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Teva Pharmaceuticals USA, Inc.

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

HORIZON MEDICINES LLC,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA,
INC.,

Defendant.

Honorable Stanley R. Chesler, U.S.D.J.
Honorable Cathy L. Waldor, U.S.M.J.

Civil Action No. 2:20-cv-08188

**DEFENDANT TEVA
PHARMACEUTICALS USA, INC.'S
ANSWER, AFFIRMATIVE DEFENSES,
AND COUNTERCLAIMS TO PLAINTIFF'S
COMPLAINT FOR PATENT
INFRINGEMENT**

Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA” or “Teva”¹), by and through its undersigned attorneys, submits its answer, affirmative defenses, and counterclaims to the Complaint for patent infringement of Plaintiff Horizon Medicines LLC (“Plaintiff” or “Horizon”) in Civil Action No. 2:20-cv-08188 (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 ACTION²

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, arising from Defendants’ filing of an Abbreviated New Drug Application (“ANDA”) with the United States Food and Drug Administration (“FDA”) seeking approval to market a generic version of Plaintiff’s pharmaceutical product DUEXIS® (Ibuprofen of Famotidine Tablets) 800mg/16.6 mg (“DUEXIS®”) prior to the expiration of United States Patent Nos. 8,067,033 (“the ’033 patent”), 8,067,451 (“the ’451 patent”), 8,309,127 (“the ’127 patent”), 8,318,202 (“the ’202 patent”), 8,449,910 (“the ’910 patent”), and 8,501,228 (“the ’228 patent”) (collectively, the “Asserted Patents”), which cover DUEXIS® and its use.

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, Title 35 of the United States

¹ The Complaint uses “Teva” to collectively include Teva USA and Teva Pharmaceutical Industries, Ltd., (“Teva Ltd.”) which is no longer a party to this case. Pursuant to the Stipulation submitted on July 24, 2020 (DE No. 12) and so ordered on August 11, 2020 (DE No. 20) the parties have stipulated to dismissal of the action against Teva Ltd. Accordingly, all responses herein are made solely on behalf of Teva USA, and no response is made on behalf of Teva Ltd.

² This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint.

Code. 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 Horizon Medicines LLC is a corporation operating and existing under the laws of the State of Delaware, with a principal place of business at 105 S. Saunders Rd, Lake Forest, Illinois 60045.

ANSWER: Upon information and belief, Teva admits that Horizon is a corporation operating and existing under the laws of the State of Delaware, having a principal place of business at 105 S. Saunders Rd, Lake Forest, Illinois 60045.

3. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a corporation operating and existing under the laws of the Delaware, having a principal place of business at 400 Interpace Pkwy #3, Parsippany, New Jersey 07054 and 425 Privet Road, Horsham, Pennsylvania 19044.

ANSWER: Teva USA 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. Teva denies any remaining allegations in this paragraph. Further, paragraph 3 of the Complaint does not direct any allegations to Teva Ltd. and therefore no response on behalf of Teva Ltd. is required.

4. On information and belief, Defendant Teva Pharmaceutical Industries Ltd. is a corporation operating and existing under the laws of Israel, with principal places of business at 145 Brandywine Pkwy, West Chester, PA 19380 and 2945 W. Corporate Lakes Blvd, Weston, Florida 33331.

ANSWER: To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action. Further answering, Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva, Israel 4951033. Teva denies any remaining allegations in this paragraph.

5. Upon information and belief, Defendant Teva Pharmaceuticals USA, Inc. is a subsidiary of Teva Pharmaceuticals Industries Ltd.

ANSWER: Teva admits that Teva USA is an indirect wholly-owned subsidiary of Teva Ltd.

To the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

6. Upon information and belief, Defendants are in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including within this judicial district, through their own actions.

ANSWER: Teva admits that it develops, manufactures and seeks approval to commercially market, offers for sale, and sells pharmaceutical products throughout the United States, including in the State of New Jersey. Teva denies any remaining allegations in paragraph 6 of the Complaint.

Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

7. On information and belief, Defendants participated in the research and development, and the preparation and filing, of ANDA No. 211278 (“the Teva ANDA”) for ibuprofen and famotidine tablets (“the Teva Product”), continue to seek FDA approval of that application, and intend to commercially manufacture, market, offer for sale and sell the Teva Product throughout the United States, including in the State of New Jersey, in the event the FDA approves Teva’s ANDA.

ANSWER: Teva admits that it submitted to the FDA ANDA No. 211278 seeking approval of Teva’s Product and that, if Teva’s ANDA is approved, it may sell Teva’s Product in the United States. Teva denies any remaining allegations in this paragraph. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

8. On information and belief, should the Teva ANDA be finally approved by FDA, Defendants will sell, offer for sale, and distribute the Teva Product throughout the United States, including within this jurisdiction.

ANSWER: Teva admits that, if Teva's ANDA is approved, it may sell Teva's ANDA Product in the United States. Teva denies any remaining allegations in paragraph 8 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action.

9. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. have admitted to, consented to, or have not contested, the jurisdiction of this Court in numerous prior District of New Jersey actions, e.g.: *Indivior Inc. et al. v. Teva Pharms. USA, Inc.*, Civil Action No. 2:17-cv-07115; *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al.*, Civil Action No. 2:16-cv-07721; *Eisai Co., Ltd. et al. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al.*, Civil Action No. 2:05-cv-05727; *Novartis Pharms. Corp. et al. v. Teva Pharms. USA, Inc.*, Civil Action No. 2:05-cv-01887; *Altana Pharma AG et al. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd.*, Civil Action No. 2:04-cv-02355.

ANSWER: Denied as stated. Teva does not contest personal jurisdiction for the purposes of this action only. Further, Teva admits to participating in actions in this District including *Indivior Inc. et al. v. Teva Pharms. USA, Inc.*, Civil Action No. 2:17-cv-07115; *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al.*, Civil Action No. 2:16-cv-07721; *Eisai Co., Ltd. et al. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al.*, Civil Action No. 2:05-cv-05727; *Novartis Pharms. Corp. et al. v. Teva Pharms. USA, Inc.*, Civil Action No. 2:05-cv-01887; *Altana Pharma AG et al. v. Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd.*, Civil Action No. 2:04-cv-02355. Further to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action.

10. On information and belief, Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. have availed themselves of the rights, benefits, and privileges of this Court by filing lawsuits in numerous prior District of New Jersey actions, e.g.: *Teva Pharms.*

USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al., Civil Action No. 3:17-cv-00517; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Sandoz Inc. et al.*, Civil Action No. 3:17-cv-00275; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 2:15-cv-00471; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Synthon Pharms., Inc. et al.*, Civil Action No. 2:15-cv-00472; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 3:14-cv-05672; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Apotex, Inc. et al.*, Civil Action No. 3:07-cv-05514; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cadila Pharms. Ltd.*, Civil Action No. 3:07-cv-02912; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cobalt Pharms., Inc. et al.*, Civil Action No. 2:07-cv-01690; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:07-cv-00621; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Andrx Corp.*, Civil Action No. 2:07-cv-00244; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cipla Ltd. et al.*, Civil Action No. 2:07-cv-00240.

ANSWER: Denied as stated. Teva does not contest personal jurisdiction for the purposes of this action only. Further, Teva admits to participating in actions in this District including *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 3:17-cv-00517; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Sandoz Inc. et al.*, Civil Action No. 3:17-cv-00275; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 2:15-cv-00471; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Synthon Pharms., Inc. et al.*, Civil Action No. 2:15-cv-00472; *Teva Pharms. USA, Inc. and Teva Pharm. Industries Ltd. et al. v. Dr. Reddy's Labs., Ltd. et al.*, Civil Action No. 3:14-cv-05672; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Apotex, Inc. et al.*, Civil Action No. 3:07-cv-05514; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cadila Pharms. Ltd.*, Civil Action No. 3:07-cv-02912; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cobalt Pharms., Inc. et al.*, Civil Action No. 2:07-cv-01690; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 2:07-cv-00621; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Andrx Corp.*, Civil Action No. 2:07-cv-00244; *Teva Pharm. Industries Ltd. and Teva Pharms. USA, Inc. v. Cipla Ltd. et al.*, Civil Action No. 2:07-cv-00240. Further, to the

extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 11 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 cites the patent laws of the United States generally. Teva does not contest subject matter jurisdiction for purposes of this case only. Teva denies the remaining allegations of paragraph 11 of the Complaint.

12. This Court has personal jurisdiction over Defendants by virtue of, *inter alia*, their presence in New Jersey, having conducted business in New Jersey, having availed themselves of the rights and benefits of New Jersey law such that Defendants should reasonably anticipate being haled into court in this judicial district, previously submitting to personal jurisdiction in this Court, availing themselves of the jurisdiction of this Court (e.g., by assertion of claims and counterclaims), and having engaged in systematic and continuous contacts with the State of New Jersey through the marketing and sales of drug products throughout the United States, and in particular within this judicial district, through the receipt of revenue from the sales and marketing of drug products, including Teva products, within this judicial district, and through their intent to market and sell the Teva Product, if approved, to residents of this judicial district.

ANSWER: Paragraph 12 of the Complaint contains conclusions of law for which no response is required. Teva does not contest personal jurisdiction for this action only. Teva denies the remaining allegations of paragraph 12 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

ANSWER: Paragraph 13 of the Complaint contains conclusions of law for which no response is required. To the extent that a response is required, Teva states that Teva does not contest that venue is proper in this Court for the purposes of this action only.

THE PATENTS-IN-SUIT

14. On November 29, 2011, the U.S. Patent and Trademark Office (“USPTO”) duly and legally issued the ’033 patent entitled “Stable Compositions of Famotidine and Ibuprofen.”

ANSWER: Teva admits, on information and belief, that the ’033 patent, entitled “Stable Compositions of Famotidine and Ibuprofen,” and bears an issue date of November 29, 2011, but denies that the ’033 patent was duly and legally issued. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 14 of the Complaint and, therefore, denies them.

15. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the ’033 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the ’033 patent is attached hereto as Exhibit A.

ANSWER: Teva admits that what appears to be a copy of the ’033 patent is attached as Exhibit A to the Complaint. To the extent that paragraph 15 of the Complaint purports to characterize Exhibit A, 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 or falsity of the remaining allegations of paragraph 15 of the Complaint and, therefore, denies them.

