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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ATHENA BIOSCIENCE, LLC, *Plaintiff,* v. NOVITIUM PHARMA LLC, *Defendant.*	Civil Action No. **COMPLAINT**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Athena Bioscience, LLC ("Athena" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendant Novitium Pharma LLC ("Defendant"), hereby allege as follows:

THE PARTIES

1. Plaintiff Athena Bioscience, LLC is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1272 Virgil Langford Road, Suite 201A, Watkinsville, GA 30677.

2. On information and belief, Defendant Novitium Pharma LLC ("Novitium") is a corporation operating and existing under the laws of the State of Delaware, with a principal place of at 70 Lake Dr, East Windsor, NJ 08520.

3. On information and belief, Novitium, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through its own actions.

4. On information and belief, Defendant participated and collaborated in the research and development, and the preparation and filing, of Abbreviated New Drug Application ("ANDA") No. 219647 ("Novitium's ANDA") for tramadol hydrochloride oral solution 5 mg/mL ("Novitium's Product"), continues to participate and collaborate in seeking U.S. Food and Drug Administration ("FDA") approval of that application, and intends to participate and collaborate in the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States, including in the State of Delaware, in the event the FDA approves Novitium's ANDA.

NATURE OF THE ACTION

5. This is a civil action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., arising from Defendant's filing of Novitium's ANDA with the FDA seeking approval to market a generic version of Plaintiff's pharmaceutical product QDOLO® (tramadol hydrochloride oral solution 5 mg/mL) ("QDOLO®") prior to the expiration of United States Patent Nos. 11,103,452 ("'452 patent") and 11,752,103 ("'103 patent") (collectively, "the patents-in-suit"), including any applicable exclusivities or extensions.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Defendant by virtue of the fact, *inter alia*, on information and belief Defendant has committed, encouraged, aided, abetted and/or participated in the commission of a tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led and/or or will lead to foreseeable harm and injury to Athena in the State of Delaware and throughout the United States.

8. This Court has personal jurisdiction over Defendant by first by virtue of the fact that Defendant is at home in Delaware as reflected by the fact that, on information and belief, Defendant regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including by selling its pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Defendant conducts marketing and sales activities in the State of Delaware, including but not limited to, distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic. On information and belief, if Novitium's ANDA is approved by the FDA, Defendant will sell, offer for sale, and distribute generic version of QDOLO® throughout the United States, including within this judicial district.

9. Upon information and belief, if ANDA 219647 is approved, Novitium's Product will, *inter alia*, be marketed and distributed by Defendant in the State of Delaware, prescribed by physicians practicing in the State of Delaware, dispensed by pharmacies located within the State of Delaware, and/or used by patients in the State of Delaware.

10. This Court also has personal jurisdiction over Novitium by virtue of the fact that it previously submitted to the jurisdiction of this Court and availed itself of this Court by

consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction including, but not limited to, *e.g.*: *iCeutica Pty Ltd. et al v. Novitium Pharma LLC*, No. 1:18-cv-00599 (D. Del.), *Orphalan SA v. Novitium Pharma LLC*, No. 1:23-cv-01079 (D. Del.) and *Azurity Pharmaceuticals, Inc. v. Novitium Pharma, LLC*, No. 1:23-cv-00163 (D. Del.).

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

THE PATENTS-IN-SUIT

12. On August 31, 2021, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '452 patent entitled "Tramadol Hydrochloride Solution." The '452 patent will expire no later than September 1, 2040. At the time of its issue, the '452 patent was assigned to Athena Bioscience, LLC. Athena Bioscience, LLC currently is the sole assignee and owner of all legal right, title, and interest in and to the '452 patent with claims directed towards an oral solution comprising tramadol hydrochloride. A true and correct copy of the '452 patent is attached hereto as Exhibit A.

13. On September 12, 2023, the USPTO duly and legally issued the '103 patent entitled "Tramadol Hydrochloride Solution." The '103 patent will expire no later than September 1, 2040. At the time of its issue, the '103 patent was assigned to Athena Bioscience, LLC. Athena Bioscience, LLC currently is the sole assignee and owner of all legal right, title, and interest in and to the '103 patent with claims directed towards an oral solution comprising tramadol hydrochloride. A true and correct copy of the '103 patent is attached hereto as Exhibit B.

ATHENA'S QDOLO® PRODUCT

14. Athena Bioscience, LLC is the owner of FDA-approved New Drug Application No. 214044 ("the QDOLO® NDA") for tramadol hydrochloride oral solution 5 mg/mL in the United States ("US"), which is sold in the United States under the trademark QDOLO®.

