IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORBICULAR PHARMACEUTICAL TECHNOLOGIES, PVT. LTD., CIPLA USA, INC., Plaintiff, v. SHIRE-NPS PHARMACEUTICALS, INC. and TAKEDA PHARMACEUTICALS U.S.A., INC., Defendants.	C.A. No.

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Orbicular Pharmaceutical Technologies Pvt. Ltd. ("Orbicular Pharma" and Cipla USA, Inc. ("Cipla"; Orbicular Pharma and Cipla are collectively referred to as "Orbicular") , by and through their undersigned counsel, hereby bring their Complaint for Declaratory Judgment against Shire-NPS Pharmaceuticals, Inc. ("Shire") and Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") (Shire and Takeda are collectively "Defendants"), and allege as follows:

NATURE OF THE ACTION

1. Orbicular seeks a declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., that United States Patent No. 7,847,061 ("the '061 patent") (attached as **Exhibit A**) and United States Patent No. 9,060,992 ("the '992 patent") (attached as **Exhibit B)**, are not infringed by Orbicular's Teduglutide for Injection product as described in Orbicular's Abbreviated New Drug Application ("Orbicular's ANDA") No. 218582 ("Orbicular's ANDA Product").

2. A declaration of noninfringement of the '061 and '992 patents will enable Orbicular to market Orbicular's ANDA Product at the earliest possible date under the applicable statutory and regulatory provisions and allow the public to benefit from increased generic availability for this product.

THE PARTIES

3. Plaintiff Orbicular Pharma is an Indian corporation, with its principal place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar, Kukatpally, Hyderabad: 500 090, Telangana, India.

4. Plaintiff Cipla is a Delaware Corporation with a principal place of business at 10 Independence Blvd., Suite 300, Warren, NJ 07059.

5. Upon information and belief, Defendant Shire is a Delaware corporation and is a wholly owned subsidiary of Takeda Pharmaceuticals U.S.A., Inc. Shire has a principal place of business at 300 Shire Way, Lexington, MA 02421.

6. Upon information and belief, Shire was formerly known as NPS Pharmaceuticals, Inc.

7. Upon information and belief, Defendant Takeda is a Delaware corporation with a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

JURISDICTION AND VENUE

8. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.,* the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.,* as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355), and by the Medicare Prescription Drug, Improvement and

Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) ("the MMA") (collectively herein the "Hatch-Waxman Act"), based upon an actual controversy between the parties for a final judgment declaring that the '061 and '992 patents are not infringed by Orbicular's ANDA Product and that Orbicular is free, upon approval by the United States Food and Drug Administration ("FDA"), to manufacture, use, market, sell, offer to sell, and/or import Orbicular's ANDA Product.

9. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Shire because Shire is incorporated under the laws of Delaware.

11. This Court has personal jurisdiction over Takeda because Takeda is incorporated under the laws of Delaware.

12. On information and belief, this Court also has personal jurisdiction over Shire and Takeda because of their continuous and systematic contacts with the State of Delaware, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in Delaware.

13. Further, both Shire and Takeda have frequently subjected themselves to the jurisdiction of this Court, including, but not limited to: *Shire-NPS Pharmaceuticals, Inc. v. Ambio, Inc., et al.,* 1:17-cv-00397 (D. Del.) (litigation claiming patent infringement of the '061 and '992 patents-in-suit based on ANDA filing for a generic version of GATTEX®); *Shire-NPS Pharmaceuticals, Inc. v. Par Pharmaceutical Companies, Inc.*, *et al.*, 1:18-cv-01115 (D. Del.) (patent litigation based on ANDA filing for a generic version of GATTEX®); *Takeda Pharmaceuticals, U.S.A., Inc. v. Scilex Pharmaceuticals, Inc., et al.*, 1:23-cv-cv-01264 (D .Del.);

Takeda Pharmaceuticals U S.A., Inc. v. Mylan Pharmaceuticals Inc., 1:16-cv-987 (D. Del.); *Takeda Pharmaceuticals U.S.A., Inc. v. Watson Laboratories, et al.*, 1:14-cv-00268 (D. Del.); *Takeda Pharmaceuticals, U.S.A., Inc. v. West-Ward Pharmaceutical Corp., et al.*, 1:14-cv-1268 (D. Del.).

14. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and 1400(b).

THE PATENTS-IN-SUIT

15. On its face, the ’061 patent entitled “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” indicates that it was issued by the United States Patent and Trademark Office on December 7, 2010.

16. According to the records at the United States Patent and Trademark Office, Shire-NPS Pharmaceuticals, Inc. is currently the Assignee of the ’061 patent. NPS Pharmaceuticals, Inc. is the assignee designated on the face of the ’061 patent. A change of name was recorded in the United States Patent and Trademark Office on January 23, 2017 indicating that assignee NPS Pharmaceuticals Inc. had changed its name to Shire-NPS Pharmaceuticals, Inc.

17. Upon information and belief, Takeda is the exclusive licensee of the ’061 patent with respect to commercializing pharmaceutical products containing teduglutide in the United States under the trademark GATTEX®.

18. On its face, the ’992 patent entitled, “Treatment of Short Bowel Syndrome Patients with Colon-In-Continuity” indicates that it was issued by the United States Patent and Trademark Office on June 23, 2015.

