IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS COMPANY GMBH AND RAKS PHARMA PVT. LTD., Defendants.	C.A. No. 19-1952-LPS

ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS AMNEAL PHARMACEUTICALS LLC, AMNEAL PHAMACEUTICALS COMPANY GMBH, AND RAKS PHARMA PVT. LTD.

Defendants Amneal Pharmaceuticals LLC ("Amneal LLC"), Amneal Pharmaceuticals Company GmbH ("Amneal GmbH"), and Raks Pharma Pvt. Ltd. ("Raks") (collectively, "Amneal"), by and through their undersigned attorneys, answer the averments made in the numbered paragraphs of the Complaint filed by Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") as set forth below. Pursuant to Fed. R. Civ. P. 8(b)(3), Amneal denies all allegations in Plaintiffs' Complaint except those specifically admitted below. All responses from Amneal are made solely on behalf of Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals Company GmbH, and Raks Pharma Pvt. Ltd., and no response is made to any allegation that is directed to Amneal Pharmaceuticals, Inc., which was previously dismissed from the above-captioned action. (*See* D.I. 11.)

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Amneal's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use and/or sale of generic pharmaceutical products before the expiration of the patents in suit.

ANSWER: Paragraph 1 is proffered as a legal conclusion to which no response is required. To the extent an answer is required, Amneal admits that the Plaintiffs filed an action for purported patent infringement of U.S. Patent Nos. 7,888,362 ("the '362 patent"), 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent"), and 10,307,419 ("the '419 patent") (collectively, "patents in suit"). Amneal further admits that Amneal GmbH, through Amneal LLC, filed Abbreviated New Drug Application ("ANDA") No. 212562 to obtain approval from the U.S. Food and Drug Administration ("FDA") to market generic pharmaceutical products before the expiration of the patents in suit. Amneal does not contest that Plaintiffs' action arises under the patent laws of the United States, 35 U.S.C. § 100, *et. seq.*, including 35 U.S.C. §§ 271 and 281. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 1 of the Complaint.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

ANSWER: Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 2, and therefore denies the allegations therein.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the '362, '840, '109, '637 and '419 patents.

ANSWER: Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies the allegations therein.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

ANSWER: Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies the allegations therein.

5. Upon information and belief, Amneal Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

ANSWER: Pursuant to the stipulation filed on January 22, 2020 (D.I. 11) and granted on January 27, 2020, all counts directed to Amneal Pharmaceuticals, Inc. have been dismissed. Accordingly, the factual allegations contained in Paragraph 5 require no response, and Amneal therefore denies the allegations therein.

6. Upon information and belief, Amneal LLC is a limited liability company organized under the laws of Delaware and its principal place of business is located at 400 Crossing Boulevard, Bridgewater, NJ 08807. Upon information and belief, Amneal LLC is a wholly owned subsidiary of Amneal Inc.

ANSWER: Amneal admits that Amneal LLC is a limited liability company organized under the laws of the State of Delaware, having a principal place of business at 400 Crossing Boulevard, Bridgewater, New Jersey 08807. Amneal admits that Amneal LLC is a wholly owned subsidiary of Amneal Pharmaceuticals, Inc.

7. Upon information and belief, Amneal GmbH is a limited liability company organized under the laws of Switzerland and its principal place of business is located at Turmstrasse 30 5312, Steinhausen, Switzerland. Upon information and belief, Amneal GmbH is a wholly owned subsidiary of Amneal Inc. and Amneal LLC.

ANSWER: Amneal admits that Amneal GmbH is a limited liability company organized under the laws of Switzerland and its principal place of business is located at Turmstrasse 30 6312, Steinhausen, Switzerland. Amneal admits that Amneal GmbH is a wholly owned subsidiary

of Amneal Pharmaceuticals, Inc. and Amneal LLC.

8. Upon information and belief, Raks is a corporation organized under the laws of India and its principal place of business is located at Plot No. 68, Survey No. 60, 62 & 63, Jawaharlal Nehru Pharma City, E-Bonangi Revenue Village, Parawada Mandal, Visakhapatnam 531 021, Andhra Pradesh, India. Upon information and belief, Raks is a wholly owned subsidiary of Amneal Inc. and Amneal LLC.

ANSWER: Amneal admits that Raks is a corporation organized under the laws of India and its principal place of business is located at Plot No. 68, Survey No. 60, 62 & 63, Jawaharlal Nehru Pharma City, E-Bonangi Revenue Village, Parawada Mandal, Visakhapatnam 531 021, Andhra Pradesh, India. Amneal admits that Raks is a wholly owned subsidiary of Amneal Pharmaceuticals, Inc. and Amneal LLC.

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 9 is proffered as a legal conclusion to which no response is required. To the extent that a response is required, and solely for the purposes of this litigation, Amneal does not contest that this Court has jurisdiction over the subject matter of the Complaint, pursuant to 28 U.S.C. §§ 1331 and 1338(a). Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 9 of the Complaint.

10. This Court has personal jurisdiction over Amneal Inc. Upon information and belief, Amneal Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

ANSWER: Paragraph 10 is proffered as a legal conclusion to which no response is required. Further, pursuant to the stipulation filed on January 22, 2020 (D.I. 11) and granted on January 27, 2020, all counts directed to Amneal Pharmaceuticals, Inc. have been dismissed.

