IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED, and GEDEON RICHTER PLC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
DEVA HOLDING A.S.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INRINGEMENT

Plaintiffs AbbVie Inc. ("AbbVie"); Allergan Pharmaceuticals International Limited ("APIL"); and Gedeon Richter Plc. ("Gedeon Richter") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Deva Holding A.S. ("Deva") and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Deva's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of all strengths of Plaintiffs' pharmaceutical product VRAYLAR® (cariprazine capsules, 1.5 mg, 3 mg, 4.5 mg, and 6 mg) prior to the expiration of United States Patent Nos. 7,737,142 ("the '142 Patent"); 7,943,621 ("the '621 Patent"); RE47,350 ("the RE'350 Patent"); RE49,110 ("the RE'110 Patent"); and RE49,302 ("the RE'302 Patent") (collectively "the asserted patents"). Specifically, Deva has submitted ANDA No. 219532 (the "Deva ANDA") to the FDA prior to the expiration of the asserted patents. Plaintiffs seek injunctive relief and any other relief the Court deems just and proper.

PARTIES

2. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. AbbVie's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas. AbbVie holds New Drug Application ("NDA") No. 204370, under which the FDA approved the marketing of VRAYLAR® for the treatment of schizophrenia in adults, acute treatment of manic or mixed episodes associated with bipolar I disorder in adults, treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults, and as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults. AbbVie distributes VRAYLAR® in the United States.

3. Plaintiff APIL is a company organized and existing under the laws of Ireland, with its principal place of business at Clonshaugh Business & Technology Park, Dublin 17, D17 E400, Ireland. APIL is the exclusive licensee of the asserted patents.

4. Plaintiff Gedeon Richter (a/k/a Richter Gedeon Nyrt.) is a corporation organized under the laws of Hungary, with offices at Gyömrői út 19-21, H-1103 Budapest, Hungary. Gedeon Richter owns the asserted patents.

5. On information and belief, defendant Deva is a corporation organized and existing under the laws of Turkey, with a principal place of business at Halkali Merkez Mahallesi Basin Ekspres Cad. No: 1 34303 Küçükçekmece – Istanbul Sicil No: 70061.

6. On information and belief, Deva caused the Deva ANDA to be submitted to the FDA and seeks the FDA's approval of the Deva ANDA and to market its proposed generic cariprazine capsules, 1.5 mg, 3 mg, 4.5 mg, and 6 mg (the "Deva ANDA Products").

7. On information and belief, Deva intends to commercially manufacture, market, offer for sale, and sell the Deva ANDA Products throughout the United States, including in Delaware, in the event the FDA approves the Deva ANDA.

JURISDICTION AND VENUE

8. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the asserted patents. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

9. This Court has personal jurisdiction over Deva because, on information and belief, Deva, *inter alia*, has continuous and systematic contacts with Delaware, regularly conducts business in Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos, has purposefully availed itself of the privilege of doing business in Delaware, and intends to sell the Deva ANDA Products in Delaware upon approval of the Deva ANDA.

10. On information and belief, Deva is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Deva manufactures, distributes, markets and/or sells throughout the United States and in this judicial district.

11. On information and belief, Deva is licensed to sell generic and proprietary pharmaceutical products in Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

12. Deva has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patents that will lead to foreseeable harm and injury to Plaintiffs. On information and belief, and as indicated by a letter dated September 17, 2025 sent by Deva to AbbVie and Gedeon Richter pursuant to

21 U.S.C. § 355(j)(2)(b) ("Deva's Notice Letter"), Deva prepared and filed the Deva ANDA with the intention of seeking to market the Deva ANDA Products nationwide, including within this judicial district.

13. On information and belief, Deva plans to sell the Deva ANDA Products in Delaware, list the Deva ANDA Products on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of the Deva ANDA Products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

14. On information and belief, Deva knows and intends that the Deva ANDA Products will be distributed and sold in Delaware and will thereby displace sales of VRAYLAR®, causing injury to Plaintiffs. Deva intends to take advantage of its established channels of distribution in Delaware for the sale of the Deva ANDA Products.

15. Deva has engaged in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue, and has filed counterclaims in this judicial district in such litigation. *See, e.g.*, *Astellas Pharma Inc., et al. v. Deva Holding A/S*, No. 25-233, Dkt. 14, (D. Del. June 9, 2025) (MN) (not contesting personal jurisdiction and asserting counterclaims).