19. According to the records at the United States Patent and Trademark Office, Shire-NPS Pharmaceuticals, Inc. is currently the Assignee of the ’992 patent. NPS Pharmaceuticals, Inc. is the assignee designated on the face of the ‘992 patent. A change of name was recorded in

the United States Patent and Trademark Office on January 23, 2017 indicating that assignee NPS Pharmaceuticals Inc. had changed its name to Shire-NPS Pharmaceuticals, Inc.

20. Upon information and belief, Takeda is the exclusive licensee of the '992 patent with respect to commercializing pharmaceutical products containing teduglutide in the United States under the trademark GATTEX®.

ADDITIONAL PATENTS WHICH COVERED GATTEX®

21. U.S. Patent No. 9,539,310 ("'310 patent") was issued by the United States Patent and Trademark Office on January 10, 2017.

22. U.S. Patent No. 9,545,434 ("'434 patent") was issued by the United States Patent and Trademark Office on January 10, 2017.

23. U.S. Patent No. 9,545,435 ("'435 patent") was issued by the United States Patent and Trademark Office on January 17, 2017.

24. U.S. Patent No. 9,555,079 ("'079 patent") was issued by the United States Patent and Trademark Office on January 31, 2017.

25. U.S. Patent No. 9,572,867 ("'867 patent") was issued by the United States Patent and Trademark Office on February 21, 2017.

26. U.S. Patent No. 9,592,273 ("'273 patent") was issued by the United States Patent and Trademark Office on March 14, 2017.

27. U.S. Patent No. 9,592,274 ("'274 patent") was issued by the United States Patent and Trademark Office on March 14, 2017.

28. U.S. Patent No. 9,968,655 ("'655 patent") was issued by the United States Patent and Trademark Office on May 15, 2018.

29. U.S. Patent No. 9,968,656 ("'656 patent") was issued by the United States Patent and Trademark Office on May 15, 2018.

30. U.S. Patent No. 9,968,658 ("'658 patent") was issued by the United States Patent and Trademark Office on May 15, 2018.

31. U.S. Patent No. 9,974,835 ("'835 patent") was issued by the United States Patent and Trademark Office on May 22, 2018.

32. U.S. Patent No. 9,974,837 ("'837 patent") was issued by the United States Patent and Trademark Office on May 22, 2018.

33. U.S. Patent No. 9,981,014 ("'014 patent") was issued by the United States Patent and Trademark Office on May 29, 2018.

34. U.S. Patent No. 9,981,016 ("'016 patent") was issued by the United States Patent and Trademark Office on May 29, 2018.

35. U.S. Patent No. 9,987,334 ("'334 patent") was issued by the United States Patent and Trademark Office on June 5, 2018.

36. U.S. Patent No. 9,987,335 ("'335 patent") was issued by the United States Patent and Trademark Office on June 5, 2018.

37. U.S. Patent No. 9,993,528 ("'528 patent") was issued by the United States Patent and Trademark Office on June 12, 2018.

38. The '310 patent, '434 patent, '435 patent, '079 patent, '867 patent, '273 patent, '274 patent, '655 patent, '656 patent, '658 patent, '835 patent, '837 patent, '014 patent, '016 patent, '334 patent, '335 patent, and '528 patent are hereafter collectively referred to as "Disclaimed & Delisted OB Patents".

39. Two additional patents may have covered GATTEX® but their patent terms have

expired. U.S. Patent No. 5,789,379 expired in 2020. U.S. Patent No. 7,056,886 expired in 2023.

40. The Disclaimed & Delisted OB Patents were all entitled "Treatment of Short Bowel Syndrome Patients With Colon-In-Continuity."

41. According to the records at the United States Patent and Trademark Office, the assignee of the Disclaimed & Delisted OB Patents was either Shire-NPS Pharmaceuticals, Inc. or NPS Pharma (which underwent a name change to Shire-NPS Pharmaceuticals, Inc.)..

42. Upon information and belief, Takeda was the exclusive licensee of the Disclaimed & Delisted OB Patents with respect to commercializing pharmaceutical products containing teduglutide in the United States under the trademark GATTEX®.

43. The Disclaimed & Delisted OB Patents were originally set to expire on November 1, 2025 and pediatric exclusivity for the Disclaimed & Delisted Patents was originally set to expire on May 1, 2026.

44. As explained further below, the Disclaimed & Delisted OB Patents, as well as U.S. Patent Nos. 5,789,379 and 7,056,886, were all previously listed in the Orange Book with respect to NDA No. 20-3441 for GATTEX®.

PATENT DISCLAIMERS

45. 35 U.S.C. § 253(a) states that a "patentee… may, on payment of the fee required by law, make disclaimer of any complete claim, stating therein the extent of his interest in such patent."

46. 35 U.S.C. § 253(b) states that the patentee "may disclaim or dedicate to the public the entire term, or any terminal part of the term…."

47. 37 CFR § 1.321 sets forth the process for a patentee to disclaim any patent claims with the United State Patent Office.

48. Disclaiming patent claims withdraws the claims from patent protection and the public is entitled to manufacture and use the device originally claimed as though it had been abandoned. *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935).