Accordingly, the factual allegations contained in Paragraph 10 require no response, and Amneal therefore denies the allegations therein.

11. Upon information and belief, Amneal Inc. admits it has a "generics portfolio of more than 300 medicines" in the United States. https://www.amneal.com/products/our-portfolio (accessed Oct. 12, 2019). Upon information and belief, Amneal Inc. admits its "generic business has grown to be among the largest in the U.S." https://www.amneal.com/products/our-portfolio/generic-products (accessed Oct. 12, 2019).

ANSWER: Pursuant to the stipulation filed on January 22, 2020 (D.I. 11) and granted on January 27, 2020, all counts directed to Amneal Pharmaceuticals, Inc. have been dismissed. Accordingly, the factual allegations contained in Paragraph 11 require no response, and Amneal therefore denies the allegations therein.

12. This Court has personal jurisdiction over Amneal LLC. Upon information and belief, Amneal LLC is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal LLC directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal LLC purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

ANSWER: Paragraph 12 is proffered as a legal conclusion to which no response is required. To the extent a response is required, and solely for the purposes of this litigation, Amneal does not contest that this Court has personal jurisdiction over Amneal LLC. Amneal admits that Amneal LLC manufactures and/or distributes generic pharmaceutical versions of branded products for sale and use throughout the United States, including the State of New Jersey. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 12 of the Complaint.

13. Upon information and belief, Amneal LLC "is a generic pharmaceutical company specializing in developing, manufacturing, marketing and distributing high-value generic pharmaceutical products across a broad array of dosage forms and therapeutic areas." Amneal Pharmaceuticals, Inc., Final Prospectus Filed Pursuant to Rule 424(b)(3) 10 (May 9, 2018).

ANSWER: Paragraph 13 is proffered as a legal conclusion to which no response is

required. To the extent a response is required, Amneal admits that the website states Amneal LLC "is a generic pharmaceutical company specializing in developing, manufacturing, marketing and distributing high-value generic pharmaceutical products across a broad array of dosage forms and therapeutic areas." Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 13 of the Complaint.

14. Upon information and belief, Amneal LLC has active pharmacy wholesale licenses in the state of Delaware with license numbers A4-0002541, A4-0002542 and A4-0002655, and active controlled substances distributor/manufacturer licenses in the state of Delaware with the license numbers DM-0013197 and DM-0013893.

ANSWER: Amneal admits that Amneal LLC is the holder of active pharmacy wholesale licenses in the State of Delaware with license numbers A4-0002541, A4-0002542 and A4-0002655. Amneal admits that Amneal LLC is the holder of active controlled substances distributor/manufacturer licenses in the State of Delaware with license numbers DM-0013197 and DM-0013893. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 14 of the Complaint.

15. This Court has personal jurisdiction over Amneal GmbH. Upon information and belief, Amneal GmbH is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal GmbH directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal GmbH purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

ANSWER: Paragraph 15 is proffered as a legal conclusion to which no response is required. To the extent a response is required, and solely for purposes of this litigation, Amneal does not contest personal jurisdiction of the Court over Amneal GmbH. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 15 of the Complaint.

16. Upon information and belief, Amneal GmbH is the international headquarters for Amneal. https://www.amneal.com/contact (accessed Oct. 12, 2019).

ANSWER: Paragraph 16 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that the website https://www.amneal.com/contact lists Amneal GmbH as "International Headquarters" for Amneal. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 16 of the Complaint.

17. Upon information and belief, Amneal GmbH is engaged in the development and/or manufacturing of Amneal's generic products. Upon information and belief, Amneal GmbH applied for one or more patent applications directed to the preparation of brexpiprazole. *See, e.g.*, International Publication No. WO 2018/172463, titled "Process for the Preparation of Brexpiprazole," designating the United States for the national phase.

ANSWER: Paragraph 17 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that Amneal GmbH is engaged in development and/or manufacturing of Amneal's generic products. Amneal admits that Amneal GmbH applied for one or more patent applications directed to the preparation of brexpiprazole, including International Publication No. WO 2018/172463, titled "Process for the Preparation of Brexpiprazole. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 17 of the Complaint.

18. This Court has personal jurisdiction over Raks. Upon information and belief, Raks is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Raks directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Raks purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

ANSWER: Paragraph 18 is proffered as a legal conclusion to which no response is required. To the extent a response is required, and solely for purposes of this litigation, Amneal does not contest personal jurisdiction of the Court over Raks. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 18 of the Complaint.

19. Upon information and belief, Raks is the holder of FDA Drug Master File No.33451 for brexpiprazole.

ANSWER: Amneal admits that Raks is the holder of Drug Master File No. 33451, whose subject is brexpiprazole. Except as expressly admitted, Amneal denies any remaining allegations in Paragraph 19 of the Complaint.

