

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORBICULAR PHARMACEUTICAL TECHNOLOGIES, PVT. LTD. and CIPLA USA, INC.,)
)
Plaintiffs,)
) C.A. No. 24-1366 (JLH)
v.)
)
SHIRE-NPS PHARMACEUTICALS, INC. and TAKEDA PHARMACEUTICALS U.S.A., INC.,)
)
Defendants.)

ANSWER TO COMPLAINT FOR DECLARATORY JUDGMENT

Shire-NPS Pharmaceuticals, Inc. (“Shire”), having merged with and into Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals U.S.A., Inc. (“Takeda”) (the former Shire now merged with and into Takeda and Takeda collectively referred to herein as “Defendants”), by and through their undersigned counsel, respectfully submit their Answer to Complaint for Declaratory Judgment brought by Orbicular Pharmaceutical Technologies Pvt. Ltd. (“Orbicular Pharma” or “Orbicular”) and Cipla USA, Inc. (“Cipla”) (collectively “Plaintiffs”).

Defendants deny all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. The Headings of the Complaint are repeated here for convenience and Defendants do not admit the allegations therein.

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").

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent that an answer is required, Defendants admit that the Complaint for Declaratory Judgment purports to seek a declaratory judgment under the patent laws of the United States and the Declaratory Judgment Act that United States Patent No. 7,847,061 ("the '061 patent") and United States Patent No. 9,060,992 ("the '992 patent") 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"). Defendants further admit that Exhibits A and B purport to be copies of the '061 patent and the '992 patent, respectively. To the extent any further allegations in paragraph 1 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: The allegations of paragraph 2 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that the website <https://orbicular.co.in/> identifies the address of Orbicular as P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar, Kukatpally,

Hyderabad: 500 090. Telangana. India. To the extent any further allegations in paragraph 3 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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

ANSWER: Defendants admit that the website <https://usa.cipla.com/ciplausa-contact-us> identifies the address of the commercial offices of Cipla as 10 Independence Boulevard, Suite 300 Warren, NJ 07059. Defendants further admit, upon information and belief, that Cipla is a corporation organized and existing under the laws of the State of Delaware. To the extent any further allegations in paragraph 4 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Denied. Shire-NPS Pharmaceuticals, Inc. was merged with and into Defendant Takeda Pharmaceuticals U.S.A., Inc. on August 1, 2022, after which Shire-NPS Pharmaceuticals, Inc. ceased to exist. *See Exhibit A*, attached. Defendants will work with Plaintiffs to file a stipulation to correct the parties in due course.

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

ANSWER: Defendants admit that NPS Pharmaceuticals, Inc. changed its name to Shire-NPS Pharmaceuticals, Inc. on July 1, 2016. To the extent any further allegations in paragraph 6 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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

ANSWER: Defendants admit that Takeda is a Delaware corporation, but deny the remaining allegations in this paragraph. Defendants further state that Takeda's principal place of business is 500 Kendall St., Cambridge, MA 02142.

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.

ANSWER: Paragraph 8 contains legal conclusions to which no response is required. To the extent that an answer is required, Defendants admit that the Complaint purports to arise under the Patent Laws of the United States, the Declaratory Judgment Act, and the Federal Food, Drug and Cosmetic Act and that the Complaint seeks a final judgment declaring that the '061 and '992 patents are not infringed by Orbicular's ANDA Product. To the extent any further allegations in paragraph 8 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent that an answer is required, Defendants admit that this Court has subject-matter jurisdiction, at least in part, 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.

ANSWER: Denied. Shire no longer exists. *See ANSWER to Paragraph 5.*

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

ANSWER: Paragraph 11 contains legal conclusions to which no response is required.

To the extent that an answer is required, Defendants admit that Takeda is incorporated under the laws of the State of Delaware. Takeda does not contest this Court exercising personal jurisdiction over it solely for purposes of this action.

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.

ANSWER: Paragraph 12 contains legal conclusions to which no response is required.