16. Additionally, this Court has personal jurisdiction over Deva because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Deva is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Deva has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of the Deva ANDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United

States, including in this judicial district, such that this Court's exercise of jurisdiction over Deva satisfies due process.

17. Venue is proper in this district for Deva pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, Deva is a corporation organized and existing under the laws of Turkey and may be sued in any judicial district.

THE ASSERTED PATENTS AND VRAYLAR®

18. VRAYLAR® is an atypical antipsychotic indicated for (1) treatment of schizophrenia in adults, (2) acute treatment of manic or mixed episodes associated with bipolar I disorder in adults, (3) treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults, and (4) adjunctive therapy to antidepressants for treating major depressive disorder.

19. The '142 Patent, titled "(Thio) Carbamoyl-Cyclohexane Derivatives as D3/D2 Receptor Antagonists," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on June 15, 2010. A true and correct copy of the '142 Patent is attached as Exhibit A.

20. The '621 Patent, titled "Salts of Piperazine Compounds as D_3/D_2 Antagonists," was duly and legally issued by the USPTO on May 17, 2011. A true and correct copy of the '621 Patent is attached as Exhibit B.

21. The RE'350 Patent, titled "Pharmaceutical Formulations Containing Dopamine Receptor Ligands," was duly and legally issued by the USPTO on April 16, 2019. A true and correct copy of the RE'350 Patent is attached as Exhibit C.

22. The RE'110 Patent, titled "Pharmaceutical Formulations Containing Dopamine Receptor Ligands," was duly and legally issued by the USPTO on June 21, 2022. A true and correct copy of the RE'110 Patent is attached as Exhibit D.

23. The RE'302 Patent, titled "Pharmaceutical Formulations Containing Dopamine Receptor Ligands," was duly and legally issued by the USPTO on November 15, 2022. A true and correct copy of the RE'302 Patent is attached as Exhibit E.

24. AbbVie holds NDA No. 204370, under which the FDA approved the marketing of VRAYLAR® for the treatment of schizophrenia in adults, and for the treatment of manic or mixed episodes associated with bipolar I disorder in adults, on September 17, 2015. The FDA approved the marketing of VRAYLAR® for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults on May 24, 2019. The FDA approved the marketing of VRAYLAR® as an adjunctive therapy to antidepressants for the treatment of major depressive disorder (MDD) in adults on December 16, 2022.

25. The FDA has listed the asserted patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") for NDA No. 204370.

THE DEVA ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

26. On information and belief, Deva submitted the Deva ANDA to FDA under 21 U.S.C. § 355(j), to obtain approval to engage in the commercial manufacture, use, or sale of the products described therein as purported generic versions of VRAYLAR® (cariprazine capsules, 1.5 mg, 3 mg, 4.5 mg, and 6 mg) prior to the expiration of the asserted patents.

27. Deva sent Plaintiffs Deva's Notice Letter. Deva's Notice Letter represented that Deva had submitted the Deva ANDA to FDA with a purported Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Deva ANDA, before the expiration of the asserted patents. Hence, Deva's purpose in submitting the Deva ANDA is to manufacture and market the Deva ANDA Products before the expiration of the asserted patents. Deva's Notice Letter also stated that the purported Paragraph IV Certification alleges that the asserted patents are invalid,

unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the Deva ANDA Products.

28. For at least one claim of each of the '142 and '621 Patents, Deva's Notice Letter failed to allege that the Deva ANDA Products or the proposed administration of the Deva ANDA Products would not meet the limitations of that claim.

29. Deva's Notice Letter did not allege that any claims of the RE'350, RE'110, or RE'302 Patents were invalid.

30. In Deva's Notice Letter, Deva purported to offer confidential access to portions of ANDA No. 219532 on terms and conditions set forth in Deva's Notice Letter ("the Deva Offer"). Deva requested that AbbVie accept the Deva Offer before receiving access to ANDA No. 219532. The Deva Offer contained unreasonable restrictions regarding access to its ANDA, well beyond those that would apply under a protective order. For example, the Deva Offer did not permit AbbVie's in-house counsel or scientific experts to access ANDA No. 219532. The restrictions the Deva Offer placed on access to ANDA No. 219532 contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, ***as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information***" (emphasis added).

