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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

ABBVIE INC., ALLERGAN)	
PHARMACEUTICALS INTERNATIONAL)	
LIMITED, AND MERCK SHARP &)	
DOHME LLC,)	
)
Plaintiffs,)	
)
v.)	Civil Action No. 3:24-4603 (ZNQ)(JBD)
)
)
ZYDUS PHARMACEUTICALS (USA) INC.,)	
AND ZYDUS LIFESCIENCES LIMITED,)	
)
Defendants.)	

**ZYDUS PHARMACEUTICALS (USA) INC.'S, AND
ZYDUS LIFESCIENCES LIMITED'S ANSWER AND
AFFIRMATIVE DEFENSES TO PLAINTIFFS' THIRD AMENDED COMPLAINT**

Defendants Zydus Pharmaceuticals (USA) Inc. (“Zydus USA”) and Zydus Lifesciences Limited (“Zydus Lifesciences”) (collectively, “Defendants”) for their Answer and Affirmative Defenses to the Third Amended Complaint of AbbVie, Inc. (“AbbVie”), Allergan Pharmaceuticals International Limited, (“Allergan”), and Merck Sharp & Dohme LLC (“Merck”) (collectively, “Plaintiffs”) state as follows:

All averments not expressly admitted are denied.

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,117,836 (“the ’836 patent”), 11,717,515 (“the ’515 patent”), 11,857,542 (“the ’542 patent”), 11,925,709 (“the ’709 patent”), 12,070,450 (“the ’450 patent”), 12,168,004 (“the ’004 patent”), 12,194,030 (“the ’030 patent”), 12,220,408 (“the ’408 patent”), 12,310,953 (“the ’953 patent”), and 12,329,750 (“the ’750 patent”) (collectively, “the Patents-in-Suit”) arising under the United States Patent Laws, Title 35, United States Code, § 1, *et seq.*, and in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to Zydus’ recent submission to the United States Food and Drug Administration (“FDA”) of an Abbreviated New Drug Application (“ANDA”) seeking approval to market generic versions of Plaintiffs’ commercial pharmaceutical product UBRELVY® (ubrogepant) oral tablets in 50 mg and 100 mg dosage forms (“UBRELVY® Tablets”) submitted under New Drug Application (“NDA”) No. 211765, prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for UBRELVY® Tablets. Zydus has submitted ANDA No. 218662 (“Zydus’ ANDA”), which seeks approval to market its generic version of UBRELVY® Tablets, ubrogepant oral tablets, 50 mg, 100 mg (“Zydus’ generic products”), prior to the expiration of the Patents-in- Suit.

ANSWER: The allegations in paragraph 1 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of U.S. Patent Nos. 10,117,836 (“the ’836 patent”), 11,717,515 (“the ’515 patent”), 11,857,542 (“the ’542 patent”), and 11,925,709 (“the ’709 patent”), 12,070,450 (“the ’450 patent”), 12,168,004 (“the ’004 patent”), 12,194,030 (“the ’030 patent”), 12,220,408 (“the ’408 patent”), 12,310,953 (“the ’953 patent”), and 12,329,750 (“the ’750 patent”) (collectively, “the Patents-In-Suit”). Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial

importation, manufacture, use, and sale of ubrogepant oral tablets, 50 mg and 100 mg (“Zydus USA’s Proposed ANDA Product”) in or into the United States and that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’836, ’515, ’542 ’709, ’450, ’004, ’030, and ’408 patents. Defendants further admit that FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”) lists “ABBVIE INC” as Applicant Holder and “UBRELVY” as Proprietary Name and “TABLET;ORAL” as Dosage Form and Route of Administration in connection with New Drug Application (“NDA”) No. 211765. Defendants deny all other allegations in paragraph 1.

2. Zydus has infringed one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 218662 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Zydus’ generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof. Zydus will infringe one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Zydus’ generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof.

ANSWER: Denied.

THE PARTIES

3. Plaintiff AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie holds NDA No. 211765 for UBRELVY® Tablets.

ANSWER: Defendants admit that FDA’s Orange Book lists “ABBVIE INC” as Applicant Holder and “UBRELVY” as Proprietary Name and “TABLET;ORAL” as Dosage Form and Route of Administration in connection with NDA No. 211765. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 3 and therefore deny them.

4. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including migraine treatment.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 4 and therefore deny them.

5. AbbVie markets, distributes, and sells therapeutic drug products, including UBRELVY® Tablets, in this judicial district and throughout the United States.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 5 and therefore deny them.

6. Plaintiff Allergan is a corporation organized and existing under the laws of Ireland, with a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400. Allergan is the assignee of the '515, '542, '450, '030, and '750 patents and the exclusive licensee of the '836, '709, '004, '408, and '953 patents. Allergan is an indirectly wholly owned subsidiary of AbbVie.

ANSWER: Defendants admit that USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '515 patent under Reel/Frame No. 063519/0307. Defendants further admit that USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '542 patent under Reel/Frame No. 064076/0407. Defendants further admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '450 patent under Reel/Frame No. 065814/0254. Defendants further admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '030 patent under Reel/Frame No. 068953/0640. Defendants further admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '750 patent under Reel/Frame No. 070679/0475. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 6 and therefore deny them.

7. Plaintiff Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065. Merck is the assignee of the '836, '709, '004, '408, and '953 patents.

ANSWER: Defendants admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '836 patent under Reel/Frame no. 061102/0145. Defendants further admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '709 patent under Reel/Frame no. 067034/0711. Defendants further admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '004 patent under Reel/Frame No. 069116/0667. Defendants further admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '408 patent under Reel/Frame No. 069185/0001. Defendants admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '953 patent under Reel/Frame No. 069494/0051. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 7 and therefore deny them.

8. Merck is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve health.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 8 and therefore deny them.

9. Plaintiffs allege the following about Zydus on information and belief formed after a reasonable inquiry.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 9 and therefore deny them.

10. Zydus Pharmaceuticals is a corporation organized and existing under the laws of New Jersey and its principal place of business is located at 73 Route 31 N., Pennington, New Jersey 08534. It is a wholly owned subsidiary of Zydus Lifesciences.

ANSWER: Admitted.

11. Zydus Lifesciences is a corporation organized and existing under the laws of the Republic of India and its principal place of business is located at Zydus Corporate Park, Scheme

No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat India.

ANSWER: Defendants admit that Zydus Lifesciences is an entity organized and existing under the laws of India and that Zydus Lifesciences has a place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382 481, India. Defendants deny all other allegations in paragraph 11.

12. Zydus is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: Defendants admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 12.

13. Following any FDA approval of Zydus' ANDA, Zydus will distribute and sell the proposed Zydus generic products described in Zydus' ANDA throughout the United States, including in this judicial district.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 13.

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: The allegations in paragraph 14 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 14.

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

ANSWER: The allegations in paragraph 15 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as those alleged claims apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 15.

16. This Court has personal jurisdiction over Defendant Zydus Pharmaceuticals. On information and belief, Zydus Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Zydus Pharmaceuticals directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Zydus Pharmaceuticals has purposefully conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Zydus' generic products upon approval of Zydus' ANDA.

ANSWER: The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as those alleged claims apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus USA imports and sells pharmaceutical products, including generic pharmaceutical products, in the United States. Defendants further admit that Zydus USA's principal place of business is in New Jersey. Defendants deny all other allegations in paragraph 16.

17. This Court has personal jurisdiction over Defendant Zydus Lifesciences. On information and belief, Zydus Lifesciences is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Zydus Lifesciences directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Zydus Lifesciences purposefully has conducted and continues to conduct

business in this judicial district, and this judicial district is a likely destination of Zydus' generic products upon approval of Zydus' ANDA.

ANSWER: The allegations in paragraph 17 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as those alleged claims apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceutical products, and that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 17.

18. On information and belief, Zydus Pharmaceuticals is a United States agent for Zydus Lifesciences. Zydus Pharmaceuticals claims that it "is the US generic drug division of a much larger company known as Zydus Lifesciences. . . . [,] a global, fully integrated pharmaceutical company with a presence in 50 countries," and "is committed to growing its presence around the world and in the United States." *Zydus Pharmaceuticals*, <https://zydususa.com/> (last visited Apr. 5, 2024).

ANSWER: The allegations in paragraph 18 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA's website states that "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Lifesciences. Zydus Lifesciences is a global, fully integrated pharmaceutical company with a presence in 50 countries and is committed to growing its presence around the world and in the United States." See *ZYDUS PHARMACEUTICALS USA*, <https://zydususa.com/> (last visited July 2, 2025). Defendants deny all other allegations in paragraph 18.

19. On information and belief, Zydus Pharmaceuticals and Zydus Lifesciences hold themselves out as a unitary entity and operate as a single integrated business with respect to the

regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: The allegations in paragraph 19 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 19.

20. Zydus Pharmaceuticals and Zydus Lifesciences each directly or indirectly currently sells significant quantities of generic drug products and derives substantial revenue from the sale of those products in the United States and in this judicial district.

ANSWER: Defendants admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 20.

21. Zydus Pharmaceuticals claims that it “is ranked the fifth largest unbranded generic corporation in the US based on dispensed prescriptions” and “focus[es] on expanding [its] portfolio of complex generics, including modified release solid orals, transdermals, injectables, and oral suspensions.” *Overview*, Zydus Pharmaceuticals, <https://zydususa.com/overview/> (last visited Apr. 5, 2024). Zydus Pharmaceuticals claims that “[its] generic products can be found across the [United States] in most pharmacies, both in store as well as mail order.” *FAQ*, Zydus Pharmaceuticals, <https://zydususa.com/faq/> (last visited Apr. 5, 2024).

ANSWER: Defendants admit that Zydus USA’s website states that Zydus USA “is ranked the fifth largest unbranded generic corporation in the US based on dispensed prescriptions” and that it is “focused on expanding our portfolio of complex generics, including modified release solid orals, transdermals, injectables, and oral suspensions.” See *Overview*, ZYDUS PHARMACEUTICALS USA, <https://zydususa.com/overview/> (last visited July 2, 2025). Defendants further admit that Zydus USA’s website states that “Zydus’s generic products can be found across the country in most pharmacies, both in store as well as mail order.” See *FAQ*, ZYDUS

PHARMACEUTICALS USA, <https://zydususa.com/faq/> (last visited July 2, 2025). Defendants deny all other allegations in paragraph 21.

22. Zydus Pharmaceuticals is engaged in the submission and approval of ANDAs for the United States market, claiming that “[it] has filed over 129 drug master files (DMFs), received final USFDA approval on 287 [ANDAs], and has over 85 ANDAs pending approval with the USFDA.” *Overview*, Zydus Pharmaceuticals, <https://zydususa.com/overview/> (last visited Apr. 5, 2024). Zydus claims that “[it] also has approximately 300 additional products in various stages of development.” *Id.*

ANSWER: Defendants admit that Zydus USA’s website states that “Zydus Pharmaceuticals has filed over 129 drug master files (DMFs), received final USFDA approval on 287 Abbreviated New Drug Applications (ANDAs), and has over 85 ANDAs pending approval with the USFDA. The company also has approximately 300 additional products in various stages of development.” See *Overview*, ZYDUS PHARMACEUTICALS USA, <https://zydususa.com/overview/> (last visited July 2, 2025). Defendants deny all other allegations in paragraph 22.