To the extent that an answer is required, Takeda does not contest this Court exercising personal jurisdiction over it solely for purposes of this action. Defendants deny that this Court has personal jurisdiction over Shire, as Shire ceased to exist as of August 1, 2022. *See ANSWER to Paragraph 5.*

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-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.).

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent that an answer is required, Defendants admit that they have filed the above-referenced actions in this Court.

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

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent that an answer is required, Takeda does not contest venue in this Court solely for purposes of this action.

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.

ANSWER: Admitted.

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.

ANSWER: Defendants admit that the '061 patent was issued to NPS Pharmaceuticals, Inc. Defendants further admit that NPS Pharmaceuticals, Inc. is the assignee named on the face of the '061 patent. Defendants also admit that United States Patent and Trademark Office records identify Shire-NPS Pharmaceuticals, Inc. as the owner of the '061 patent, and that the change of name from NPS Pharmaceuticals, Inc. to Shire-NPS Pharmaceuticals, Inc. was recorded in the USPTO at least on January 23, 2017. To the extent any further allegations in paragraph 16 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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®.

ANSWER: Denied. As a consequence of Shire's merger with and into Takeda, Takeda is now the owner of any remaining interest in the '061 patent. To the extent any further allegations in paragraph 17 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Admitted.

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.

ANSWER: Defendants admit that the '992 patent was issued to NPS Pharmaceuticals, Inc. Defendants further admit that NPS Pharmaceuticals, Inc. is the assignee named on the face of the '992 patent. Defendants also admit that United States Patent and Trademark Office records identify Shire-NPS Pharmaceuticals, Inc. as the owner of the '992 patent, and that the change of name from NPS Pharmaceuticals, Inc. to Shire-NPS Pharmaceuticals, Inc. was recorded in the USPTO at least on January 23, 2017. To the extent any further allegations in paragraph 19 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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®.

ANSWER: Denied. As a consequence of Shire's merger with and into Takeda, Takeda is now the owner of any remaining interest in the '992 patent. To the extent any further allegations

in paragraph 20 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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".

ANSWER: Paragraph 38 contains no allegation of fact that can be admitted or denied.

To the extent allegations in paragraph 38 contain factual allegations, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Paragraph 39 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that U.S. Patent No. 5,789,379 expired in 2020. Defendants further admit that U.S. Patent No. 7,056,886 expired in 2023. Defendants also admit that U.S. Patent No. 5,789,379 and U.S. Patent No. 7,056,886 were previously listed in the Orange Book with respect to NDA No. 20-3441 for GATTEX®. To the extent any further allegations in paragraph 39 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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

ANSWER: Admitted.

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.).

ANSWER: Defendants admit that what Plaintiffs call the Disclaimed & Delisted OB Patents were issued to NPS Pharmaceuticals, Inc. or Shire-NPS Pharmaceuticals, Inc. Defendants further admit that NPS Pharmaceuticals, Inc. or Shire-NPS Pharmaceuticals, Inc. is the assignee named on the face of what Plaintiffs call the Disclaimed & Delisted OB Patents. Defendants also

admit that United States Patent and Trademark Office records identify Shire-NPS Pharmaceuticals, Inc. as the owner of what Plaintiffs call the Disclaimed & Delisted OB Patents, and that the change of name from NPS Pharmaceuticals, Inc. to Shire-NPS Pharmaceuticals, Inc. was recorded in the USPTO. To the extent any further allegations in paragraph 41 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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®.

ANSWER: Takeda admits that it was the exclusive licensee of what Plaintiffs call the Disclaimed & Delisted OB Patents before Shire's merger with and into Takeda. Takeda is now the owner of any remaining interest in what Plaintiffs call the Disclaimed & Delisted OB Patents. To the extent any further allegations in paragraph 42 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Admitted.

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®.

ANSWER: Admitted.

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."

ANSWER: Paragraph 45 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that an excerpt of 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....”

ANSWER: Paragraph 46 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that an excerpt of 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.