31. On information and belief, Deva prepared and submitted the Deva ANDA, and intends to further prosecute the Deva ANDA. On information and belief, if the FDA approves the Deva ANDA, Deva will manufacture, offer for sale, or sell the Deva ANDA Products within the United States, or will import the Deva ANDA Products into the United States. On information and

belief, if the FDA approves the Deva ANDA, Deva will actively induce or contribute to the manufacture, use, offer for sale, or sale of the Deva ANDA Products in the United States.

32. Plaintiffs bring this action within forty-five days of receipt of Deva's Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 21 U.S.C. § 355(j)(5)(F)(ii).

COUNT 1:
INFRINGEMENT OF THE '142 PATENT BY DEVA

33. Plaintiffs state, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

34. On information and belief, Deva has submitted the Deva ANDA to the FDA, and continues to seek FDA approval of the Deva ANDA.

35. Plaintiffs own all rights, title, and interest in and to the '142 Patent.

36. The Deva ANDA Products infringe one or more claims of the '142 Patent.

37. Deva did not contest infringement of any claims of the '142 Patent in Deva's Notice Letter. If Deva had a factual or legal basis to contest infringement of the claims of the '142 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

38. Deva has infringed the '142 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Deva ANDA with a Paragraph IV Certification and seeking FDA approval of the Deva ANDA prior to the expiration of the '142 Patent.

39. Upon information and belief, Deva's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the Deva ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '142 Patent. *See* 35 U.S.C. § 271(a), (b), (c), and (g). Accordingly, unless enjoined by this Court, upon

FDA approval of the Deva ANDA, Deva will make, use, offer to sell, or sell the Deva ANDA Products within the United States, or will import the Deva ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '142 Patent. *See id.*

40. On information and belief, upon FDA approval of the Deva ANDA, Deva will market and distribute the Deva ANDA Products to resellers, pharmacies, health care professionals, and end users of the Deva ANDA Products. Accompanying the Deva ANDA Products, Deva will also knowingly and intentionally include a product label and insert containing instructions for administering the Deva ANDA Products. Accordingly, Deva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Deva ANDA Products to directly infringe one or more claims of the '142 Patent. In addition, on information and belief, Deva will encourage acts of direct infringement with knowledge of the '142 Patent and knowledge that it is encouraging infringement.

41. Deva had actual and constructive notice of the '142 Patent prior to filing the Deva ANDA, and was aware that the filing of the Deva ANDA with the request for FDA approval prior to the expiration of the '142 Patent would constitute an act of infringement of the '142 Patent.

42. Deva filed the Deva ANDA without adequate justification for asserting that the '142 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Deva ANDA Products. Deva's conduct in certifying invalidity with respect to the '142 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

43. Plaintiffs will be irreparably harmed if Deva is not enjoined from infringing, and from actively inducing and contributing to the infringement of the ’142 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT 2:
INFRINGEMENT OF THE ’621 PATENT BY DEVA

44. Plaintiffs state, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

45. On information and belief, Deva has submitted the Deva ANDA to the FDA, and continues to seek FDA approval of the Deva ANDA.

46. Plaintiffs own all rights, title, and interest in and to the ’621 Patent.

47. The Deva ANDA Products infringe one or more claims of the ’621 Patent.

48. Deva did not contest infringement of at least claims 1 and 8–17 of the ’621 Patent in Deva’s Notice Letter. If Deva had a factual or legal basis to contest infringement of the claims of the ’621 Patent, it was required by applicable regulations to state such a basis in its Notice Letter. *See* 21 CFR § 314.95(c)(7); 21 CFR § 314.52.

49. Deva has infringed the ’621 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Deva ANDA with a Paragraph IV Certification and seeking FDA approval of the Deva ANDA prior to the expiration of the ’621 Patent.

50. Upon information and belief, Deva’s commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the Deva ANDA Products would directly infringe, and would actively induce and contribute to infringement of the ’621 Patent. *See* 35 U.S.C. § 271(a), (b), (c), and (g). Accordingly, unless enjoined by this Court, upon FDA approval of the Deva ANDA, Deva will make, use, offer to sell, or sell the Deva ANDA Products within the United States, or will import the Deva ANDA Products into the United States,

and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the ’621 Patent. *See id.*

51. On information and belief, Deva will encourage acts of direct infringement with knowledge of the ’621 Patent and knowledge that it is encouraging infringement.

52. Deva had actual and constructive notice of the ’621 Patent prior to filing the Deva ANDA, and was aware that the filing of the Deva ANDA with the request for FDA approval prior to the expiration of the ’621 Patent would constitute an act of infringement of the ’621 Patent.