16. On November 29, 2011, the USPTO duly and legally issued the ’451 patent entitled “Methods and Medicaments for Administration of Ibuprofen.”

ANSWER: Teva admits, on information and belief, that the ’451 patent entitled “Methods and Medicaments for Administration of Ibuprofen,” and bears an issue date of November 29, 2011, but denies that the ’451 patent was duly and legally issued. Teva lacks knowledge or information

sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 16 of the Complaint and, therefore, denies them.

17. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '451 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '451 patent is attached hereto as Exhibit B.

ANSWER: Teva admits that what appears to be a copy of the '451 patent is attached as Exhibit B to the Complaint. To the extent that paragraph 17 of the Complaint purports to characterize Exhibit B, 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 or falsity of the remaining allegations of paragraph 17 of the Complaint and, therefore, denies them.

18. On November 13, 2012, the USPTO duly and legally issued the '127 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

ANSWER: Teva admits, on information and belief, that the '127 patent entitled, "Stable Compositions of Famotidine and Ibuprofen," bears an issue date of November 13, 2012, but denies that the '127 patent was duly and legally issued. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 18 of the Complaint and, therefore, denies them.

19. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '127 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '127 patent is attached hereto as Exhibit C.

ANSWER: Teva admits that what appears to be a copy of the '127 patent is attached as Exhibit C to the Complaint. To the extent that paragraph 19 of the Complaint purports to characterize Exhibit C, 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 or falsity of the remaining allegations of paragraph 19 of the Complaint and, therefore, denies them.

20. On November 27, 2012, the USPTO duly and legally issued the '202 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

ANSWER: Teva admits, on information and belief, that the '202 patent entitled, "Stable Compositions of Famotidine and Ibuprofen," and bears an issue date of November 27, 2012, but denies that the '202 patent was duly and legally issued. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 20 of the Complaint and, therefore, denies them.

21. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '202 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '202 patent is attached hereto as Exhibit D.

ANSWER: Teva admits that what appears to be a copy of the '202 patent is attached as Exhibit D to the Complaint. To the extent that paragraph 21 of the Complaint purports to characterize Exhibit D, 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 or falsity of the remaining allegations of paragraph 21 of the Complaint and, therefore, denies them.

22. On May 28, 2013, the USPTO duly and legally issued the '910 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

ANSWER: Teva admits, on information and belief, that the '910 patent entitled, "Stable Compositions of Famotidine and Ibuprofen," bears an issue date of May 28, 2013, but denies that the '910 patent was duly and legally issued. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 22 of the Complaint and, therefore, denies them.

23. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '910 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '910 patent is attached hereto as Exhibit E.

ANSWER: Teva admits that what appears to be a copy of the '910 patent is attached as Exhibit E to the Complaint. To the extent that paragraph 23 of the Complaint purports to characterize Exhibit E, 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 or falsity of the remaining allegations of paragraph 23 of the Complaint and, therefore, denies them.

24. On August 6, 2013, the USPTO duly and legally issued the '228 patent entitled "Stable Compositions of Famotidine and Ibuprofen."

ANSWER: Teva admits, on information and belief, that the '228 patent entitled, "Stable Compositions of Famotidine and Ibuprofen," and bears an issue date of August 6, 2013, but denies that the '228 patent was duly and legally issued. Teva lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of paragraph 24 of the Complaint and, therefore, denies them.

25. Horizon Medicines LLC is the sole assignee and owner of all right, title and interest in and to the '228 patent, which discloses and claims, *inter alia*, methods for manufacturing tablets containing ibuprofen and famotidine for the treatment of ibuprofen-responsive ailments while reducing the risk of developing gastro-intestinal problems, such as ulcers. A true and correct copy of the '228 patent is attached hereto as Exhibit F.

ANSWER: Teva admits that what appears to be a copy of the '228 patent is attached as Exhibit F to the Complaint. To the extent that paragraph 25 of the Complaint purports to characterize Exhibit F, 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 or falsity of the remaining allegations of paragraph 25 of the Complaint and, therefore, denies them.

DUEXIS®

26. Horizon Medicines LLC is the owner of FDA-approved New Drug Application No. 025519 (“the DUEXIS® NDA”) for ibuprofen and famotidine tablets (DUEXIS®), which is sold in the U.S. under the trade name DUEXIS®, and which is sold by Horizon Medicines LLC.

ANSWER: Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 26 of the Complaint, and therefore denies those allegations.

27. The DUEXIS® tablet is currently approved by the FDA for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers, which in the clinical trials was defined as gastric and/or duodenal ulcer, in patents who are taking ibuprofen for those indications.

ANSWER: Teva is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 27 of the Complaint, and therefore denies those allegations.

28. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’033, ’451, ’127, ’202, ’910 and ’228 patents are currently listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations (“the Orange Book”) for the DUEXIS® NDA.

ANSWER: Paragraph 28 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 or falsity of the remaining allegations of paragraph 28 of the Complaint and, therefore, denies them.

29. The ’033, ’451, ’127, ’202, ’910 and ’228 patents cover DUEXIS® and FDA-approved uses thereof.

ANSWER: Paragraph 29 contains a legal conclusion to which no response is required. To the extent a response is required, Teva denies the allegations in paragraph 29 of the Complaint.