20. Upon information and belief, Amneal Inc., Amneal LLC, Amneal GmbH and Raks hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: Paragraph 20 is proffered as a legal conclusion to which no response is required. To the extent Paragraph 20 contains factual allegations directed to Amneal Inc., no response is required. Amneal denies the remaining allegations in Paragraph 20 of the Complaint.

21. Amneal's ANDA filing regarding the patents in suit relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Amneal's intent to market and sell Amneal's generic products in this judicial district.

ANSWER: Paragraph 21 is proffered as a legal conclusion to which no response is required. To the extent a response is required, and solely for purposes of this litigation, Amneal does not contest personal jurisdiction of the Court or venue in this judicial district. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 21 of the Complaint.

22. Amneal has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Amneal intends to direct sales of its generic drugs in this judicial district, among other places, once Amneal receives the requested FDA approval to market its generic products. Upon information and belief, Amneal will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

ANSWER: Paragraph 22 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that Amneal GmbH, through Amneal LLC, filed an ANDA with the FDA, seeking approval of Amneal's ANDA Product.

Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 22 of the Complaint.

23. Upon information and belief, Amneal has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of ANDA No. 212562.

ANSWER: Paragraph 23 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that Amneal GmbH, through Amneal LLC, drafted and submitted ANDA No. 212562 with the FDA, seeking approval of Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 23 of the Complaint.

24. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Amneal Inc. and Amneal LLC are incorporated in the state of Delaware.

ANSWER: Paragraph 24 is proffered as a legal conclusion to which no response is required. To the extent Paragraph 24 contains factual allegations directed to Amneal Inc., no response is required. To the extent a response is required, and solely for purposes of this litigation, Amneal does not contest personal jurisdiction or venue over Amneal LLC. Except as expressly admitted, Amneal LLC denies the remaining allegations in Paragraph 24 of the Complaint.

25. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Amneal GmbH is incorporated in Switzerland, Raks is incorporated in India and both may be sued in any judicial district.

ANSWER: Paragraph 25 is proffered as a legal conclusion to which no response is required. To the extent a response is required, and solely for purposes of this litigation, Amneal does not contest personal jurisdiction or venue of Amneal GmbH and Raks. Except as expressly admitted, Amneal GmbH and Raks deny the remaining allegations in Paragraph 25 of the Complaint.

FACTUAL BACKGROUND

The NDA

26. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets").

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), Otsuka is the purported holder of New Drug Application ("NDA") No. 205422 for REXULTI® brand brexpiprazole tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 26, and therefore denies the allegations therein.

27. The FDA approved NDA No. 205422 on July 10, 2015.

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the Orange Book, the approval date of NDA No. 205422 is listed as July 10, 2015. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 27, and therefore denies the allegations therein.

28. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

ANSWER: On information and belief, Amneal admits that the "Indication and Usage" section of the REXULTI® label states that REXULTI® is indicated for the treatment of Major Depressive Disorder (MDD) and the treatment of schizophrenia. On information and belief, Amneal further admits that the "Medication Guide" section of the label states brexpiprazole is the

active ingredient in REXULTI® Tablets. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 28, and therefore denies the allegations therein.

The Patents In Suit

29. The United States Patent and Trademark Office ("the PTO") issued the '362 patent on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '362 patent is attached as Exhibit A.

ANSWER: On information and belief, Amneal admits that the '362 patent is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and bears an issue date of February 15, 2011. Amneal further admits that Exhibit A to the Complaint purports to be a copy of the '362 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 29, and therefore denies the allegations therein.

30. Otsuka owns the '362 patent through assignment as recorded by the PTO at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

ANSWER: On information and belief, Amneal admits that what purports to be an assignment of the '362 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746; and Reel 048501, Frame 0122. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 30, and therefore denies the allegations therein.

31. The '362 patent currently expires on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed the 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the Orange Book, the expiration date

for the ’362 patent is listed as April 12, 2026. Amneal further admits that Exhibit B to the Complaint purports to be a copy of the terminal disclaimer. Amneal admits that Exhibit B states: “Assignee hereby disclaims, except as provided below, the terminal part of the statutory term of U.S. Patent No. 7,888,362 that would extend beyond April 12, 2026, which is equivalent to the 317 days of patent term adjustment granted to this patent under 35 U.S.C. § 154(b).” Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 31, and therefore denies the allegations therein.

32. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, which is attached as Exhibit C. In Exhibit C, Otsuka requests an extension under 35 U.S.C. § 156(c) of 986 days. Accordingly, the ’362 patent will expire on December 23, 2028, if granted the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

ANSWER: Amneal admits that what purports to be a copy of Otsuka’s Submission for Patent Term Extension for the ’362 patent is attached to the Complaint as Exhibit C. Amneal further admits that Exhibit C states: “the terminal disclaimer filed June 4, 2019 will change the original expiration date of the ‘362 Patent to April 12, 2026, change the period of § 156 term extension to 986 days, and change the expiration of the term extension to December 23, 2028.” Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 32, and therefore denies the allegations therein.

33. The ’362 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations (“the Orange Book”) in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

ANSWER: On information and belief, Amneal admits that according the Orange Book, the ‘362 patent is currently listed in connection with No. 205422 for REXULTI® brand brexpiprazole tablets. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 33, and therefore denies the allegations therein.

