IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PFIZER INC. and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs, v. TEVA PHARMACEUTICALS, INC., Defendant.	)	C.A. No. 24-627-CFC

DEFENDANT TEVA PHARMACEUTICALS, INC.'S ANSWER TO COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant Teva Pharmaceuticals, Inc. ("Teva" or "Defendant") hereby answers the Complaint of Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer" or "Plaintiffs") as set forth below. This pleading is based upon Teva's knowledge as to its own activities, and upon information and belief as to the activities of others. Teva denies all allegations except those specifically admitted below. *See* FED. R. CIV. P. 8(b)(3).

NATURE OF THE ACTION[1]

Complaint ¶ 1. This is a civil action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, and the

[1] For ease of reference, Teva includes the headings contained in Plaintiffs' Complaint. Although Teva believes that no response is necessary for each of those

Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, arising from Teva's submission of Abbreviated New Drug Application ("ANDA") No. 219365 (the "Teva ANDA") to the United States Food and Drug Administration ("FDA"), seeking approval to market a generic version of Pfizer's NURTEC ODT® (rimegepant sulfate) tablet before the expiration of U.S. Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit").

ANSWER: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that Plaintiffs purport to bring an action for patent infringement under patent laws of the United States. Teva further admits that Teva submitted Abbreviated New Drug Application ("ANDA") No. 219365 (the "Teva ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to market Teva's rimegepant sulfate tablets (the "Teva ANDA Product"). Except as expressly admitted, Teva denies the remaining allegations of Paragraph 1.

THE PARTIES

Complaint ¶ 2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 2, and therefore denies them.

Complaint ¶ 3. Plaintiff Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its

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headings, to the extent a response is required and that the headings could be construed to contain factual allegations, Teva denies the allegations.

registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 3, and therefore denies them.

Complaint ¶ 4. Upon information and belief, Defendant Teva Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway # 3, Parsippany, New Jersey 07054.

ANSWER: Teva admits that it is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

Complaint ¶ 5. Upon information and belief, Defendant Teva Industries is a company organized and existing under the laws of Israel, having a principal place of business at 124 Dvora HaNevi'a St., Tel Aviv, Israel 6944020.

ANSWER: Paragraph 5 is directed to a party other than Teva so requires no answer. To the extent an answer is required, Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 6. Upon information and belief, Teva Pharmaceuticals is a wholly owned, indirect subsidiary of Teva Industries.

ANSWER: Teva admits that Teva is a wholly owned subsidiary of Teva Industries. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries). Teva denies the remaining allegations in Paragraph 6.

Complaint ¶ 7. Upon information and belief, Teva Industries and Teva Pharmaceuticals are generic pharmaceutical companies that, in coordination with each other or at the direction of Teva Industries, develop, manufacture, market, and distribute generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

ANSWER: Paragraph 7 states legal conclusions to which no response is required. To the extent an answer is required, Teva admits that Teva is a pharmaceutical company that develops, manufactures, and distributes generic pharmaceutical products for sale in the United States. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries). Teva denies the remaining allegations in Paragraph 7.

THE PATENT-IN-SUIT

Complaint ¶ 8. On August 10, 2021, the USPTO duly and legally issued the '724 patent, entitled "Rimegepant for CGRP Related Disorders." The '724 patent is assigned to Pfizer Ireland Pharmaceuticals. A copy of the '724 patent is attached to this Complaint as Exhibit A.

ANSWER: Paragraph 8 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that Exhibit A purports to be a copy of United States Patent No. 11,083,724 (the "'724 patent"). Teva admits that the face of the '724 patent lists the title as "Rimegepant for CGRP Related Disorders" and August 10, 2021 as the issue date. Teva also admits that the face of the '724 patent lists Biohaven Pharmaceutical Ireland DAC as the assignee of the '724 patent. To the extent a further response is required, Teva lacks knowledge or

information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 8, and therefore denies them.

NURTEC ODT®

Complaint ¶ 9. Pfizer Inc. holds approved New Drug Application No. 212728 for rimegepant sulfate orally disintegrating tablets (trade name NURTEC ODT®) for the acute treatment of migraine with or without aura in adults and the preventive treatment of episodic migraine in adults.