TEVA’S ANDA

30. On information and belief, Teva submitted the Teva ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market ibuprofen and famotidine tablets, 800 mg/26.6 mg. On information and belief, the Teva ANDA seeks approval to market the Teva Product for treatment of ibuprofen-responsive disorders with reduction of risk of gastro-intestinal problems.

ANSWER: Teva admits that it submitted ANDA No. 211278 seeking approval to commercially market the products described in the Teva ANDA (the “Teva’s Proposed Products”). Teva denies any remaining allegations in paragraph 30 of the Complaint.

31. On information and belief, the Teva ANDA refers to and relies upon the DUEXIS® NDA and contains data that, according to Teva, demonstrate the bioequivalence of the Teva Product and DUEXIS®.

ANSWER: Paragraph 31 of the Complaint purports to characterize Teva’s ANDA and its contents, and Teva avers that the document speaks for itself as to its contents.

32. Plaintiff received from Teva a letter, dated September 26, 2018 (the “Teva Notification”), stating that Teva had included a certification in the Teva ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the ’033, ’451, ’127, ’202, ’910 and ’228 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Teva Product (“the Paragraph IV Certification”).

ANSWER: Teva admits the allegations paragraph 32 of the Complaint.

33. The Teva Notification states that the Teva ANDA seeks approval to engage in the commercial manufacture, use or sale of ibuprofen and famotidine tablets, 800 mg/26.6 mg before the expiration of the ’033, ’451, ’127, ’202, ’910 and ’228 patents.

ANSWER: Teva admits the allegations paragraph 33 of the Complaint.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,067,033

34. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-33 of the Complaint

ANSWER: Teva incorporates by reference its responses to paragraphs 1-33 of the Complaint as if fully set forth herein.

35. The ’033 Patent issued on November 29, 2011, and will expire no earlier than July 18, 2026.

ANSWER: Teva admits that the ’033 patent issued on November 29, 2011 and avers that the ’033 patent speaks for itself as to its contents and duration. Teva denies that the ’033 Patent was duly and legally issued.

36. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the '033 patent expires, Defendants have infringed the '033 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva denies the allegations in paragraph 36 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

37. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the '033 patent, also would infringe, either literally or under the doctrine of equivalents, the '033 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Teva denies the allegations in paragraph 37 of the Complaint.

38. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the '033 patent.

ANSWER: Teva denies the allegations in paragraph 38 of the Complaint.

39. Upon information and belief, Defendants had actual and constructive notice of the '033 patent as of its issue date, and Defendants’ infringement of the '033 patent is willful.

ANSWER: Teva denies the allegations in paragraph 39 of the Complaint.

40. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the '033 patent, or any later expiration of any exclusivity or extension of the '033 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '033 patent, or any later expiration of any exclusivity or extension of the '033 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '033 patent, or any later expiration of any exclusivity or extension of the '033 patent to which Plaintiff or the patent may become entitled.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

41. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty

and/or lost profits for the use made of the invention of the '033 patent by Defendants, together with interest and costs.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

42. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '033 patent.

ANSWER: Teva denies the allegations in paragraph 42 of the Complaint.

43. Plaintiff has no adequate remedy at law.

ANSWER: Teva denies the allegations in paragraph 43 of the Complaint.

44. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Teva denies the allegations in paragraph 44 of the Complaint.

COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 8,067,451

45. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-44 of the Complaint

ANSWER: Teva incorporates by reference its responses to paragraphs 1-44 of the Complaint as if fully set forth herein.

46. The '451 Patent issued on November 29, 2011, and will expire no earlier than July 18, 2026.

ANSWER: Teva admits that the '451 patent issued on November 29, 2011 and avers that the '451 patent speaks for itself as to its contents and duration. Teva denies that the '451 Patent was duly and legally issued.

47. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the '451 patent expires, Defendants have infringed the '451 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva denies the allegations in paragraph 47 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case,

no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

48. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the ’451 patent, also would infringe, either literally or under the doctrine of equivalents, the ’451 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Teva denies the allegations in paragraph 48 of the Complaint.

49. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’451 patent.

ANSWER: Teva denies the allegations in paragraph 49 of the Complaint.

50. Upon information and belief, Defendants had actual and constructive notice of the ’451 patent as of its issue date, and Defendants’ infringement of the ’451 patent is willful.

ANSWER: Teva denies the allegations in paragraph 50 of the Complaint.

51. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the ’451 patent, or any later expiration of any exclusivity or extension of the ’451 patent to which Plaintiff or the patent may become entitled.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

52. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the ’451 patent by Defendants, together with interest and costs.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

53. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the ’451 patent.

ANSWER: Teva denies the allegations in paragraph 53 of the Complaint

54. Plaintiff has no adequate remedy at law.

ANSWER: Teva denies the allegations in paragraph 54 of the Complaint.

55. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Teva denies the allegations in paragraph 55 of the Complaint.

COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 8,309,127

56. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-55 of the Complaint

ANSWER: Teva incorporates by reference its responses to paragraphs 1-55 of the Complaint as if fully set forth herein.