ANSWER: Paragraph 47 contains legal conclusions to which no response is required. To the extent that a response is required, Defendants admit that 37 CFR § 1.321 sets forth some of the process for a patentee to disclaim any patent claims with the United State Patent Office. Defendants further admit that MPEP § 1490 sets forth additional details regarding the process for a patentee to disclaim any patent claims with the United State Patent Office. To the extent any further allegations in paragraph 47 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: Paragraph 48 contains legal conclusions to which no response is required. To the extent that a response is required, Defendants admit that *Altoona Publix Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 492 (1935) states that “[u]pon the filing of the

disclaimers, the original claims were withdrawn from the protection of the patent laws, and the public was entitled to manufacture and use the device originally claimed as freely as though it had been abandoned.” To the extent any further allegations in paragraph 48 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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

ANSWER: Paragraph 49 contains legal conclusions to which no response is required. To the extent that a response is required, Defendants deny that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that a disclaimed patent is unenforceable. To the extent that Plaintiffs interpret “unenforceable” in the context of a disclaimed patent to mean only that there is no legal basis to assert infringement of such patent, and not to imply any wrongdoing by the patentee (e.g., inequitable conduct or patent misuse), Defendants admit that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that “non-infringement of the [disclaimed] patent follows as a matter of law.” To the extent any further allegations in paragraph 49 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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

ANSWER: Paragraph 50 contains legal conclusions to which no response is required. To the extent that a response is required, Defendants admit that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that “non-infringement of the [disclaimed] patent follows as a matter of law.” To the extent any further allegations in paragraph 50 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

LITIGATION WHICH ALLEGEDLY 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)).

ANSWER: Defendants admit that the action *Rigshospitalet v. Shire-NPS Pharmaceuticals, Inc. and Takeda Pharmaceuticals U.S.A.*, Inc., 1:21cv11602 was filed in the District of Massachusetts on September 29, 2021. Defendants further admit that Exhibit C purports to be a copy of the complaint (“Rigshospitalet Complaint”) in such action, without the attached exhibits. Defendants state that the Rigshospitalet Complaint speaks for itself. Defendants deny the allegations in the Rigshospitalet Complaint and assert that the allegations in such complaint are meritless. Defendants deny any remaining allegations in paragraph 51.

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).

ANSWER: Defendants state that the Rigshospitalet Complaint speaks for itself. Defendants deny the allegations in the Rigshospitalet Complaint and assert that the allegations in such complaint are meritless. Defendants deny any remaining allegations in paragraph 52.

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).

ANSWER: Defendants state that the Rigshospitalet Complaint speaks for itself. Defendants deny the allegations in the Rigshospitalet Complaint and assert that the allegations in such complaint are meritless. Defendants deny any remaining allegations in paragraph 53.

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).

ANSWER: Defendants state that the Rigshospitalet Complaint speaks for itself. Defendants deny the allegations in the Rigshospitalet Complaint and assert that the allegations in such complaint are meritless. Defendants deny any remaining allegations in paragraph 54.

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.*

ANSWER: Admitted.

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.

ANSWER: Admitted.

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**.

ANSWER: Defendants admit that 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, and that such statutory disclaimer was accompanied by the required fee pursuant to 37 CFR § 1.20(d) and

recorded by the USPTO. Defendants further admit that Exhibit D purports to be a copy of such statutory disclaimer. Defendants deny any remaining allegations of paragraph 57.

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.

ANSWER: Defendants admit that 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, and that such statutory disclaimer was accompanied by the required fee pursuant to 37 CFR § 1.20(d) and recorded by the USPTO. Defendants further admit that Exhibit E purports to be a copy of such statutory disclaimer. Defendants deny any remaining allegations of paragraph 58.

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.