34. The PTO issued the ’840 patent on January 8, 2013, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’840 patent is attached as Exhibit D.

ANSWER: On information and belief, Amneal admits that the ’840 patent is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and bears an issue date of January 8, 2013. Amneal further admits that Exhibit D to the Complaint purports to be a copy of the ’840 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 34, and therefore denies the allegations therein.

35. Otsuka owns the ’840 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

ANSWER: On information and belief, Amneal admits that what purports to be an assignment of the ’840 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166 and Reel 048501, Frame 0122. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 35. Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 35, and therefore denies the allegations therein.

36. The ’840 patent is subject to a terminal disclaimer and expires on April 12, 2026.

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the Orange Book, the expiration date for the ’840 patent is listed as April 12, 2026. Amneal further admits that the PTO discloses a terminal disclaimer for the ’840 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 36, and therefore denies the allegations therein.

37. The ’840 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

ANSWER: On information and belief, Amneal admits that according the Orange Book, the '840 patent is currently listed in connection with No. 205422 for REXULTI® brand brexpiprazole tablets. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 37, and therefore denies the allegations therein.

38. The PTO issued the '109 patent on December 31, 2013, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders." A true and correct copy of the '109 patent is attached as Exhibit E.

ANSWER: On information and belief, Amneal admits that the '109 patent is entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders" and bears an issue date of December 31, 2013. Amneal further admits that Exhibit E to the Complaint purports to be a copy of the '109 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 38, and therefore denies the allegations therein.

39. Otsuka owns the '109 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

ANSWER: On information and belief, Amneal admits that what purports to be an assignment of the '109 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166 and Reel 048501, Frame 0122. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 39, and therefore denies the allegations therein.

40. The '109 patent is subject to a terminal disclaimer and expires on April 12, 2026.

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the Orange Book, the expiration date for the '109 patent is listed as April 12, 2026. Amneal further admits that the PTO discloses a

terminal disclaimer for the ’109 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 40, and therefore denies the allegations therein.

41. The ’109 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

ANSWER: On information and belief, Amneal admits that according the Orange Book, the ‘109 patent is currently listed in connection with No. 205422 for REXULTI® brand brexpiprazole tablets. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 41, and therefore denies the allegations therein.

42. The PTO issued the ’637 patent on December 12, 2017, entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders.” A true and correct copy of the ’637 patent is attached as Exhibit F.

ANSWER: On information and belief, Amneal admits that the ’637 patent is entitled “Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders” and bears an issue date of December 12, 2017. Amneal further admits that Exhibit F to the Complaint purports to be a copy of the ’637 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 42, and therefore denies the allegations therein.

43. Otsuka owns the ’637 patent through assignment as recorded by the PTO at Reel 048501, Frame 0166; Reel 021939, Frame 0746 and Reel 048501, Frame 0122.

ANSWER: On information and belief, Amneal admits that what purports to be an assignment of the ’637 patent to Otsuka was recorded by the PTO at Reel 048501, Frame 0166 and Reel 048501, Frame 0122. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 43, and therefore

denies the allegations therein.

44. The ’637 patent is subject to a terminal disclaimer and expires on April 12, 2026.

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the Orange Book, the expiration date for the ‘637 patent is listed as April 12, 2026. Amneal further admits that the PTO discloses a terminal disclaimer for the ’637 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 44, and therefore denies the allegations therein.

45. The ’637 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

ANSWER: On information and belief, Amneal admits that according the Orange Book, the ‘637 patent is currently listed in connection with No. 205422 for REXULTI® brand brexpiprazole tablets. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 45, and therefore denies the allegations therein.

46. The PTO issued the ’419 patent on June 4, 2019, entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof.” A true and correct copy of the ’419 patent is attached as Exhibit G.

ANSWER: On information and belief, Amneal admits that the ’419 patent is entitled “Tablet Comprising 7-[4-(4-benzo[b]thiopen-4-yl-piperazine-1-yl)butoxy]-1H-quinolin-2-one or a Salt Thereof” and bears an issue date of June 4, 2019. Amneal further admits that Exhibit G to the Complaint purports to be a copy of the ’419 patent. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 46, and therefore denies the allegations therein.

47. Otsuka owns the ’419 patent through assignment as recorded by the PTO at Reel

033930, Frame 0447.

ANSWER: Amneal is without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47, and therefore denies the allegations therein.

48. The ’419 patent expires on October 12, 2032.

ANSWER: On information and belief, Amneal admits that according to publicly available FDA information, such as the electronic version of the Orange Book, the expiration date for the ’419 patent is listed as October 12, 2032. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 48, and therefore denies the allegations therein.

49. The ’419 patent is listed in the Orange Book in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

ANSWER: On information and belief, Amneal admits that according the Orange Book, the ‘419 patent is currently listed in connection with No. 205422 for REXULTI® brand brexpiprazole tablets. Except as expressly admitted, Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 49, and therefore denies the allegations therein.

The ANDA

50. Upon information and belief, Amneal filed ANDA No. 212562 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use and/or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg (“Amneal’s generic products”), which are generic versions of Otsuka’s REXULTI® (brexpiprazole) Tablets.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA seeking approval to market Amneal’s proposed brexpiprazole 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg tablets. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 50 of the Complaint.