23. Zydus Pharmaceuticals claims that it “manufactures its products in state-of-the-art facilities in . . . the US.” *Our Facilities*, Zydus Pharmaceuticals, <https://zydususa.com/our-facilities/> (last visited Apr. 5, 2024).

ANSWER: Defendants admit that Zydus USA’s website states that “Zydus manufactures its products in state-of-the-art facilities in India and the US.” See *Our Facilities*, ZYDUS PHARMACEUTICALS USA, <https://zydususa.com/our-facilities/> (last visited July 2, 2025). Defendants deny all other allegations in paragraph 23.

24. Zydus Lifesciences claims to “[have] manufacturing sites and research facilities . . . in the US” and “a strong presence in the regulated markets of the US.” *Zydus Group*, <https://www.zyduslife.com/index> (last visited Apr. 5, 2024). Zydus Lifesciences describes itself “[a]s one of the key players amongst the pharmaceutical manufacturing companies.” *Id.*

ANSWER: Defendants admit that Zydus Lifesciences’s website states that Zydus Lifesciences “has manufacturing sites and research facilities spread across five states of Gujarat, Maharashtra, Goa, Himachal Pradesh and Sikkim in India and in the US and Brazil” and that

“Zydus’ global business has a strong presence in the regulated markets of the US, Europe (France and Spain).” *See ZYDUS*, <https://www.zyduslife.com/index> (last visited July 2, 2025). Defendants further admit that Zydus Lifesciences’s website states that Zydus Lifesciences is “one of the key players amongst the pharmaceutical manufacturing companies.” *Id.* Defendants deny all other allegations in paragraph 24.

25. On information and belief, the acts of Zydus Pharmaceuticals complained of herein were done with the cooperation, participation, and assistance of Zydus Lifesciences.

ANSWER: The allegations in paragraph 25 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Defendants further admit that Zydus USA sells pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 25.

26. Zydus’ ANDA filing regarding the Patents-in-Suit relates to this litigation and is substantially connected with this judicial district because it predicts Zydus’ intent to market and sell Zydus’ generic products in this judicial district.

ANSWER: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA’s Proposed ANDA Products in the United States. Defendants deny all other allegations in paragraph 26.

27. On information and belief, Zydus Pharmaceuticals and Zydus Lifesciences have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 218662.

ANSWER: The allegations in paragraph 27 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Defendants further admit that Zydus USA sells

pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 27.

28. Following FDA approval of ANDA No. 218662, Zydus will act in concert to import, market, distribute, offer for sale, and/or sell Zydus' generic products described in ANDA No. 218662 throughout the United States, including in New Jersey and will derive substantial revenue from the use, consumption, or sale of Zydus' generic products in the state of New Jersey.

ANSWER: The allegations in paragraph 28 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 28.

29. If ANDA No. 218662 is approved, Zydus' generic products will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by healthcare providers practicing in New Jersey; administered by healthcare providers located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

ANSWER: The allegations in paragraph 29 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 29.

30. If ANDA No. 218662 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Zydus' generic products, including in New Jersey.

ANSWER: Denied.

31. This Court also has personal jurisdiction over Zydus because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. Zydus has been sued multiple times in this district without challenging personal jurisdiction. See, e.g., Defs.' Answer to Pls.' Compl., *Astellas Pharma Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:22-cv-04499-JMV-JSA (D.N.J. Dec. 15, 2022); Defs.' Answer to Pl.'s Compl., *Supernus Pharms., Inc. v. Zydus Pharms. (USA) Inc.*, No. 3:21-cv-17104-GC-LHG (D.N.J. Dec. 28, 2021); Defs.' Answer to Pls.' Compl., *Merck Sharp & Dohme B.V. v. Zydus Pharms. (USA) Inc.*, No. 2:20-cv-03068-CCC-MF

(D.N.J. June 30, 2020); Def.’s Answer to Pls.’ Compl., *Gilead Scis., Inc. v. Zydus Pharms. (USA) Inc.*, No. 3:19-cv-00529-BRM-LHG (D.N.J. June 14, 2019).

ANSWER: The allegations in paragraph 31 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs’ claims against Defendants in this case and solely as those alleged claims apply to Zydus USA’s Proposed ANDA Product. Defendants admit that in *Astellas Pharma Inc. v. Zydus Pharms. (USA) Inc.*, No. 2:22-cv-04499 (D.N.J.), Defendants stated that “Zydus does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs’ claims against Zydus in this case and solely as they apply to Zydus USA’s Proposed ANDA Products described in ANDA No. 217322.” Defendants further admit that in *Supernus Pharm., Inc., v. Zydus Pharm. (USA) Inc.*, Civil Action No. 3:21-cv-17104 (D.N.J.), Defendants stated “Defendants do not contest personal jurisdiction in this Court for the limited purpose of Plaintiffs’ claims against Defendants in this case and solely with respect to the proposed product described in ANDA No. 216167.” Defendants further admit that in *Merck Sharp & Dohme B.V., v. Zydus Pharms. (USA) Inc.*, No. 2:20-cv-03068 (D.N.J.), Defendants stated “[Zydus] does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs’ claims against [Zydus] in this case and solely as they apply to the proposed products described in ANDA No. 214290.” Defendants further admit that in *Gilead Scis., Inc. v. Zydus Pharms. (USA) Inc.*, No. 3:19-cv-00529 (D.N.J.), Defendants stated that “[Zydus] does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs’ claims against [Zydus] in this case and solely as they apply to the proposed product described in ANDA No. 212689.” Defendants deny all other allegations in paragraph 31.

32. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Zydus.

ANSWER: The allegations in paragraph 32 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as those alleged claims apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 32.

33. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Pharmaceuticals is incorporated in the state of New Jersey and has a principal place of business in New Jersey.

ANSWER: The allegations in paragraph 33 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest venue in this judicial district solely for the limited purpose of Plaintiffs' alleged claims arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus USA and solely as those alleged claims apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus USA maintains its principal place of business in New Jersey. Defendants deny all other allegations in paragraph 33.

34. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Zydus Lifesciences is incorporated in the Republic of India and may be sued in any judicial district in the United States.

ANSWER: The allegations in paragraph 34 are legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest venue in this Court solely for the limited purpose of Plaintiffs' alleged claims against Zydus Lifesciences in this case arising under 28 U.S.C. §§ 1391 and 1400(b) and solely as they apply to Zydus USA's Proposed ANDA Products. Defendants admit that Zydus Lifesciences is an entity organized and existing under the laws of India and that Zydus Lifesciences has a place of business at Zydus

Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382 481, India. Defendants deny all other allegations in paragraph 34.

FACTUAL BACKGROUND

UBRELVY® and the NDA

35. AbbVie is the holder of the New Drug Application (“NDA”) No. 211765 for UBRELVY® (ubrogepant) tablets in 50 mg and 100 mg dosages forms.

ANSWER: Defendants admit that FDA’s Orange Book lists “ABBVIE INC” as Applicant Holder, “UBRELVY” as Proprietary Name, “TABLET;ORAL” as Dosage Form and Route of Administration, and “50 MG” and “100 MG” as Strength in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 35.

36. The FDA approved NDA No. 211765 on December 23, 2019.

ANSWER: Defendants admit that FDA’s Orange Book lists “Dec 23, 2019” as the approval date for NDA No. 211765. Defendants deny all other allegations in paragraph 36.

37. The FDA Orange Book for NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg, lists U.S. Patent No. 8,754,096 (“the ’096 patent”); U.S. Patent No. 8,912,210 (“the ’210 patent”); U.S. Patent No. 9,499,545 (“the ’545 patent”); U.S. Patent No. 9,833,448 (“the ’448 patent”); the ’836 patent; the ’515 patent; the ’542 patent; the ’709 patent; the ’450 patent; the ’004 patent; and the ’030 patent.

ANSWER: Defendants admit that FDA’s Orange Book lists U.S. Patent Nos. 8,754,096 (“the ’096 patent”), 8,912,210 (“the ’210 patent”), 9,499,545 (“the ’545 patent”), 9,833,448 (“the ’448 patent”), the ’836 patent, the ’515 patent, the ’542 patent, the ’709 patent, the ’450 patent, the ’004 patent, and the ’030 patent under “Patent and Exclusivity” in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 37.

38. UBRELVY® Tablets are approved for the acute treatment of migraine attacks with or without aura in adults. Ubrogepant is the active ingredient of UBRELVY® Tablets. Ubrogepant is a calcitonin gene-related (CGRP) receptor antagonist.

ANSWER: Defendants admit that the NDA Approval letter for NDA No. 211765, dated December 23, 2019, states that “[t]his NDA provides for the use of Ubrelvy (ubrogepant) tablets for the acute treatment of migraine with or without aura in adults.” *See New Drug Application 211765, Drugs@FDA: FDA-Approved Drugs, U.S. FOOD & DRUG ADMIN.,* https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2019/211765Orig1s000ltr.pdf (last visited February 5, 2025). Defendants further admit that the UBRELVY® prescribing information, revised December 2019, states under Section 11 titled “DESCRIPTION” that “[t]he active ingredient of UBRELVY is ubrogepant, a calcitonin gene-related peptide (CGRP) receptor.” *See UBRELVY PRESCRIBING INFORMATION* (Dec. 2019) at 6. Defendants deny all other allegations in paragraph 38.

39. Migraine is a debilitating disease. Migraine impacts more than 37 million men, women, and children in the United States. Migraine costs millions of dollars each year in the United States due to direct medical expenses and lost productivity. Migraine is also associated with other illnesses.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 39 and therefore deny them.

40. The recommended dose of UBRELVY® Tablets is 50 mg or 100 mg taken orally with or without food. If needed, a second dose may be administered at least 2 hours after the initial dose. For patients with severe hepatic impairment or severe renal impairment, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients with severe hepatic impairment or severe renal impairment, and information concerning these patients is included in the UBRELVY® Label.

ANSWER: Defendants admit that the UBRELVY® prescribing information, revised December 2019, states under Section 2.1, titled “Recommended Dosage” that “[t]he recommended dose of UBRELVY is 50 mg or 100 mg taken orally with or without food. If needed, a second

dose may be taken at least 2 hours after the initial dose.” See UBRELVY PRESCRIBING INFORMATION (Dec. 2019) at 2. Defendants further admit that the UBRELVY® prescribing information, revised December 2019, lists “50 mg” under “Initial Dose” and “50 mg” under “Second Dose (if needed)” for “Specific Populations” with “Severe Hepatic Impairment (Child-Pugh Class C)” and “Severe Renal Impairment (CLer 15-29 mL/min)” under Section 2.2, titled “Dosage Modifications.” *Id.* at tbl. 1. Defendants admit that Section 2.2 further states that the “[s]econd dose may be taken at least 2 hours after the initial dose.” *Id.* Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 40 and therefore deny them.

