IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORPHALAN SA, Plaintiff, v. NOVITIUM PHARMA LLC, Defendant.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Orphalan SA ("Plaintiff"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and for declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201, *et seq*. This action relates to the Abbreviated New Drug Application ("ANDA") submitted by Novitium Pharma, LLC ("Novitium") to the U.S. Food and Drug Administration ("FDA") for approval to engage in the commercial manufacture, use, or sale of triethylenetetramine ("trientine") tetrachloride tablets, 300 mg, generic versions of Plaintiff's CUVRIOR® tablets, 300 mg, prior to the expiration of U.S. Patent Nos. 10,988,436 ("the '436 patent"); and 11,072,577 ("the '577 patent") (collectively hereinafter "the CUVRIOR® patents").

THE PARTIES

2. Plaintiff Orphalan SA is a company existing under the laws of France, having a principal place of business at 226 Boulevard Voltaire, 75011 Paris, France. Orphalan SA is a pioneering, international orphan drug development and commercialization company.

3. On information and belief, Novitium is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 70 Lake Drive, East

Windsor, NJ 08520. On information and belief, Novitium is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical drugs throughout the United States.

4. On information and belief, Novitium assembled and caused to be submitted to the FDA ANDA No. 218493 pursuant to § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and Section 314.95 of the Food and Drug Administration Regulation (21 C.F.R. § 314.95) (hereinafter "Novitium's ANDA") concerning proposed drug product, trientine tetrahydrochloride, 300 mg (hereinafter "Novitium's Proposed ANDA Product"). On information and belief, Novitium's ANDA refers to and relies upon Orphalan SA's New Drug Application ("NDA") No. 215760 for CUVRIOR®.

5. By letter dated August 17, 2023, received August 21, 2023 ("Novitium's Notice Letter"), Novitium notified Plaintiff that, as part of its ANDA, Novitium had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '436 patent and the '577 patent, each of which is listed in the FDA's Approved Drug Product with Therapeutic Equivalence Evaluations (the "Orange Book") for CUVRIOR®, asserting that the '436 patent and the '577 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Novitium's Proposed ANDA Product.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. This Court has personal jurisdiction over Novitium because, *inter alia*, Novitium is organized and existing under the laws of the State of Delaware.

8. On information and belief, Novitium maintains continuous and systematic contacts with Delaware through its authorized agent, Corporation Service Company, located at 251 Little Falls Drive, Wilmington, DE 19808.

9. This Court also has personal jurisdiction over Novitium because Novitium has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Novitium develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and therefore transacts business within Delaware relating to Plaintiff's claims, and/or has engaged in systematic and continuous business contacts within Delaware.

10. In addition, this Court has personal jurisdiction over Novitium because, among other things, on information and belief, (1) Novitium filed Novitium's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of Novitium's Proposed ANDA Product in the United States, including in Delaware, and (2) upon approval of Novitium's ANDA, Novitium will market, distribute, offer for sale, sell, and/or import Novitium's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of Novitium's Proposed ANDA Product in

Delaware. On information and belief, upon approval of Novitium's ANDA, Novitium's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware and lead to foreseeable harm and injury to Plaintiff. Novitium has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware.

11. In addition, this Court has personal jurisdiction over Novitium because it engages in patent litigation concerning Novitium's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this District. *See, e.g.*, *Azurity Pharm., Inc. v. Bionpharma Inc., et al.*, No. 21-1286 (D. Del. Sept. 10, 2021); and *Iceutica Pty Ltd. et al. v. Novitium Pharma LLC*, No. 18-599 (D. Del. Apr. 20, 2018). Further, Novitium has filed a motion to transfer a case to this District and conceded that it is subject to personal jurisdiction here. *See* Mot. to Transfer Case to District of Delaware by Bionpharma Inc., Novitium Pharma, LLC, Oct. 14, 2022, ECF 10, *Azurity Pharm., Inc. v. Novitium Pharma, LLC*, No. 22-5860 (D.N.J.).

12. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for Novitium to litigate this action in this District, and Novitium is subject to personal jurisdiction in this District.

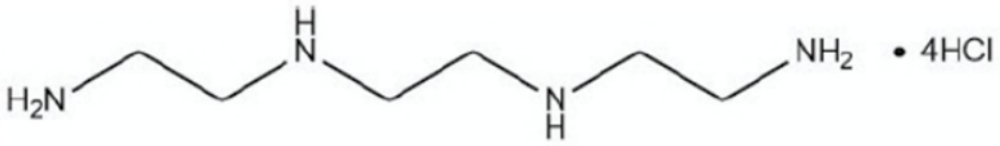
13. Venue is proper in this district for Novitium under 28 U.S.C. § 1400(b).