53. Deva filed the Deva ANDA without adequate justification for asserting that the ’621 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Deva ANDA Products. Deva’s conduct in certifying invalidity with respect to the ’621 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys’ fees and such other relief as this Court deems proper.

54. Plaintiffs will be irreparably harmed if Deva is not enjoined from infringing, and from actively inducing and contributing to the infringement of the ’621 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT 3:
INFRINGEMENT OF THE RE’350 PATENT BY DEVA

55. Plaintiffs state, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

56. On information and belief, Deva has submitted the Deva ANDA to the FDA, and continues to seek FDA approval of the Deva ANDA.

57. Plaintiffs own all rights, title, and interest in and to the RE’350 Patent.

58. The Deva ANDA Products infringe one or more claims of the RE’350 Patent.

59. Deva has infringed the RE'350 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Deva ANDA with a Paragraph IV Certification and seeking FDA approval of the Deva ANDA prior to the expiration of the RE'350 Patent.

60. Upon information and belief, Deva's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the Deva ANDA Products would directly infringe, and would actively induce and contribute to infringement of the RE'350 Patent. *See* 35 U.S.C. § 271(a), (b), (c), and (g). Accordingly, unless enjoined by this Court, upon FDA approval of the Deva ANDA, Deva will make, use, offer to sell, or sell the Deva ANDA Products within the United States, or will import the Deva ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the RE'350 Patent. *See id.*

61. On information and belief, upon FDA approval of the Deva ANDA, Deva will market and distribute the Deva ANDA Products to resellers, pharmacies, health care professionals, and end users of the Deva ANDA Products. Accompanying the Deva ANDA Products, Deva will also knowingly and intentionally include a product label and insert containing instructions for administering the Deva ANDA Products. Accordingly, Deva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Deva ANDA Products to directly infringe one or more claims of the RE'350 Patent. In addition, on information and belief, Deva will encourage acts of direct infringement with knowledge of the RE'350 Patent and knowledge that it is encouraging infringement.

62. Deva had actual and constructive notice of the RE'350 Patent prior to filing the Deva ANDA, and was aware that the filing of the Deva ANDA with the request for FDA approval

prior to the expiration of the RE'350 Patent would constitute an act of infringement of the RE'350 Patent.

63. Deva filed the Deva ANDA without adequate justification for asserting that the RE'350 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Deva ANDA Products. Deva's conduct in certifying invalidity with respect to the RE'350 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

64. Plaintiffs will be irreparably harmed if Deva is not enjoined from infringing, and from actively inducing and contributing to the infringement of the RE'350 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT 4:
INFRINGEMENT OF THE RE'110 PATENT BY DEVA

65. Plaintiffs state, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

66. On information and belief, Deva has submitted the Deva ANDA to the FDA, and continues to seek FDA approval of the Deva ANDA.

67. Plaintiffs own all rights, title, and interest in and to the RE'110 Patent.

68. The Deva ANDA Products infringe one or more claims of the RE'110 Patent.

69. Deva has infringed the RE'110 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Deva ANDA with a Paragraph IV Certification and seeking FDA approval of the Deva ANDA prior to the expiration of the RE'110 Patent.

70. Upon information and belief, Deva's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the Deva ANDA Products

would directly infringe, and would actively induce and contribute to infringement of the RE'110 Patent. *See* 35 U.S.C. § 271(a), (b), (c), and (g). Accordingly, unless enjoined by this Court, upon FDA approval of the Deva ANDA, Deva will make, use, offer to sell, or sell the Deva ANDA Products within the United States, or will import the Deva ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the RE'110 Patent. *See id.*

71. On information and belief, upon FDA approval of the Deva ANDA, Deva will market and distribute the Deva ANDA Products to resellers, pharmacies, health care professionals, and end users of the Deva ANDA Products. Accompanying the Deva ANDA Products, Deva will also knowingly and intentionally include a product label and insert containing instructions for administering the Deva ANDA Products. Accordingly, Deva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Deva ANDA Products to directly infringe one or more claims of the RE'110 Patent. In addition, on information and belief, Deva will encourage acts of direct infringement with knowledge of the RE'110 Patent and knowledge that it is encouraging infringement.

72. Deva had actual and constructive notice of the RE'110 Patent prior to filing the Deva ANDA, and was aware that the filing of the Deva ANDA with the request for FDA approval prior to the expiration of the RE'110 Patent would constitute an act of infringement of the RE'110 Patent.

