ("Padagis's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Incyte's Opzelura® (ruxolitinib) drug product prior to the

expiration of United States Patent Nos. 10,758,543 (the "'543 patent"); 10,869,870 (the "'870 patent"); 11,219,624 (the "'624 patent"); 11,510,923 (the "'923 patent"); 11,571,425 (the "'425 patent"); 11,590,136 (the "'136 patent"); 11,590,137 (the "'137 patent"); 11,590,138 (the "'138 patent"); and 11,602,536 (the "'536 patent") (collectively, "the patents-in-suit"). The patents-in-suit are owned by Incyte Corporation and/or Incyte Holdings Corporation.

The Parties

2. Plaintiff Incyte Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

3. Plaintiff Incyte Holdings Corporation is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

4. On information and belief, Defendant Padagis is an Israeli corporation having a principal place of business at 1 Zvi Borenstein Street, Yeruham, Israel 80500.

The Patents-in-Suit

5. On September 1, 2020, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '543 patent, entitled, "Topical Formulation for a JAK Inhibitor." A copy of the '543 patent is attached hereto as Exhibit A.

6. On December 22, 2020, the USPTO duly and lawfully issued the '870 patent, entitled, "Topical Formulation for a JAK Inhibitor." A copy of the '870 patent is attached hereto as Exhibit B.

7. On January 11, 2022, the USPTO duly and lawfully issued the ’624 patent, entitled, “Topical Formulation for a JAK Inhibitor.” A copy of the ’624 patent is attached hereto as Exhibit C.

8. On November 29, 2022, the USPTO duly and lawfully issued the ’923 patent, entitled, “Ruxolitinib Formulation for Reduction of Itch in Atopic Dermatitis.” A copy of the ’923 patent is attached hereto as Exhibit D.

9. On February 7, 2023, the USPTO duly and lawfully issued the ’425 patent, entitled, “Topical Formulation for a JAK Inhibitor.” A copy of the ’425 patent is attached hereto as Exhibit E.

10. On February 28, 2023, the USPTO duly and lawfully issued the ’136 patent, entitled, “Topical Formulation for a JAK Inhibitor.” A copy of the ’136 patent is attached hereto as Exhibit F

11. On February 28, 2023, the USPTO duly and lawfully issued the ’137 patent, entitled, “Ruxolitinib Formulation for Reduction of Itch in Atopic Dermatitis.” A copy of the ’137 patent is attached hereto as Exhibit G.

12. On February 28, 2023, the USPTO duly and lawfully issued the ’138 patent, entitled “Topical Treatment of Vitiligo by a JAK Inhibitor.” A copy of the ’138 patent is attached hereto as Exhibit H.

13. On March 14, 2023, the USPTO duly and lawfully issued the ’536 patent, entitled, “Topical Treatment of Vitiligo by a JAK Inhibitor.” A copy of the ’536 patent is attached hereto as Exhibit I.

The Opzelura® Drug Product

14. Incyte Corporation 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 Opzelura® (ruxolitinib) cream (NDA No. 215309).

15. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions comprising ruxolitinib and methods of using and administering pharmaceutical compositions comprising ruxolitinib.

16. 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 Opzelura®.

17. The FDA-approved prescribing information Opzelura® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Opzelura® for, *inter alia*, the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.

18. The FDA-approved prescribing information for Opzelura® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Opzelura® for, *inter alia*, the topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older.

19. The FDA-approved prescribing information for Opzelura® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Opzelura® according to one or more of the methods claimed in the patents-in-suit.

Jurisdiction and Venue

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

21. On information and belief, Padagis is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

22. This Court has personal jurisdiction over Padagis pursuant to Federal Rule of Civil Procedure 4(k)(2), including because (a) Incyte's claims arise under federal law; (b) Padagis is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Padagis has sufficient contacts with the United States as a whole, including, without limitation, 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 Padagis satisfies due process.

23. On information and belief, Padagis submitted ANDA No. 218657 seeking FDA approval to engage in the manufacture, use, importation, distribution, offer to sell, and/or sale of the generic drug product that is the subject of Padagis's ANDA ("Padagis's Proposed Product"), throughout the United States, including in New Jersey and in this Judicial District, prior to the expiration of the patents-in-suit.

