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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS IRELAND LIMITED, **Plaintiff,** **v.** **TEVA PHARMACEUTICALS, INC.,** **Defendant.**	**Honorable Stanley R. Chesler, U.S.D.J.** **Honorable Jessica S. Allen, U.S.M.J.** **Civil Action No. 2:24-cv-08785-SRC-JSA** **DEFENDANT TEVA PHARMACEUTICALS, INC. ANSWER AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Defendant Teva Pharmaceuticals USA, Inc. ("Teva"), by and through its undersigned attorneys, submits its answer, affirmative defenses, and counterclaims to the Complaint for patent

infringement of Plaintiff Jazz Pharmaceuticals Ireland Limited ("Jazz Pharmaceuticals" or "Jazz") in Civil Action No. 2:24-cv-08785-SRC-JSA (DE No. 1).

Answer to Complaint

Teva denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications or speculations that arguably follow from the admitted facts. Teva denies that Plaintiff is entitled to the relief requested or any other relief. Teva responds to the Complaint as follows:

Nature of the Action

1. This complaint is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, arising from the Defendant's submission of Abbreviated New Drug Application ("ANDA") No. 216884 ("Teva's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell a generic version of Jazz Pharmaceuticals' Xywav® drug product prior to the expiration of United States Patent No. 11,986,446 ("the '446 patent" or "the patent-in-suit"), which is owned by Jazz Pharmaceuticals.

ANSWER: Paragraph 1 of the Complaint contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that the Complaint purports to bring an action for infringement under the patent laws of the United States, 35 U.S.C. §100 *et seq*. Teva lacks knowledge or information sufficient to form a belief as to the ownership of any or all of the patent-in-suit. Teva denies that Plaintiff is entitled to any relief in this action. Teva denies any remaining allegations in paragraph 1 of the Complaint.

The Parties

2. Plaintiff Jazz Pharmaceuticals is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

ANSWER: Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 2 of the Complaint and therefore denies those allegations.

3. On information and belief, Defendant Teva is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, 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, New Jersey 07054.

The Patent-in-Suit

3[1]. On May 21, 2024, the United States Patent and Trademark Office duly and lawfully issued the '446 patent, entitled, "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters." A copy of the '446 patent is attached hereto as Exhibit A.

ANSWER: Teva admits, on information and belief, that the '446 patent is entitled "Method of administration of gamma hydroxybutyrate with monocarboxylate transporters," bears an issue date of May 21, 2024 but denies that that the '446 patent was duly and lawfully issued. Teva admits that what appears to be a copy of the '446 patent is attached as Exhibit A to the Complaint. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph and, therefore, denies them.

The Xywav® Drug Product

4. Jazz Pharmaceuticals holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for calcium, magnesium, potassium, and sodium oxybates oral solution (NDA No. 212690), which it sells under the trade name Xywav®. The claims of the patent-in-suit cover, *inter alia*, methods of use and administration of calcium, magnesium, potassium, and sodium oxybates. Jazz Pharmaceuticals owns the patent-in-suit.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva admits that that the FDA website indicates that Jazz Pharmaceuticals is the holder of NDA No. 212690 for 0.5 g/ml calcium, magnesium, potassium,

[1] Teva's answer includes two paragraphs bearing the number "3" in order to match the Complaint which recites two consecutive paragraphs that are both numbered as paragraph 3.

and sodium oxybates oral solution, and that Jazz Pharmaceuticals sells product under the trade name Xywav®. Teva lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies them.

5. Pursuant to 21 U.S.C. § 355(b)(1) 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 Xywav®.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva admits that Paragraph 5 of the Complaint purports to characterize the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") and Teva avers that the document speaks for itself as to its contents. Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 5 of the Complaint and, therefore, denies them.

6. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav® for the treatment of, *inter alia*, cataplexy or excessive daytime sleepiness in patients with narcolepsy.

ANSWER: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 6 of the Complaint and, therefore, denies them.

7. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to modify the dose of Xywav® for patients receiving calcium, magnesium, potassium, and sodium oxybates when divalproex sodium (valproate) is concomitantly administered.

ANSWER: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 7 of the Complaint and, therefore, denies them.

8. The labeling for Xywav® instructs and encourages physicians, pharmacists, other healthcare workers, and patients to administer Xywav® according to one or more of the methods claimed in the patent-in-suit.

ANSWER: This paragraph contains conclusions of law to which no response is required. To the extent a response is required, Teva lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations of paragraph 8 of the Complaint and, therefore, denies them.