41. For patients who concomitantly use weak or moderate CYP3A4 inducers, the recommended dose is 100 mg. If needed, a second 100 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use weak or moderate CYP3A4 inducers, and information concerning these patients is included in the UBRELVY® Label. For patients who concomitantly use weak CYP3A4 inhibitors, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. For patients who concomitantly use moderate CYP3A4 inhibitors, the recommended dose is 50 mg. The UBRELVY® Label states that those patients should avoid taking a second dose within 24 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use weak or moderate CYP3A4 inhibitors, and information concerning these patients is included in the UBRELVY® Label. For patients who concomitantly use BCRP and/or P-gp only inhibitors, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use BCRP and/or P-gp only inhibitors, and information concerning these patients is included in the UBRELVY® Label.

ANSWER: Defendants admit that the UBRELVY® prescribing information, revised December 2019, lists “100 mg” under “Initial Dose” and “100 mg” under “Second Dose (if needed)” for “Weak & Moderate CYP3A4 Inducers” under Section 2.2, titled “Dosage Modifications.” See UBRELVY PRESCRIBING INFORMATION (Dec. 2019) at tbl. 1. Defendants admit that Section 2.2 further states that the “[s]econd dose may be taken at least 2 hours after the initial dose.” *Id.* Defendants further admit that Section 2.2 lists “50 mg” under “Initial Dose” and

“50 mg” under “Second Dose (if needed)” for “Weak CYP3A4 Inhibitors.” *Id.* Defendants admit that Section 2.2 further states that the “[s]econd dose may be taken at least 2 hours after the initial dose.” *Id.* Defendants further admit that Section 2.2 lists “50 mg” under “Initial Dose” and “Avoid within 24 hours” under “Second Dose (if needed)” for “Moderate CYP3A4 Inhibitors.” *Id.* Defendants further admit that Section 2.2 lists “50 mg” under “Initial Dose” and “50 mg” under “Second Dose (if needed)” for “BCRP and/or P-gp only inhibitors.” Defendants further admit that Section 2.2 states that the “[s]econd dose may be taken at least 2 hours after the initial dose.” Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 41 and therefore deny them.

42. To date, only two orally available CGRP receptor antagonists have been approved by FDA for acute treatment of migraine. UBRELVY® Tablets were the first. The prescribing information for the other, NURTEC® ODT, states that use of the drug should be avoided in patients with severe hepatic impairment. The prescribing information for NURTEC® ODT further states that use of the drug should be avoided in patients who concomitantly use moderate CYP3A inducers. Thus, UBRELVY® Tablets are the only orally available CGRP receptor antagonist in the United States indicated for acute treatment of migraine in patients with severe hepatic impairment and patients who concomitantly use moderate CYP3A inducers.

ANSWER: Defendants admit that NURTEC® ODT prescribing information, revised February 2020, states under section 8.6: “Plasma concentrations of rimegepant were significantly higher in subjects with severe (Child-Pugh C) hepatic impairment. Avoid use in patients with severe hepatic impairment (Child-Pugh C).” *See* NURTEC ODT PRESCRIBING INFORMATION (Feb. 2020). Defendants further admit that the NURTEC® ODT prescribing information states under section 7.2: “Concomitant administration of NURTEC ODT with strong or moderate inducers of CYP3A can result in a significant reduction in rimegepant exposure, which may lead to loss of efficacy of NURTEC ODT. Avoid concomitant administration of NURTEC ODT with strong or moderate inducers of CYP3A.” *Id.* Defendants further admit that the NURTEC® ODT prescribing information lists “2020” as the “Initial U.S. Approval” and that the UBRELVY® prescribing

information lists “2019” as the “Initial U.S. Approval.” *See id.*; UBRELVY PRESCRIBING INFORMATION (Dec. 2019) at 1. Defendants lack knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 42 and therefore deny them.

43. UBRELVY® Tablets are marketed and sold in the United States by AbbVie.

ANSWER: Defendants admit that FDA’s Orange Book lists “ABBVIE INC” as Applicant Holder, “UBRELVY” as Proprietary Name, and “TABLET” as Dosage Form in connection with NDA No. 211765. Defendants lack knowledge or information sufficient to form a belief about all other allegations in paragraph 43 and therefore deny them.

The Patents-in-Suit

44. The ’836 patent, titled “Tablet Formulation for CGRP Active Compounds,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on November 6, 2018. A true and correct copy of the ’836 patent is attached as Exhibit A.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the ’836 patent is attached to Plaintiffs’ Third Amended Complaint as Exhibit A. Defendants further admit that Exhibit A is titled “Tablet Formulation for CGRP Active Compounds” and lists November 6, 2018, as the Date of Patent. Defendants deny all other allegations in paragraph 44.

45. Merck is the assignee of the ’836 patent through assignment as recorded by the USPTO at Reel 041662, Frame 0851; Reel 041829, Frame 0001; and Reel 061102, Frame 0145.

ANSWER: Defendants admit that the USPTO lists “Merck Sharp & Dohme LLC” as the assignee of the ’836 patent under Reel/Frame No. 041662/0851, Reel/Frame No. 041829/0001, and Reel/Frame No. 061102/0145. Defendants deny all other allegations in paragraph 45.

46. The ’836 patent currently expires on January 30, 2035.

ANSWER: Defendants admit that FDA’s Orange Book lists January 30, 2035, as the expiration date for the ’836 patent. Defendants deny all other allegations in paragraph 46.

47. Allergan is the exclusive licensee of the '836 patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 47 and therefore deny them.

48. The '836 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '836 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 48.

49. The '515 patent, titled "Treatment of Migraine," was duly and legally issued by the USPTO on August 8, 2023. A true and correct copy of the '515 patent is attached as Exhibit B.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '515 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit B. Defendants further admit that Exhibit B is titled "Treatment of Migraine" and lists August 8, 2023, as the Date of Patent. Defendants deny all other allegations in paragraph 49.

50. Allergan is the assignee of the '515 patent through assignment as recorded by the USPTO at Reel 063519, Frame 0307.

ANSWER: Defendants admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '515 patent under Reel/Frame No. 063519/0307. Defendants deny all other allegations in paragraph 50.

51. The '515 patent currently expires on December 22, 2041.

ANSWER: Defendants admit that FDA's Orange Book lists December 22, 2041, as the expiration date for the '515 patent. Defendants deny all other allegations in paragraph 51.

52. The '515 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '515 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 52.

53. The '542 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on January 2, 2024. A true and correct copy of the '542 patent is attached as Exhibit C.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '542 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit C. Defendants further admit that Exhibit C is titled "Treatment of Migraine" and lists January 2, 2024, as the Date of Patent. Defendants deny all other allegations in paragraph 53.

54. Allergan is the assignee of the '542 patent through assignment as recorded by the USPTO at Reel 064076, Frame 0407.

ANSWER: Defendants admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '542 patent under Reel/Frame No. 064076/0407. Defendants deny all other allegations in paragraph 54.

55. The '542 patent currently expires on December 22, 2041.

ANSWER: Defendants admit that FDA's Orange Book lists December 22, 2041, as the expiration date for the '542 patent. Defendants deny all other allegations in paragraph 55.

56. The '542 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '542 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 56.

57. The '709 patent, titled "Tablet Formulation for CGRP Active Compounds," was duly and legally issued by the United States Patent and Trademark Office on March 12, 2024. A true and correct copy of the '709 patent is attached as Exhibit D.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '709 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit D. Defendants further admit that Exhibit D is titled "Tablet Formulation for CGRP Active Compounds" and lists March 12, 2024, as the Date of Patent. Defendants deny all other allegations in paragraph 57.

58. Merck is the assignee of the '709 patent through assignment as recorded by the USPTO at Reel 061200, Frame 0836.

ANSWER: Defendants admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '709 patent under Reel/Frame No. 061200/0836 and Reel/Frame No. 067034/0711. Defendants deny all other allegations in paragraph 58.

59. The '709 patent currently expires on January 30, 2035.

ANSWER: Defendants admit that FDA's Orange Book lists January 30, 2035, as the expiration date for the '709 patent. Defendants deny all other allegations in paragraph 59.

60. Allergan is the exclusive licensee of the '709 patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 60 and therefore deny them.

61. The '709 patent will be submitted for listing in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '709 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 61.

62. The '450 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on August 27, 2024. A true and correct copy of the '450 patent is attached as Exhibit E.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '450 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit E. Defendants further admit that Exhibit E is titled "Treatment of Migraine" and lists August 27, 2024, as the Date of Patent. Defendants deny all other allegations in paragraph 62.

63. Allergan is the assignee of the '450 patent through assignment as recorded by the USPTO at Reel 065814, Frame 0254.

ANSWER: Defendants admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '450 patent under Reel/Frame No. 65814/0254. Defendants deny all other allegations in paragraph 63.

64. The '450 patent currently expires on December 22, 2041.

ANSWER: Defendants admit that FDA's Orange Book lists December 22, 2041, as the expiration date for the '450 patent. Defendants deny all other allegations in paragraph 64.

65. The '450 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 100 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '450 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 65.

66. The '004 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on December 17, 2024. A true and correct copy of the '004 patent is attached as Exhibit F.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '004 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit F. Defendants further admit that Exhibit F is titled "Treatment of Migraine" and lists December 17, 2024, as the Date of Patent. Defendants deny all other allegations in paragraph 66.

67. Merck is the assignee of the '004 patent through assignment as recorded by the USPTO at Reel 069116, Frame 0667.

ANSWER: Defendants admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '004 patent under Reel/Frame No. 069116/0667. Defendants deny all other allegations in paragraph 67.

68. The '004 patent currently expires on January 30, 2035.

ANSWER: Defendants admit that FDA's Orange Book lists January 30, 2025, as the expiration date for the '004 patent. Defendants deny all other allegations in paragraph 68.

69. Allergan is the exclusive licensee of the '004 patent.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 69 and therefore deny them.

70. The '004 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '004 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 70.

71. The '030 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on January 14, 2025. A true and correct copy of the '030 patent is attached as Exhibit G.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '030 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit G. Defendants further admit that Exhibit G is titled "Treatment of Migraine" and lists January 14, 2025, as the Date of Patent. Defendants deny all other allegations in paragraph 71.

72. Allergan is the assignee of the '030 patent through assignment as recorded by the USPTO at Reel 068953, Frame 0640.

ANSWER: Defendants admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '030 patent under Reel/Frame No. 068953/0640. Defendants deny all other allegations in paragraph 72.

73. The '030 patent currently expires on December 22, 2041.

ANSWER: Defendants admit that FDA's Orange Book lists December 22, 2041, as the expiration date for the '030 patent. Defendants deny all other allegations in paragraph 73.

74. The '030 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Defendants admit that FDA's Orange Book lists the '030 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 74.

75. The '408 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on February 11, 2025. A true and correct copy of the '408 patent is attached as Exhibit H.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '408 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit H. Defendants further admit that Exhibit H is titled "Treatment of Migraine" and lists February 11, 2025, as the Date of Patent. Defendants deny all other allegations in paragraph 75.