24. On information and belief, this Judicial District is a likely destination for Padagis's Proposed Product.

25. On information and belief, Padagis intends to benefit directly if its ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Padagis's Proposed Product.

26. Padagis has purposefully availed itself of the rights, benefits, and privileges of New Jersey, including by asserting counterclaims in this Court. *See, e.g.*, *Evofem Biosciences, Inc., et al. v. Padagis Israel Pharmaceuticals Ltd., et al.,* No. 23-3003 (ZNQ)(DEA) (D.N.J.) (D.I. 10).

27. Venue is proper in this Judicial District for Padagis pursuant to 28 U.S.C. §§ 1391 and/or 1400(b), including, for example, because Padagis is a company organized and existing under the laws of Israel and may be sued in any judicial district.

Acts Giving Rise To This Suit

28. Pursuant to Section 505 of the FFDCA, Padagis submitted ANDA No. 218657 seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product before the patents-in-suit expire.

29. On information and belief, following FDA approval of Padagis's ANDA, Padagis will make, use, sell, or offer to sell Padagis's Proposed Product throughout the United States, and/or import such generic product into the United States.

30. On information and belief, in connection with the submission of ANDA No. 218657 as described above, Padagis provided a written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Padagis's Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Padagis's ANDA.

31. No earlier than September 21, 2023, Padagis sent to Incyte a written notice of Padagis's Paragraph IV Certification ("Padagis's Notice Letter"). Padagis's Notice Letter alleged that the claims of the patents-in-suit are invalid and/or will not be infringed by the activities described in Padagis's ANDA. Padagis's Notice Letter conveyed that Padagis seeks approval to market Padagis's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '543 Patent

32. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

33. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '543 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

34. There is a justiciable controversy between the parties hereto as to the infringement of the '543 patent.

35. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '543 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

36. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '543 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will

intentionally encourage acts of direct infringement with knowledge of the '543 patent and knowledge that its acts are encouraging infringement.

37. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '543 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '543 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

38. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '543 patent is not enjoined.

39. Incyte does not have an adequate remedy at law.

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

Count II: Infringement of the '870 Patent

41. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

42. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '870 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

43. There is a justiciable controversy between the parties hereto as to the infringement of the ’870 patent.

44. Unless enjoined by this Court, upon FDA approval of Padagis’s ANDA, Padagis will infringe one or more claims of the ’870 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis’s Proposed Product in the United States.

45. Unless enjoined by this Court, upon FDA approval of Padagis’s ANDA, Padagis will induce infringement of one or more claims of the ’870 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis’s Proposed Product in the United States. On information and belief, upon FDA approval of Padagis’s ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the ’870 patent and knowledge that its acts are encouraging infringement.

46. Unless enjoined by this Court, upon FDA approval of Padagis’s ANDA, Padagis will contributorily infringe one or more claims of the ’870 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis’s Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis’s Proposed Product is especially adapted for a use that infringes one or more claims of the ’870 patent and that there is no substantial non-infringing use for Padagis’s Proposed Product.

47. Incyte will be substantially and irreparably damaged and harmed if Padagis’s infringement of the ’870 patent is not enjoined.

48. Incyte does not have an adequate remedy at law.

49. This case is an exceptional one, and Incyte is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

Count III: Infringement of the '624 Patent

50. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

51. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '624 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

52. There is a justiciable controversy between the parties hereto as to the infringement of the '624 patent.

53. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '624 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

54. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '624 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '624 patent and knowledge that its acts are encouraging infringement.

55. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '624 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that

Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '624 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

56. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '624 patent is not enjoined.

57. Incyte does not have an adequate remedy at law.

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

Count IV: Infringement of the '923 Patent

59. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

60. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '923 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

61. There is a justiciable controversy between the parties hereto as to the infringement of the '923 patent.

62. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '923 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

63. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '923 patent under 35 U.S.C. § 271(b) by

making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '923 patent and knowledge that its acts are encouraging infringement.

64. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '923 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '923 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

65. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '923 patent is not enjoined.