51. Upon information and belief, ANDA No. 212562 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the patents in suit are invalid, unenforceable and/or would not be infringed by Amneal's generic products.

ANSWER: Amneal admits that ANDA No. 212562 contains Paragraph IV Certifications asserting that the patents in suit are invalid, unenforceable, and/or would not be infringed by Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 51 of the Complaint.

52. Otsuka received a letter sent by Amneal, dated September 9, 2019, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 212562 ("Amneal's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I), (iv)(I) and 21 C.F.R. § 314.95(c). Amneal's Notice Letter notified Otsuka that Amneal had filed ANDA No. 212562, seeking approval to engage in the commercial manufacture, use and/or sale of Amneal's generic products before the expiration of the patents in suit.

ANSWER: Amneal admits that Amneal LLC sent a Notice Letter dated September 9, 2019, referencing submission of ANDA No. 212562, which included Paragraph IV Certifications. Amneal further admits that the Notice Letter notified Otsuka that Amneal LLC filed ANDA No. 212562, seeking approval to engage in the commercial manufacture, use and/or sale of Amneal's ANDA Product before the expiration of the patents in suit. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 52 of the Complaint.

53. Plaintiffs commenced this action within 45 days of receiving Amneal's September 9, 2019, Notice Letter.

ANSWER: Amneal is without knowledge or information sufficient to form a belief as the truth of the allegations in Paragraph 53, and therefore denies the allegations therein.

COUNT I

(INFRINGEMENT OF THE '362 PATENT)

54. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: Paragraph 54 contains no allegations of fact to which a response is required. To the extent an answer is required, Amneal repeats, realleges, and incorporates by reference paragraphs 1–53 of the Answer as if fully set forth herein.

55. Upon information and belief, Amneal filed ANDA No. 212562 seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the '362 patent.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA seeking approval to market Amneal's ANDA Product before the expiration of the '362 patent. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 55 of the Complaint.

56. Upon information and belief, Amneal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '362 patent are invalid, unenforceable and/or not infringed.

ANSWER: Amneal admits that ANDA No. 212562 contains Paragraph IV Certifications, pursuant to § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the patents in suit are invalid, unenforceable, and/or would not be infringed by Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 56 of the Complaint.

57. Upon information and belief, in its ANDA No. 212562, Amneal has represented to the FDA that Amneal's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 57 of the Complaint.

58. Amneal has actual knowledge of Otsuka's '362 patent, as evidenced by Amneal's

September 9, 2019, Notice Letter.

ANSWER: Paragraph 58 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that it is presently aware of the '362 patent. Amneal further admits that its Notice Letter referred to the '362 Patent. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 58 of the Complaint.

59. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed one or more claims of the '362 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212562, seeking approval to commercially manufacture, use, import, offer to sell or sell Amneal's generic products before the expiration date of the '362 patent.

ANSWER: Paragraph 59 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 59 of the Complaint.

60. Upon information and belief, if ANDA No. 212562 is approved, Amneal intends to and will offer to sell, sell and/or import in the United States Amneal's generic products.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 60 of the Complaint.

61. Upon information and belief, if ANDA No. 212562 is approved, Amneal will infringe one or more claims of the '362 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Amneal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 212562 shall be no earlier than the expiration of the '362 patent and any additional periods of exclusivity.

ANSWER: Paragraph 61 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 61 of the Complaint.

62. Upon information and belief, Amneal's actions relating to Amneal's ANDA No.212562 complained of herein were done by and for the benefit of Amneal.

ANSWER: Paragraph 62 is proffered as a legal conclusion to which no response is required. To the extent a response is required, the allegations of Paragraph 62 are vague as to which "actions" are referred to, which "Amneal" entity is being referenced, and which "benefits" the entity is purported to receive. Accordingly, Amneal denies the remaining allegations in Paragraph 62 of the Complaint.

63. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless this Court enjoins those activities.

ANSWER: Paragraph 63 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 63 of the Complaint.

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

ANSWER: Paragraph 64 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 64 of the Complaint.

COUNT II

(INFRINGEMENT OF THE '840 PATENT)

65. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: Paragraph 65 contains no allegations of fact to which a response is required. To the extent an answer is required, Amneal repeats, realleges, and incorporates by reference paragraphs 1–64 of the Answer as if fully set forth herein.

66. Upon information and belief, Amneal filed ANDA No. 212562 seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the '840 patent.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA seeking approval to market Amneal's ANDA Product before the expiration of the '840 patent. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 66 of the Complaint.

67. Upon information and belief, Amneal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '840 patent are invalid, unenforceable and/or not infringed.

ANSWER: Amneal admits that ANDA No. 212562 contains Paragraph IV Certifications, pursuant to § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the patents in suit are invalid, unenforceable, and/or would not be infringed by Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 67 of the Complaint.

68. Upon information and belief, in its ANDA No. 212562, Amneal has represented to the FDA that Amneal's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 68 of the Complaint.