49. A disclaimed patent is unenforceable. *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015).

50. A disclaimed patent cannot be infringed. *Id.*

LITIGATION WHICH LED TO THE DISCLAIMER OF THE PATENTS-IN-SUIT AND THE DISCLAIMED & DELISTED OB PATENTS"

51. On September 21, 2021, Rigshospitalet, a hospital in Denmark, filed a litigation against Shire-NPS Pharmaceuticals, Inc. and Takeda Pharmaceuticals U.S.A., Inc., 1:21-cv-11602 (D. Mass.). In the complaint, Rigshospitalet alleged breach of contract, that Rigshospitalet owns the intellectual property rights in a large number of patents owned/licensed by Shire and Takeda including the '061 and '992 patents, and that Defendants "misappropriated Rigshospitalet's inventions" by "theft of inventions relating to the revolutionary treatment of short bowel syndrome [SBS]…." (Rigshospitalet Complaint at ¶ 1 (Attached hereto as **Exhibit C**)).

52. Rigshospitalet alleged that two of its doctors "invented the treatment … as part of clinical trials involving the treatment of SBS patients with teduglutide…." (Rigshospitalet Complaint at ¶ 3). The hospital alleged that Shire-NPS submitted the two doctors' manuscript to the United States Patent and Trademark Office as a patent application without informing the doctors or naming them as inventors. (Rigshospitalet Complaint at ¶¶ 5-6).

53. Rigshospitalet included 27 counts in its complaint including counts for breach of contract (Count I), breach of the implied covenant of good faith and fair dealing (Count II),

transfer of ownership of the patents and applications which included the ’061 and ’992 patents (Count III), correction of inventorship for patents and applications which included the ’061 and ’992 patents (Count IV), infringement of the ’061 patent (Count V), infringement of the ’992 patent (Count VI), unjust enrichment (Count XXIV), fraudulent nondisclosure (Count XXIV, second instance), conversion (Count XXVI) and unfair and deceptive trade practices (Count XXVII). Rigshospitalet also sought a permanent injunction against Shire and Takeda with respect to distribution and sale of GATTEX®. (Rigshospitalet Complaint).

54. The Disclaimed & Delisted OB Patents were also named in the Rigshospitalet Complaint and included in several counts of the Rigshospitalet Complaint. *See, e.g.,* **Exhibit C** at ¶ 43 (listing the patents which were issued to Shire-NPS including the ’061 and ’992 patents and all of the Disclaimed & Delisted OB Patents).

55. Defendants moved to dismiss the litigation on February 14, 2022. *Rigshospitalet v. Shire-NPS Pharmaceuticals, Inc.,* 1:21-cv-11602 (Dkt. Nos. 16-18; Memo of Law (Dkt. No. 17). The motion argued that the claims were untimely and past the statute of limitations, they cannot state a claim for which relief can be granted (for example because Rigshospitalet did not perform its obligations under the contract), and for failure to join an indispensable party with whom the contract was executed, the University of Copenhagen. *Id.*

56. Before Rigshospitalet responded to that motion to dismiss, the parties reported a settlement of the litigation and a stipulation of dismissal was filed on May 9, 2022 (*Id.* at Dkt. Nos. 23-24), thereby dismissing the case.

57. On July 20, 2022, Shire, filed a statutory disclaimer under 37 CFR §1.321(a) disclaiming claims 1-18, all of the claims, of the ’061 patent. The disclaimer was accompanied by the required fee and recorded by the USPTO. A copy of the ’061 patent disclaimer is attached

hereto as **Exhibit D.**

58. On July 20, 2022, Shire filed a statutory disclaimer under 37 CFR §1.321(a) disclaiming claims 1-26, all of the claims, of the '992 patent. The disclaimer was accompanied by the required fee and recorded by the USPTO. A copy of the '992 patent disclaimer is attached hereto as **Exhibit E.**

59. In addition to the '061 and '992 patents, on July 20, 2022 Shire filed statutory disclaimers with the United States Patent and Trademark Office pursuant to 37 CFR § 1.321(a) disclaiming the entire remaining terms of each of the Disclaimed & Delisted OB Patents. See **Exhibit F**.

BACKGROUND

60. Before marketing a new drug in the United States, a manufacturer must submit a New Drug Application ("NDA") to the FDA, and the FDA must approve it. Once approved, new drugs generally are referred to as brand name drugs because they are marketed under a trade name or trademark for the drug product rather than the chemical name for the active ingredient in the drug product.

61. In addition to the technical data submitted in an NDA, a brand name drug manufacturer is required to submit to the FDA information on each patent, including the patent's number and its expiration date, that claims the drug or a method of using the drug that is the subject of the NDA with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, sale or importation of the drug product. 21 U.S.C. §355(b)(1); 21 C.F.R. §314.53.

62. Once the FDA approves an NDA, the FDA lists the patent information submitted

by the brand name drug manufacturer in its publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). 21 U.S.C. §355(b)(1).

63. With respect to generic drug products, the Hatch-Waxman Act authorizes the submission of an ANDA to seek approval of a generic version of any Reference Listed Drug ("RLD") in the Orange Book. The Hatch-Waxman Act further authorizes the inclusion within an ANDA of a so-called "Paragraph IV" certification, in which the applicant certifies to the FDA that one or more patents in the Orange Book for the RLD is invalid, unenforceable, or will not be infringed by the proposed ANDA product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

64. With respect to any such Paragraph IV certification, the ANDA applicant must provide notice of the certification to the patent holder and the holder of the New Drug Application for the RLD ("the NDA holder"), along with a statement of the factual and legal basis for its certification ("Notice Letter"). The filing of an ANDA with a Paragraph IV certification creates jurisdiction so that the patent and NDA holder may commence a patent infringement action within 45 days of receiving that notice ("the 45-day statutory period"). *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa) and 35 U.S.C. § 271(e)(2).