57. The '127 Patent issued on November 13, 2012, and will expire no earlier than July 18, 2026.

ANSWER: Teva admits that the '127 patent issued on November 13, 2012 and avers that the '127 patent speaks for itself as to its contents and duration. Teva denies that the '127 Patent was duly and legally issued.

58. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the '127 patent expires, Defendants have infringed the '127 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva denies the allegations in paragraph 58 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action.

59. Defendants' commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the '127 patent, also would infringe, either literally or under the doctrine of equivalents, the '127 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Teva denies the allegations in paragraph 59 of the Complaint.

60. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the '127 patent.

ANSWER: Teva denies the allegations in paragraph 60 of the Complaint.

61. Upon information and belief, Defendants had actual and constructive notice of the '127 patent as of its issue date, and Defendants' infringement of the '127 patent is willful.

ANSWER: Teva denies the allegations in paragraph 61 of the Complaint.

62. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '127 patent, or any later expiration of any exclusivity or extension of the '127 patent to which Plaintiff or the patent may become entitled.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

63. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '127 patent by Defendants, together with interest and costs.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

64. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '127 patent.

ANSWER: Teva denies the allegations in paragraph 64 of the Complaint.

65. Plaintiff has no adequate remedy at law.

ANSWER: Teva denies the allegations in paragraph 65 of the Complaint.

66. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Teva denies the allegations in paragraph 66 of the Complaint.

COUNT IV FOR INFRINGEMENT OF U.S. PATENT NO. 8,318,202

67. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-66 of the Complaint

ANSWER: Teva incorporates by reference its responses to paragraphs 1-66 of the Complaint as if fully set forth herein.

68. The '202 Patent issued on November 27, 2012, and will expire no earlier than July 18, 2026.

ANSWER: Teva admits that the '202 patent issued on November 13, 2012 and avers that the '202 patent speaks for itself as to its contents and duration. Teva denies that the '202 Patent was duly and legally issued.

69. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the '202 patent expires, Defendants have infringed the '202 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva denies the allegations in paragraph 69 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action.

70. Defendants' commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the '202 patent, also would infringe, either literally or under the doctrine of equivalents, the '202 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Teva denies the allegations in paragraph 70 of the Complaint.

71. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the '202 patent.

ANSWER: Teva denies the allegations in paragraph 71 of the Complaint.

72. Upon information and belief, Defendants had actual and constructive notice of the '202 patent as of its issue date, and Defendants' infringement of the '202 patent is willful.

ANSWER: Teva denies the allegations in paragraph 72 of the Complaint.

73. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration of the '202 patent, or any later expiration of any exclusivity or extension of the '202 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '202 patent, or any later expiration of any exclusivity or extension of the '202 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '202 patent, or any later expiration of any exclusivity or extension of the '202 patent to which Plaintiff or the patent may become entitled.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

74. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the '202 patent by Defendants, together with interest and costs.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

75. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '202 patent.

ANSWER: Teva denies the allegations in paragraph 75 of the Complaint.

76. Plaintiff has no adequate remedy at law.

ANSWER: Teva denies the allegations in paragraph 76 of the Complaint.

77. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Teva denies the allegations in paragraph 77 of the Complaint.

COUNT V FOR INFRINGEMENT OF U.S. PATENT NO. 8,449,910

78. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-77 of the Complaint

ANSWER: Teva incorporates by reference its responses to paragraphs 1-77 of the Complaint as if fully set forth herein.

79. The '910 Patent issued on May 28, 2013, and will expire no earlier than July 18, 2026.

ANSWER: Teva admits that the '910 patent issued on May 28, 2013 and avers that the '910 patent speaks for itself as to its contents and duration. Teva denies that the '910 Patent was duly and legally issued.

80. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the '910 patent expires, Defendants have infringed the '910 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva denies the allegations in paragraph 80 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a "Defendant" to this action.

81. Defendants' commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the '910 patent, also would infringe, either literally or under the doctrine of equivalents, the '910 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Teva denies the allegations in paragraph 81 of the Complaint.

82. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the '910 patent.

ANSWER: Teva denies the allegations in paragraph 82 of the Complaint.

83. Upon information and belief, Defendants had actual and constructive notice of the '910 patent as of its issue date, and Defendants' infringement of the '910 patent is willful.

ANSWER: Teva denies the allegations in paragraph 83 of the Complaint.

84. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva's ANDA be a date that is not earlier than the expiration of the '910 patent, or any later expiration of any exclusivity or extension of the '910 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the '910 patent, or any later expiration of any exclusivity or extension of the '910 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the '910 patent, or any later expiration of any exclusivity or extension of the '910 patent to which Plaintiff or the patent may become entitled.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

85. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the '910 patent by Defendants, together with interest and costs.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

86. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '910 patent.

ANSWER: Teva denies the allegations in paragraph 86 of the Complaint.

87. Plaintiff has no adequate remedy at law.

ANSWER: Teva denies the allegations in paragraph 87 of the Complaint.

88. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Teva denies the allegations in paragraph 88 of the Complaint.

