IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHEMO RESEARCH SL, AND BAUSCH HEALTH IRELAND, LTD.,

Plaintiffs,

v.

ENCUBE ETHICALS PRIVATE, LTD.,

Defendant.

Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Chemo Research SL and Bausch Health Ireland, Ltd. (individually "Chemo" and "Bausch," and collectively "Plaintiffs"), by and through their undersigned attorneys, for their Complaint against Defendant Encube Ethicals Private, Ltd. ("Encube" or "Defendant") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 7,893,097 (the "′097 Patent"), 8,658,678 (the "′678 Patent"), 8,877,792 (the "′792 Patent"), 8,946,276 (the "′276 Patent"), 9,198,858 (the "′858 Patent"), 10,238,634 (the "′634 Patent"), and 10,596,155 (the "′155 Patent"), arising under the patent laws of the United States, Title 35, United States Code, § 100 et seq., and in particular under 35 U.S.C. § 271(e). Encube notified Chemo pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "Notice Letter") that Encube is the owner of Abbreviated New Drug Application ("ANDA") No. 216795, (the "Encube ANDA"), which Encube filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use or sale of a generic version of NUVESSA® (metronidazole), 1.3% vaginal gel, which is sold in the United States. The

Encube proposed product described in the Encube ANDA is referred to herein as the "Generic Gel Product."

THE PARTIES

2. Plaintiff Chemo 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. Chemo has over a 45-year history and employs over 7,000 people around the world. Chemo focuses on the development, manufacture, and commercialization of pioneering drug products to enhance patients' outcomes and lives. Chemo is a wholly-owned subsidiary of Insud Pharma S.L.

3. Plaintiff Bausch is a company organized and existing under the laws of Ireland, having its principal place of business at 3013 Lake Drive, Citywest Business Campus, Dublin, 24, Ireland.

4. On information and belief, Defendant Encube Ethicals Pvt. Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Unit 24, Steelmade Industrial Estates, Andheri (E), Mumbai, 400 069 India. On information and belief, Encube is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Encube as a foreign entity that is subject to jurisdiction throughout the United States. *See* Fed. R. Civ. P. 4(k)(2).

7. This Court has personal jurisdiction over Encube by virtue of, *inter alia*, the fact that Encube has committed, or aided, abetted, contributed to, and/or participated in the

commission of the tortious act of patent infringement that has led, or will lead, to foreseeable harm and injury to Plaintiffs, including in the State of Delaware, and because Encube has engaged in purposeful systematic and continuous contacts with the State of Delaware.

8. This Court has personal jurisdiction over Encube because, on information and belief, Encube regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

9. This Court has personal jurisdiction over Encube by virtue of, *inter alia*, the fact that Encube distributes drug products for sale throughout the United States, including in this judicial district.

10. This Court has personal jurisdiction over Encube because, on information and belief, Encube has engaged in conduct that reliably predicts Delaware activities by Encube. On information and belief, by submitting ANDA No. 216795, Encube has taken the significant step of applying to the FDA for approval to engage in future activities that will be purposefully directed to Delaware.

11. This Court has personal jurisdiction over Encube by virtue of the fact that Encube has availed itself of the rights and benefits of Delaware law, and has engaged in systematic, continuous, constant, and pervasive contacts with the State of Delaware.

12. Venue is proper in this judicial district under 28 U.S.C. § 1391(c)(3) because Encube is a foreign entity who may be sued in any judicial district. Venue is also proper in this judicial district under 28 U.S.C. § 1400(b) because Encube has committed acts of infringement in this judicial district and has a regular and established place of business in this judicial district.