ANSWER: Defendants admit that on July 20, 2022, Shire filed statutory disclaimers under 37 CFR §1.321(a) disclaiming the entire remaining terms of each of what Plaintiffs call the Disclaimed & Delisted OB Patents and that each statutory disclaimer was accompanied by the required fee pursuant to 37 CFR § 1.20(d) and recorded by the USPTO. Defendants further admit that Exhibit F purports to contain copies of such statutory disclaimers. Defendants deny any remaining allegations of paragraph 59.

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.

ANSWER: Paragraph 60 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that the FDA is responsible for the approval of

the marketing of new drugs through NDAs in the United States. *See generally* 21 C.F.R. § 314. The other allegations of paragraph 60 contain legal conclusions to which no response is required. To the extent any further allegations in paragraph 60 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Paragraph 61 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. §355(b)(1) generally describes the contents of applications that are filed with the FDA and refers to the statute for its terms. To the extent any further allegations in paragraph 61 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: Paragraph 62 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. §355(b)(1) generally describes the contents of applications that are filed with the FDA and refers to the statute for its terms. To the extent any further allegations in paragraph 62 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: Paragraph 63 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355(j)(2)(A)(vii)(IV) generally describes one of four patent certifications that may be submitted with an ANDA and refers to the statute for its terms. To the extent any further allegations in paragraph 63 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: Paragraph 64 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355(j)(5)(C)(i) concerns “Civil action to obtain patent certainty” and “Declaratory judgment absent infringement action.” To the extent any further allegations in paragraph 64 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: Paragraph 65 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355(j)(5)(C)(i) concerns “Civil action to obtain patent certainty” and “Declaratory judgment absent infringement action.” To the extent any further allegations in paragraph 65 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: Paragraph 66 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355 (j)(5)(D)(i)(I) concerns the “Forfeiture of 180-day exclusivity period” based upon “Failure to market.” To the extent any further allegations in paragraph 66 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Paragraph 67 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355 (j)(5)(D)(i)(I) concerns the “Forfeiture of 180-day exclusivity period” based upon “Failure to market.” Defendants further admit that no company (including the GATTEX® First Filer) has begun selling a generic equivalent to a GATTEX® product in the United States. To the extent any further allegations in

paragraph 67 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Paragraph 68 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355 (j)(5)(D)(i)(I) concerns the “Forfeiture of 180-day exclusivity period” based upon “Failure to market.” To the extent any further allegations in paragraph 68 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.*

ANSWER: Paragraph 69 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 21 U.S.C. § 355 (j)(5)(D)(i)(I) concerns the “Forfeiture of 180-day exclusivity period” based upon “Failure to market.” To the extent any further allegations in paragraph 69 are not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Defendants admit that Exhibit G purports to be a copy of the 2022 Orange Book listing for GATTEX®.

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®.

ANSWER: Defendants deny that Takeda filed a request with the FDA to delist the '061 and '992 patents from the Orange Book with respect to GATTEX®. Defendants state that Shire 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®.

ANSWER: Defendants deny that Takeda filed a request with the FDA to delist what Plaintiffs call the Disclaimed & Delisted OB Patents from the Orange Book with respect to GATTEX®. Defendants state that Shire filed a request with the FDA to delist what Plaintiffs call the Disclaimed & Delisted OB Patents from the Orange Book with respect to GATTEX®.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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).

ANSWER: Defendants admit that the 2023 Orange Book did not list any of what Plaintiffs call the Disclaimed & Delisted OB Patents for GATTEX®. Defendants further admit that Exhibit H purports to be a copy of the 2023 Orange Book listing for GATTEX®.

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

ANSWER: Admitted.

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”.

ANSWER: Admitted.

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.

ANSWER: Paragraph 82 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that 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. To the extent any further allegations in paragraph 82 are

not addressed by the foregoing, Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations and therefore deny them.

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).

ANSWER: The allegations of paragraph 83 contain legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Defendants admit that the FDA has not removed the '061 patent 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.

ANSWER: Defendants admit that the FDA has not removed the '992 patent 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).