COUNT VI FOR INFRINGEMENT OF U.S. PATENT NO. 8,501,228

89. Plaintiff re-alleges and incorporates by reference the allegations of paragraphs 1-88 of the Complaint

ANSWER: Teva incorporates by reference its responses to paragraphs 1-88 of the Complaint as if fully set forth herein.

90. The '228 Patent issued on August 6, 2013, and will expire no earlier than July 18, 2026.

ANSWER: Teva admits that the '228 patent issued on May 28, 2013 and avers that the '228 patent speaks for itself as to its contents and duration. Teva denies that the '228 Patent was duly and legally issued.

91. By submitting and seeking approval of the Teva ANDA, and also seeking approval to engage in the commercial manufacture, use, offer to sell, sale or importation of the Teva Product, prior to date on which the '228 patent expires, Defendants have infringed the '228 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

ANSWER: Teva denies the allegations in paragraph 91 of the Complaint. Further, to the extent the allegations in this paragraph are directed to Teva Ltd., which is no longer a party to this case, no response is required. To the extent a response is required, Teva denies that Teva Ltd. is a “Defendant” to this action.

92. Defendants’ commercial manufacture, use, offer to sell, or sale of the Teva Product within the United States, or importation of the Teva Product into the United States, during the term of the ’228 patent, also would infringe, either literally or under the doctrine of equivalents, the ’228 patent under 35 U.S.C. § 271(a), (b) and/or (c).

ANSWER: Teva denies the allegations in paragraph 92 of the Complaint.

93. Upon approval of the Teva ANDA, and commercialization of the Teva Product, Defendants will actively induce and/or contribute to infringement of the ’228 patent.

ANSWER: Teva denies the allegations in paragraph 93 of the Complaint.

94. Upon information and belief, Defendants had actual and constructive notice of the ’228 patent as of its issue date, and Defendants’ infringement of the ’228 patent is willful.

ANSWER: Teva denies the allegations in paragraph 94 of the Complaint.

95. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including: (i) an order of this Court that the effective date of the approval of Teva’s ANDA be a date that is not earlier than the expiration of the ’228 patent, or any later expiration of any exclusivity or extension of the ’228 patent to which Plaintiff or the patent may become entitled; (ii) an order of this Court enjoining Teva from commercially manufacturing, using, offering to sell, selling within the United States, or importing into the United States, the Teva Product prior to the expiration of the ’228 patent, or any later expiration of any exclusivity or extension of the ’228 patent to which Plaintiff or the patent may become entitled; and (iii) damages against Teva to the extent Teva commercially manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, the Teva Product prior to the expiration of the ’228 patent, or any later expiration of any exclusivity or extension of the ’228 patent to which Plaintiff or the patent may become entitled.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

96. Plaintiff is entitled to the relief provided by 35 U.S.C. § 284, including, *inter alia*, damages adequate to compensate Plaintiff for infringement, but not less than a reasonable royalty and/or lost profits for the use made of the invention of the ’228 patent by Defendants, together with interest and costs.

ANSWER: Teva denies that Plaintiff is entitled to any relief.

97. Plaintiff will be substantially and irreparably harmed if Defendants are not enjoined from infringing or actively inducing or contributing to the infringement of the '228 patent.

ANSWER: Teva denies the allegations in paragraph 97 of the Complaint.

98. Plaintiff has no adequate remedy at law.

ANSWER: Teva denies the allegations in paragraph 98 of the Complaint.

99. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

ANSWER: Teva denies the allegations in paragraph 99 of the Complaint.

JURY TRIAL DEMANDED

Teva denies that Plaintiff is entitled to a trial by jury.

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.

AFFIRMATIVE DEFENSES

Teva hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. Teva reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The filing of Teva's ANDA has not infringed and does not infringe any valid and enforceable claim of United States Patent Nos. 8,067,033 ("the '033 patent"), 8,067,451 ("the '451 patent"), 8,309,127 ("the '127 patent"), 8,318,202 ("the '202 patent"), 8,449,910 ("the '910 patent"), and 8,501,228 ("the '228 patent") (collectively, the "Asserted Patents"), either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Affirmative Defense

The manufacture, use, sale, or offer for sale of Teva's proposed ANDA Product that is the subject of Teva's ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claims of the '033, '451, '127, '202, '910, and '228 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

Third Affirmative Defense

Claims of the '033, '451, '127, '202, '910, and '228 patents are invalid under one or more provisions of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

Fourth Affirmative Defense

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

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

Teva has not willfully infringed any claim of the '033, '451, '127, '202, '910, or '228 patent.

Seventh Affirmative Defense

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

Eighth Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiff/Counterclaim-Defendant Horizon Medicines, LLC (“Horizon”), Defendant/Counterclaimant Teva Pharmaceuticals USA, Inc. (“Teva”) states as follows:

PARTIES

1. Teva Pharmaceuticals USA, 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.

2. On information and belief, Horizon is a corporation duly existing and operating under the laws of the State of Delaware with a principal place of business located at 150 S. Saunders Rd., Lake forest, Illinois 60045.

JURISDICTION AND VENUE

3. These counterclaims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

4. These counterclaims arise under the patent laws of the United States, Title 35 of the United States Code. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

5. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant Horizon because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its Complaint here.