15. QDOLO® is currently approved by the FDA for use in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

16. Pursuant to 21 U.S.C. § 355, and attendant FDA regulations, the patents-in-suit are listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") for the QDOLO® NDA.

17. The patents-in-suit qualify for listing in the Orange Book in connection with NDA No. 214044 because they claim QDOLO® and/or an approved use thereof.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

18. By a letter dated November 14, 2024 ("Novitium's Notice Letter"), Novitium advised Athena that ANDA No. 219647 was submitted to the FDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions. Novitium's Notice Letter also advised Athena that Novitium's ANDA submission included certifications under 355(j)(2)(A)(vii)(IV) that certain claims of the patents-in-suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product.

19. On information and belief, Defendant submitted ANDA No. 219647 to the FDA under § 355(j) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product as a generic version of QDOLO®.

20. On information and belief, ANDA No. 219647 seeks FDA approval of Novitium's Product for use as a nitrogen-binding agent for use in adults for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

21. On information and belief, the conditions of use for which Defendant seeks approval of Novitium's Product in ANDA No. 219647 are the same as those set forth in the FDA-approved labeling for QDOLO®.

22. On information and belief, ANDA No. 219647 refers to and relies upon the QDOLO® NDA and contains data that, according to Defendant, demonstrate the bioequivalence of Novitium's Product and QDOLO®.

23. On information and belief, upon approval of ANDA No. 219647, Defendant will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of the Novitium Product. On information and belief, Defendant intends, conditioned upon FDA approval of ANDA No. 219647, to market the Novitium Product for the indication included in the approved label for QDOLO®. On information and belief, Defendant also intends for medical practitioners and/or physicians to prescribe, and for patients to use, the Novitium Product in accordance with, and as directed by, Novitium's proposed labeling for the Novitium Product.

24. Athena is commencing this action within 45 days of receiving Novitium's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I

(Infringement of the '452 patent)

25. Athena incorporates each of the preceding paragraphs 1 to 24 as if fully set forth herein.

26. By submitting ANDA No. 219647 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States, including Delaware, prior to the expiration of the '452 patent (including any applicable exclusivities or extensions), Defendant committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. On information and belief, Defendant's commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States prior to the expiration of the '452 patent, including any applicable exclusivities or extensions, will infringe under 35 U.S.C. § 271(a), (b) and/or (c).

28. On information and belief, the conditions of use for Novitium's Product for which Defendant seeks approval in Novitium's ANDA fall within one or more of the claims of the '452 patent. On information and belief, if approved, use of Novitium's Product in accordance with the proposed labeling submitted in Novitium's ANDA would infringe one or more of the claims of the '452 patent.

29. On information and belief, upon approval of Novitium's ANDA, and the commercial marketing thereof, Defendant will actively induce and/or contribute to infringement of the '452 patent.

30. On information and belief, Defendant had actual and constructive notice of the '452 patent as of its issue date, and Defendant's infringement of the '452 patent is willful.

31. Athena is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order by this Court that the effective date of the approval of Novitium's ANDA be a date that is not earlier than the expiration of the '452 patent, or any later expiration of any exclusivity or extension of the '452 patent to which Plaintiff or the patent may become entitled.

32. On information and belief, the detailed statement of the factual and legal bases that each of the '452 claims is invalid, unenforceable, and/or not infringed is devoid of an objective good faith basis in either the facts or the law. This case is exceptional and Athena is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

33. Athena will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Athena has no adequate remedy at law.

COUNT II

(Declaration of Infringement of the '452 patent)

34. Athena incorporates each of the preceding paragraphs 1 to 33 as if fully set forth herein.

35. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

36. There currently exists an actual case or controversy such that the Court may enter Athena's 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.

37. Defendant's commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States, including Delaware, prior to the expiration of

the ’452 patent (including any applicable exclusivities or extensions), would infringe the ’452 patent.

38. Defendant seeks approval of Novitium’s ANDA, and to market Novitium’s Product, prior to the expiration of the ’452 patent, including any applicable exclusivities or extensions.

39. Defendant has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, import, offer for sale, and/or sell Novitium’s Product prior to the expiration of the ’452 patent, including any applicable exclusivities or extensions.

40. Athena is entitled to a declaratory judgment that the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium’s Product throughout the United States, including Delaware, prior to the expiration of the ’452 patent (including any applicable exclusivities or extensions) by Defendant would constitute active inducement and/or contributory infringement of the ’452 patent.