65. The Hatch-Waxman Act expressly authorizes the bringing of a declaratory judgment action under 28 U.S.C. § 2201 to obtain a declaration of invalidity or noninfringement of a patent where the following conditions are met: (1) the ANDA applicant included with its Paragraph IV certification notice a statutory offer of confidential access to review the ANDA to the patent and NDA holders, and (2) the 45-day statutory period for the patent owner and NDA holder to bring suit has passed, without either entity having brought suit against the ANDA applicant. *See* 21 U.S.C. § 355(j)(5)(C)(i).

66. In order to encourage generic market entry, the first ANDA applicant to file a substantially complete ANDA with a Paragraph IV certification (the "First Filer") may be awarded a 180-day period in which it is the only applicant allowed to market a generic version of the brand name product. This is commonly referred to as the 180-day exclusivity period. In order to prevent a First Filer from unduly delaying generic market competition, the MMA also added provisions whereby the First Filer will forfeit the 180-day exclusivity period. 21 U.S.C. § 355 (j)(5)(D)(i)(I).

67. The First Filer will forfeit the 180-day exclusivity period if each prong of the forfeiture provisions is triggered. One prong for the forfeiture provision is the failure by the First Filer to market its product within 30 months after the date of submission of the ANDA application (21 U.S.C. § 355 (j)(5)(D)(i)(I))(aa)(BB)). As set forth below, the First Filer of an ANDA for a generic version of GATTEX® has not marketed such a product within 30 months of the date of its ANDA filing.

68. The other prong for forfeiture of 180-day exclusivity is failure by the First Filer to market its product within 75 days after "a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the patent(s) [which entitled the first applicant to exclusivity] is invalid or not infringed." 21 U.S.C. § 355 (j)(5)(D)(i)(I)(bb)(AA). Once the exclusivity period has run or been forfeited, the FDA may grant final approval to subsequently filed ANDAs.

69. Thus, where the first prong of the forfeiture provision has been met (failure to market the first-filed generic ANDA product by 30 months after the date of submission of the first filer's ANDA application), removal of a blocking exclusivity period may be obtained by a final judgment that all patents which are the subject of the Paragraph IV certification giving rise

to exclusivity are not infringed or are invalid. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I). The Hatch-Waxman Act expressly provides that such a final judgment may come from a declaratory judgment action brought by a generic challenger. *Id.*

FACTS

(a) Takeda's Product and listing of patents in the Orange Book

70. Upon information and belief, Takeda is the holder of approved NDA No. 20-3441 for GATTEX® which is an injectable pharmaceutical product that contains 5mg teduglutide recombinant per single-use vial.

71. Takeda caused the '061 and '992 patents to be listed in the Orange Book with respect to GATTEX®.

72. Takeda also caused the Disclaimed & Delisted OB Patents to be listed in the Orange Book with respect to GATTEX®.

73. A copy of the 2022 Orange Book listing for GATTEX® is attached hereto as **Exhibit G**.

74. On information and belief, Takeda filed a request with the FDA to delist the '061 and '992 patents from the Orange Book with respect to GATTEX®.

75. On information and belief, Takeda filed a request with the FDA to delist the Disclaimed & Delisted OB Patents from Orange Book with respect to GATTEX®.

76. The FDA delisted the Disclaimed & Delisted OB Patents from the Orange Book.

77. The FDA did not remove or delist the '061 patent.

78. The FDA did not remove or delist the '992 patent.

79. The 2023 Orange Book did not list any of the Disclaimed & Delisted OB Patents for GATTEX®. See **Exhibit H** (2023 Orange Book listing for GATTEX® which lists only the

'061 and '992 patents).

80. The 2023 Orange Book listing for GATTEX® lists only the '061 and '992 patents. **Exhibit H.**

81. As of the date of this Complaint, the '061 and '992 patents are the only two patents listed in the Orange Book for NDA No. 20-3441 with the notation "Delist Requested".

82. The Orange Book states that both the '061 and '992 patents were originally set to expire on November 1, 2025 and that pediatric exclusivity for both patents expires on May 1, 2026. The disclaimer of these patents, however, should render these dates irrelevant, but because this patent information remains in the Orange Book it serves as an impediment to Orbicular's ANDA approval which must be addressed.

83. By listing the '061 and '992 patents in the Orange Book, Takeda represented to the FDA that such patents are those to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. §355(b)(1).

84. The '061 patent has not been removed from the Orange Book for the GATTEX® NDA No. 20-3441.

85. The '992 patent has not been removed from the Orange Book for the GATTEX® NDA No. 20-3441.

86. On information and belief, the '061 and '992 patents remain listed in the Orange Book for the GATTEX® NDA No. 20-3441 because they serve as a basis for a claim of 180-day exclusivity by a First Filer. This follows the FDA's practice of not removing a patent from the Orange Book if the patent is the basis of a Paragraph IV certification giving rise to eligibility for 180-day exclusivity. *See*, *Ranbaxy Labs., Ltd. v Leavitt*, 459 F. Supp. 2d 1 (D. D.C. 2006), *aff'd*

469 F.3d 120 (D.C. Cir. 2006).

87. As a consequence of the continued listing of the ’061 and ’992 patents in the Orange Book, the ’061 and ’992 patents, although disclaimed and no longer enforceable, remain an impediment to Orbicular’s obtaining FDA approval to market a generic version of the drug prior to the expiration of the ’061 and ’992 patents.