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

7. There is an actual and justiciable controversy between the parties as to the infringement of United States Patent Nos. 8,067,033 (“the ’033 patent”), 8,067,451 (“the ’451

patent”), 8,309,127 (“the ’127 patent”), 8,318,202 (“the ’202 patent”), 8,449,910 (“the ’910 patent”), and 8,501,228 (“the ’228 patent”).

FACTUAL BACKGROUND

A. FDA Approval of New Brand Name Drugs.

8. 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.

9. 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.

10. 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).

11. 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).

12. 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.

B. FDA Approval of New Generic Drugs.

13. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FDCA. *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.

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

15. 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).

16. 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).

17. 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).

18. 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).

19. 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).

20. 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 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.*

C. **Teva's ANDA**

21. Teva submitted its ANDA No. 211278 (“Teva's ANDA”) seeking approval to engage in the commercial use, sale, offer for sale or importation into the United States of ibuprofen and famotidine tablets, 800 mg/26.6 mg (“Teva's Proposed Products”) before the expiration of the '033, '451, '127, '202, '910 and '228 patents.

22. On information and belief, FDA lists Horizon as the holder of New Drug Application (“NDA”) No. 025519.

23. On information and belief, NDA No. 025519 covers Horizon's DUEXIS®.

24. On information and belief, Horizon lists the '033, '451, '127, '202, '910 and '228 patents in the Orange Book in connection with NDA No. 025519.

25. Teva's ANDA includes a Paragraph IV certification with respect to the '033, '451, '127, '202, '910 and '228 patents.

26. On September 26, 2018, Teva sent a Notice Letter (“Teva's Notice Letter”) to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '033, '451, '127, '202, '910 and '228 patents are 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 Products.

27. 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 Horizon the opportunity to review the relevant portions of Teva's ANDA.

28. Horizon filed a complaint against Teva on July 2, 2020 in *Horizon Medicines LLC v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 2:20-cv-08188 (D.N.J.), alleging that Teva has infringed and will infringe the '033, '451, '127, '202, '910 and '228 patents by filing ANDA No. 211278 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

29. As a consequence of the foregoing, there is an actual and justiciable controversy between Teva, on the one hand, and Horizon, on the other hand, as to whether the claims of the '033, '451, '127, '202, '910 and '228 patents are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by Teva's ANDA No. 211278, or by the manufacture, use, or sale of the products described therein.

COUNT I
(Declaration of Noninfringement of the '033 Patent)

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

31. Horizon alleges ownership, title, and/or interest to the '033 patent and has brought claims against Teva alleging infringement of the '033 patent.

32. The manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '033 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

33. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '033 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 Products.

34. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Horizon, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Products would infringe any valid or enforceable claim of the '033 patent.

35. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '033 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
(Declaration of Invalidity of the '033 Patent)

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

38. Horizon alleges ownership, title, and/or interest to the '033 patent and has brought claims against Teva alleging infringement of the '033 patent.

39. One or more of the claims of the '033 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

40. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '033 patent is invalid.

41. A present, genuine, and justiciable controversy exists between Teva and Horizon regarding, *inter alia*, the validity of claims of the '033 patent.

42. Teva is entitled to a declaration that claims of the '033 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.

COUNT III
(Declaration of Noninfringement of the '451 Patent)

44. Teva re-alleges and incorporates the allegations of paragraphs 1-43 as if fully set forth herein.

45. Horizon alleges ownership, title, and/or interest to the '451 patent and have brought claims against Teva alleging infringement of the '451 patent.

46. The manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '451 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

47. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '451 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 Products.

48. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Horizon, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Products would infringe any valid or enforceable claim of the '451 patent.

49. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '451 patent.

50. 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 IV
(Declaration of Invalidity of the '451 Patent)

51. Teva re-alleges and incorporates the allegations of paragraphs 1-50 as if fully set forth herein.

52. Horizon alleges ownership, title, and/or interest to the '451 patent and have brought claims against Teva alleging infringement of the '451 patent.

53. One or more of the claims of the '451 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

54. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '451 patent is invalid.

55. A present, genuine, and justiciable controversy exists between Teva and Horizon regarding, *inter alia*, the validity of claims of the '451 patent.

56. Teva is entitled to a declaration that claims of the '451 patent are invalid.

57. 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 V
(Declaration of Noninfringement of the '127 Patent)

58. Teva re-alleges and incorporates the allegations of paragraphs 1-57 as if fully set forth herein.

59. Horizon alleges ownership, title, and/or interest to the '127 patent and has brought claims against Teva alleging infringement of the '127 patent.

60. The manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '127 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

61. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '127 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 Products.

62. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Horizon, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Products would infringe any valid or enforceable claim of the '127 patent.

63. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '127 patent.

64. 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 VI
(Declaration of Invalidity of the '127 Patent)

65. Teva re-alleges and incorporates the allegations of paragraphs 1-64 as if fully set forth herein.

66. Horizon alleges ownership, title, and/or interest to the '127 patent and has brought claims against Teva alleging infringement of the '127 patent.

67. One or more of the claims of the '127 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

68. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '127 patent is invalid.

69. A present, genuine, and justiciable controversy exists between Teva and Horizon regarding, *inter alia*, the validity of claims of the '127 patent.