Jurisdiction and Venue

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva does not contest that this Court has jurisdiction over the subject matter of this action against Teva for the purposes of this action only. Teva denies any remaining allegations in this paragraph.

10. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva does not contest personal jurisdiction for the purposes of this action only. Teva denies any remaining allegations in this paragraph.

11. On information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District.

ANSWER: Teva admits that it has a principal place of business in New Jersey and conducts business in New Jersey, and that it does not contest personal jurisdiction for the purposes of this action only. Teva denies any remaining allegations in this paragraph.

12. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Teva admits that it develops, manufactures, offers for sale, and sells pharmaceutical products in the United States. Teva does not contest personal jurisdiction in New Jersey for the purposes of this action only. Teva denies any remaining allegations in this paragraph.

13. On information and belief, this Judicial District is a likely destination for the generic drug product described in Teva's ANDA.

ANSWER: Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 13 of the Complaint, and therefore denies those allegations.

14. On information and belief, Teva maintains a regular and established, physical place of business in this Judicial District, in at least Parsippany, New Jersey. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* https://www.tevausa.com/contact-us/ (last visited August 27, 2024). In court filings, Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey. *See, e.g.*, *Jazz Pharmaceuticals Ireland Limited v. Teva Pharm., Inc.*, No. 23-1617, D.I. No. 13 at ¶ 26 (May 23, 2023); *Neurocrine Biosci., Inc. v. Teva Pharm., Inc., et. al.*, No. 22-965, D.I. No. 14 at ¶ 12 (D. Del. Nov. 1, 2022).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Teva admits that it has a principal place of business at 400 Interpace Parkway, Parsippany, NJ 07054. Teva denies the remaining allegations of paragraph 14 of the Complaint.

15. On information and belief, Teva is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

ANSWER: Teva admits the allegations in paragraph 15 of the Complaint.

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva does not contest venue in this Judicial District under 28 U.S.C. §§ 1391 and/or 1400(b) for purposes of this action only.

Acts Giving Rise to This Suit

17. Pursuant to Section 505 of the FFDCA, Teva submitted Teva's ANDA seeking approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of calcium, magnesium, potassium, and sodium oxybates oral solution ("Teva's Proposed Product") before the expiration of the patent-in-suit.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that it submitted to the FDA ANDA No. 216884 seeking approval of Teva's Proposed Product before the expiration of the patent-in-suit. Teva denies any remaining allegations in this paragraph.

18. On information and belief, following FDA approval of Teva's ANDA, Teva will make, use, sell, or offer to sell Teva's Proposed Product throughout the United States, or import such generic product into the United States.

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

19. On information and belief, in connection with the submission of Teva's ANDA as described above, Teva provided written certification to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Teva's Paragraph IV Certification"), alleging that the claims of the '446 patent are invalid and/or will not be infringed by the activities described in Teva's ANDA.

ANSWER: Teva admits that Teva's ANDA provided written certifications to the FDA pursuant to Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating that the claims of the patent-in-suit is invalid and/or will not be infringed by the manufacture, use, or sale of Teva's Proposed Product. Teva denies any remaining allegations in this paragraph.

20. No earlier than July 15, 2024, Teva sent notice of its Paragraph IV Certification to Jazz Pharmaceuticals ("Teva's Notice Letter"). Teva's Notice Letter alleged that the claims of the '446 patent are invalid and/or will not be infringed by the activities described in Teva's ANDA. Teva's Notice Letter also informed Jazz Pharmaceuticals that Teva seeks approval to market Teva's Proposed Product before the expiration of the '446 patent.

ANSWER: Teva admits that it sent a letter to Plaintiff on or about July 15, 2024, that provided written notice of Teva's ANDA and Paragraph IV Certifications that included a statement of the

factual and legal bases that the '446 patent is invalid, unenforceable, and/or will not be infringed by Teva's Proposed Product. Teva also admits that its July 15, 2024 Notice Letter informed Plaintiff that Teva seeks approval to market Teva's Proposed Product prior to the expiration of the '446 patent. Teva denies any remaining allegations in this paragraph.

Count for Infringement of the '446 Patent

21. Jazz Pharmaceuticals repeats and realleges the allegations of the preceding paragraphs as if fully set forth herein.

ANSWER: Teva repeats and incorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

22. Teva's submission of its ANDA to obtain approval to engage in the commercial manufacture, use, sale, or offer for sale in, or importation into, the United States of Teva's Proposed Product, prior to the expiration of the '446 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies that it infringes any valid and enforceable claims of the '466 patent. Teva denies any remaining allegations of this paragraph.