ANSWER: Teva admits that that the Orange Book entry for NDA No. 212728 for rimegepant sulfate orally disintegrating tablets, sold under the name NURTEC ODT®, lists Pfizer Inc., as the applicant holder. Teva admits that the Orange Book lists the "active ingredients" for NURTEC ODT® as "rimegepant sulfate." Teva admits that the Orange Book provides a product label (revised April 2022), which states that NURTEC ODT® is indicated for the "acute treatment of migraine with or without aura in adults" and the "preventative treatment of episodic migraine in adults." To the extent a further response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 9, and therefore denies them.

Complaint ¶ 10. Pursuant to 21 U.S.C. § 355(c)(2), and attendant FDA regulations, the patent-in-suit is listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to NURTEC ODT®.

ANSWER: Teva admits that the Orange Book entry for NDA No. 212728 for rimegepant sulfate orally disintegrating tablets, sold under the trade name NURTEC ODT®, identifies the '724 patent. To the extent a further response is

required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10, and therefore denies them.

THE TEVA ANDA

Complaint ¶ 11. Upon information and belief, Teva Industries prepared and submitted, through Teva Pharmaceuticals, the Teva ANDA to the FDA in accordance with 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of rimegepant orally disintegrating tablets ("Teva's ANDA Product") before the expiration of the patent-in-suit.

ANSWER: Paragraph 11 states legal conclusions to which no response is required. To the extent an answer is required, Teva admits that it submitted the Teva ANDA to FDA seeking approval to sell the Teva ANDA Product. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries). Teva denies any remaining allegations in Paragraph 11.

Complaint ¶ 12. Upon information and belief, Teva Industries acted in concert with or directed Teva Pharmaceuticals to prepare and submit the Teva ANDA.

ANSWER: Paragraph 12 states legal conclusions to which no answer is required. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries). To the extent an answer is required, Teva denies the allegations in Paragraph 12.

Complaint ¶ 13. Upon information and belief, Teva's ANDA Product is a generic copy of NURTEC ODT®.

ANSWER: Teva admits that Teva's ANDA references New Drug Application ("NDA") No. 212728. Teva states that the ANDA otherwise speaks for itself. Teva denies the remaining allegations in Paragraph 13.

Complaint ¶ 14. Upon information and belief, the Teva ANDA refers to and relies upon Pfizer's New Drug Application No. 212728 and purports to contain data on the bioequivalence of Teva's ANDA Product to NURTEC ODT®.

ANSWER: Teva admits that Teva's ANDA references NDA No. 212728. Teva states that the ANDA otherwise speaks for itself. Teva denies any remaining allegations in Paragraph 14.

Complaint ¶ 15. By a letter to Pfizer Inc. dated April 10, 2024 ("Teva's Paragraph IV Notice Letter"), Teva stated that the Teva ANDA contained a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that no valid and enforceable claim of the patent-in-suit will be infringed by the manufacture, use, or sale of Teva's ANDA Product (the "Paragraph IV Certification"). Teva's Paragraph IV Notice Letter included a statement purporting to allege the factual and legal bases for the Paragraph IV Certification.

ANSWER: Teva states that Teva's April 10, 2024 letter to Pfizer Inc. ("Teva's Notice Letter") speaks for itself. Teva admits that Teva's Notice Letter contained a Paragraph IV certification with respect to the '724 patent. Teva denies any remaining allegations in Paragraph 15.

Complaint ¶ 16. Upon information and belief, if the FDA approves the Teva ANDA, Teva will manufacture, distribute, import, offer for sale and/or sell

Teva's ANDA Product throughout the United States, including within the State of Delaware.

ANSWER: Paragraph 16 states a legal conclusion to which no response is required and relates to future events. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 16 and therefore denies them.

Complaint ¶ 17. This action is being filed within 45 days of Pfizer Inc.'s receipt of Teva's Paragraph IV Notice Letter.

ANSWER: Teva admits that that Teva's Notice Letter was dated April 10, 2024 and that Plaintiffs filed the Complaint in this action on May 23, 2024. Teva otherwise lacks knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 17 and therefore denies them.