CUVRIOR®

14. Orphalan SA holds approved NDA No. 215760 for CUVRIOR® (trientine tetrahydrochloride) 300 mg tablets. The FDA approved NDA No. 215760 for CUVRIOR®

trientine tetrahydrochloride) 300 mg tablets on April 28, 2022. CUVRIOR® is a copper chelator indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine. CUVRIOR® was granted Orphan Drug Exclusivity for this patient group through April 28, 2029.

15. CUVRIOR® contains trientine tetrahydrochloride, which is a salt of trientine, a copper chelator. Trientine tetrachloride has the following chemical structure:



THE PATENTS-IN-SUIT

16. On April 27, 2021, the '436 patent, entitled "Crystalline form of triethylenetetramine tetrahydrochloride and its pharmaceutical use," was duly and legally issued. The '436 patent is assigned to and owned by Orphalan SA. A true and correct copy of the '436 patent is attached hereto as Exhibit A.

17. On July 27, 2021, the '577 patent, entitled "Crystalline form of triethylenetetramine tetrahydrochloride and its pharmaceutical use," was duly and legally issued. The '577 patent is assigned to and owned by Orphalan SA. A true and correct copy of the '577 patent is attached hereto as Exhibit B.

18. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, and in conjunction with NDA No. 215760, the CUVRIOR® patents are listed in the Orange Book for CUVRIOR® (trientine tetrahydrochloride) 300 mg tablets.

19. The submission of Novitium's ANDA and Novitium's certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sell, and/or import of Novitium's Proposed ANDA Product before the expiration of the CUVRIOR® patents create an actual case or controversy with respect to infringement of the CUVRIOR® patents.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,988,436 UNDER 35 U.S.C. § 271(e)

20. Plaintiff incorporates each of the preceding paragraphs 1–19 as if fully set forth herein.

21. By submitting ANDA No. 218493 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Novitium's Proposed ANDA Product throughout the United States, including Delaware, prior to expiration of the '436 patent, Novitium committed an act of infringement of the '436 patent under 35 U.S.C. § 271(e)(2)(A).

22. The '436 patent is directed to a crystalline form of triethylenetetramine tetrahydrochloride and pharmaceutical and solid oral dosage compositions comprising that form.

23. On information and belief, Novitium's Proposed ANDA Product contains and/or is manufactured using a crystalline form of trientine tetrahydrochloride Form B wherein the crystalline form contains no more than 10 weight % of trientine tetrahydrochloride Form A and, therefore, Novitium's manufacture, use, sale, offer for sale, or importation into the United States of Novitium's Proposed ANDA Product will directly infringe at least one claim of the '436 patent under 35 U.S.C. § 271(a), (b) and/or (c).

24. On information and belief, Novitium has actual knowledge of the '436 patent and its listing in the Orange Book as demonstrated by at least Novitium's reference to the '436 patent in Novitium's Notice Letter.

25. If Novitium's infringement of the '436 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,988,436 UNDER 35 U.S.C. §§ 271(a), (b) and/or (c)

26. Plaintiff incorporates each of the preceding paragraphs 1–25 as if fully set forth herein.

27. The '436 patent is directed to a crystalline form of triethylenetetramine tetrahydrochloride and pharmaceutical and solid oral dosage compositions comprising that form.

28. On information and belief, Novitium's Proposed ANDA Product contains and/or is manufactured using a crystalline form of trientine tetrahydrochloride Form B wherein the crystalline form contains no more than 10 weight % of trientine tetrahydrochloride Form A and, therefore, Novitium's manufacture, use, sale, offer for sale, or importation into the United States of Novitium's Proposed ANDA Product will infringe at least one claim of the '436 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

29. On information and belief, Novitium has actual knowledge of the '436 patent and its listing in the Orange Book as demonstrated by at least Novitium's reference to the '436 patent in Novitium's Notice Letter.

30. If Novitium's infringement of the '436 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 11,072,577 UNDER 35 U.S.C. § 271(e)

31. Plaintiff incorporates each of the preceding paragraphs 1–30 as if fully set forth herein.

32. By submitting ANDA No. 218493 to the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Novitium's Proposed ANDA Product throughout the United States, including Delaware, prior to expiration of the '577 patent, Novitium committed an act of infringement of the '577 patent under 35 U.S.C. § 271(e)(2)(A).

33. The '577 patent is directed to methods of treating or preventing Wilson's disease in patients with a crystalline form of triethylenetetramine tetrahydrochloride, including the use of CUVRIOR® in accordance with the labeling approved by the FDA.

34. On information and belief, Novitium intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product with proposed labeling immediately and imminently upon final approval of its ANDA.

35. On information and belief, Novitium's Proposed ANDA Product contains and/or is manufactured using a crystalline form of trientine tetrahydrochloride Form B wherein the crystalline form contains no more than 10 weight % of trientine tetrahydrochloride Form A.