76. Merck is the assignee of the '408 patent through assignment as recorded by the USPTO at Reel 069185, Frame 0001.

ANSWER: Defendants admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '408 patent under Reel/Frame No. 069185/0001. Defendants deny all other allegations in paragraph 76.

77. The '408 patent currently expires on January 30, 2035.

ANSWER: Defendants admit that FDA's Orange Book lists January 30, 2035, as the expiration date for the '408 patent. Defendants deny all other allegations in paragraph 77.

78. The '408 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Defendants admit that FDA's Orange Book lists the '408 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 78.

79. The '953 patent, titled "Pharmaceutical Formulations for the Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on May 27, 2025. A true and correct copy of the '953 patent is attached as Exhibit I.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '953 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit I. Defendants further admit that Exhibit I is titled "Pharmaceutical Formulations for the Treatment of Migraine," and lists May 27, 2025, as the Date of Patent. Defendants deny all other allegations in paragraph 79.

80. Merck is the assignee of the '953 patent through assignment as recorded by the USPTO at Reel 069494, Frame 0051.

ANSWER: Defendants admit that the USPTO lists "Merck Sharp & Dohme LLC" as the assignee of the '953 patent under Reel/Frame No. 069494/0051. Defendants deny all other allegations in paragraph 80.

81. The '953 patent currently expires on January 30, 2035.

ANSWER: Defendants admit that FDA's Orange Book lists January 30, 2035, as the expiration date for the '953 patent. Defendants deny all other allegations in paragraph 81.

82. The '953 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Defendants admit that FDA's Orange Book lists the '953 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 82.

83. The '750 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on June 17, 2025. A true and correct copy of the '750 patent is attached as Exhibit J.

ANSWER: Defendants admit on information and belief that what purports to be a copy of the '750 patent is attached to Plaintiffs' Third Amended Complaint as Exhibit J. Defendants further admit that Exhibit J is titled "Treatment of Migraine," and lists June 17, 2025, as the Date of Patent. Defendants deny all other allegations in paragraph 83.

84. Allergan is the assignee of the '750 patent through assignment as recorded by the USPTO at Reel 070679, Frame 0475.

ANSWER: Defendants admit that the USPTO lists "Allergan Pharmaceuticals International Limited" as the assignee of the '750 patent under Reel/Frame No. 070679/0475. Defendants deny all other allegations in paragraph 84.

85. The '750 patent currently expires on December 22, 2041.

ANSWER: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 85 and therefore deny them.

86. The '750 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: The allegations in paragraph 86 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the remaining allegations in paragraph 86 and therefore deny them.

Zydus' ANDA No. 218662

87. On information and belief, Zydus filed ANDA No. 218662 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of ubrogepant oral tablets, 50 mg, 100 mg, which are generic versions of AbbVie's UBRELVY® Tablets.

ANSWER: The allegations in paragraph 87 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer for sale, sale, and importation of Zydus USA's Proposed ANDA Product. Defendants further admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug. Defendants deny all other allegations in paragraph 87.

88. AbbVie received a letter sent by Zydus ("Zydus' Notice Letter I"), dated February 20, 2024, purporting to be a notice letter "[p]ursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act."

ANSWER: Defendants admit that Zydus USA sent a letter dated February 20, 2024 to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act ("Zydus USA's First Notice Letter"). Defendants admit, on information and belief, that AbbVie and Merck received Zydus USA's First Notice Letter on February 21, 2024 and that Allergan received Zydus USA's First Notice Letter on February 22, 2024. Defendants deny all other allegations in paragraph 88.

89. Zydus' Notice Letter I represents that Zydus' ANDA No. 218662 contains a Paragraph IV certification, alleging that the claims of the '836, '515, and '542 patents are invalid, unenforceable, and/or will not be infringed by Zydus' generic products.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus

[USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 89.

90. AbbVie received a letter sent by Zydus ("Zydus' Notice Letter II"), dated May 23, 2024 purporting to be a notice letter "[p]ursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act."

ANSWER: Defendants admit that Zydus USA sent a letter dated May 23, 2024, to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act with respect to the '709 patent ("Zydus USA's Second Notice Letter"). Defendants admit, on information and belief, that Merck, Allergan, and AbbVie received Zydus USA's Second Notice Letter on May 24, 2024, May 27, 2024, and May 28, 2024, respectively. Defendants deny all other allegations in paragraph 90.

91. Zydus' Notice Letter II represents that Zydus' ANDA No. 218662 contains a Paragraph IV certification, alleging that the claims of the '709 patent will not be infringed by Zydus's generic products.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Second Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '709 patent." Defendants deny all other allegations in paragraph 91.

92. AbbVie received a letter sent by Zydus (“Zydus’ Notice Letter III”), dated December 10, 2024 purporting to be a notice letter “[p]ursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act.”

ANSWER: Defendants admit that Zydus USA sent a letter dated December 10, 2024, to AbbVie and Allergan pursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act with respect to the ’450 patent (“Zydus USA’s Third Notice Letter”). Defendants admit, on information and belief, that AbbVie and Allergan received Zydus USA’s Third Notice Letter on December 11, 2025 and December 12, 2025, respectively. Defendants deny all other allegations in paragraph 92.

93. Zydus’ Notice Letter III represents that Zydus’ ANDA No. 218662 contains a Paragraph IV certification, alleging that the claims of the ’450 patent are invalid and unenforceable.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’836, ’515, ’542, ’709, ’450, ’004, ’030, and ’408 patents. Defendants further admit that USA’s Third Notice Letter states: “Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus [USA]’s proposed ANDA product will not infringe any valid and enforceable claim of the ’450 patent.” Defendants deny all other allegations in paragraph 93.

94. AbbVie received a letter sent by Zydus (“Zydus’ Notice Letter IV”), dated June 18, 2025 purporting to be a notice letter “[p]ursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act.”

ANSWER: Defendants admit that Zydus USA sent a letter dated June 18, 2025, to AbbVie, Allergan, and Merck pursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act with respect to the ’004, ’030, and ’408 patents (“Zydus USA’s Fourth Notice Letter”). Defendants admit, on information and belief, that Merck received Zydus

USA's Fourth Notice Letter on June 19, 2025, and AbbVie and Allergan received Zydus USA's Fourth Notice Letter on June 20, 2025. Defendants deny all other allegations in paragraph 94.

95. Zydus' Notice Letter IV represents that Zydus' ANDA No. 218662 contains a Paragraph IV certification, alleging that the claims of the '004, '030, and '408 patents are invalid, unenforceable, and/or will not be infringed by Zydus' generic products.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 95.

96. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding Zydus' ANDA No. 218662 for the '953 patent and '750 patent under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

ANSWER: Defendants admit that Zydus USA has not yet sent a letter to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B), Section 505(j)(2)(B) of the Food, Drug and Cosmetic Act with respect to the '953 and '750 patents. Defendants deny all other allegations in paragraph 96.

97. On information and belief, Zydus' Notice Letters I, II, III, and IV and the information contained therein, coupled with regulatory requirements, demonstrate Zydus' infringement of the '953 and '750 patents.

ANSWER: Denied.

98. Zydus' Notice Letters I, II, III, or IV do not state or otherwise indicate that Zydus submitted a Paragraph IV certification for the '096, '210, '545, and '448 patents, each of which is listed in the FDA Orange Book for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Accordingly, on information and belief, Zydus submitted a Paragraph III certification for the '096,

'210, '545, and '448 patents, and informed the FDA that it would not launch at least before December 23, 2033.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents and certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) with respect to the '096, '210, '545, and '448 patents. Defendants further admit that FDA's Orange Book lists the '096, '210, '545 patent, and '448 patents under "Patent and Exclusivity" in connection with NDA No. 211765 and that FDA's Orange Book lists November 10, 2031, as the expiration date for '448 and '545 patents, July 19, 2032, as the expiration date for the '096 patent, and December 23, 2033, as the expiration date for the '210 patent. Defendants deny all other allegations in paragraph 98.

99. Zydus' purpose in submitting ANDA No. 218662 and a Paragraph IV certification is to market Zydus' generic products before the expiration of the '836, '709, '515, '542, '450, '004, '030, and '408 patents. Zydus intends to market Zydus' generic products before the expiration of the '004, '030, and '408 patents.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of the Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that the FDA's Orange Book lists the expiration dates for the Patents-in-Suit as follows: January 30, 2035, for the '836, '709, '004, '408, and '953 patents; December 22, 2041, for the '515, '542, '450, and '030 patents. Defendants deny all other allegations in paragraph 99.

100. To obtain approval of an ANDA for a generic drug, an ANDA applicant must show, *inter alia*, that the generic drug is bioequivalent to its reference listed drug. See 21 U.S.C. §

355(j)(2)(A)(iv). If approved, Zydus' generic products will be bioequivalent to AbbVie's UBRELVY® Tablets.

ANSWER: The allegations in paragraph 100 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 100.

101. To obtain approval of an ANDA for a generic drug, an ANDA applicant must also show, *inter alia*, that the conditions of use prescribed, recommended, or suggested in the proposed labeling have been previously approved for its reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(i). Further, the FDA will refuse to approve an ANDA if the labeling proposed for a generic drug product differs from the labeling approved for its reference listed drug product and such differences make the proposed generic drug product less safe or effective. *See* 21 C.F.R. § 314.127(a)(7). On information and belief, if approved, Zydus' generic products will have the same indication and safety and efficacy information as AbbVie's UBRELVY® Tablets.

ANSWER: The allegations in paragraph 101 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug. Defendants further admit that the product labeling for Zydus USA's Proposed ANDA Products will comply with applicable law. Defendants deny all other allegations in paragraph 101.

102. Following FDA approval of Zydus' ANDA No. 218662, Zydus will make, use, sell, and/or offer to sell Zydus' generic products throughout the United States, or import such generic products into the United States before the Patents-in-Suit expire. The manufacture, use, offer for sale, sale, and/or importation of Zydus' generic products will directly infringe the Patents-in-Suit.

ANSWER: The allegations in paragraph 102 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with

respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny the allegations in the second sentence of paragraph 102. Defendants deny all other allegations in paragraph 102.

103. Following FDA approval of Zydus' ANDA No. 218662, Zydus will actively induce or contribute to the manufacture, use, offer for sale, and/or sale of Zydus' generic products in a manner that infringes the Patents-in-Suit.

ANSWER: Denied.

104. Plaintiffs commenced this action within 45 days of receiving Zydus' Notice Letter.

ANSWER: Defendants admit, on information and belief, that AbbVie and Merck received Zydus USA's First Notice Letter on February 21, 2024, and that Allergan received Zydus USA's First Notice Letter on February 22, 2024. Defendants admit that Plaintiffs filed the Complaint alleging infringement of the '836, '515, '542, and '709 patents on April 5, 2024. Defendants deny all other allegations in paragraph 104.

COUNT I
INFRINGEMENT BY ZYDUS OF THE '836 PATENT

105. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-104, as if fully set forth herein.

106. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '836 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 106.

107. Zydus' Notice Letter states that Zydus submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification that the claims of the '836 patent are purportedly invalid, unenforceable, and/or will not be infringed.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 107.

108. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 108.

109. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '836 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

110. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '836 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

ANSWER: Denied.

111. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '836 patent.

ANSWER: Denied.

112. Zydus had knowledge of the '836 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 112 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 112.

113. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

ANSWER: Denied.

114. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the '836 patent, as evidenced by Zydus' Notice Letter.

ANSWER: The allegations in paragraph 114 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first

sentence of paragraph 114. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 114.

115. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 115.

116. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '836 patent.

ANSWER: Denied.

117. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

118. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 118 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that

ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 118.

119. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '836 patent.

ANSWER: Denied.

120. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '836 PATENT

121. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-120, as if fully set forth herein.

122. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 122 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 122.

123. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '836 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in or into the United States and that ANDA No. 218662 includes

certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 123.

124. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 124.

125. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '836 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

ANSWER: Denied.

126. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '836 patent.

ANSWER: Denied.

127. Zydus had knowledge of the '836 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 127 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable

claim of the '836, '515, and '542 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 127.

128. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

ANSWER: Denied.

129. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the '836 patent, as evidenced by Zydus' Notice Letter.

ANSWER: The allegations in paragraph 129 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 129. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s proposed ANDA product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 129.

130. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 130.

131. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '836 patent.

ANSWER: Denied.

132. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

133. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 133 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 133.

134. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '836 patent will constitute infringement of one or more claims of the '836 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

135. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '836 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

136. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '836 patent.

ANSWER: Denied.

137. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT III
INFRINGEMENT BY ZYDUS OF THE '515 PATENT

138. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-137, as if fully set forth herein.

139. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '515 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 139.

140. Zydus' Notice Letter states that Zydus submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification that the claims of the '515 patent are purportedly invalid, unenforceable, and/or will not be infringed.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 140.

141. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 141.

142. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '515 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

143. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '515 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

ANSWER: Denied.

144. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '515 patent.

ANSWER: Denied.

145. Zydus had knowledge of the '515 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 145 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United

States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’836, ’515, and ’542 patents.” Defendants deny that they will induce direct infringement of at least one of the claims of the ’515 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 145.

146. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus’ generic products according to the instructions in the proposed package insert in a way that directly infringes the ’515 patent.

ANSWER: Denied.

147. The offering to sell, sale, making, and/or importation of Zydus’ generic products will actively induce infringement of at least one of the claims of the ’515 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the ’515 patent, as evidenced by Zydus’ Notice Letter.

ANSWER: The allegations in paragraph 147 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 147. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’836, ’515, ’542, ’709, ’450, ’004, ’030, and ’408 patents. Defendants further admit that Zydus USA’s First Notice Letter states: “Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’836, ’515, and ’542 patents.” Defendants deny all other allegations in paragraph 147.

148. If Zydus’ ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus’ generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus

USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 148.

149. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 149 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 149.

150. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '515 patent.

ANSWER: Denied.

151. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '515 PATENT

152. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-151, as if fully set forth herein.

153. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 153 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended

Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 153.

154. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '515 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 154.

155. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 155.

156. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '515 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

ANSWER: Denied.

157. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '515 patent.

ANSWER: Denied.

158. Zydus had knowledge of the '515 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows

or should know that it will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 158 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 158.

159. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

ANSWER: Denied.

160. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the '515 patent, as evidenced by Zydus' Notice Letter.

ANSWER: The allegations in paragraph 160 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 160. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge,

the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’836, ’515, and ’542 patents.” Defendants deny all other allegations in paragraph 160.

161. If Zydus’ ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus’ generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA’s Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 161.

162. Zydus’ actions relating to Zydus’ ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 162 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA’s Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA’s Proposed ANDA Product. Defendants deny all other allegations in paragraph 162.

163. On information and belief, Zydus’ infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus’ generic products in the United States, will begin immediately after FDA approves Zydus’ generic products. Such activity before the expiration of the ’515 patent will constitute infringement of one or more claims of the ’515 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

164. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the ’515 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

165. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '515 patent.

ANSWER: Denied.

166. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT V
INFRINGEMENT BY ZYDUS OF THE '542 PATENT

167. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-166, as if fully set forth herein.

168. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '542 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 168.

169. Zydus' Notice Letter states that Zydus submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification that the claims of the '542 patent are purportedly invalid, unenforceable, and/or will not be infringed.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s

Proposed ANDA Product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 169.

170. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 170.

171. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '542 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

172. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '542 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

ANSWER: Denied.

173. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '542 patent.

ANSWER: Denied.

174. Zydus had knowledge of the '542 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 174 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First

Notice Letter states: “Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’836, ’515, and ’542 patents.” Defendants deny that they will induce direct infringement of at least one of the claims of the ’542 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 174.

175. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus’ generic products according to the instructions in the proposed package insert in a way that directly infringes the ’542 patent.

ANSWER: Denied.

176. The offering to sell, sale, making, and/or importation of Zydus’ generic products will actively induce infringement of at least one of the claims of the ’542 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the ’542 patent, as evidenced by Zydus’ Notice Letter.

ANSWER: The allegations in paragraph 176 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 176. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’836, ’515, ’542, ’709, ’450, ’004, ’030, and ’408 patents. Defendants further admit that Zydus USA’s First Notice Letter states: “Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’836, ’515, and ’542 patents.” Defendants deny all other allegations in paragraph 176.

177. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 177.

178. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 178 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 178.

179. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '542 patent.

ANSWER: Denied.

180. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '542 PATENT

181. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-180, as if fully set forth herein.

182. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 182 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 182.

183. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '542 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 183.

184. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 184.

185. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '542 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

ANSWER: Denied.

186. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '542 patent.

ANSWER: Denied.

187. Zydus had knowledge of the '542 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 187 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 187.

188. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

ANSWER: Denied.

189. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the '542 patent, as evidenced by Zydus' Notice Letter.

ANSWER: The allegations in paragraph 189 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first

sentence of paragraph 189. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's First Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '836, '515, and '542 patents." Defendants deny all other allegations in paragraph 189.

190. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 190.

191. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 191 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 191.

192. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '542 patent will constitute infringement of one or more claims of the '542 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

193. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '542 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

194. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '542 patent.

ANSWER: Denied.

195. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT VII
INFRINGEMENT BY ZYDUS OF THE '709 PATENT

196. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-195, as if fully set forth herein.

197. This Complaint provides notice of the '709 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 197 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '709 patent. Defendants deny all other allegations in paragraph 197.

198. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '709 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes

certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 198.

199. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 199.

200. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '709 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

201. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '709 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

ANSWER: Denied.

202. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '709 patent.

ANSWER: Denied.

203. Zydus had knowledge of the '709 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 203 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the FDA's Orange Book lists the '709 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants further admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Second Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '709 patent." Defendants deny that they will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 203.

204. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

ANSWER: Denied.

205. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '709 patent.

ANSWER: The allegations in paragraph 205 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 205. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Second Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '709 patent." Defendants deny all other allegations in paragraph 205.

206. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 206.

207. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '709 patent.

ANSWER: Denied.

208. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

209. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 209 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 209.

210. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '709 patent.

ANSWER: Denied.

211. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '709 PATENT

212. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-211, as if fully set forth herein.

213. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 213 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 213.

214. This Complaint provides notice of the '709 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 214 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '709 patent. Defendants deny all other allegations in paragraph 214.

215. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '709 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 215.

216. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 216.

217. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '709 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

ANSWER: Denied.

218. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '709 patent.

ANSWER: Denied.

219. Zydus had knowledge of the '709 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 219 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the FDA's Orange Book lists the '709 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants further admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Second Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '709 patent." Defendants

deny that they will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 219.

220. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

ANSWER: Denied.

221. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '709 patent.

ANSWER: The allegations in paragraph 221 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 221. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Second Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '709 patent." Defendants deny all other allegations in paragraph 221.

222. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 222.

223. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '709 patent.

ANSWER: Denied.

224. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

225. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 225 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 225.

226. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '709 patent will constitute infringement of one or more claims of the '709 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

227. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '709 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

228. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '709 patent.

ANSWER: Denied.

229. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT IX
INFRINGEMENT BY ZYDUS OF THE '450 PATENT

230. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-229, as if fully set forth herein.

231. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '450 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants deny all other allegations in paragraph 231.

232. Zydus' Notice Letter III states that Zydus submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification that the claims of the '450 patent are purportedly invalid and unenforceable.

ANSWER: Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Third Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '450 patent." Defendants deny all other allegations in paragraph 232.

233. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 233.

234. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '450 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

235. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '450 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '450 patent and any additional periods of exclusivity.

ANSWER: Denied.

236. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '450 patent.

ANSWER: Denied.

237. Zydus had knowledge of the '450 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 237 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Third Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States,

of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’450 patent.” Defendants deny that they will induce direct infringement of at least one of the claims of the ’450 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 237.

238. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus’ generic products according to the instructions in the proposed package insert in a way that directly infringes the ’450 patent.

ANSWER: Denied.

239. The offering to sell, sale, making, and/or importation of Zydus’ generic products will actively induce infringement of at least one of the claims of the ’450 patent, either literally or under the doctrine of equivalents. Zydus has knowledge and is aware of the ’450 patent, as evidenced by Zydus’ Notice Letter.

ANSWER: The allegations in paragraph 239 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 239. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’836, ’515, ’542, ’709, ’450, ’004, ’030, and ’408 patents. Defendants further admit that Zydus USA’s Third Notice Letter states: “Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’450 patent.” Defendants deny all other allegations in paragraph 239.

240. If Zydus’ ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus’ generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus

USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 240.

241. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 241 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 241.

242. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '450 patent.

ANSWER: Denied.

243. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '450 PATENT

244. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-243, as if fully set forth herein.

245. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 245 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended

Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 245.

246. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '450 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Third Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '450 patent." Defendants deny all other allegations in paragraph 246.

247. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 247.

248. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '450 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '450 patent and any additional periods of exclusivity.

ANSWER: Denied.

249. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '450 patent.

ANSWER: Denied.

250. Zydus had knowledge of the '450 patent, as evidenced by Zydus' Notice Letter, and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 250 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Third Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '450 patent." Defendants deny that they will induce direct infringement of at least one of the claims of the '450 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 250.

251. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '450 patent.

ANSWER: Denied.

252. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '450 patent, either literally or

under the doctrine of equivalents. Zydus has knowledge and is aware of the '450 patent, as evidenced by Zydus' Notice Letter.

ANSWER: The allegations in paragraph 252 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 252. Defendants admit that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Third Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '450 patent." Defendants deny all other allegations in paragraph 252.

253. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 253.

254. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 254 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 254.

255. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '450 patent will constitute infringement of one or more claims of the '450 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

256. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '450 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

257. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '450 patent.

ANSWER: Denied.

258. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XI
INFRINGEMENT BY ZYDUS OF THE '004 PATENT

259. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-258, as if fully set forth herein.

260. This Complaint provides notice of the '004 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 260 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '004 patent. Defendants deny all other allegations in paragraph 260.

261. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '004 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 261.

262. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 262.

263. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '004 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

264. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '004 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '004 patent and any additional periods of exclusivity.

ANSWER: Denied.

265. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '004 patent.

ANSWER: Denied.

266. Zydus had knowledge of the '004 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 266 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 266.

267. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '004 patent.

ANSWER: Denied.

268. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '004 patent, either literally or

under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '004 patent.

ANSWER: The allegations in paragraph 268 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 268. Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 268.

269. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 269.

270. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '004 patent.

ANSWER: Denied.

271. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

272. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 272 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 272.

273. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '004 patent.

ANSWER: Denied.

274. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XII
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '004 PATENT

275. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-274, as if fully set forth herein.

276. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 276 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 276.

277. This Complaint provides notice of the '004 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 277 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '004 patent. Defendants deny all other allegations in paragraph 277.

278. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '004 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 278.

279. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 279.

280. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '004 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless

this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '004 patent and any additional periods of exclusivity.

ANSWER: Denied.

281. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '004 patent.

ANSWER: Denied.

282. Zydus had knowledge of the '004 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 282 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 282.

283. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '004 patent.

ANSWER: Denied.

284. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '004 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '004 patent.

ANSWER: The allegations in paragraph 284 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 284. Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 284.

285. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 285.

286. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '004 patent.

ANSWER: Denied.

287. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

288. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 288 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 288.

289. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '004 patent will constitute infringement of one or more claims of the '004 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

290. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '004 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

291. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '004 patent.

ANSWER: Denied.

292. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XIII
INFRINGEMENT BY ZYDUS OF THE '030 PATENT

293. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-292, as if fully set forth herein.

294. This Complaint provides notice of the '030 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 294 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '030 patent. Defendants deny all other allegations in paragraph 294.

295. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '030 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 295.

296. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 296.

297. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '030 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

298. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '030 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '030 patent and any additional periods of exclusivity.

ANSWER: Denied.

299. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '030 patent.

ANSWER: Denied.

300. Zydus had knowledge of the '030 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 300 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit

that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 300.

301. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '030 patent.

ANSWER: Denied.

302. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '030 patent.

ANSWER: The allegations in paragraph 302 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 302. Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 302.

303. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 303.

304. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 304 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 304.

305. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '030 patent.

ANSWER: Denied.

306. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XIV
DECLARATORY JUDGMENT OF
INFRINGEMENT BY ZYDUS OF THE '030 PATENT

307. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-306, as if fully set forth herein.

308. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 308 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 308.

309. This Complaint provides notice of the '030 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 309 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '030 patent. Defendants deny all other allegations in paragraph 309.

310. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '030 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 310.

311. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 311.

312. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '030 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, by actively inducing infringement by others under § 271(b), and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '030 patent and any additional periods of exclusivity.

ANSWER: Denied.

313. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '030 patent.

ANSWER: Denied.

314. Zydus had knowledge of the '030 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 314 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any

valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 314.

315. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '030 patent.

ANSWER: Denied.

316. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '030 patent.

ANSWER: The allegations in paragraph 316 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 316. Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 316.

317. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus

USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 317.

318. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 318 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 318.

319. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '030 patent will constitute infringement of one or more claims of the '030 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

320. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '030 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

321. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '030 patent.

ANSWER: Denied.

322. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XV
INFRINGEMENT BY ZYDUS OF THE '408 PATENT

323. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-322, as if fully set forth herein.

324. This Complaint provides notice of the '408 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 324 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '408 patent. Defendants deny all other allegations in paragraph 324.

325. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '408 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 325.

326. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 326.

327. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '408 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

328. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '408 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '408 patent and any additional periods of exclusivity.

ANSWER: Denied.

329. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '408 patent.

ANSWER: Denied.

330. Zydus had knowledge of the '408 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 330 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit

that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 330.

331. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '408 patent.

ANSWER: Denied.

332. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '408 patent.

ANSWER: The allegations in paragraph 332 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 332. Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 332.

333. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 333.

334. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '408 patent.

ANSWER: Denied.

335. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

336. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 336 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 336.

337. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '408 patent.

ANSWER: Denied.

338. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XVI
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '408 PATENT

339. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-338, as if fully set forth herein.

340. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 340 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 340.

341. This Complaint provides notice of the '408 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 341 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '408 patent. Defendants deny all other allegations in paragraph 341.

342. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '408 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice

Letter states: “Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]’s Proposed ANDA Product will not infringe any valid and enforceable claim of the ’004, ’030, and ’408 patents.” Defendants deny all other allegations in paragraph 342.

343. On information and belief, Zydus represented to the FDA that Zydus’ generic products are pharmaceutically and therapeutically equivalent to AbbVie’s UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 343.

344. After FDA approval of Zydus’ ANDA, Zydus will infringe one or more claims of the ’408 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus’ generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus’ ANDA shall be no earlier than the expiration of the ’408 patent and any additional periods of exclusivity.

ANSWER: Denied.

345. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus’ generic products for which approval is sought in Zydus’ ANDA, and therefore will infringe at least one claim in the ’408 patent.

ANSWER: Denied.

346. Zydus had knowledge of the ’408 patent and, by its promotional activities and proposed package insert for Zydus’ generic products, knows or should know that it will induce direct infringement of at least one of the claims of the ’408 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 346 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA’s Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with

respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny that they will induce direct infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 346.

347. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '408 patent.

ANSWER: Denied.

348. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '408 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '408 patent.

ANSWER: The allegations in paragraph 348 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 348. Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that Zydus USA's Fourth Notice Letter states: "Zydus [USA] has certified that, in the opinion of Zydus [USA] and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States, of Zydus [USA]'s Proposed ANDA Product will not infringe any valid and enforceable claim of the '004, '030, and '408 patents." Defendants deny all other allegations in paragraph 348.

349. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 349.

350. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '408 patent.

ANSWER: Denied.

351. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

352. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 352 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 352.

353. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '408 patent will constitute infringement of one or more claims of the '408 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

354. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of

the '408 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

355. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '408 patent.

ANSWER: Denied.

356. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XVII
INFRINGEMENT BY ZYDUS OF THE '953 PATENT

357. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-356, as if fully set forth herein.

358. This Complaint provides notice of the '953 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 358 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '953 patent. Defendants deny all other allegations in paragraph 358.

359. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '953 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542,

'709, '450, '004, '030, and '408 patents. Defendants further admit that the FDA's Orange Book lists the expiration dates for the Patents-in-Suit as follows: January 30, 2035, for the '836, '709, '004, '408, and '953 patents; December 22, 2041, for the '515, '542, '450, and '030 patents. Defendants deny all other allegations in paragraph 359.

360. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 360.

361. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '953 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

362. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '953 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '953 patent and any additional periods of exclusivity.

ANSWER: Denied.

363. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '953 patent.

ANSWER: Denied.

364. Zydus had knowledge of the '953 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 364 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the FDA's Orange Book lists

the '953 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny that they will induce direct infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 364.

365. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '953 patent.

ANSWER: Denied.

366. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '953 patent.

ANSWER: The allegations in paragraph 366 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 366. Defendants admit the FDA's Orange Book lists the '953 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 366.

367. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 367.

368. Zydus should have had and/or has had and continues to have knowledge that Zydus' generic products are especially adapted for a use that infringes the '953 patent.

ANSWER: Denied.

369. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus' generic products.

ANSWER: Denied.

370. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 370 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 370.

371. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '953 patent.

ANSWER: Denied.

372. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XVIII
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '953 PATENT

373. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-372, as if fully set forth herein.

374. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 374 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended

Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 374.

375. This Complaint provides notice of the '953 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 375 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '953 patent. Defendants deny all other allegations in paragraph 375.

376. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '953 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that the FDA's Orange Book lists the expiration dates for the Patents-in-Suit as follows: January 30, 2035, for the '836, '709, '004, '408, and '953 patents; December 22, 2041, for the '515, '542, '450, and '030 patents. Defendants deny all other allegations in paragraph 376.

377. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 377.

378. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '953 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing

infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '953 patent and any additional periods of exclusivity.

ANSWER: Denied.

379. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '953 patent.

ANSWER: Denied.

380. Zydus had knowledge of the '953 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 380 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit the FDA's Orange Book lists the '953 patent under "Patent and Exclusivity" in connection with NDA No. 211765. Defendants deny that they will induce direct infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 380.

381. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '953 patent.

ANSWER: Denied.

382. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '953 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '953 patent.

ANSWER: The allegations in paragraph 382 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 382. Defendants admit the FDA's Orange Book lists the '953 patent under

“Patent and Exclusivity” in connection with NDA No. 211765. Defendants deny all other allegations in paragraph 382.

383. If Zydus’ ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus’ generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA’s Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 383.

384. Zydus should have had and/or has had and continues to have knowledge that Zydus’ generic products are especially adapted for a use that infringes the ’953 patent.

ANSWER: Denied.

385. Zydus should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Zydus’ generic products.

ANSWER: Denied.

386. Zydus’ actions relating to Zydus’ ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 386 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA’s Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA’s Proposed ANDA Product. Defendants deny all other allegations in paragraph 386.

387. On information and belief, Zydus’ infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus’ generic products in the United States, will begin immediately after FDA approves Zydus’ generic products. Such activity before the expiration of the ’953 patent will constitute infringement of one or more claims of the ’953 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

388. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '953 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

389. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '953 patent.

ANSWER: Denied.

390. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XIX
INFRINGEMENT BY ZYDUS OF THE '750 PATENT

391. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-390, as if fully set forth herein.

392. This Complaint provides notice of the '750 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 392 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '750 patent. Defendants deny all other allegations in paragraph 392.

393. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '750 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes

certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that the FDA's Orange Book lists the expiration dates for the Patents-in-Suit as follows: January 30, 2035, for the '836, '709, '004, '408, and '953 patents; December 22, 2041, for the '515, '542, '450, and '030 patents. Defendants deny all other allegations in paragraph 393.

394. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 394.

395. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Zydus' ANDA seeking approval for the commercial manufacture, use, or sale of Zydus' generic products before the expiration date of the '750 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

396. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '750 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '750 patent and any additional periods of exclusivity.

ANSWER: Denied.

397. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '750 patent.

ANSWER: Denied.

398. Zydus had knowledge of the '750 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce

direct infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 398 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '750 patent. Defendants deny that they will induce direct infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 398.

399. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '750 patent.

ANSWER: Denied.

400. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '750 patent.

ANSWER: The allegations in paragraph 400 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 400. Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '750 patent. Defendants deny all other allegations in paragraph 400.

401. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 401.

402. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 402 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 402.

403. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '750 patent.

ANSWER: Denied.

404. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

COUNT XX
DECLARATORY JUDGMENT OF INFRINGEMENT BY
ZYDUS OF THE '750 PATENT

405. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

ANSWER: Defendants incorporate their answers to each of the preceding paragraphs 1-404, as if fully set forth herein.

406. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER: The allegations in paragraph 406 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit. Defendants deny all other allegations in paragraph 406.

407. This Complaint provides notice of the '750 patent to the extent that Zydus did not already have notice of this patent.