88. A court ruling on the issue of infringement of the ’061 and ’992 patents is thus necessary to activate the court decision trigger on the blocking 180-day exclusivity which is harming Orbicular.

(b) Following Orbicular’s ANDA submission, Paragraph IV Certification and Notice Letter, Defendants failed to sue Orbicular for infringement of the Patents In Suit

89. On December 5, 2023, Orbicular submitted the Orbicular ANDA to obtain FDA approval for the Orbicular’s ANDA Product that is the subject of the Orbicular ANDA.

90. Orbicular Pharma licensed to Cipla the Orbicular ANDA and the rights to market Orbicular’s ANDA Product in the United States once it is approved by the FDA.

91. The Orbicular ANDA included a Paragraph IV certification for each of the ’061 and ’992 patents that the ’061 and ’992 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of Orbicular’s ANDA Product.

92. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on January 5, 2024, Orbicular served both Shire and Takeda with a Notice Letter dated January 5, 2024 informing them of the filing of the Orbicular ANDA seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Orbicular’s ANDA Product before the expiration of the ’061 and ’992 patents. The Notice Letter was received by Defendants on or about January 8, 2024.

93. Orbicular's Notice Letter complied fully with 35 U.S.C. §§ 355(j)(2)(B) and 21 C.F.R. § 314.95. In addition, Orbicular's Notice Letter included an offer of confidential access to relevant portions of Orbicular's ANDA to each Defendant so that each could determine whether Orbicular's ANDA Product would infringe any claim of the '061 and '992 patents within the meaning of 271 U.S.C. § 355(j)(5)(C)(i)(III).

94. Receipt of Orbicular's Notice Letter initiated the 45-day statutory period during which Defendants had the opportunity to file an action for patent infringement and obtain an automatic 30-month stay of the FDA's approval of Orbicular's ANDA.

95. Neither Shire nor Takeda brought an action for infringement of the '061 and/or the '992 patents against Orbicular within the 45-day statutory period.

96. Accordingly, both requirements are met for the declaratory judgment action expressly authorized by the Hatch-Waxman Act: (1) Orbicular made the statutory offer of confidential access in connection with both the '061 and '992 patents, and (2) the 45-day statutory period has passed without either Shire or Takeda bringing an action for infringement. *See* 21 U.S.C. § 355(j)(5)(C)(i).

97. Orbicular has not yet received tentative approval for the Orbicular ANDA but it expects to do so soon.

98. Tentative approval is "not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book." *Apotex Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1366 (Fed. Cir. 2015).

(c) Defendants have refused to provide a consent judgment of noninfringement to Orbicular

99. On February 26, 2024, once the 45-day statutory period had passed without Defendants initiating an action for patent infringement of the '061 and '992 patents, Orbicular,

through its counsel Frank Rodriguez at Windels Marx Lane & Mittendorf, contacted counsel for Defendants, Ira Finkelstein, Lead Counsel for IP at Takeda Pharmaceuticals U.S.A., Inc.

100. On February 27, 2024, counsel for Defendants confirmed that they did not file a patent infringement action against Orbicular for infringement of the ’061 and ’992 patents based on the filing of the Orbicular ANDA within the 45-day statutory period.

101. To date, Defendants have not filed a patent litigation action against Orbicular for infringement of the ’061 and ’992 patents.

102. On information and belief, Defendants did not file a patent litigation action against Orbicular for infringement of the ’061 patent because Orbicular does not infringe any valid or enforceable claim of the disclaimed ’061 patent.

103. On information and belief, Defendants did not file a patent litigation action against Orbicular for infringement of the ’992 patent because Orbicular does not infringe any valid or enforceable claim of the disclaimed ’992 patent.

104. Defendants do not have a basis consistent with Fed. R. Civ. P. 11 to allege that Orbicular’s ANDA Product infringes any claim of the ’061 or ’992 patents.

105. If Defendants had a basis to file a patent infringement action for infringement of the ’061 and ’992 patents, they would have sued Orbicular.

106. On February 27, 2024, through their respective counsel, Orbicular requested that Defendants provide Orbicular with a consent judgment of noninfringement of the ’061 patent and the ’992 patent.

107. On March 5, 2024, Defendants declined to enter into a consent judgment with Orbicular with respect to the ’061 patent and the ’992 patent.

108. No consent judgment of noninfringement of the ’061 and ’992 patents has been

offered to or provided to Orbicular as of the date of the filing of this Complaint.

109. On May 22, 2024, Mr. Rodriguez and Mr. Finkelstein had a follow-up call in which Mr. Finkelstein confirmed that Takeda still would not agree to provide a consent judgment to Orbicular.

110. On June 11, 2024 Mr. Finkelstein confirmed that Takeda still would not agree to provide a consent judgment to Orbicular.