JURISDICTION AND VENUE

Complaint ¶ 18. This case arises under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 18 states legal conclusions to which no response is required. To the extent a response is deemed required, for purposes of this case only, Teva does not contest that this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202. Teva denies any remaining allegations in Paragraph 18.

Complaint ¶ 19. This Court has personal jurisdiction over Teva Industries because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here.

Upon information and belief, Teva Industries is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Industries directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Teva Industries's contacts with Delaware have been systematic and continuous, and this judicial district is a likely destination of Teva's ANDA Product.

ANSWER: Paragraph 19 is directed at an entity other than Teva and does not require a response. To the extent an answer is required, Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 20. Upon information and belief, Teva Industries is the holder of the Teva ANDA.

ANSWER: Paragraph 20 states legal conclusions to which no response is required. To the extent a response is required, Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 21. Upon information and belief, Teva Industries acted in concert with or directed Teva Pharmaceuticals to prepare and submit the Teva ANDA, with the intention of receiving a significant financial benefit from the FDA's approval of the Teva ANDA.

ANSWER: Paragraph 21 states legal conclusions to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 21. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 22. This Court has personal jurisdiction over Teva Pharmaceuticals because its affiliations with the State of Delaware, including by virtue of its incorporation in Delaware, are so continuous and systematic that Teva Pharmaceuticals resides in Delaware.

ANSWER: Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies any remaining allegations Paragraph 22.

Complaint ¶ 23. This Court also has personal jurisdiction over Teva Pharmaceuticals because, inter alia, it has purposefully availed itself of the privileges and benefits of Delaware's laws such that it should reasonably anticipate being haled into court here. Upon information and belief, Teva Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Pharmaceuticals directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and Delaware. By continuously placing its products into the stream of commerce for distribution and consumption in Delaware, Teva Pharmaceuticals's contacts with the State of Delaware have been systematic and continuous, and this judicial district is a likely destination of Teva's ANDA Product.

ANSWER: Paragraph 23 states legal conclusions to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies any remaining allegations Paragraph 23.

Complaint ¶ 24. Upon information and belief, Teva Pharmaceuticals acted in concert with or at the direction of Teva Industries to prepare and submit the Teva ANDA, with the intention of receiving a significant financial benefit from marketing

and distribution of Teva's ANDA Product throughout the United States, including in Delaware.

ANSWER: Paragraph 24 states a legal conclusion to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 24. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 25. Upon information and belief, Teva Industries and Teva Pharmaceuticals have thus been, and continue to be, agents of each other and/or operate in concert with respect to the drafting, submission, approval, and maintenance of the Teva ANDA.

ANSWER: Paragraph 25 states a legal conclusion to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 25. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 26. Upon information and belief, Teva Industries and Teva Pharmaceuticals are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Teva's ANDA Product.

ANSWER: Paragraph 26 states a legal conclusion to which no response is required. To the extent a response is required, Teva denies the allegations in Paragraph 26. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 27. This Court also has personal jurisdiction over Teva Industries and Teva Pharmaceuticals because they have availed themselves of the legal protections of the State of Delaware by previously consenting to personal jurisdiction in this judicial district and by asserting counterclaims against plaintiffs. *See, e.g.*, *Azurity Pharms., Inc. v. Teva Pharms., Inc.*, C.A. No. 23-1080 (D. Del.);

Celgene Corp. v. Teva Pharms. Inc., C.A. No. 23-1008 (D. Del.); *Array Biopharma Inc. v. Teva Pharms., Inc.*, C.A. No. 23-625 (D. Del.); *Abbvie Inc. v. Teva Pharms. Inc.*, C.A. No. 23-374 (D. Del.); *Amicus Therapeutics US, LLC v. Teva Pharms. USA Inc., Teva Pharms. Inc. & Teva Pharms. Indus. Ltd.*, C.A. No. 22-1461 (D. Del.).

ANSWER: Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction in this Judicial District. Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries). Teva denies any remaining allegations in Paragraph 27.

Complaint ¶ 28. For these and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

ANSWER: Paragraph 28 states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest personal jurisdiction Teva denies any remaining allegations in Paragraph 28.

Complaint ¶ 29. Venue is proper in this Court for Teva Industries under 28 U.S.C. § 1391 because, upon information and belief, Teva Industries is not a resident of the United States and may thus be sued in any judicial district.