36. On information and belief, the proposed labeling for Novitium's Proposed ANDA Product will be substantially identical to the CUVRIOR® label and instructs and encourages physicians to practice the claimed methods of the '577 patent.

37. The CUVRIOR® label states that CUVRIOR® is "indicated for the treatment of adult patients with stable Wilson's disease who are de-coppered and tolerant to penicillamine" (CUVRIOR® label at § 1, copy attached as Exhibit C).

38. Thus, on information and belief, the use of Novitium's Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the '577 patent under 35 U.S.C. § 271(a).

39. On information and belief, Novitium has actual knowledge of the '577 patent and its listing in the Orange Book as demonstrated by at least Novitium's reference to the '577 patent in Novitium's Notice Letter. The foregoing acts by Novitium constitute and/or will constitute infringement of the '577 patent and/or active inducement of infringement of the '577 patent under 35 U.S.C. § 271(b).

40. On information and belief, Novitium knows or should know that Novitium's Proposed ANDA Product will be especially made or especially adapted for use in infringing the '577 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

41. On information and belief, Novitium knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Novitium's Proposed ANDA Product prior to the '577 patent's expiration will contribute to the direct infringement of one or more claims of the '577 patent under 35 U.S.C. § 271(c).

42. If Novitium's infringement of the '577 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 11,072,577 UNDER 35 U.S.C. §§ 271(b) and (c)

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

44. The ’577 patent is directed to methods of treating or preventing Wilson’s disease in patients with a crystalline form of triethylenetetramine tetrahydrochloride, including the use of CUVRIOR® in accordance with the labeling approved by the FDA.

45. On information and belief, Novitium intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of its Proposed ANDA Product with proposed labeling immediately and imminently upon final approval of its ANDA.

46. On information and belief, Novitium’s Proposed ANDA Product contains and/or is manufactured using a crystalline form of trientine tetrahydrochloride Form B wherein the crystalline form contains no more than 10 weight % of trientine tetrahydrochloride Form A.

47. On information and belief, the proposed labeling for Novitium’s Proposed ANDA Product will be substantially identical to the CUVRIOR® label and instructs and encourages physicians to practice the claimed methods of the ’577 patent.

48. The CUVRIOR® label states that CUVRIOR® is “indicated for the treatment of adult patients with stable Wilson’s disease who are de-coppered and tolerant to penicillamine” (CUVRIOR® label at § 1, copy attached as Exhibit C).

49. Thus, on information and belief, the use of Novitium’s Proposed ANDA Product in accordance with its proposed labeling will directly infringe at least one claim of the ’577 patent under 35 U.S.C. § 271(a).

50. On information and belief, Novitium has actual knowledge of the ’577 patent and its listing in the Orange Book as demonstrated by at least Novitium’s reference to the ’577 patent in Novitium’s Notice Letter. The foregoing acts by Novitium constitute and/or will constitute

infringement of the ’577 patent and/or active inducement of infringement of the ’577 patent under 35 U.S.C. § 271(b).

51. On information and belief, Novitium knows or should know that Novitium’s Proposed ANDA Product will be especially made or especially adapted for use in infringing the ’577 patent and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

52. On information and belief, Novitium knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Novitium’s Proposed ANDA Product prior to the ’577 patent’s expiration will contribute to the direct infringement of one or more claims of the ’577 patent under 35 U.S.C. § 271(c).

53. If Novitium’s infringement of the ’577 patent is not permanently enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiff respectfully requests the following relief:

A. A judgment that Novitium has infringed one or more claims of U.S. Patent Nos. 10,988,436 and 11,072,577 by submitting and maintaining ANDA No. 218493 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Novitium’s Proposed ANDA Product before the expiration of the CUVRIOR® patents, inclusive of any exclusivities and extensions, under 35 U.S.C. § 271(e)(2)(A);

B. A judgment (or a declaration) that Novitium’s commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Novitium’s Proposed ANDA Product will infringe one or more claims of U.S. Patent Nos. 10,988,436 and 11,072,577 under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A judgment that U.S. Patent Nos. 10,988,436 and 11,072,577 remain valid and enforceable;

D. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Novitium, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Novitium's Proposed ANDA Product prior to the expiration date of U.S. Patent Nos. 10,988,436 and 11,072,577 inclusive of any exclusivities and extensions;

E. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 2180493 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 U.S. Patent Nos. 10,988,436 and 11,072,577 inclusive of any exclusivities and extensions;

F. Damages, including monetary and other relief, to Plaintiff if Novitium engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of its Proposed ANDA Product prior to the expiration date of U.S. Patent Nos. 10,988,436 and 11,072,577, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of reasonable attorney fees, costs, expenses, and disbursements of this action;

H. Costs and expenses in this action; and

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

Dated: September 29, 2023

MCCARTER & ENGLISH, LLP

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