23. There is a justiciable controversy between the parties hereto as to the infringement of the '446 patent.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva admits that Plaintiff has filed suit accusing Teva of infringing the '446 Patent. Teva denies any remaining allegations of this paragraph.

24. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe one or more claims of the '446 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies the allegations of this paragraph.

25. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of one or more claims of the '446 patent under 35 U.S.C. § 271(b) by making,

using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '446 patent and knowledge that its acts are encouraging infringement.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies the allegations of this paragraph.

26. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe one or more claims of the '446 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing Teva's Proposed Product in or for the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes one or more claims of the '446 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies the allegations of this paragraph.

27. Jazz Pharmaceuticals will be substantially and irreparably damaged and harmed if Teva's infringement of the '446 patent is not enjoined.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies the allegations of this paragraph.

28. Jazz Pharmaceuticals does not have an adequate remedy at law.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies the allegations of this paragraph.

29. This case is an exceptional one, and Jazz Pharmaceuticals is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Teva denies the allegations of this paragraph.

PRAYER FOR RELIEF

The remainder of Plaintiff's Complaint is a prayer for relief and does not require a response. To the extent any response is required, Teva denies that Plaintiff is entitled to any remedy or relief.

TEVA'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Teva asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Teva reserves the right to assert additional defenses, as warranted, by facts learned through investigation and discovery. Teva asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(No Direct Infringement)

The filing of Teva's ANDA has not and does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '446 patent.

The manufacture, use, sale, or offer for sale of Teva's Proposed Product that is the subject of Teva's ANDA has not infringed, does not infringe, and would not, if marketed infringe any valid and enforceable claim of the '446 patent either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE
(No Indirect Infringement)

Teva has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '446 patent. If Teva's Proposed Product that is the subject of Teva's ANDA were marketed, Teva would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '446 patent.

THIRD AFFIRMATIVE DEFENSE
(Invalidity)

The ’446 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 or under other judicially created bases for invalidation

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted against Teva.

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

Plaintiff’s claims are barred, in whole or in part, by the doctrines of prosecution history estoppel and/or prosecution history disclaimer.

SEVENTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

COUNTERCLAIMS FOR DECLARATORY JUDGMENT

For its counterclaims against Jazz Pharmaceuticals Ireland Limited (“Counterclaim Defendant” or “Jazz Pharmaceuticals”), Defendant Teva Pharmaceuticals, Inc. (“Counterclaim Plaintiff” or “Teva”) states as follows:

PARTIES

1. On information and belief, Jazz Pharmaceuticals is a corporation organized and existing under the laws of Ireland, having a principal place of business at Waterloo Exchange, Waterloo Road, Dublin, Ireland 4.

2. Teva Pharmaceuticals, Inc. 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, New Jersey 07054.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. This Court has personal jurisdiction over Counterclaim Defendant on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed this suit.

5. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400.

6. There is an actual and justiciable controversy between the parties as to the infringement of United States Patent No. 11,986,446 ("the patent-in-suit").

FACTUAL BACKGROUND

FDA Approval of New Brand Name Drugs.

7. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

8. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

9. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for

which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

10. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 C.F.R. § 314.53(e).

11. The FDA's duties with respect to the Orange Book listings are purely ministerial. If the NDA-holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). The FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

FDA Approval of New Generic Drugs.

12. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

13. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

14. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

15. A "Paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

16. An applicant submitting an ANDA containing a Paragraph IV certification must notify both the patent holder and NDA holder of each of its Paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

17. Upon receiving notice of the Paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

18. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit, automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

19. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

Teva's ANDA

20. Teva submitted its ANDA No. 216884 ("Teva's ANDA") seeking approval to engage in the commercial use, sale, offer for sale or importation into the United States of an oral solution and containing as the active pharmaceutical ingredients Calcium, Magnesium, Potassium, and Sodium Oxybates, 0.5 g/mL ("Teva's Proposed Product") before the expiration of the patent-in-suit.

21. On information and belief, the FDA lists Jazz Pharmaceuticals as the holder of New Drug Application ("NDA") No. 212690.

22. On information and belief, NDA No. 212690 covers Jazz's XYWAV®.

23. On information and belief, Jazz Pharmaceuticals lists the patent-in-suit in the Orange Book in connection with NDA No. 212690.