70. Teva is entitled to a declaration that claims of the '127 patent are invalid.

71. 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 VII
(Declaration of Noninfringement of the '202 Patent)

72. Teva re-alleges and incorporates the allegations of paragraphs 1-71 as if fully set forth herein.

73. Horizon alleges ownership, title, and/or interest to the '202 patent and has brought claims against Teva alleging infringement of the '202 patent.

74. The manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '202 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

75. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '202 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 Products.

76. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Horizon, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Products would infringe any valid or enforceable claim of the '202 patent.

77. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '202 patent.

78. 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 VIII
(Declaration of Invalidity of the '202 Patent)

79. Teva re-alleges and incorporates the allegations of paragraphs 1-78 as if fully set forth herein.

80. Horizon alleges ownership, title, and/or interest to the '202 patent and has brought claims against Teva alleging infringement of the '202 patent.

81. One or more of the claims of the '202 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

82. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '202 patent is invalid.

83. A present, genuine, and justiciable controversy exists between Teva and Horizon regarding, *inter alia*, the validity of claims of the '202 patent.

84. Teva is entitled to a declaration that claims of the '202 patent are invalid.

85. 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 IX
(Declaration of Noninfringement of the '910 Patent)

86. Teva re-alleges and incorporates the allegations of paragraphs 1-85 as if fully set forth herein.

87. Horizon alleges ownership, title, and/or interest to the '910 patent and has brought claims against Teva alleging infringement of the '910 patent.

88. The manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '910 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

89. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '910 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 Products.

90. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Horizon, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Products would infringe any valid or enforceable claim of the '910 patent.

91. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '910 patent.

92. 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 X
(Declaration of Invalidity of the '910 Patent)

93. Teva re-alleges and incorporates the allegations of paragraphs 1-92 as if fully set forth herein.

94. Horizon alleges ownership, title, and/or interest to the '910 patent and has brought claims against Teva alleging infringement of the '910 patent.

95. One or more of the claims of the '910 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

96. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '910 patent is invalid.

97. A present, genuine, and justiciable controversy exists between Teva and Horizon regarding, *inter alia*, the validity of claims of the '910 patent.

98. Teva is entitled to a declaration that claims of the '910 patent are invalid.

99. 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 XI
(Declaration of Noninfringement of the '228 Patent)

100. Teva re-alleges and incorporates the allegations of paragraphs 1-99 as if fully set forth herein.

101. Horizon alleges ownership, title, and/or interest to the '228 patent and has brought claims against Teva alleging infringement of the '228 patent.

102. The manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '228 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

103. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '228 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 Products.

104. A present, genuine, and justiciable controversy exists between Teva, on the one hand, and Horizon, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Teva's Proposed Products would infringe any valid or enforceable claim of the '228 patent.

105. Teva is entitled to a declaration that the manufacture, use, or sale of Teva's Proposed Products would not infringe any valid or enforceable claim of the '228 patent.

106. 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 XII
(Declaration of Invalidity of the '228 Patent)

107. Teva re-alleges and incorporates the allegations of paragraphs 1-106 as if fully set forth herein.

108. Horizon alleges ownership, title, and/or interest to the '228 patent and has brought claims against Teva alleging infringement of the '228 patent.

109. One or more of the claims of the '228 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

110. On September 26, 2018, Teva sent a Notice Letter to Horizon providing a detailed statement of the factual and legal bases, which are incorporated herein by reference, for its opinion that the '228 patent is invalid.

111. A present, genuine, and justiciable controversy exists between Teva and Horizon regarding, *inter alia*, the validity of claims of the '228 patent.

112. Teva is entitled to a declaration that claims of the '228 patent are invalid.

113. 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 Counterclaim-Defendant Horizon as follows:

1. Declaring that Teva has not infringed any valid and enforceable claim of the U.S. Patent No. 8,067,033;
2. Declaring that the claims of U.S. Patent No. 8,067,033 are invalid;
3. Declaring that Teva has not infringed any valid and enforceable claim of the U.S. Patent No. 8,067,451;
4. Declaring that the claims of U.S. Patent No. 8,067,451 are invalid;
5. Declaring that Teva has not infringed any valid and enforceable claim of the U.S. Patent No. 8,309,127;
6. Declaring that the claims of U.S. Patent No. 8,309,127 are invalid;
7. Declaring that Teva has not infringed any valid and enforceable claim of the U.S. Patent No. 8,318,202;
8. Declaring that the claims of U.S. Patent No. 8,318,202 are invalid;
9. Declaring that Teva has not infringed any valid and enforceable claim of the U.S. Patent No. 8,449,910;
10. Declaring that the claims of U.S. Patent No. 8,449,910 are invalid;

11. Declaring that Teva has not infringed any valid and enforceable claim of the U.S. Patent No. 8,501,228;
12. Declaring that the claims of U.S. Patent No. 8,501,228 are invalid;
13. 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
14. Awarding Teva any further and additional relief as the Court deems just and proper.

Dated: August 14, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 14, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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Teva Pharmaceuticals USA, Inc.*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant/Counterclaimant Teva Pharmaceuticals USA, 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: August 14, 2020

WALSH PIZZI O'REILLY FALANGA LLP

s/Liza M. Walsh

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