111. Notwithstanding Defendants' decision not to bring suit, Orbicular's ability to obtain final FDA approval of Orbicular's ANDA Product at the soonest possible date depends on Orbicular's ability to obtain a final judgment that Orbicular's ANDA Product does not infringe the '061 and '992 patents.

(d) Approval of the Orbicular ANDA is blocked by a First Filer

112. Upon information and belief, Orbicular is not the first generic drug manufacturer to file an ANDA directed a generic version of Takeda's GATTEX®.

113. Upon information and belief, there is a GATTEX® First Filer that is entitled to 180 days of exclusivity for a generic GATTEX® product.

114. Publicly available FDA records reflect that a generic challenger first filed an ANDA with a Paragraph IV certification on December 21, 2016 ("GATTEX® First Filer"). *See* https://www.fda.gov/media/166048/download?attachment (last visited 12/09/2024).

115. Upon information and belief, Ambio, Inc. and Par Pharmaceutical, Inc. ("Par Defendants") sent a Paragraph IV Notice Letter dated February 28, 2017 to Shire ("Par Notice Letter"). *See Shire v. Ambio, Inc., et al.*, 1:17-cv-00397 (D. Del.) (RGA) (Complaint (Dkt. No. 1) at ¶¶ 39-41; Amended Complaint (Dkt. No. 15) at ¶¶ 56-57, 59).

116. The Par Notice Letter informed Shire that the Par Defendants had filed ANDA

No. 210023 which included a Paragraph IV certification with respect to the '061 and '992 patents, as well as other patents. (Complaint (Dkt. No. 1) at ¶¶ at 38-43; Amended Complaint (Dkt. No. 15) at ¶¶ 53-63).

117. Upon information and belief, the Par Defendants and/or their parent company Endo International plc is/are the GATTEX® First Filer. *See* Endo Pharmaceuticals, Inc. September 28, 2015 press release announcing Endo International plc's acquisition of Par Pharmaceutical Holdings, Inc.[1]

118. Upon information and belief, Takeda is aware that the Par Defendants and/or Endo Pharmaceuticals is/are the GATTEX® First Filer.

119. Upon information and belief, the Par Defendants' ANDA No. 210023 was the first ANDA to be filed with a Paragraph IV certification to the '061 patent and the '992 patent. *See, e.g.,* Endo International plc (parent company of Par) Form 8-K dated January 18, 2020 at 14 of 17 (including GATTEX® on a list of "FTF" settlements which stands for "First-to-File")[2].

120. The GATTEX® First Filer is presumptively entitled to a 180-day period of exclusivity, during which the FDA is statutorily barred from granting Final Approval of Orbicular's ANDA.

121. Upon information and belief, there is no publicly available information which indicates that the Par Defendants have not maintained their Paragraph IV certifications to the '061 and '992 patents.

122. On April 10, 2017, Shire filed a patent infringement litigation in the District of

[1] Available at: https://investor.endo.com/news-releases/news-release-details/endo-completes-acquisition-par-pharmaceutical-and-provides#:~:text=DUBLIN%20%2C%20Sept.,of%20Par%20Pharmaceutical%20Holdings%2C%20Inc. (last visited March 27, 2024).
[2] Available at: https://investor.endo.com/static-files/404a1ea6-edea-497f-b53f-a79f0e8abeff (last visited March 27, 2024).

Delaware naming the Par Defendants, as well as AmbioPharm, Inc. and Par Pharmaceutical Companies, Inc. as defendants and alleging infringement of the '061 patent, the '992 patent and other patents. *Id.*

123. On November 26, 2018 the Court So Ordered and entered a Stipulated Dismissal and Judgment and Order of Permanent Injunction that stated that "Shire and Par have agreed to dismiss all claims and counterclaims concerning the Litigated Patents [including the '061 patent and the '992 patent]…." 1:17-cv-00397 (D. Del.) (Dkt. No. 93).

124. Case No 1:17-cv-00397 (D. Del.) was dismissed pursuant to a settlement agreement on "confidential terms" between the parties. *See, e.g.,* Endo International plc (parent company of Par) Form 8-K dated January 18, 2020 at 14 of 17 (including GATTEX® on a list of "FTF" settlements which stands for "First-to-File").

125. Due to the dismissal of case No. 1:17-cv-00397 (D. Del.), there has been no "final decision" as described in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) with respect to the '061 and '992 patents that either patent is invalid or not infringed. Such a decision would have provided a basis for forfeiture of 180-day exclusivity.

126. Upon information and belief, no other court has entered a final decision" as described in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) with respect to the '061 and '992 patents that either patent is invalid or not infringed.

127. Upon information and belief, no forfeiture event has occurred that would divest the GATTEX® First Filer of 180-day exclusivity under 21 U.S.C. §§ 355(j)(5)(D), nor has the FDA determined nor declared that any such forfeiture has occurred.

128. Upon information and belief, no generic pharmaceutical company has received final approval from the FDA to market a generic equivalent to GATTEX®.

129. Upon information and belief, no company (including the GATTEX® First Filer) has begun selling a generic equivalent to a GATTEX® product.

130. The FDA is currently prohibited from granting final approval to the Orbicular ANDA to allow Orbicular to market Orbicular's ANDA Product until 180 days after the GATTEX® First Filer markets its own teduglutide for injection ANDA product unless there is a forfeiture of the 180-day exclusivity.