41. Athena will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Athena has no adequate remedy at law.

42. This case is exceptional and Athena is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT III

(Infringement of the ’103 patent)

43. Athena incorporates each of the preceding paragraphs 1 to 42 as if fully set forth herein.

44. By submitting ANDA No. 219647 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium’s Product throughout the United States, including Delaware, prior to the expiration of the ’103 patent (including any applicable

exclusivities or extensions), Defendant has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

45. On information and belief, Defendant's commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States prior to the expiration of the '103 patent, including any applicable exclusivities or extensions, will infringe under 35 U.S.C. § 271(a), (b) and/or (c).

46. On information and belief, the conditions of use for Novitium's Product for which Defendant seeks approval in Novitium's ANDA fall within one or more of the claims of the '197 patent. On information and belief, if approved, use of Novitium's Product in accordance with the proposed labeling submitted in Novitium's ANDA would infringe one or more of the claims of the '103 patent.

47. On information and belief, upon approval of Novitium's ANDA, and the commercial marketing thereof, Defendant will actively induce and/or contribute to infringement of the '103 patent.

48. On information and belief, Defendant had actual and constructive notice of the '103 patent as of its issue date, and Defendant's infringement of the '103 patent is willful.

49. Athena is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order by this Court that the effective date of the approval of Novitium's ANDA be a date that is not earlier than the expiration of the '103 patent, or any later expiration of any exclusivity or extension of the '103 patent to which Plaintiff or the patent may become entitled.

50. On information and belief, the detailed statement of the factual and legal bases that each of the '103 patent is invalid, unenforceable, and/or not infringed is devoid of an

objective good faith basis in either the facts or the law. This case is exceptional and Athena is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

51. Athena will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Athena has no adequate remedy at law.

COUNT IV

(Declaration of Infringement of the '103 patent)

52. Athena incorporates each of the preceding paragraphs 1 to 51 as if fully set forth herein.

53. This count arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

54. There currently exists an actual case or controversy such that the Court may enter Athena's 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.

55. Defendant's commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States, including Delaware, prior to the expiration of the '103 patent (including any applicable exclusivities or extensions), would infringe the '103 patent.

56. Defendant seeks approval of Novitium's ANDA, and to market Novitium's Product, prior to the expiration of the '103 patent, including any applicable exclusivities or extensions.

57. Defendant has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, import, offer for sale, and/or sell Novitium's Product prior to the expiration of the '103 patent, including any applicable exclusivities or extensions.

58. Athena is entitled to a declaratory judgment that the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States, including Delaware, prior to the expiration of the '103 patent (including any applicable

exclusivities or extensions) by Defendant would constitute active inducement and/or contributory infringement of the '103 patent.

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

60. This case is exceptional and Athena is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Athena respectfully requests the following relief:

A. A judgment declaring that Defendant has infringed one or more claims of the patents-in-suit by submitting ANDA No. 219647 seeking FDA approval for the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States before the expiration of any of the patents-in-suit (including any applicable exclusivities or extensions) under 35 U.S.C. § 271(e)(2)(A);

B. A declaration pursuant to 28 U.S.C. §§ 2201 and 2202 that if Defendant, its officers, directors, employees, representatives, agents, parents, subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and their successors and assigns, commercially manufacture, use, import, offer for sale, and/or sell Novitium's Product throughout the United States, including Delaware, prior to the expiration of any of the patents-in-suit (including any applicable exclusivities or extensions), it will constitute an act of infringement under 35 U.S.C. § 271(a), (b) and/or (c);

C. A judgment pursuant to 35 U.S.C. § 271(e)(4) preliminarily and permanently enjoining Defendant, its officers, directors, employees, representatives, agents, parents,

subsidiaries, affiliates, customers, distributors, suppliers, and those persons in active concert or participation with any of them, and its successors and assigns, from engaging in the commercial manufacture, use, importation, offer for sale, and/or sale of Novitium's Product throughout the United States prior to the expiration of any of the patents-in-suit, including any applicable exclusivities or extensions;

D. A judgment awarding Athena monetary relief together with interest if Defendant does commercially manufacture, use, import, offer for sale, and/or sell Novitium's Product throughout the United States prior to the expiration of any of the patents-in-suit, including any applicable exclusivities or extensions;

E. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219647 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of any of the patents-in-suit, including any applicable exclusivities or extensions;

F. A declaration that this case is "exceptional" case under 35 U.S.C. § 285 and an award for attorney fees;

G. An award of costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Date: December 27, 2024

/s/ Elizabeth Fenton

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