ANSWER: Paragraph 29 is directed at an entity other than Teva and does not require a response. To the extent an answer is required, Teva denies that Teva Industries is a proper party to this lawsuit. *See* D.I. 12 (Order Granting Stipulation of Dismissal as to Teva Industries).

Complaint ¶ 30. Venue is proper in this Court for Teva Pharmaceuticals under 28 U.S.C. §§ 1391 and 1400(b) because Teva Pharmaceuticals is a corporation organized and existing under the laws of Delaware.

ANSWER: Paragraph 30 states a legal conclusion to which no response is required. To the extent a response is required, for the purposes of this case only, solely to conserve the resources of the parties and the Court, Teva does not contest venue. Teva denies any remaining allegations in Paragraph 30.

COUNT I
(INFRINGEMENT OF THE '724 PATENT)

Complaint ¶ 31. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

ANSWER: Teva repeats and incorporates here by reference its responses to the preceding paragraphs.

Complaint ¶ 32. Defendants have infringed one or more claims of the '724 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting to the FDA and maintaining the Teva ANDA, by which Defendants seek approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Teva's ANDA Product before the expiration of the '724 patent.

ANSWER: Paragraph 32 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 33. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Teva's ANDA Product within the United States, or importation of Teva's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 33 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 34. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Teva's ANDA Product within the United States, or importation of Teva's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 35. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Teva admits that claim 1 of the '724 patent recites "[a] pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form." Teva denies any remaining allegations in Paragraph 35.

Complaint ¶ 36. Upon information and belief, Teva's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Teva's ANDA Product will be in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Teva admits that its ANDA product will be formulated in accordance with the requirements of all applicable laws and regulations. Teva states

that Teva's ANDA otherwise speaks for itself. Teva denies any remaining allegations in Paragraph 36.

Complaint ¶ 37. Upon information and belief, Defendants have acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of the Teva ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '724 patent.

ANSWER: Paragraph 37 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 38. Upon information and belief, if the FDA approves the Teva ANDA, Defendants plan and intend to, and will, infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

ANSWER: Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 39. Upon information and belief, Defendants know that Teva's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Teva's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Teva ANDA.

ANSWER: Paragraph 39 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 40. Pfizer will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '724 patent.

ANSWER: Paragraph 40 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 41. Pfizer has no adequate remedy at law.

ANSWER: Paragraph 41 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 42. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 42 states legal conclusions to which no response is required. To the extent a response is required, denied.

COUNT II
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '724 PATENT)

Complaint ¶ 43. Pfizer realleges, and incorporates fully herein, each preceding paragraph.

ANSWER: Teva repeats and incorporates here by reference its responses to the preceding paragraphs.

Complaint ¶ 44. There is a substantial and immediate controversy between Pfizer and Teva concerning the '724 patent. Pfizer is entitled to a declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that Teva will infringe, actively induce infringement of, and/or contribute to the infringement of the '724 patent upon approval of the Teva ANDA.

ANSWER: Paragraph 44 states legal conclusions to which no response is required. To the extent a response is required, Teva admits that, as a result of

Plaintiffs' filing of the Complaint against Teva in this action, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '724 patent. Teva denies any remaining allegations in Paragraph 44.

Complaint ¶ 45. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Teva's ANDA Product within the United States, or importation of Teva's ANDA Product into the United States, during the term of the '724 patent would infringe one or more claims of the '724 patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

ANSWER: Paragraph 45 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 46. Upon information and belief, Defendants' commercial manufacture, sale, offer for sale, or use of Teva's ANDA Product within the United States, or importation of Teva's ANDA Product into the United States, during the term of the '724 patent would induce and/or contribute to the infringement of one or more claims of the '724 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Paragraph 46 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 47. For example, claim 1 of the '724 patent recites:

> A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Teva admits that claim 1 of the '724 patent recites "[a] pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of a CGRP receptor antagonist, or a

pharmaceutically acceptable salt thereof, wherein the pharmaceutical composition is in a form of an oral solid molded fast-dispersing dosage form." Teva denies any remaining allegations in Paragraph 47.