24. Teva's ANDA includes a Paragraph IV certification with respect to the patent-in-suit.

25. On July 15, 2024, Teva sent a Notice Letter ("Teva's Notice Letter") regarding Teva's ANDA, which includes a Paragraph IV certification, to Jazz Pharmaceuticals providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the claims of the '446 patent is not infringed, directly or indirectly, either literally or under the doctrine of equivalents, by the commercial manufacture use, offer for sale, and/or sale of Teva's Proposed Product.

26. Teva's Notice Letter also contained an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow Jazz Pharmaceuticals the opportunity to review the relevant portions of Teva's ANDA.

27. Jazz filed a complaint against Teva on August 27, 2024 in *Jazz Pharmaceuticals Ireland, Ltd. v. Teva Pharmaceuticals, Inc.,* Civil Action No. 2:24-cv-08785 (D.N.J.), alleging that

Teva has infringed and will infringe the patent-in-suit by filing ANDA No. 216884 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

28. As a consequence of the foregoing, there is an actual and justiciable controversy between Teva, on the one hand, and Jazz Pharmaceuticals, on the other hand, as to whether the claims of the patent-in-suit are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by Teva's ANDA No. 216884, or by the manufacture, use, or sale of the product described therein.

COUNT I
(Declaratory Judgment of Non-Infringement of the '446 Patent)

29. Teva re-alleges and incorporates the allegations of paragraphs 1-28 as if fully set forth herein.

30. Jazz Pharmaceuticals alleges ownership of the '446 patent, and Jazz Pharmaceuticals has brought claims against Teva alleging infringement of the '446 patent.

31. The manufacture, use, sale, offer for sale, and/or importation of Teva's Proposed Product has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '446 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

32. 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 '446 patent.

33. On July 15, 2024, Teva sent a Notice Letter to Jazz Pharmaceuticals providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '446 patent is not infringed, directly or indirectly, either literally or under the

doctrine of equivalents, by the commercial manufacture use, offer for sale, and/or sale of Teva's Proposed Product.

34. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Jazz Pharmaceuticals, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Product would infringe any valid or enforceable claim of the '446 patent.

35. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Product would not infringe any valid or enforceable claim of the '446 patent.

36. This case is an exceptional one, and Teva is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaratory Judgment of Invalidity of the '446 Patent)

37. Teva re-alleges and incorporates the allegations of paragraphs 1-36 as if fully set forth herein.

38. Jazz Pharmaceuticals alleges ownership of the '446 patent, and Jazz Pharmaceuticals has brought claims against Teva alleging infringement of the '446 patent.

39. One or more claims of the '446 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or in view of defenses recognized in 35 U.S.C. § 282(b).

40. On July 15, 2024, Teva sent a Notice Letter to Jazz Pharmaceuticals providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '446 patent is invalid.

41. A present, genuine, and justiciable controversy exists between Teva and Jazz Pharmaceuticals regarding, *inter alia*, the validity of claims of the '446 patent.

42. Teva is entitled to a declaration that claims of the ’446 patent are invalid.

43. This case is an exceptional one, and Teva is entitled to an award of its reasonable attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests that this Court enter a Judgment and Order in its favor and against Defendant Jazz Pharmaceutical as follows:

1. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Teva’s Proposed Product has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the patent-in-suit, either directly or indirectly, literally or under the doctrine of equivalents any valid and enforceable claim of the U.S. Patent No. 11,986,446;
2. Declaring that the claims of U.S. Patent No. 11,986,446 are invalid;
3. Declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 and awarding Teva its costs, expenses, and reasonable attorneys’ fees in this action; and
4. Awarding Teva any further and additional relief as the Court deems just and proper.

Dated: October 17, 2024

WALSH PIZZI O'REILLY FALANGA LLP

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2 and 40.1

Defendant Teva Pharmaceuticals, Inc. by its undersigned counsel, hereby certifies that to the best of its knowledge, the matter in controversy is related to the following actions:

- *Jazz Pharmaceuticals Ireland Ltd. v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-cv-01617 (SRC)(JSA)
- *Jazz Pharmaceuticals Ireland Ltd. v. Lupin Inc., et al.*, Civil Action No. 21-cv-14271 (SRC)(JSA) (Consolidated)

Dated: October 17, 2024

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Teva Pharmaceuticals, Inc. by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: October 17, 2024

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