ANSWER: The allegations in paragraph 407 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '750 patent. Defendants deny all other allegations in paragraph 407.

408. Zydus filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Zydus' generic products in the United States before the expiration of the '750 patent.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '836, '515, '542, '709, '450, '004, '030, and '408 patents. Defendants further admit that the FDA's Orange Book lists the expiration dates for the Patents-in-Suit as follows: January 30, 2035, for the '836, '709, '004, '408, and '953 patents; December 22, 2041, for the '515, '542, '450, and '030 patents. Defendants deny all other allegations in paragraph 408.

409. On information and belief, Zydus represented to the FDA that Zydus' generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

ANSWER: Defendants admit that ANDA No. 218662 identifies UBRELVY® (ubrogepant) oral tablets, 50 mg and 100 mg, as the Reference Listed Drug and that ANDA No. 218662 complies with applicable law. Defendants deny all other allegations in paragraph 409.

410. After FDA approval of Zydus' ANDA, Zydus will infringe one or more claims of the '750 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Zydus' generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless

this Court orders that the effective date of any FDA approval of Zydus' ANDA shall be no earlier than the expiration of the '750 patent and any additional periods of exclusivity.

ANSWER: Denied.

411. Zydus knows or should know, and intends that healthcare providers will prescribe and patients will take Zydus' generic products for which approval is sought in Zydus' ANDA, and therefore will infringe at least one claim in the '750 patent.

ANSWER: Denied.

412. Zydus had knowledge of the '750 patent and, by its promotional activities and proposed package insert for Zydus' generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents.

ANSWER: The allegations in paragraph 412 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Third Amended Complaint purports to be a civil action alleging infringement of the Patents-In-Suit, including the '750 patent. Defendants deny that they will induce direct infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. Defendants deny all other allegations in paragraph 412.

413. Zydus is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Zydus' generic products according to the instructions in the proposed package insert in a way that directly infringes the '750 patent.

ANSWER: Denied.

414. The offering to sell, sale, making, and/or importation of Zydus' generic products will actively induce infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. On information and belief, Zydus has knowledge and is aware of the '750 patent.

ANSWER: The allegations in paragraph 414 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 414. Defendants admit that the Third Amended Complaint purports to be a

civil action alleging infringement of the Patents-In-Suit, including the '750 patent. Defendants deny all other allegations in paragraph 414.

415. If Zydus' ANDA is approved, Zydus intends to and will offer to sell, sell, and/or import in the United States Zydus' generic products.

ANSWER: Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States. Defendants deny all other allegations in paragraph 415.

416. Zydus' actions relating to Zydus' ANDA complained of herein were done by and for the benefit of Zydus.

ANSWER: The allegations in paragraph 416 are legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 218662 to FDA to obtain approval to engage in the commercial importation, manufacture, use, and sale of Zydus USA's Proposed ANDA Product in the United States and that ANDA No. 218662 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 416.

417. On information and belief, Zydus' infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Zydus' generic products in the United States, will begin immediately after FDA approves Zydus' generic products. Such activity before the expiration of the '750 patent will constitute infringement of one or more claims of the '750 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

418. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Zydus concerning liability for the infringement of the '750 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

419. Plaintiffs will be irreparably harmed if Zydus is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '750 patent.

ANSWER: Denied.

420. Plaintiffs do not have an adequate remedy at law.

ANSWER: Denied.

REQUEST FOR RELIEF

Defendants specifically deny that Plaintiffs are entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorney's fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of Plaintiffs' Third Amended Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiffs' Third Amended Complaint.

**FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,117,836)**

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '836 patent.

**SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,117,836)**

Upon information and belief, the claims of the '836 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,717,515)**

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '515 patent.

**FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,717,515)**

Upon information and belief, the claims of the '515 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,857,542)**

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '542 patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,857,542)

Upon information and belief, the claims of the '542 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,925,709)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '709 patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,925,709)

Upon information and belief, the claims of the '709 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,070,450)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '450 patent.

**TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,070,450)**

Upon information and belief, the claims of the '450 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**ELEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,168,004)**

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '004 patent.

**TWELVETH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,168,004)**

Upon information and belief, the claims of the '004 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**THIRTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,194,030)**

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '030 patent.

FOURTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,194,030)

Upon information and belief, the claims of the '030 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

FIFTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,220,408)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '408 patent.

SIXTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,220,408)

Upon information and belief, the claims of the '408 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

SEVENTEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,310,953)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '953 patent.

**EIGHTEENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,310,953)**

Upon information and belief, the claims of the '953 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

**NINETEENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 12,329,750)**

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial importation, manufacture, use, sale, or offer to sell within, and/or importation into the United States of Zydus USA's Proposed ANDA Product, will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '750 patent.

**TWENTIETH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 12,329,750)**

Upon information and belief, the claims of the '750 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Counterclaimants") by their attorneys, allege the following counterclaims against Counterclaim Defendants AbbVie, Inc. ("AbbVie"), Allergan

Pharmaceuticals International Limited, (“Allergan”), and Merck Sharp & Dohme LLC (“Merck”) (collectively, “Counterclaim Defendants”).

PARTIES

1. Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its primary place of business at 73 Route 31 N., Pennington, New Jersey 08534.

2. Zydus Lifesciences is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S. G. Highway, Ahmedabad 382 481, India.

3. Upon information and belief, AbbVie is a corporation organized and existing under the laws of the State of Delaware, having its headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064.

4. Upon information and belief, Allergan is a corporation organized and existing under the laws of Ireland, having its principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400.

5. Upon information and belief, Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having its principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

7. This Court has personal jurisdiction over Counterclaim Defendants because Counterclaim Defendants commenced and continue to maintain this action against Defendants in this district.

8. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II) and because Counterclaim Defendants commenced and continue to maintain this action against Counterclaimants in this district.

REGULATORY FRAMEWORK

9. Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the “Hatch-Waxman Act”), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration (“FDA”) to sell a new drug must file a New Drug Application (“NDA”), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

10. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes “claims the drug for which the applicant submitted the [NDA] . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug.” 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and

expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (“Orange Book”).

ORANGE BOOK LISTED PATENTS FOR UBRELVY®

11. Upon information and belief, AbbVie is the holder of NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg.

12. United States Patent No. 10,117,836 (“the ’836 patent”), titled “Tablet Formulation for CGRP Active Compounds”— a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit A—was issued on November 6, 2018. According to the United States Patent and Trademark Office’s (“USPTO”) Patent Assignment Search database, Reel/Frame No. 061102/0145, the ’836 patent is assigned to Merck. FDA’s Orange Book lists the expiration date of the ’836 patent as January 30, 2035.

13. Upon information and belief, AbbVie submitted the ’836 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on January 21, 2020. Accordingly, AbbVie maintains and has affirmatively represented that the ’836 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the ’836 patent has a reasonable apprehension of suit with respect to the ’836 patent.

14. United States Patent No. 11,717,515 (“the ’515 patent”), titled “Treatment of Migraine”— a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit B—was issued on August 8, 2023. According to the USPTO’s Patent Assignment Search database, Reel/Frame No. 063519/0307, the ’515 patent is assigned to Allergan. FDA’s Orange Book lists the expiration date of the ’515 patent as December 22, 2041.

15. Upon information and belief, AbbVie submitted the '515 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on September 7, 2023. Accordingly, AbbVie maintains and has affirmatively represented that the '515 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the '515 patent has a reasonable apprehension of suit with respect to the '515 patent.

16. United States Patent No. 11,857,542 ("the '542 patent"), titled "Treatment of Migraine"—a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit C—was issued on January 2, 2024. According to the USPTO's Patent Assignment Search database, Reel/Frame No. 064076/0407, the '542 patent is assigned to Allergan. FDA's Orange Book lists the expiration date of the '542 patent as December 22, 2041.

17. Upon information and belief, AbbVie submitted the '542 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on January 31, 2024. Accordingly, AbbVie maintains and has affirmatively represented that the '542 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the '542 patent has a reasonable apprehension of suit with respect to the '542 patent.

18. United States Patent No. 11,925,709 ("the '709 patent"), titled "Tablet Formulation for CGRP Active Compounds"—a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit D—was issued on March 12, 2024. According to the USPTO's

Patent Assignment Search database, Reel/Frame no. 067034/0711, the '709 patent is assigned to Merck. FDA's Orange Book lists the expiration date of the '709 patent as January 30, 2035.

19. Upon information and belief, AbbVie submitted the '709 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on April 10, 2024. Accordingly, AbbVie maintains and has affirmatively represented that the '709 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the '709 patent has a reasonable apprehension of suit with respect to the '709 patent.

20. United States Patent No. 12,070,450 ("the '450 patent"), titled "Treatment of Migraine"—a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit E—was issued on August 27, 2024. According to the USPTO's Patent Assignment Search database, Reel/Frame No. 065814/0254, the '450 patent is assigned to Allergan. FDA's Orange Book lists the expiration date of the '450 patent as December 22, 2041.

21. Upon information and belief, AbbVie submitted the '450 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg, on September 25, 2024. Accordingly, AbbVie maintains and has affirmatively represented that the '450 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the '450 patent has a reasonable apprehension of suit with respect to the '450 patent.

22. United States Patent No. 12,168,004 ("the '004 patent"), titled "Treatment of Migraine"—a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit F—was issued on December 17, 2024. According to the USPTO's Patent Assignment

Search database, Reel/Frame No. 069116/0667, the '004 patent is assigned to Merck. FDA's Orange Book lists the expiration date of the '004 patent as January 30, 2035.

23. Upon information and belief, AbbVie submitted the '004 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on January 15, 2025. Accordingly, AbbVie maintains and has affirmatively represented that the '004 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the '004 patent has a reasonable apprehension of suit with respect to the '004 patent.

24. United States Patent No. 12,194,030 ("the '030 patent"), titled "Treatment of Migraine"—a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit G—was issued on January 14, 2025. According to the USPTO's Patent Assignment Search database, Reel/Frame No. 068953/0640, the '030 patent is assigned to Allergan. FDA's Orange Book lists the expiration date of the '030 patent as December 22, 2041.

25. Upon information and belief, AbbVie submitted the '030 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg, on February 11, 2025. Accordingly, AbbVie maintains and has affirmatively represented that the '030 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the '030 patent has a reasonable apprehension of suit with respect to the '030 patent.

26. United States Patent No. 12,220,408 ("the '408 patent"), titled "Treatment of Migraine"—a copy of which Counterclaim Defendants purported to attach to their Complaint as

Exhibit H—was issued on February 11, 2025. According to the USPTO’s Patent Assignment Search database, Reel/Frame No. 069185/0001, the ’408 patent is assigned to Merck.

27. Upon information and belief, AbbVie submitted the ’408 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on March 12, 2025. Accordingly, AbbVie maintains and has affirmatively represented that the ’408 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the ’408 patent has a reasonable apprehension of suit with respect to the ’408 patent.