Complaint ¶ 48. Upon information and belief, Teva's ANDA Product will contain a pharmaceutical composition comprising a therapeutically effective amount of rimegepant sulfate, which is a pharmaceutically acceptable salt of the CGRP receptor antagonist rimegepant. Upon information and belief, the pharmaceutical composition of Teva's ANDA product will be in a form of an oral solid molded fast-dispersing dosage form.

ANSWER: Teva admits that its ANDA product will be formulated in accordance with the requirements of all applicable laws and regulations. Teva states that Teva's ANDA otherwise speaks for itself. Teva denies any remaining allegations in Paragraph 48.

Complaint ¶ 49. Upon information and belief, Defendants have acted with full knowledge of the '724 patent and without a reasonable basis for believing that they would not be liable for infringement of the '724 patent. Notwithstanding this knowledge, Defendants have continued to assert their intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of the Teva ANDA. Upon information and belief, through such activities, Defendants specifically intend infringement of the '724 patent.

ANSWER: Paragraph 49 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 50. Upon information and belief, if the FDA approves the Teva ANDA, Defendants plan and intend to, and will, infringe, actively induce

infringement of, and/or contribute to the infringement of the '724 patent, and will do so immediately and imminently upon approval.

ANSWER: Paragraph 50 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 51. Upon information and belief, Defendants know that Teva's ANDA Product is especially made or adapted for use in infringing the '724 patent, and that Teva's ANDA Product is not suitable for any substantial non-infringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to infringement of the '724 patent immediately and imminently upon approval of the Teva ANDA.

ANSWER: Paragraph 51 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 52. Pfizer will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '724 patent.

ANSWER: Paragraph 52 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 53. Pfizer has no adequate remedy at law.

ANSWER: Paragraph 53 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 54. Pfizer is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Paragraph 54 states legal conclusions to which no response is required. To the extent a response is required, denied.

Complaint ¶ 55. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Teva's ANDA Product with

its proposed labeling will infringe the '724 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 55 states legal conclusions to which no response is required. To the extent a response is required, denied.

PLAINTIFFS' PRAYER FOR RELIEF

The remainder of Plaintiffs' Complaint recites a prayer for relief to which no response is required. To the extent a response is required, Teva denies that Plaintiffs are entitled to any remedy or relief in this action, including those requested.

AFFIRMATIVE DEFENSES

Without any admission as to the burden of proof, burden of persuasion, or the truth of anyallegation in Plaintiffs' Complaint, and expressly reserving its right to assert additional defenses, Teva states the following affirmative defenses:

First Affirmative Defense

The manufacture, use, sale, offer for sale, or importation of the Teva ANDA Product will not infringe, directly or indirectly, any valid or enforceable claim of the patent-in-suit.

Second Affirmative Defense

The filing of Teva's ANDA has not infringed, and will not infringe, directly or indirectly, any valid or enforceable claim of the patent-in-suit.

Third Affirmative Defense

The claims of the patent-in-suit are invalid and/or unenforceable for failure to satisfy the statutory provisions of Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

Fourth Affirmative Defense

The Complaint fails to state a claim for willful infringement.

Fifth Affirmative Defense

Teva's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Sixth Affirmative Defense

Any additional defenses or counterclaims that discovery may reveal.

* * *

COUNTERCLAIMS

Without admitting any of Plaintiffs' allegations other than those expressly admitted herein, and without prejudice to the rights of Defendant to plead additional Counterclaims as the facts of the matter warrant, Defendant Teva Pharmaceuticals, Inc. ("Teva" or "Counterclaim-Plaintiff") hereby asserts the following Counterclaims against Plaintiffs Pfizer Inc. and Pfizer Ireland Pharmaceuticals (collectively, "Pfizer," "Plaintiffs," or "Counterclaim-Defendants").

PARTIES

1. Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054.

2. On information and belief, Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 66 Hudson Boulevard East, New York, NY 10001.

3. On information and belief, Plaintiff Pfizer Ireland Pharmaceuticals is a private unlimited liability company organized under the laws of Ireland and has its registered office at Operations Support Group, Ringaskiddy, Co. Cork, Ireland. Pfizer Ireland Pharmaceuticals is a wholly owned, indirect subsidiary of Pfizer Inc.