13. In addition, this Court has personal jurisdiction and venue over Encube because Encube has engaged in patent litigation concerning FDA-approved branded drug products in this district, has not contested personal jurisdiction or venue in this district, and has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court. *See, e.g.*, Encube's Answer at ¶¶ 7-12, *Taro Pharmaceutical Industries, Ltd., et al. v. Encube Ethicals Private Limited*, Case No. 1:21-cv-01614-RGA (D. Del. Nov. 19, 2021) (stating Encube will not contest personal jurisdiction or venue "for the limited purpose of this action only"); *id*. at 9-15 (asserting counterclaims); Encube's Answer at ¶ 28, *Anacor Pharmaceuticals, Inc., et al. v. Lupin Limited, et al*., Case No. 1:18-cv-01606-RGA (D. Del. Nov. 15, 2018) (stating Encube will not contest personal jurisdiction "for purposes of this case only"); *id*. at 31-43 (asserting counterclaims).

NUVESSA®

14. Chemo is the holder of New Drug Application ("NDA") 205223 for the manufacture and sale of metronidazole vaginal gel, which Chemo's U.S. subsidiary, Exeltis, U.S.A., Inc., markets and sells under the registered trademark NUVESSA®. NUVESSA® is approved for the treatment of bacterial vaginosis.

15. NUVESSA® is an embodiment of one or more claims of the ′097 Patent, the ′678 Patent, the ′792 Patent, the ′276 Patent, the ′858 Patent, the ′634 Patent, and the ′155 Patent (collectively, the "Patents-in-Suit"). The Patents-in-Suit are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") for NUVESSA®.

PATENTS-IN-SUIT

16. The ′097 Patent, entitled "Methods and Compositions for Increasing Solubility of Azole Drug Compounds that are Poorly Soluble in Water," was duly and legally issued by the

USPTO on February 22, 2011. The Orange Book lists the expiration date of the ′097 Patent as February 19, 2028. Bausch is the owner of all title, right and interest in and to the ′097 Patent by assignment and Chemo is Bausch's exclusive licensee. A copy of the ′097 Patent is attached as **Exhibit A**.

17. The ′678 Patent, entitled "Methods and Compositions for Increasing Solubility of Azole Drug Compounds that are Poorly Soluble in Water," was duly and legally issued by the USPTO on February 25, 2014. The Orange Book lists the expiration date of the ′678 Patent as June 27, 2028. Bausch is the owner of all title, right and interest in and to the ′678 Patent by assignment and Chemo is Bausch's exclusive licensee. A copy of the ′678 Patent is attached as **Exhibit B**.

18. The ′792 Patent, entitled "Compositions for Increasing Solubility of Azole Drug Compounds that are Poorly Soluble in Water," was duly and legally issued by the USPTO on November 4, 2014. The Orange Book lists the expiration date of the ′792 Patent as February 2, 2028. Bausch is the owner of all title, right and interest in and to the ′792 Patent by assignment and Chemo is Bausch's exclusive licensee. A copy of the ′792 Patent is attached as **Exhibit C**.

19. The ′276 Patent, entitled "High Dosage Mucoadhesive Metronidazole Aqueous-Based Gel Formulations and Their Use to Treat Bacterial Vaginosis," was duly and legally issued by the USPTO on February 3, 2015. The Orange Book lists the expiration date of the ′276 Patent as June 28, 2032. Chemo is the owner of all right, title, and interest in and to the ′276 Patent by assignment. A copy of the ′276 Patent is attached as **Exhibit D**.

20. The ′858 Patent, entitled "Methods of Treating Bacterial Vaginosis with Aqueous-based Metronidazole Gel Formulations," was duly and legally issued by the USPTO on December 1, 2015. The Orange Book lists the expiration date of the ′858 Patent as June 28,

2032. Chemo is the owner of all right, title, and interest in and to the ′858 Patent by assignment. A copy of the ′858 Patent is attached as **Exhibit E**.

21. The ′634 Patent, entitled "Aqueous-based Metronidazole Gel Formulations," was duly and legally issued by the USPTO on March 26, 2019. The Orange Book lists the expiration date of the ′634 Patent as June 28, 2032. Chemo is the owner of all right, title, and interest in and to the ′634 Patent by assignment. A copy of the ′634 Patent is attached as **Exhibit F**.