28. United States Patent No. 12,310,953 (“the ’953 patent”), titled “Pharmaceutical Formulations for the Treatment of Migraine”— a copy of which Counterclaim Defendants purported to attach to their Complaint as Exhibit I—was issued on May 27, 2025. According to the USPTO’s Patent Assignment Search database, Reel/Frame No. 069494/0051, the ’953 patent is assigned to Merck.

29. Upon information and belief, AbbVie submitted the ’953 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg, on June 25, 2025. Accordingly, AbbVie maintains and has affirmatively represented that the ’953 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the ’953 patent has a reasonable apprehension of suit with respect to the ’953 patent.

30. United States Patent No. 12,329,750 (“the ’750 patent”), titled “Treatment of Migraine”— a copy of which Counterclaim Defendants purported to attach to their Complaint as

Exhibit J—was issued on June 17, 2025. According to the USPTO’s Patent Assignment Search database, Reel/Frame No. 070679/0475, the ’750 patent is assigned to Allergan.

31. Upon information and belief, AbbVie has submitted or will submit the ’750 patent to FDA for listing in the Orange Book concerning NDA No. 211765 for UBRELVY® (ubrogepant) tablets, 50 mg and 100 mg. AbbVie maintains and has affirmatively represented that the ’750 patent claims the approved drug UBRELVY® or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell ubrogepant oral tablets before the expiration of the ’750 patent has a reasonable apprehension of suit with respect to the ’750 patent.

ZYDUS USA’S ANDA

32. On December 23, 2023, Zydus USA submitted to FDA ANDA No. 218662 (“Zydus USA’s ANDA”) under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, or sale of ubrogepant oral tablets, 50 mg and 100 mg (“Zydus USA’s Proposed ANDA Product”).

33. Because Zydus USA seeks FDA approval to engage in the commercial importation, manufacture, use, or sale of Zydus USA’s Proposed ANDA Product before the expiration of the ’836, ’515, ’542, ’709, and ’450 patents, ANDA No. 218662 included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) with respect to the ’836, ’515, and ’542 patents and was later amended to include a Paragraph IV Certification with respect to the ’709, ’450, ’004, ’030, and ’408 patents.

34. Zydus USA sent a letter dated February 20, 2024 (“Zydus USA’s First Notice Letter”), notifying AbbVie, Allergan, and Merck that Zydus USA submitted to FDA ANDA No. 218662 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial importation,

manufacture, use, or sale of Zydus USA's Proposed ANDA Product, and that ANDA No. 218662 included a Paragraph IV Certification with respect to the '836, '515, and '542 patents.

35. In Zydus USA's First Notice Letter, Zydus USA included a detailed statement of the factual and legal bases in support of Zydus USA's Paragraph IV Certification for the '836, '515, and '542 patents.

36. Zydus USA sent a second letter dated May 23, 2024 ("Zydus USA's Second Notice Letter"), notifying AbbVie, Allergan, and Merck that Zydus USA submitted to FDA ANDA No. 218662 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial importation, manufacture, use, or sale of Zydus USA's Proposed ANDA Product, and that ANDA No. 218662 was amended to include a Paragraph IV Certification with respect to the '709 patent.

37. In Zydus USA's Second Notice Letter, Zydus USA included a detailed statement of the factual and legal bases in support of Zydus USA's Paragraph IV Certification for the '709 patent.

38. Zydus USA sent a third letter dated December 10, 2024 ("Zydus USA's Third Notice Letter"), notifying AbbVie and Allergan that Zydus USA submitted to FDA ANDA No. 218662 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial importation, manufacture, use, or sale of Zydus USA's Proposed ANDA Product, and that ANDA No. 218662 was amended to include a Paragraph IV Certification with respect to the '450 patent.

39. In Zydus USA's Third Notice Letter, Zydus USA included a detailed statement of the factual and legal bases in support of Zydus USA's Paragraph IV Certification for the '450 patent.

40. Zydus USA sent a fourth letter dated June 18, 2025 ("Zydus USA's Fourth Notice Letter"), notifying AbbVie, Allergan, and Merck that Zydus USA submitted to FDA ANDA No.

218662 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial importation, manufacture, use, or sale of Zydus USA's Proposed ANDA Product, and that ANDA No. 218662 was amended to include a Paragraph IV Certification with respect to the '004, '030, and '408 patents.

41. In Zydus USA's Fourth Notice Letter, Zydus USA included a detailed statement of the factual and legal bases in support of Zydus USA's Paragraph IV Certification for the '004, '030, and '408 patents.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,117,836)

42. Counterclaimants repeat and reallege the allegations in paragraphs 1-41 above as though fully set forth herein.

43. By asserting their claim against Counterclaimants for infringement of the '836 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '836 patent.

44. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '836 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,117,836)

45. Counterclaimants repeat and reallege the allegations in paragraphs 1-44 above as though fully set forth herein.

46. By asserting their claim against Counterclaimants for infringement of the '836 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the

'836 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

47. The claims of the '836 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,717,515)

48. Counterclaimants repeat and reallege the allegations in paragraphs 1-48 above as though fully set forth herein.

49. By asserting their claim against Counterclaimants for infringement of the '515 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '515 patent.

50. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '515 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,717,515)

51. Counterclaimants repeat and reallege the allegations in paragraphs 1-50 above as though fully set forth herein.

52. By asserting their claim against Counterclaimants for infringement of the '515 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '515 patent for failure to comply with one or more of the provisions of Title 35 of the United States

Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

53. The claims of the '515 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT V
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,857,542)

54. Counterclaimants repeat and reallege the allegations in paragraphs 1-53 above as though fully set forth herein.

55. By asserting their claim against Counterclaimants for infringement of the '542 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '542 patent.

56. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '542 patent.

COUNT VI
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,857,542)

57. Counterclaimants repeat and reallege the allegations in paragraphs 1-56 above as though fully set forth herein.

58. By asserting their claim against Counterclaimants for infringement of the '542 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '542 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

59. The claims of the '542 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT VII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,925,709)

60. Counterclaimants repeat and reallege the allegations in paragraphs 1-59 above as though fully set forth herein.

61. By asserting their claim against Counterclaimants for infringement of the '709 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '709 patent.

62. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '709 patent.

COUNT VIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,925,709)

63. Counterclaimants repeat and reallege the allegations in paragraphs 1-63 above as though fully set forth herein.

64. By asserting their claim against Counterclaimants for infringement of the '709 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '709 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

65. The claims of the '709 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT IX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,070,450)

66. Counterclaimants repeat and reallege the allegations in paragraphs 1-65 above as though fully set forth herein.

67. By asserting their claim against Counterclaimants for infringement of the '450 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '450 patent.

68. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '450 patent.

COUNT X
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,070,450)

69. Counterclaimants repeat and reallege the allegations in paragraphs 1-68 above as though fully set forth herein.

70. By asserting their claim against Counterclaimants for infringement of the '450 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '450 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

71. The claims of the '450 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XI
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,168,004)

72. Counterclaimants repeat and reallege the allegations in paragraphs 1-71 above as though fully set forth herein.

73. By asserting their claim against Counterclaimants for infringement of the '004 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '004 patent.

74. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '004 patent.

COUNT XII
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,168,004)

75. Counterclaimants repeat and reallege the allegations in paragraphs 1-74 above as though fully set forth herein.

76. By asserting their claim against Counterclaimants for infringement of the '004 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '004 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

77. The claims of the '004 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XIII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,194,030)

78. Counterclaimants repeat and reallege the allegations in paragraphs 1-77 above as though fully set forth herein.

79. By asserting their claim against Counterclaimants for infringement of the '030 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '030 patent.

80. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '030 patent.

COUNT XIV
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,194,030)

81. Counterclaimants repeat and reallege the allegations in paragraphs 1-80 above as though fully set forth herein.

82. By asserting their claim against Counterclaimants for infringement of the '030 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '030 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

83. The claims of the '030 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XV
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,220,408)

84. Counterclaimants repeat and reallege the allegations in paragraphs 1-83 above as though fully set forth herein.

85. By asserting their claim against Counterclaimants for infringement of the '408 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '408 patent.

86. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '408 patent.

COUNT XVI
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,220,408)

87. Counterclaimants repeat and reallege the allegations in paragraphs 1-86 above as though fully set forth herein.

88. By asserting their claim against Counterclaimants for infringement of the '408 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '408 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

89. The claims of the '408 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XVII
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,310,953)

90. Counterclaimants repeat and reallege the allegations in paragraphs 1-89 above as though fully set forth herein.

91. By asserting their claim against Counterclaimants for infringement of the '953 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '953 patent.

92. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '953 patent.

COUNT XVIII
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,310,953)

93. Counterclaimants repeat and reallege the allegations in paragraphs 1-92 above as though fully set forth herein.

94. By asserting their claim against Counterclaimants for infringement of the '953 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '953 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

95. The claims of the '953 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

COUNT XIX
(Declaratory Judgment of Noninfringement of U.S. Patent No. 12,329,750)

96. Counterclaimants repeat and reallege the allegations in paragraphs 1-95 above as though fully set forth herein.

97. By asserting their claim against Counterclaimants for infringement of the '750 patent, Counterclaim Defendants have created a case or controversy regarding the noninfringement of the '750 patent.

98. The commercial importation, manufacture, use, sale, and/or offer to sell within, the United States of Zydus USA's Proposed ANDA Product would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '750 patent.

COUNT XX
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,329,750)

99. Counterclaimants repeat and reallege the allegations in paragraphs 1-98 above as though fully set forth herein.

100. By asserting their claim against Counterclaimants for infringement of the '750 patent, Counterclaim Defendants have created a case or controversy regarding the validity of the '750 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

101. The claims of the '750 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Counterclaimants respectfully request that the Court enter judgment against Counterclaim Defendants as follows:

- A. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '836 patent;
- B. A declaration that the claims of the '836 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;
- C. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '515 patent;
- D. A declaration that the claims of the '515 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;
- E. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '542 patent;
- F. A declaration that the claims of the '542 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;
- G. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '709 patent;

H. A declaration that the claims of the '709 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

I. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '450 patent;

J. A declaration that the claims of the '450 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

K. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '004 patent;

L. A declaration that the claims of the '004 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

M. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '030 patent;

N. A declaration that the claims of the '030 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

O. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '408 patent;

P. A declaration that the claims of the '408 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

Q. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '953 patent;

R. A declaration that the claims of the '953 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

S. A declaration that Counterclaimants have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '750 patent;

T. A declaration that the claims of the '750 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

U. A declaration that Counterclaim Defendants take nothing by their Third Amended Complaint;

V. A dismissal of Counterclaim Defendants' Third Amended Complaint with prejudice;

W. An award to Counterclaimants of their reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

X. An award of any other and further relief that this Court may deem just and proper.

Dated: July 11, 2025

Respectfully submitted,

s/ Eric I. Abraham

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*Attorneys for Zydus Pharmaceuticals (USA)
Inc. and Zydus Lifesciences Limited*

CERTIFICATE OF SERVICE

I hereby certify that on July 11, 2025, I caused a true and correct copy of the foregoing document to be served via electronic mail on counsel of record in this matter.

Dated: July 11, 2025

Respectfully submitted,

By: *s/Eric I. Abraham*
Eric I. Abraham