131. It is uncertain, however, when or even if the exclusivity period of the GATTEX® First Filer will begin. Accordingly, Orbicular may be indefinitely blocked from marketing a generic teduglutide for injection product that would compete with Takeda's GATTEX®.

132. Even if Defendants provided a covenant not to sue with respect to the '061 and '992 patents, it would not render this declaratory judgment action moot because a covenant not to sue is not the same as a court's entry of a final decision that the '061 and '992 patents are invalid or not infringed. Orbicular's ANDA Product approval and commercialization will therefore still be indefinitely blocked from the market.

133. Additionally, if Orbicular is delayed all the way to the expiration date of the '061 and '992 patents (to November 1, 2025) it will also likely be further blocked from approval for an additional six months due to the pediatric exclusivity period attached to the '061 and '992 patents (May 1, 2026) which also remains listed in the Orange Book.

134. Upon information and belief, there was no First Filer who was entitled to 180-days of marketing exclusivity based on filing and maintaining a Paragraph IV Certification(s) for any of the Disclaimed & Delisted OB Patents.

135. On information and belief, the FDA delisted the Disclaimed & Delisted OB Patents upon the request of the NDA owner sometime after the 2022 publication of the Orange

Book because there was no First Filer who was entitled to marketing exclusivity for Paragraph IV Certification(s) directed to the Disclaimed & Delisted OB Patents.

136. On information and belief, the FDA did not delist the '061 and the '992 patents from the Orange Book because these patents are the basis for exclusivity for the GATTEX® First Filer.

137. The '061 and '992 patents and their associated blocking exclusivity are thus a barrier to Orbicular's entry into the market. This unreasonable and unjustified delay will prevent Orbicular from marketing Orbicular's ANDA product for an extended period of time despite the facts that the '061 and '992 patents are disclaimed and no longer enforceable.

138. But for the '061 and '992 patents and their associated blocking exclusivity, Orbicular could market Orbicular's ANDA product as soon as it is otherwise eligible for FDA approval.

139. To prevent such a bottleneck to market entry, the Hatch-Waxman Act expressly provides Orbicular the right to attempt to trigger a forfeiture of the GATTEX® First Filer's 180-day exclusivity period by obtaining a judgment that the relevant Orange Book listed patents for NDA 20-2441, the '061 and '992 patents, are not infringed by Orbicular's ANDA Product or are invalid. *See* 21 U.S.C. § 355(j)(5)(D)(i)(l).

140. Upon information and belief, the GATTEX® First Filer for a generic version of GATTEX® has not entered the market. Orbicular's ANDA is therefore "parked" and blocked behind the GATTEX® First Filer's ANDA.

141. Orbicular will be delayed entry into the market unless and until it can trigger the forfeiture of the GATTEX® First Filer's 180-day exclusivity by receiving a judgment of noninfringement of the '061 and '992 patents.

142. When a final judgment of invalidity or noninfringement of the ’061 and ’992 patents in favor of Orbicular is obtained, it will trigger the GATTEX® First Filer’s 180-day exclusivity period. If the GATTEX® First Filer launches its ANDA product within 75 days of this judgment, the Orbicular Product can be approved and launch 180 days later, once the GATTEX® First Filer’s exclusivity runs out. If the GATTEX® First Filer does not launch within 75 days of Orbicular obtaining the final judgment, the GATTEX® First Filer will have forfeited its exclusivity and this will thus allow Orbicular to obtain FDA approval to market Orbicular’s ANDA Product immediately after this 75-day period following the final judgment. Absent such a final judgment, FDA approval of Orbicular’s ANDA Product and the subsequent marketing and sale of Orbicular’s ANDA Product may be indefinitely delayed unnecessarily all the way potentially to the expiration date of the ’061 and ’992 patents and their pediatric exclusivity period.

143. Accordingly, this dispute as to infringement of the ’061 and ’992 patents constitutes an actual and justiciable controversy between Orbicular and Defendants relating to the ’061 and ’992 patents which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

144. Orbicular will suffer irreparable harm if Final Approval and/or launch of Orbicular’s ANDA Product is blocked by the exclusivity of the GATTEX® First Filer.

THE CLAIMS OF THE DISCLAIMED ’061 PATENT AND THE DISCLAIMED ’992 PATENT ARE UNENFORCEABLE AND CANNOT BE INFRINGED BY ORBICULAR’S ANDA PRODUCT OR METHODS OF USING ORBICULAR’S ANDA PRODUCT

COUNT 1

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE ’061 PATENT

145. Orbicular repeats and realleges each of the allegations in paragraphs 1-101set forth above, as if fully set forth herein.

146. There is a substantial and continuing controversy between Defendants and Orbicular, and a declaration of rights is both necessary and appropriate to establish that Orbicular's ANDA Product does not infringe any valid or enforceable claim of the '061 patent.

147. Defendants listed the '061 patent in the Orange Book.

148. Defendants disclaimed the '061 patent. See **Exhibit D.**

149. The '061 patent is still listed in the Orange Book.

150. Disclaimed claims cannot be revived, through reissue or otherwise. *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing *Altoona Publix Theatres, Inc.,* 294 U.S. 477).