69. Amneal has actual knowledge of Otsuka's '840 patent, as evidenced by Amneal's September 9, 2019, Notice Letter.

ANSWER: Paragraph 69 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that it was aware of the '840 patent at least as early as September 9, 2019. Amneal denies the remaining allegations of Paragraph 69.

70. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed one or more claims of the '840 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212562, seeking approval to commercially manufacture, use, import, offer to sell

or sell Amneal's generic products before the expiration date of the '840 patent.

ANSWER: Paragraph 70 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 70 of the Complaint.

71. Upon information and belief, if ANDA No. 212562 is approved, Amneal will infringe one or more claims of the '840 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Amneal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 212562 shall be no earlier than the expiration of the '840 patent and any additional periods of exclusivity.

ANSWER: Paragraph 71 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 71 of the Complaint.

72. Upon information and belief, Amneal knows, should know and intends that physicians will prescribe and patients will take Amneal's generic products for which approval is sought in ANDA No. 212562, and therefore will infringe at least one claim of the '840 patent.

ANSWER: Paragraph 72 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 72 of the Complaint.

73. Upon information and belief, Amneal has knowledge of the '840 patent and, by its proposed package insert for Amneal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '840 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 73 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 73 of the Complaint.

74. Upon information and belief, Amneal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Amneal's generic

products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '840 patent.

ANSWER: Paragraph 74 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 74 of the Complaint.

75. Upon information and belief, if ANDA No. 212562 is approved, Amneal intends to and will offer to sell, sell and/or import in the United States Amneal's generic products.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 75 of the Complaint.

76. Upon information and belief, Amneal's actions relating to Amneal's ANDA No.212562 complained of herein were done by and for the benefit of Amneal.

ANSWER: Paragraph 76 is proffered as a legal conclusion to which no response is required. To the extent a response is required, the allegations of Paragraph 76 are vague as to which "actions" are referred to, which "Amneal" entity is being referenced, and which "benefits" the entity is purported to receive. Accordingly, Amneal denies the remaining allegations in Paragraph 76 of the Complaint.

77. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless this Court enjoins those activities.

ANSWER: Paragraph 77 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 77 of the Complaint.

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

ANSWER: Paragraph 78 is proffered as a legal conclusion to which no response is

required. To the extent a response is required, Amneal denies the allegations of Paragraph 78 of the Complaint.

COUNT III

(INFRINGEMENT OF THE '109 PATENT)

79. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: Paragraph 79 contains no allegations of fact to which a response is required. To the extent an answer is required, Amneal repeats, realleges, and incorporates by reference paragraphs 1–78 of the Answer as if fully set forth herein.

80. Upon information and belief, Amneal filed ANDA No. 212562 seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the '109 patent.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA seeking approval to market Amneal's ANDA Product before the expiration of the '109 patent. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 80 of the Complaint.

81. Upon information and belief, Amneal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '109 patent are invalid, unenforceable and/or not infringed.

ANSWER: Amneal admits that ANDA No. 212562 contains Paragraph IV Certifications, pursuant to § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the patents in suit are invalid, unenforceable, and/or would not be infringed by Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 81 of the Complaint.

82. Upon information and belief, in its ANDA No. 212562, Amneal has represented to the FDA that Amneal's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 82 of the Complaint.

83. Amneal has actual knowledge of Otsuka's '109 patent, as evidenced by Amneal's September 9, 2019, Notice Letter.

ANSWER: Paragraph 83 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that it was aware of the '109 patent at least as early as September 9, 2019. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 83 of the Complaint.

84. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed one or more claims of the '109 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212562, seeking approval to commercially manufacture, use, import, offer to sell or sell Amneal's generic products before the expiration date of the '109 patent.

ANSWER: Paragraph 84 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 84 of the Complaint.

85. Upon information and belief, if ANDA No. 212562 is approved, Amneal will infringe one or more claims of the '109 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Amneal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 212562 shall be no earlier than the expiration of the '109 patent and any additional periods of exclusivity.

ANSWER: Paragraph 85 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 85 of the Complaint.

86. Upon information and belief, Amneal knows, should know and intends that physicians will prescribe and patients will take Amneal's generic products for which approval is

sought in ANDA No. 212562, and therefore will infringe at least one claim of the '109 patent.

ANSWER: Paragraph 86 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 86 of the Complaint.

87. Upon information and belief, Amneal has knowledge of the '109 patent and, by its proposed package insert for Amneal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '109 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 87 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 87 of the Complaint.

88. Upon information and belief, Amneal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Amneal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '109 patent.

ANSWER: Paragraph 88 is proffered as a legal conclusion to which no response is required. To the extent a response is required, denies the allegations of Paragraph 88 of the Complaint.

89. Upon information and belief, if ANDA No. 212562 is approved, Amneal intends to and will offer to sell, sell and/or import in the United States Amneal's generic products.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 89 of the Complaint.

90. Upon information and belief, Amneal's actions relating to Amneal's ANDA No.212562 complained of herein were done by and for the benefit of Amneal.

ANSWER: Paragraph 90 is proffered as a legal conclusion to which no response is

required. To the extent a response is required, the allegations of Paragraph 90 are vague as to which "actions" are referred to, which "Amneal" entity is being referenced, and which "benefits" the entity is purported to receive. Accordingly, Amneal denies the remaining allegations in Paragraph 90 of the Complaint.

91. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless this Court enjoins those activities.

ANSWER: Paragraph 91 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 91 of the Complaint.

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

ANSWER: Paragraph 92 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 92 of the Complaint.

COUNT IV

(INFRINGEMENT OF THE '637 PATENT)

93. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: Paragraph 93 contains no allegations of fact to which a response is required. To the extent an answer is required, Amneal repeats, realleges, and incorporates by reference paragraphs 1–92 of the Answer as if fully set forth herein.

94. Upon information and belief, Amneal filed ANDA No. 212562 seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the '637 patent.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA seeking approval to market Amneal's ANDA Product before the expiration of the '637 patent. Except as expressly admitted, Amneal denies the remaining

allegations in Paragraph 94 of the Complaint.

95. Upon information and belief, Amneal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '637 patent are invalid, unenforceable and/or not infringed.

ANSWER: Amneal admits that ANDA No. 212562 contains Paragraph IV Certifications, pursuant to § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the patents in suit are invalid, unenforceable, and/or would not be infringed by Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 95 of the Complaint.

96. Upon information and belief, in its ANDA No. 212562, Amneal has represented to the FDA that Amneal's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 96 of the Complaint.

97. Amneal has actual knowledge of Otsuka's '637 patent, as evidenced by Amneal's September 9, 2019, Notice Letter.

ANSWER: Paragraph 97 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that it was aware of the '637 patent at least as early as September 9, 2019. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 97 of the Complaint.

98. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed one or more claims of the '637 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212562, seeking approval to commercially manufacture, use, import, offer to sell or sell Amneal's generic products before the expiration date of the '637 patent.

ANSWER: Paragraph 98 is proffered as a legal conclusion to which no response is

required. To the extent a response is required, Amneal denies the allegations of Paragraph 98 of the Complaint.

99. Upon information and belief, if ANDA No. 212562 is approved, Amneal will infringe one or more claims of the '637 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Amneal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 212562 shall be no earlier than the expiration of the '637 patent and any additional periods of exclusivity.

ANSWER: Paragraph 99 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 99 of the Complaint.

100. Upon information and belief, Amneal knows, should know and intends that physicians will prescribe and patients will take Amneal's generic products for which approval is sought in ANDA No. 212562, and therefore will infringe at least one claim of the '637 patent.

ANSWER: Paragraph 100 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 100 of the Complaint.

101. Upon information and belief, Amneal has knowledge of the '637 patent and, by its proposed package insert for Amneal's generic products, knows or should know that it will induce direct infringement of at least one claim of the '637 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 101 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 101 of the Complaint.

102. Upon information and belief, Amneal is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Amneal's generic products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '637 patent.

ANSWER: Paragraph 102 is proffered as a legal conclusion to which no response is

required. To the extent a response is required, Amneal denies the allegations of Paragraph 102 of the Complaint.

103. Upon information and belief, if ANDA No. 212562 is approved, Amneal intends to and will offer to sell, sell and/or import in the United States Amneal's generic products.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval to market Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 103 of the Complaint.

104. Upon information and belief, Amneal's actions relating to Amneal's ANDA No.212562 complained of herein were done by and for the benefit of Amneal.

ANSWER: Paragraph 104 is proffered as a legal conclusion to which no response is required. To the extent a response is required, the allegations of Paragraph 104 are vague as to which "actions" are referred to, which "Amneal" entity is being referenced, and which "benefits" the entity is purported to receive. Accordingly, Amneal denies the remaining allegations in Paragraph 104 of the Complaint.

105. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless this Court enjoins those activities.

ANSWER: Paragraph 105 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 105 of the Complaint.

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

ANSWER: Paragraph 106 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 106 of the Complaint.

COUNT V

(INFRINGEMENT OF THE '419 PATENT)

107. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

ANSWER: Paragraph 107 contains no allegations of fact to which a response is required. To the extent an answer is required, Amneal repeats, realleges, and incorporates by reference paragraphs 1–106 of the Answer as if fully set forth herein.

108. Upon information and belief, Amneal filed ANDA No. 212562 seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the '419 patent.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 to the FDA seeking approval to market Amneal's ANDA Product before the expiration of the '419 patent. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 108 of the Complaint.

109. Upon information and belief, Amneal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '419 patent are invalid, unenforceable and/or not infringed.

ANSWER: Amneal admits that ANDA No. 212562 contains Paragraph IV Certifications, pursuant to § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), asserting that the patents in suit are invalid, unenforceable, and/or would not be infringed by Amneal's ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 109 of the Complaint.

110. Upon information and belief, in its ANDA No. 212562, Amneal has represented to the FDA that Amneal's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

ANSWER: Amneal admits that Amneal GmbH, through Amneal LLC, submitted ANDA No. 212562 with the FDA pursuant to 21 U.S.C. § 355(j), seeking approval of Amneal's

ANDA Product. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 110 of the Complaint.