ANSWER: Paragraph 86 states legal conclusions to which no response is required. To the extent a response is required, Defendants state, on information and belief, that once a patent owner requests that a patent be delisted from the Orange Book, the FDA decides whether and when to carry out such delisting, and that the patent owner has no further input into the delisting process.

To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Paragraph 87 states a legal conclusion to which no response is required. To the extent a response is required, Defendants state that to the extent that Plaintiffs interpret "no longer enforceable" in the context of a disclaimed patent to mean only that there is no legal basis to assert infringement of such patent and not to imply any wrongdoing by the patentee (e.g., inequitable conduct or patent misuse), Defendants admit that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that "non-infringement of the [disclaimed] patent follows as a matter of law." To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 88 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

(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.

ANSWER: Defendants admit that Orbicular represented to Takeda, in a letter dated January 5, 2024, that the Orbicular ANDA had been filed with the FDA. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendant admits that Orbicular represented to Takeda, in a letter dated January 5, 2024, that the Orbicular ANDA contained a Paragraph IV certification for each of the '061 and '992 patents. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that on or about January 8, 2024, Takeda received what purports to be a Notice Letter dated January 5, 2024, announcing the filing of the Orbicular ANDA that seeks 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. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

ANSWER: The allegations in the first sentence of paragraph 93 contain legal conclusions to which no response is required. Defendants admit that Orbicular's purported Notice Letter contained what purported to be an Offer of Confidential Access. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 94 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that neither Shire nor Takeda brought an action for infringement of the '061 and/or the '992 patents against Orbicular. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

ANSWER: The allegations of paragraph 96 contain legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Orbicular's purported Notice Letter contained what purported to be an Offer of Confidential Access and that neither Shire nor Takeda brought an action for infringement of the '061 and/or the '992 patents against Orbicular. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

ANSWER: Paragraph 98 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that *Apotex Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1366 (Fed. Cir. 2015) (emphasis added) states that "tentative approval of an ANDA is generally not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book." To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

(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.

ANSWER: The allegations of paragraph 99 contain legal conclusions to which no response is required. Defendants admit that Orbicular, through its counsel Frank Rodriguez at Windels Marx Lane & Mittendorf, contacted counsel for Defendants, Ira Finkelstein, Lead Counsel, IP at Takeda Pharmaceuticals U.S.A., Inc. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that 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. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Admitted.

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.

ANSWER: Defendants admit that non-infringement of the disclaimed '061 patent follows as a matter of law. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that non-infringement of the disclaimed '992 patent follows as a matter of law. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Admitted as a legal matter based on the disclaimer of the '061 and '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.

ANSWER: Denied.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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

ANSWER: Admitted.

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.

ANSWER: The allegations of paragraph 111 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

(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®.

ANSWER: Upon information and belief, Defendants admit that 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.

ANSWER: Upon information and belief, Defendants admit that 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).

ANSWER: Admitted.

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).

ANSWER: Admitted.

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).

ANSWER: Admitted.

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

ANSWER: Upon information and belief, Defendants admit that they believe the Par Defendants and/or their parent company Endo International plc is/are the GATTEX® First Filer.

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

ANSWER: Upon information and belief, Defendants admit that they believe the Par Defendants and/or Endo International plc to be 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.

ANSWER: Upon information and belief, Defendants admit that they believe 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.

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.

ANSWER: The allegations of paragraph 120 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

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.

ANSWER: Defendants admit that they are not aware of any publicly available information which indicates that the Par Defendants have not maintained their Paragraph IV certifications to the '061 and '992 patents. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Admitted.

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).

ANSWER: Admitted.

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").

ANSWER: Defendants admit that case No 1:17-cv-00397 (D. Del.) was dismissed pursuant to a confidential settlement agreement.

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.

ANSWER: Paragraph 125 states legal conclusions to which no response was required.