66. Incyte does not have an adequate remedy at law.

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

Count V: Infringement of the '425 Patent

68. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

69. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product,

prior to the expiration of the '425 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

70. There is a justiciable controversy between the parties hereto as to the infringement of the '425 patent.

71. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '425 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

72. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '425 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '425 patent and knowledge that its acts are encouraging infringement.

73. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '425 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '425 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

74. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '425 patent is not enjoined.

75. Incyte does not have an adequate remedy at law.

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

Count VI: Infringement of the '136 Patent

77. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

78. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '136 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

79. There is a justiciable controversy between the parties hereto as to the infringement of the '136 patent.

80. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '136 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

81. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '136 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '136 patent and knowledge that its acts are encouraging infringement.

82. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '136 patent under 35 U.S.C. § 271(c) by

making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '136 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

83. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '136 patent is not enjoined.

84. Incyte does not have an adequate remedy at law.

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

Count VII: Infringement of the '137 Patent

86. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

87. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '137 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

88. There is a justiciable controversy between the parties hereto as to the infringement of the '137 patent.

89. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '137 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

90. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '137 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '137 patent and knowledge that its acts are encouraging infringement.

91. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '137 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '137 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

92. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '137 patent is not enjoined.

93. Incyte does not have an adequate remedy at law.

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

Count VIII: Infringement of the '138 Patent

95. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

96. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use,

sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '138 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

97. There is a justiciable controversy between the parties hereto as to the infringement of the '138 patent.

98. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '138 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

99. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '138 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '138 patent and knowledge that its acts are encouraging infringement.

100. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '138 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '138 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

101. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '138 patent is not enjoined.

102. Incyte does not have an adequate remedy at law.

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

Count IX: Infringement of the '536 Patent

104. Incyte repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

105. Padagis's submission of ANDA No. 218657, with the accompanying Paragraph IV Certification and notice to Incyte of same, to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Padagis's Proposed Product, prior to the expiration of the '536 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

106. There is a justiciable controversy between the parties hereto as to the infringement of the '536 patent.

107. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will infringe one or more claims of the '536 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States.

108. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will induce infringement of one or more claims of the '536 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, upon FDA approval of Padagis's ANDA, Padagis will intentionally encourage acts of direct infringement with knowledge of the '536 patent and knowledge that its acts are encouraging infringement.

109. Unless enjoined by this Court, upon FDA approval of Padagis's ANDA, Padagis will contributorily infringe one or more claims of the '536 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Padagis's Proposed Product in the United States. On information and belief, Padagis has had and continues to have knowledge that Padagis's Proposed Product is especially adapted for a use that infringes one or more claims of the '536 patent and that there is no substantial non-infringing use for Padagis's Proposed Product.

110. Incyte will be substantially and irreparably damaged and harmed if Padagis's infringement of the '536 patent is not enjoined.

111. Incyte does not have an adequate remedy at law.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Incyte respectfully request the following relief:

(A) A Judgment that Padagis has infringed the patents-in-suit by submitting ANDA No. 218657 with the accompanying Paragraph IV Certification and notice to Incyte of same;

(B) A Judgment that Padagis has infringed, and that Padagis's making, using, selling, offering to sell, and/or importing Padagis'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. 218657 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 Incyte is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Padagis and its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from making, using, offering to sell, selling, and/or importing Padagis's Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Incyte is or becomes entitled;

(E) A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Padagis, its officers, agents, attorneys, and employees, and those acting in privity and/or concert with them, from practicing any of the subject matter claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Incyte is or becomes entitled;

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

(G) To the extent that Padagis, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, has committed any acts with respect to the subject matter claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), a Judgment awarding Incyte damages for such acts;

(H) If Padagis, its officers, agents, attorneys, and/or employees, or those acting in privity and/or concert with them, engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Padagis's Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Incyte resulting from such infringement, together with interest;

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

(J) A Judgment that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Incyte its attorneys' fees incurred in this action;

(K) A Judgment awarding Incyte its costs and expenses incurred in this action; and

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

Dated: November 2, 2023

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: November 2, 2023

By: s/ Charles M. Lizza

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