22. The ′155 Patent, entitled "Aqueous-based Metronidazole Gel Formulations," was duly and legally issued by the USPTO on March 24, 2020. The Orange Book lists the expiration date of the ′155 Patent as June 28, 2032. Chemo is the owner of all right, title, and interest in and to the ′155 Patent by assignment. A copy of the ′155 Patent is attached as **Exhibit G**.

ENCUBE'S ANDA

23. Encube filed or caused to be filed the Encube ANDA with FDA, seeking FDA approval to market and sell within the United States the Generic Gel Product before the expiration of the Patents-in-Suit.

24. On information and belief, the Encube ANDA identified NUVESSA® and included a written certification, as required by 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the claims of the Patents-in-Suit are invalid.

25. On or about May 16, 2022, Chemo received the Notice Letter from Encube, dated May 13, 2022, stating that pursuant to § 505(j)(2)(B)(ii) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B)(ii), Encube had submitted the Encube ANDA to the FDA.

26. In the Notice Letter, Encube stated its allegation that the claims of the Patents-in-Suit are invalid. In the Notice Letter, Encube failed to include an allegation that the claims of the Patents-in-Suit are not infringed by the Generic Gel Product.

27. Encube does not contest that at least one claim of each Patent-In-Suit would be infringed by the manufacture, use, or sale of the Generic Gel Product, unless those claims are found to be invalid.

28. By filing or causing to be filed the Encube ANDA, Encube necessarily represented to FDA that the Generic Gel Product has the same active ingredient as NUVESSA®, has the same method of administration, dosage form, and strength as NUVESSA® and is bioequivalent to NUVESSA®.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 7,893,097

29. Plaintiffs incorporate by reference Paragraphs 1-28 of this Complaint as if fully set forth herein.

30. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the Generic Gel Product before the expiration of the ´097 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

31. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ´097 Patent.

32. Encube's Generic Gel Product is a generic version of NUVESSA® and thus includes metronidazole, which is a poorly soluble imidazole or triazole chemical compound, as recited by claim 1 of the ´097 Patent.

33. The Notice Letter fails to assert that any limitations recited by claim 1 of the ′097 Patent are absent from Encube's Generic Gel Product.

34. On information and belief, if Encube commercially makes, uses, offers to sell, or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into the United States, or induces or contributes to any such conduct during the term of the ′097 Patent, Encube would further infringe the ′097 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

35. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel Product into the United States, during the term of the ′097 Patent, would directly infringe the ′097 Patent.

36. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or contribute to infringement of the ′097 Patent. At least through its commercial sale of its Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ′097 Patent. Encube will encourage acts of direct infringement with knowledge of the ′097 Patent and knowledge that it is encouraging infringement.

37. Encube had actual and constructive knowledge of the ′097 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ′097 Patent would constitute an act of infringement of the ′097 Patent.

38. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,658,678

39. Plaintiffs incorporate by reference Paragraphs 1- 38 of this Complaint as if fully set forth herein.

40. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Gel Product before the expiration of the ´678 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

41. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ´678 Patent.

42. Encube's Generic Gel Product is a generic version of NUVESSA® and thus includes metronidazole, which is an azole compound, as recited by claim 1 of the ´678 Patent.

43. According to the Notice Letter, Encube's Generic Gel Product will be marketed with prescribing instructions substantially similar to those of the current NUVESSA® product, which includes an indication for treating a dermatologic or mucosal disorder, as recited by claim 1 of the ´678 Patent.

44. The Notice Letter fails to assert that any limitations recited by claim 1 of the ´678 Patent are absent from Encube's Generic Gel Product.

45. On information and belief, if Encube commercially makes, uses, offers to sell or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into

the United States, or induces or contributes to any such conduct during the term of the ´678 Patent, Encube would further infringe the ´678 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

46. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel Product into the United States, during the term of the ´678 Patent, would directly infringe the ´678 Patent.

47. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or contribute to infringement of the ´678 Patent. At least in light of the prescribing instructions Encube proposes to provide in connection with the Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ´678 Patent. Encube will encourage acts of direct infringement with knowledge of the ´678 Patent and knowledge that it is encouraging infringement.

48. Encube had actual and constructive knowledge of the ´678 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ´678 Patent would constitute an act of infringement of the ´678 Patent.

49. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,877,792

50. Plaintiffs incorporate by reference Paragraphs 1- 49 of this Complaint as if fully set forth herein.

51. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Gel Product before the expiration of the ′792 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

52. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ′792 Patent.

53. Encube's Generic Gel Product is a generic version of NUVESSA® and thus includes metronidazole, as recited by claim 1 of the ′792 Patent.

54. The Notice Letter fails to assert that any limitations recited by claim 1 of the ′792 Patent are absent from Encube's Generic Gel Product.

55. On information and belief, if Encube commercially makes, uses, offers to sell or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into the United States, or induces or contributes to any such conduct during the term of the ′792 Patent, Encube would further infringe the ′792 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

56. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel Product into the United States, during the term of the ′792 Patent, would directly infringe the ′792 Patent.

57. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or

contribute to infringement of the ′792 Patent. At least through its commercial sale of its Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ′792 Patent. Encube will encourage acts of direct infringement with knowledge of the ′792 Patent and knowledge that it is encouraging infringement.

58. Encube had actual and constructive knowledge of the ′792 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ′792 Patent would constitute an act of infringement of the ′792 Patent.

59. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,946,276

60. Plaintiffs incorporate by reference Paragraphs 1- 59 of this Complaint as if fully set forth herein.

61. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Gel Product before the expiration of the ′276 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

62. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ′276 Patent.

63. Encube's Generic Gel Product is a generic version of NUVESSA® and thus includes 1.3% metronidazole, as recited by claim 1 of the ′276 Patent.

64. According to the Notice Letter, Encube's Generic Gel Product will be marketed with prescribing instructions substantially similar to those of the current NUVESSA® product, which includes an indication for treating a subject suffering from bacterial vaginosis, as recited by claim 1 of the ′276 Patent.

65. The Notice Letter fails to assert that any limitations recited by claim 1 of the ′276 Patent are absent from Encube's Generic Gel Product.

66. On information and belief, if Encube commercially makes, uses, offers to sell or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into the United States, or induces or contributes to any such conduct during the term of the ′276 Patent, Encube would further infringe the ′276 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

67. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel Product into the United States, during the term of the ′276 Patent, would directly infringe the ′276 Patent.

68. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or contribute to infringement of the ′276 Patent. At least in light of the prescribing instructions Encube proposes to provide in connection with the Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ′276 Patent. Encube will encourage acts of direct infringement with knowledge of the ′276 Patent and knowledge that it is encouraging infringement.

69. Encube had actual and constructive knowledge of the ′276 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ′276 Patent would constitute an act of infringement of the ′276 Patent.

70. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 9,198,858

71. Plaintiffs incorporate by reference Paragraphs 1- 70 of this Complaint as if fully set forth herein.

72. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Gel Product before the expiration of the ′858 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

73. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ′858 Patent.

74. Encube's Generic Gel Product is a generic version of NUVESSA® and thus includes a gel composition containing 1.3% metronidazole, as recited by claim 1 of the ′858 Patent.

75. According to the Notice Letter, Encube's Generic Gel Product will be marketed with prescribing instructions substantially similar to those of the current NUVESSA® product, which includes an indication for treating bacterial vaginosis, as recited by claim 1 of the ′858 Patent.

76. The Notice Letter fails to assert that any limitations recited by claim 1 of the ′858 Patent are absent from Encube's Generic Gel Product.

77. On information and belief, if Encube commercially makes, uses, offers to sell or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into the United States, or induces or contributes to any such conduct during the term of the ′858 Patent, Encube would further infringe the ′858 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

78. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel Product into the United States, during the term of the ′858 Patent, would directly infringe the ′858 Patent.

79. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or contribute to infringement of the ′858 Patent. At least in light of the prescribing instructions Encube proposes to provide in connection with the Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ′858 Patent. Encube will encourage acts of direct infringement with knowledge of the ′858 Patent and knowledge that it is encouraging infringement.

80. Encube had actual and constructive knowledge of the ′858 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ′858 Patent would constitute an act of infringement of the ′858 Patent.

81. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 10,238,634

82. Plaintiffs incorporate by reference Paragraphs 1- 81 of this Complaint as if fully set forth herein.

83. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic Gel Product before the expiration of the ´634 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

84. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ´634 Patent.

85. Encube's Generic Gel Product is a generic version of NUVESSA® and is thus a gel composition containing 1.3% metronidazole , as recited by claim 1 of the ´634 Patent.

86. The Notice Letter fails to assert that any limitations recited by claim 1 of the ´634 Patent are absent from Encube's Generic Gel Product.

87. On information and belief, if Encube commercially makes, uses, offers to sell or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into the United States, or induces or contributes to any such conduct during the term of the ´634 Patent, Encube would further infringe the ´634 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

88. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel

Product into the United States, during the term of the ′634 Patent, would directly infringe the ′634 Patent.

89. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or contribute to infringement of the ′634 Patent. At least in light of the prescribing instructions Encube proposes to provide in connection with the Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ′634 Patent. Encube will encourage acts of direct infringement with knowledge of the ′634 Patent and knowledge that it is encouraging infringement.

90. Encube had actual and constructive knowledge of the ′634 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ′634 Patent would constitute an act of infringement of the ′634 Patent.

91. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT VII FOR INFRINGEMENT OF U.S. PATENT NO. 10,596,155

92. Plaintiffs incorporate by reference Paragraphs 1- 91 of this Complaint as if fully set forth herein.

93. By filing or causing to be filed the Encube ANDA with FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of the Generic

Gel Product before the expiration of the ′155 Patent, Encube committed an act of infringement under 35 U.S.C. § 271(e)(2).

94. On information and belief, Encube's Generic Gel Product and the use of Encube's Generic Gel Product are covered by at least claim 1 of the ′155 Patent.

95. Encube's Generic Gel Product is a generic version of NUVESSA® and thus includes metronidazole, as recited by claim 1 of the ′155 Patent.

96. According to the Notice Letter, Encube's Generic Gel Product will be marketed with prescribing instructions substantially similar to those of the current NUVESSA® product, which includes an indication for treating a subject with bacterial vaginosis, as recited by claim 1 of the ′155 Patent.

97. The Notice Letter fails to assert that any limitations recited by claim 1 of the ′155 Patent are absent from Encube's Generic Gel Product.

98. On information and belief, if Encube commercially makes, uses, offers to sell or sells the Generic Gel Product within the United States, or imports the Generic Gel Product into the United States, or induces or contributes to any such conduct during the term of the ′155 Patent, Encube would further infringe the ′155 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

99. On information and belief, Encube's commercial manufacture, use, offer to sell, or sale of the Generic Gel Product within the United States, or importation of the Generic Gel Product into the United States, during the term of the ′155 Patent, would directly infringe the ′155 Patent.

100. On information and belief, upon approval of the Encube ANDA, and the commercial marketing of the Generic Gel Product, Encube would actively induce and/or contribute to infringement of the ′155 Patent. At least in light of the prescribing instructions

Encube proposes to provide in connection with the Generic Gel Product, Encube will induce health care professionals, resellers, pharmacies, and end users of the Generic Gel Product to directly infringe one or more claims of the ´155 Patent. Encube will encourage acts of direct infringement with knowledge of the ´155 Patent and knowledge that it is encouraging infringement.

101. Encube had actual and constructive knowledge of the ´155 Patent prior to filing the Encube ANDA and was aware that the filing of the Encube ANDA with the request for FDA approval before the expiration of the ´155 Patent would constitute an act of infringement of the ´155 Patent.

102. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT VIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,893,097

103. Plaintiffs incorporate by reference Paragraphs 1- 102 of this Complaint as if fully set forth herein.

104. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

106. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the ´097 Patent, including Encube's filing of ANDA No. 216795.

107. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the´097 Patent.

COUNT IX FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,658,678

108. Plaintiffs incorporate by reference Paragraphs 1- 107 of this Complaint as if fully set forth herein.

109. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

110. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

111. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the ´678 Patent, including Encube's filing of ANDA No. 216795.

112. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ´678 Patent.

COUNT X FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,877,792

113. Plaintiffs incorporate by reference Paragraphs 1- 112 of this Complaint as if fully set forth herein.

114. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

115. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

116. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the´792 Patent, including Encube's filing of ANDA No. 216795.

117. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the´792 Patent.

COUNT XI FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,946,276

118. Plaintiffs incorporate by reference Paragraphs 1- 117 of this Complaint as if fully set forth herein.

119. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

120. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

121. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the´276 Patent, including Encube's filing of ANDA No. 216795.

122. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the´276 Patent.

COUNT XII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,198,858

123. Plaintiffs incorporate by reference Paragraphs 1- 122 of this Complaint as if fully set forth herein.

124. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

125. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

126. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the´858 Patent, including Encube's filing of ANDA No. 216795.

127. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ´858 Patent.

COUNT XIII FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,238,634

128. Plaintiffs incorporate by reference Paragraphs 1- 127 of this Complaint as if fully set forth herein.

129. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

130. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

131. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the ´634 Patent, including Encube's filing of ANDA No. 216795.

132. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ´634 Patent.

COUNT XIV FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,596,155

133. Plaintiffs incorporate by reference Paragraphs 1- 132 of this Complaint as if fully set forth herein.

134. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

135. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

136. Encube has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import the Encube ANDA Product before the expiration date of the ´155 Patent, including Encube's filing of ANDA No. 216795.

137. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ´155 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment in their favor and against Defendant and respectfully request the following relief:

A. A judgment that Defendant has infringed one or more claims of the ′097 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

B. A judgment that Defendant has infringed one or more claims of the ′678 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

C. A judgment that Defendant has infringed one or more claims of the ′792 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

D. A judgment that Defendant has infringed one or more claims of the ′276 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

E. A judgment that Defendant has infringed one or more claims of the ′858 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

F. A judgment that Defendant has infringed one or more claims of the ′634 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

G. A judgment that Defendant has infringed one or more claims of the ′155 Patent under 35 U.S.C. § 271(e)(2) by submitting the Encube ANDA;

H. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ′097 Patent, it will constitute an act of infringement of the ′097 Patent;

I. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial

manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ´678 Patent, it will constitute an act of infringement of the ´678 Patent;

J. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ´792 Patent, it will constitute an act of infringement of the ´792 Patent;

K. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ´276 Patent, it will constitute an act of infringement of the ´276 Patent;

L. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ´858 Patent, it will constitute an act of infringement of the ´858 Patent;

M. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ´634 Patent, it will constitute an act of infringement of the ´634 Patent;

N. A judgment pursuant to 28 U.S.C. §§ 2201 and 2202 declaring that if Defendant, its officers, agents, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Encube ANDA Product prior to the expiration of ´155 Patent, it will constitute an act of infringement of the ´155 Patent;

O. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, and affiliates, from making, using, selling, offering to sell, or importing any product that infringes the Patents-In-Suit, including the product described in the Encube ANDA, prior to the expiration of the Patents-In-Suit, including any extensions;

P. A judgment declaring that making, using, selling, offering to sell, or importing the product described in the Encube ANDA, or inducing or contributing to such conduct, would constitute infringement of the Patents-In-Suit by Defendant pursuant to 35 U.S.C. § 271;

Q. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Encube ANDA be a date that is not earlier than the latest expiration of the Patents-In-Suit or any later expiration of exclusivity to which Plaintiffs are or become entitled;

R. If Defendant, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliates, and those persons in active concert or participation with any of them commercially manufactures, uses, offers to sell, sells or imports the product described in the Encube ANDA prior to the expiration of the Patents-In-Suit or any later expiration of exclusivity to which Plaintiffs are or become entitled, a judgment awarding Plaintiffs' monetary relief, together with interest;

S. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and awarding reasonable attorneys' fees, costs and disbursement incurred as a result of this action; and

T. Such other and further relief as the Court deems just and proper.

Dated: June 24, 2022

PHILLIPS, MCLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.

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