151. The effect of a disclaimer is that the patent is viewed as though the disclaimed claims had never existed in the patent. *Vectra Fitness, Inc. v. TNWK Corp.,* 162 F.3d 1379, 1383 (Fed. Cir. 1998).

152. The disclaimed claims are thereafter unenforceable. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015).

153. As a matter of law, a patent that has been disclaimed cannot be infringed. *Id.*

154. The '061 patent has been disclaimed and all claims thereof have been dedicated to the public.

155. No claim of the '061 patent is enforceable or can be asserted against Orbicular's ANDA Product.

156. Orbicular's ANDA Product therefore does not and cannot infringe any claim of the '061 patent.

157. But for Takeda's decision to list the '061 patent in the Orange Book, FDA

approval of Orbicular's ANDA Product would not have been independently delayed by the '061 patent. Orbicular is being injured by Takeda's actions of requesting the FDA to list the '061 patent in the FDA Orange Book and benefitting from said listing in the FDA Orange Book to delay generic competition.

158. Orbicular's injury can be redressed by the requested relief: a declaratory judgment of noninfringement of Orbicular's ANDA Product would trigger the GATTEX® First Filer's exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of Orbicular's ANDA Product. If Orbicular is blocked by the GATTEX® First Filer's exclusivity, Orbicular will be irreparably and/or monetarily harmed, as it will lose sales of Orbicular's ANDA Product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete with Takeda and others in the market for teduglutide for injection single-dose vial of 5mg teduglutide per vial.

159. Orbicular seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale and/or importation of Orbicular's ANDA Product does not and will not infringe, directly or indirectly, any valid or enforceable claim of the '061 patent.

COUNT 2

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '992 PATENT

160. Orbicular repeats and realleges each of the allegations in paragraphs 1-116 set forth above, as if fully set forth herein.

161. There is a substantial and continuing controversy between Defendants and Orbicular, and a declaration of rights is both necessary and appropriate to establish that Orbicular's ANDA Product does not infringe any valid or enforceable claim of the '992 patent.

162. Defendants listed the ’992 patent in the Orange Book.

163. Defendants disclaimed the ’992 patent. See **Exhibit E**.

164. The ’992 patent is still listed in the Orange Book.

165. Disclaimed claims cannot be revived, through reissue or otherwise. *Guinn v. Kopf,* 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing *Altoona Publix Theatres, Inc.,* 294 U.S. 477).

166. The effect of a disclaimer is that the patent is viewed as though the disclaimed claims had never existed in the patent. *Vectra Fitness, Inc. v. TNWK Corp.,* 162 F.3d 1379, 1383 (Fed. Cir. 1998).

167. The disclaimed claims are thereafter unenforceable. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015).

168. As a matter of law, a patent that has been disclaimed cannot be infringed. *Id.*

169. The ’992 patent has been disclaimed and all claims thereof have been dedicated to the public.

170. No claim of the ’992 patent is enforceable or can be asserted against Orbicular’s ANDA Product.

171. Orbicular’s ANDA Product therefore does not and cannot infringe any claim of the ’992 patent.

172. But for Takeda’s decision to list the ’992 patent in the Orange Book, FDA approval of Orbicular’s ANDA Product would not have been independently delayed the ’992 patent. Orbicular is being injured by Takeda’s actions of requesting the FDA to list the ’992 patent in the FDA Orange Book and benefitting from said listings in the FDA Orange Book to delay generic competition.

173. Orbicular’s injury can be redressed by the requested relief: a declaratory judgment

of noninfringement of Orbicular's ANDA Product would trigger the GATTEX® First Filer's exclusivity period, which otherwise threatens to block indefinitely final FDA marketing approval of Orbicular's ANDA Product. If Orbicular is blocked by the GATTEX® First Filer's exclusivity, Orbicular will be irreparably and/or monetarily harmed, as it will lose sales of Orbicular's ANDA Product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and will be deprived of an economic opportunity to compete with Takeda and others in the market for teduglutide for injection single-dose vial of 5mg teduglutide per vial.

174. Orbicular seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale and/or importation of Orbicular's ANDA Product does not and will not infringe, directly or indirectly, any valid or enforceable claim of the '992 patent.

PRAYER FOR RELIEF

Whereas, Orbicular respectfully requests the Court enter judgment as follows:

A. Declaring that the claims of the '061 and '992 patents have not been infringed by the filing of Orbicular's ANDA No. 218582 with respect to Orbicular's ANDA Product.

B. Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of Orbicular's ANDA Product that is the subject of Orbicular's ANDA No. 218582 have not infringed, do not infringe, and would not, if marketed, infringe, or induce or contribute to the infringement by others of, any claims of the '061 and '992 patents;

C. Declaring that the United States Food & Drug Administration may approve Orbicular's ANDA Product of Orbicular's ANDA No. 218582 whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the

patents-in-suit are not infringed pursuant to 21 U.S.C. § 355(j)(5)(B)(iii)(I)(aa); and any other marketing exclusivity periods to which Takeda might otherwise be entitled (including any pediatric exclusivity) with respect to the '061 and '992 patents is shortened to expire upon the date of entry of judgment in this case;

D. Declaring that this an exceptional case in favor of Orbicular and awarding Orbicular its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

E. Awarding Orbicular its costs and such other and further relief that the Court deems just and proper under the circumstances.

Dated: December 13, 2024

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