To the extent a response is required, Defendants admit that due to the dismissal of case No. 1:17-cv-00397 (D. Del.), Defendants understand there was no "final decision" in that case 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. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Paragraph 126 states legal conclusions to which no response was required. To the extent a response is required, Defendants understand that 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. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Paragraph 127 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that the FDA has not notified Takeda that a forfeiture event has occurred with respect to the GATTEX® First Filer of 180-day exclusivity. Defendants further admit that they are not aware of a determination or declaration by the FDA that such forfeiture has occurred. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Upon information and belief, Defendants admit that they are not aware of any generic pharmaceutical company receiving 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.

ANSWER: Defendants admit that they are not aware of any company (including the GATTEX® First Filer) having begun selling a generic equivalent to a GATTEX® product in the United States.

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.

ANSWER: The allegations of paragraph 130 contain legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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®.

ANSWER: The allegations of paragraph 131 contain legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 132 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 133 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 134 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 135 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 136 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 137 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 138 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

ANSWER: The allegations of paragraph 139 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or

information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that no generic version of GATTEX® has entered the market in the United States. Regarding the allegations of paragraph 140 that contain legal conclusions, no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 141 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 142 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or

information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 143 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: The allegations of paragraph 144 contain legal conclusions to which no response is required. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

**THE CLAIMS OF THE DISCLAIMED '061 PATENT AND THE DISCLAIMED '992
PATENT ALLEGEDLY 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 1-101 set forth above, as if fully set forth herein.

ANSWER: Defendants repeat, reallege, and incorporate by reference each of the foregoing Paragraphs 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.

ANSWER: The allegations of paragraph 146 contain legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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

ANSWER: Admitted.

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).

ANSWER: Paragraph 150 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny that *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing *Altoona Publix Theatres, Inc.*, 294 U.S. 477) addresses whether disclaimed claims cannot be revived, through reissue or otherwise. Defendants do not contest that *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing *Altoona Publix Theatres, Inc.*, 294 U.S. 477) states that “[a] statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent.” To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

ANSWER: Paragraph 151 states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest the allegations of paragraph 151.

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

ANSWER: Paragraph 152 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that a disclaimed patent is unenforceable. To the extent that Plaintiffs interpret “unenforceable” in the context of a disclaimed patent only to mean that there is no legal basis to assert infringement of such patent and not to imply any wrongdoing by the patentee (e.g., inequitable conduct or patent misuse), Defendants do not contest that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that “non-infringement of the [disclaimed] patent follows as a matter of law.” To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Paragraph 153 states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that with respect to disclaimer of a complete claim, as a matter of law such claim cannot be infringed. *See* 35 U.S.C. § 253(a). Defendants deny that there can be no infringement with respect to disclaimer of only the terminal part of a patent, because such patent can be infringed during the non-disclaimed portion of the term. *See* 35 U.S.C. § 253(b). To the extent any further response is required, Defendants lack knowledge or

information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Paragraph 154 states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest the allegations of paragraph 154.

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

ANSWER: Paragraph 155 states legal conclusions to which no response is required. To the extent a response is required, Defendants state that to the extent that Plaintiffs interpret "[n]o claim of the '061 patent is enforceable" in the context of a disclaimed patent to mean only that there is no legal basis to assert infringement of such patent, Defendants do not contest that non-infringement of the disclaimed '061 patent follows as a matter of law, and therefore the claims of the '061 patent cannot be asserted against Orbicular's ANDA Product. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Paragraph 156 states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest that non-infringement of the disclaimed '061 patent follows as a matter of law.

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.

ANSWER: Denied.

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.

ANSWER: The allegations of paragraph 158 contain legal conclusions to which no response is required. To the extent a response is required, the allegations of paragraph 158 contain factual allegations for which Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that Orbicular seeks an entry of judgment declaring that, inter alia, 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 claim of the '061 patent. *See* Complaint, Dkt. No. 1 at Prayer for Relief, Paragraph B. Regarding the allegations of paragraph 159 that contain legal conclusions, including that Orbicular 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, no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants repeat, reallege, and incorporate by reference each of the foregoing Paragraphs 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.

ANSWER: The allegations of paragraph 161 contain legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Admitted.