73. Deva filed the Deva ANDA without adequate justification for asserting that the RE'110 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Deva ANDA Products. Deva's conduct in certifying invalidity with respect to the RE'110 Patent renders this case "exceptional" as that term is set forth in

35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

74. Plaintiffs will be irreparably harmed if Deva is not enjoined from infringing, and from actively inducing and contributing to the infringement of the RE'110 Patent. Plaintiffs do not have an adequate remedy at law.

COUNT 5:
INFRINGEMENT OF THE RE'302 PATENT BY DEVA

75. Plaintiffs state, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

76. On information and belief, Deva has submitted the Deva ANDA to the FDA, and continues to seek FDA approval of the Deva ANDA.

77. Plaintiffs own all rights, title, and interest in and to the RE'302 Patent.

78. The Deva ANDA Products infringe one or more claims of the RE'302 Patent.

79. Deva has infringed the RE'302 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Deva ANDA with a Paragraph IV Certification and seeking FDA approval of the Deva ANDA prior to the expiration of the RE'302 Patent.

80. Upon information and belief, Deva's commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the Deva ANDA Products would directly infringe, and would actively induce and contribute to infringement of the RE'302 Patent. *See* 35 U.S.C. § 271(a), (b), (c), and (g). Accordingly, unless enjoined by this Court, upon FDA approval of the Deva ANDA, Deva will make, use, offer to sell, or sell the Deva ANDA Products within the United States, or will import the Deva ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the RE'302 Patent. *See id.*

81. On information and belief, upon FDA approval of the Deva ANDA, Deva will market and distribute the Deva ANDA Products to resellers, pharmacies, health care professionals, and end users of the Deva ANDA Products. Accompanying the Deva ANDA Products, Deva will also knowingly and intentionally include a product label and insert containing instructions for administering the Deva ANDA Products. Accordingly, Deva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the Deva ANDA Products to directly infringe one or more claims of the RE'302 Patent. In addition, on information and belief, Deva will encourage acts of direct infringement with knowledge of the RE'302 Patent and knowledge that it is encouraging infringement.

82. Deva had actual and constructive notice of the RE'302 Patent prior to filing the Deva ANDA, and was aware that the filing of the Deva ANDA with the request for FDA approval prior to the expiration of the RE'302 Patent would constitute an act of infringement of the RE'302 Patent.

83. Deva filed the Deva ANDA without adequate justification for asserting that the RE'302 Patent is invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the Deva ANDA Products. Deva's conduct in certifying invalidity with respect to the RE'302 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285, and entitles Plaintiffs to recovery of their attorneys' fees and such other relief as this Court deems proper.

84. Plaintiffs will be irreparably harmed if Deva is not enjoined from infringing, and from actively inducing and contributing to the infringement of the RE'302 Patent. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment that Deva has infringed the '142, '621, RE'350, RE'110, and RE'302 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) A judgment and order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of the Deva ANDA shall be no earlier than the last expiration date of any of the '142, '621, RE'350, RE'110, or RE'302 Patents, or any later expiration of exclusivity for any of the '142, '621, RE'350, RE'110, or RE'302 Patents, including any extensions or regulatory exclusivities;

(c) Entry of a permanent injunction, enjoining Deva and its officers, agents, servants, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert or in participation with Deva or on its behalf from commercially manufacturing, using, offering for sale, or selling the Deva ANDA Products within the United States, or importing the Deva ANDA Products into the United States, until the day after the expiration of the '142, '621, RE'350, RE'110, and RE'302 Patents, including any additional exclusivity period applicable to those patents, and from otherwise infringing the claims of the '142, '621, RE'350, RE'110, and RE'302 Patents;

(d) A judgment declaring that making, using, selling, offering to sell, or importing the Deva ANDA Products, or inducing or contributing to such conduct, would constitute infringement of the '142, '621, RE'350, RE'110, and RE'302 Patents pursuant to 35 U.S.C. § 271 (a), (b), (c) and/or (g);

(e) A declaration under 28 U.S.C. § 2201 that if Deva, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the Deva

ANDA Products, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), (c) and/or (g);

(f) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Deva engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the Deva ANDA Products, or any product that infringes the '142, '621, RE'350, RE'110, or RE'302 Patents, or induces or contributes to such conduct, prior to the expiration of the patents including any additional exclusivity period applicable to those patents;

(g) A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) Costs and expenses in this action; and

(i) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

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