JURISDICTION AND VENUE

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

6. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges, and have subjected themselves to the jurisdiction, of this Court by filing

this action and/or because Counterclaim-Defendants conduct substantial business in, and have regular and systematic contacts with, this District.

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

FACTUAL BACKGROUND

8. According to the United States Food and Drug Administration ("FDA") publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book"), Pfizer Inc. is the holder of New Drug Application ("NDA") No. 212728 for NURTEC ODT®.

9. NDA holders are required to disclose to the FDA the patent numbers of patents claiming the drug or method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

10. As of August 6, 2024 the Orange Book entry for NURTEC ODT® lists 3 patents. One of these patents include United States Patent No. 11,083,724 ("the '724 patent" or "the patent-in-suit").

11. The face of the '724 patent lists the title as "Rimegepant for CGRP Related Disorders," the issue date as August 10, 2021, and the assignee as Biohaven Pharmaceutical Ireland DAC, Dublin (IE).

12. Pfizer Inc. purports to own, and to have the right to enforce, the patent-in-suit.

13. Pfizer Inc. purports to be an exclusive licensee of the patent-in-suit and to have the right to enforce the patent-in-suit.

14. Teva submitted Abbreviated New Drug Application ("ANDA") No. 219365 ("Teva's ANDA") to the FDA under 21 U.S.C. § 355(j) seeking approval to sell Teva's proposed Rimegepant Orally Disintegrating Tablets, 75 mg ("the Teva ANDA Product"). Teva submitted Teva's ANDA to the FDA with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the patent-in-suit.

15. Teva sent notice of this certification to Counterclaim-Defendants on or about April 10, 2024 ("Teva's Notice Letter"). On information and belief, and as Counterclaim-Defendants allege in the Complaint, Counterclaim-Defendants received Teva's Notice Letter.

16. On May 23, 2024, Counterclaim-Defendants filed suit in this Judicial District against Teva in connection with Teva's ANDA, alleging Teva's infringement of the patent-in-suit.

FIRST COUNTERCLAIM

Declaratory Judgment of Noninfringement of the '724 Patent

17. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

18. The manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if sold, infringe any valid and/or enforceable claim of the '724 patent, either directly or indirectly at least because the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product will not induce infringement or result in contributory infringement.

19. Teva has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claims of the '724 patent at least because Teva is not and will not practice the claimed methods of the '724 patent.

20. There is an actual, substantial, and continuing justiciable controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgement regarding Teva's non-infringement of the '724 patent.

21. Teva is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '724 patent, either directly or indirectly.

SECOND COUNTERCLAIM

Declaratory Judgment of Invalidity or Unenforceability of the '724 Patent

22. Teva repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

23. The claims of the '724 patent are invalid and/or unenforceable at least because of a failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation, one or more of §§ 101, 102, 103, 111, 112, 116, 135, 251, 256, and 287, and/or the doctrine of obviousness-type double patenting, and/or judicially created doctrines of invalidity or unenforceability.

24. There is an actual, substantial, and continuing justiciable case or controversy between Teva and Counterclaim-Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the invalidity and/or unenforceability of the '724 patent.

25. Teva is entitled to a judicial declaration that the claims of the '724 patent are invalid and/or unenforceable.

PRAYER FOR RELIEF

WHEREFORE, Teva requests judgment in its favor and against Counterclaim-Defendants:

A. declaring that the manufacture, use, sale, offer for sale, and/or importation of the Teva ANDA Product, that is the subject of ANDA No. 219365,

has not infringed, does not infringe and would not infringe any valid and/or enforceable claim of the patent-in-suit, either directly or indirectly;

B. declaring that the Teva ANDA Product, that is the subject of ANDA No. 219365 would not, if sold, infringe any valid and/or enforceable claim of the patent-in-suit, either directly or indirectly;

C. declaring that the claims of the patent-in-suit are invalid and/or unenforceable;

D. ordering that judgment be entered in favor of Teva and that Counterclaim-Defendants' Complaint be dismissed with prejudice;

E. declaring this case exceptional and awarding Teva its reasonable attorneys' fees and costs of defending this action and prosecuting its counterclaims under 35 U.S.C. § 285; and

F. awarding Teva such other and further relief as the Court may deem just and proper.

/s/ Karen E. Keller

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Dated: August 6, 2024