163. Defendants disclaimed the '992 patent. See Exhibit E.

ANSWER: Admitted.

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

ANSWER: Admitted.

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).

ANSWER: Paragraph 165 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny that *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing *Altoona Publix Theatres, Inc.*, 294 U.S. 477) addresses whether disclaimed claims cannot be revived, through reissue or otherwise. Defendants do not contest that *Guinn v. Kopf*, 96 F.3d 1419, 1422 (Fed. Cir. 1996) (citing *Altoona Publix Theatres, Inc.*, 294 U.S. 477)

states that “[a] statutory disclaimer under 35 U.S.C. § 253 has the effect of canceling the claims from the patent and the patent is viewed as though the disclaimed claims had never existed in the patent.” To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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).

ANSWER: Paragraph 166 states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest the allegations of paragraph 166.

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

ANSWER: Paragraph 167 states legal conclusions to which no response is required. To the extent a response is required, Defendants deny that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that a disclaimed patent is unenforceable. To the extent that Plaintiffs interpret “unenforceable” in the context of a disclaimed patent to mean only that there is no legal basis to assert infringement of such patent and not to imply any wrongdoing by the patentee (e.g., inequitable conduct or patent misuse), Defendants do not contest that *Apotex, Inc. v. Daichii Sankyo, Inc.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015) states that “non-infringement of the [disclaimed] patent follows as a matter of law.” To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Paragraph 168 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that with respect to disclaimer of a complete

claim, as a matter of law such claim cannot be infringed. *See* 35 U.S.C. § 253(a). Defendants deny that there can be no infringement with respect to disclaimer of only the terminal part of a patent, because such patent can be infringed during the non-disclaimed portion of the term. *See* 35 U.S.C. § 253(b). To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Paragraph 169 states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest the allegations of paragraph 169.

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

ANSWER: Paragraph 170 states legal conclusions to which no response is required. To the extent a response is required, to the extent that Plaintiffs interpret “[n]o claim of the '992 patent is enforceable” in the context of a disclaimed patent only to mean that there is no legal basis to assert infringement of such patent, Defendants do not contest that non-infringement of the disclaimed '992 patent follows as a matter of law, and therefore the claims of the '992 patent cannot be asserted against Orbicular's ANDA Product. To the extent any further response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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

ANSWER: Paragraph 171 states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest that non-infringement of the disclaimed '992 patent follows as a matter of law. To the extent any further response is required,

Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

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.

ANSWER: Denied.

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.

ANSWER: The allegations of paragraph 173 contain legal conclusions to which no response is required. To the extent a response is required, the allegations of paragraph 173 contain factual allegations for which Defendants lack knowledge or information sufficient to form a belief about the truth of such allegations in this paragraph and therefore deny them.

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.

ANSWER: Defendants admit that Orbicular seeks an entry of judgment declaring that, inter alia, 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 claim of the '992 patent. *See* Complaint, Dkt. No. 1 at Prayer for Relief, Paragraph B. Regarding the allegations of paragraph 174 that contain legal conclusions, including that Orbicular 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, no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore deny them.

RESPONSE TO PLAINTIFFS' PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to a declaration that this is an exceptional case in favor of Orbicular and awarding Orbicular its reasonable attorneys' fees pursuant to 35 U.S.C. § 285. Defendants further deny that Orbicular is entitled to an award of its costs.

DEFENDANTS' PRAYER FOR RELIEF

Whereas, Defendants respectfully request the Court enter judgment as follows:

- A. Denying Plaintiffs' request pursuant to 35 U.S.C. § 285 (i) declaring that this is an exceptional case in favor of Orbicular, and (ii) awarding Orbicular its reasonable attorneys' fees.
- B. Denying Plaintiffs' request that Orbicular be awarded its costs.
- C. Awarding Defendants such other and further relief as this Court may deem proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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February 5, 2025

CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2025, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 5, 2025, upon the following in the manner indicated:

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