111. Amneal has actual knowledge of Otsuka's '419 patent, as evidenced by Amneal's September 9, 2019, Notice Letter.

ANSWER: Paragraph 111 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal admits that it was aware of the '419 patent at least as early as September 9, 2019. Except as expressly admitted, Amneal denies the remaining allegations in Paragraph 111 of the Complaint.

112. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed one or more claims of the '419 patent by submitting, or causing to be submitted, to the FDA ANDA No. 212562, seeking approval to commercially manufacture, use, import, offer to sell or sell Amneal's generic products before the expiration date of the '419 patent.

ANSWER: Paragraph 112 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 112 of the Complaint.

113. Upon information and belief, if ANDA No. 212562 is approved, Amneal will infringe one or more claims of the '419 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Amneal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 212562 shall be no earlier than the expiration of the '419 patent and any additional periods of exclusivity.

ANSWER: Paragraph 113 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 113 of the Complaint.

114. Upon information and belief, Amneal's actions relating to Amneal's ANDA No.212562 complained of herein were done by and for the benefit of Amneal.

ANSWER: Paragraph 114 is proffered as a legal conclusion to which no response is required. To the extent a response is required, the allegations of Paragraph 114 are vague as to

which "actions" are referred to, which "Amneal" entity is being referenced, and which "benefits" the entity is purported to receive. Accordingly, Amneal denies the remaining allegations in Paragraph 114 of the Complaint.

115. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless this Court enjoins those activities.

ANSWER: Paragraph 115 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 115 of the Complaint.

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

ANSWER: Paragraph 116 is proffered as a legal conclusion to which no response is required. To the extent a response is required, Amneal denies the allegations of Paragraph 116 of the Complaint.

PRAYER FOR RELIEF

Amneal denies all remaining allegations not specifically admitted herein. Amneal denies that Plaintiffs are entitled to any judgement or relief against Amneal and therefore specifically denies paragraphs (A) through (H) of Plaintiffs' Request for Relief.

DEFENSES

Without prejudice to the denials set forth in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Amneal incorporates the above denials, and alleges and asserts below its defenses to the Complaint. Amneal reserves the right to seek leave to assert additional defenses based on the Court's claim construction and as it learns more information through discovery. Amneal does not assume the burden of proof with respect to those matters as to which, pursuant

to law, Plaintiffs bear the burden of proof.

First Defense

The proposed products of ANDA No. 212562 do not infringe, and would not infringe any valid and enforceable claim of the patents in suit either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Defense

The manufacture, use, sale, offer for sale, or importation of Amneal's ANDA Product has not infringed, does not infringe, and would not infringe any valid and enforceable claim of the patents in suit either directly or indirectly, and either literally or under the doctrine of equivalents.

Third Defense

The claims of the patents in suit are invalid and/or unenforceable under one or more provisions of 35 U.S.C. § 100, *et seq.*, such as sections 101, 102, 103, 112, 132, 156, and/or 253, or other judicially created bases for invalidation, such as double patenting.

Fourth Defense

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the patents in suit, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the patents in suit is infringed by the products that are the subject of Amneal's ANDA.

Fifth Defense

To the extent not encompassed by Defendants' Fourth Defense, Plaintiffs are estopped from construing the claims of the patents in suit to cover and include Amneal's ANDA Product.

Sixth Defense

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

Seventh Defense

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

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal, including unenforceability. Amneal reserves any and all defenses that are available under the Federal Rules of Civil Procedure, District of Delaware Local Rules, and the U.S. Patent Law as well as any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

Anne Shea Gaza

Anne Shea Gaza (No. 4093)
Robert M. Vrana (No. 5666)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
rvrana@ycst.com

Attorneys for Defendants

OF COUNSEL:
Kent M. Walker
Mary E. LaFleur
BRINKS GILSON & LIONE
455 North Cityfront Plaza Drive
Suite 3600
Chicago, Illinois 60611-5599
(312) 321-4200
kwalker@brinksgilson.com
mlafleur@brinksgilson.com

Dated: March 16, 2020

CERTIFICATE OF SERVICE

I, Anne Shea Gaza, Esquire, hereby certify that on March 16, 2020, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to all registered participants.

I further certify that on March 16, 2020**,** I caused the foregoing document to be served by e-mail on the following counsel of record:

Steven J. Balick
Andrew C. Mayo
ASHBY & GEDDES
500 Delaware Avenue
Eighth Floor
Wilmington, DE 19801
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

James B. Monroe
Denise Main
Erin M. Sommers
Tyler B. Latchum
C. Collette Corser
FINNEGAN, HENDERSON, FARABOW,
GARRETT &DUNNER,LLP
901 New York Avenue, N.W.
Washington, D.C. 20001-4431
james.monroe@finnegan.com
denise.main@finnegan.com
erin.sommers@finnegan.com
tyler.latcham@finnegan.com
collette.corser@finnegan.com

Attorneys for Plaintiff

Dated: March 16, 2020

YOUNG CONAWAY STARGATT & TAYLOR, LLP

/s/ Anne Shea Gaza

Anne Shea Gaza (No. 4093)
Robert M. Vrana (No. 5666)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
agaza@ycst.com
rvrana@ycst.com

Attorneys for Defendants