

Eric I. Abraham (eabraham@hillwallack.com)  
William P. Murtha (wmurtha@hillwallack.com)  
Kristine L. Butler (kbutler@hillwallack.com)

**HILL WALLACK LLP**

21 Roszel Road  
Princeton, NJ 085430  
Telephone: (609) 924-0808  
Facsimile: (609) 452-1888

*Of Counsel:*

William A. Rakoczy (*Pro Hac Vice*)  
Rachel Pernic Waldron (*Pro Hac Vice*)  
Steven J. Birkos (*Pro Hac Vice*)  
Scott Beall (*Pro Hac Vice*)  
Rebecca L. Neubauer (*Pro Hac Vice*)  
Dylan G. Sacenti (*Pro Hac Vice*)  
Claude Vandevender (*Pro Hac Vice*)  
Sarah M.L. Wilkening (*Pro Hac Vice*)  
**RAKOCZY MOLINO MAZZOCHI SIWIK LLP**  
6 West Hubbard Street, Suite 500  
Chicago, Illinois 60654  
(312) 527-2157

*Attorneys for Defendant/Counterclaim-Plaintiff Sandoz, Inc.*

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

AMNEAL PHARMACEUTICALS LLC,  
and IMPAX LABORATORIES, LLC,

Plaintiffs,

v.

SANDOZ INC.,

Defendant

Civil Action No. 3:25-cv-11981 (GC-TJB)

**DEFENDANT SANDOZ INC.'S ANSWER, DEFENSES, AND COUNTERCLAIMS TO  
PLAINTIFFS' FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Defendant/Counterclaim-Plaintiff Sandoz Inc. (“Sandoz” or “Defendant”), for its Answer, Defenses, and Counterclaims to the September 4, 2025 First Amended Complaint for Patent Infringement (Dkt. No. 1) (“25-cv-11981 First Amended Complaint”) of Plaintiffs Amneal Pharmaceuticals LLC (“Amneal”) and Impax Laboratories, LLC (“Impax”) (collectively “Plaintiffs”), responds as follows. Every allegation not expressly admitted herein is denied.

### **RESPONSE TO “NATURE OF THE ACTION”**

1. This is an Action for patent infringement arising under the food and drug laws and patent laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendant’s submission of an Abbreviated New Drug Application (“ANDA”) to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture and sell generic versions of Impax’s CREXONT® (carbidopa and levodopa) extended-release capsules prior to the expiration of United States Patent Nos. 12,201,596 (“the ’596 patent”), 12,263,148 (“the ’148 patent”), 12,263,149 (“the ’149 patent”), 12,274,793 (“the ’793 patent”), 12,295,931 (“the ’931 patent”), 12,303,481 (“the ’481 patent”), 12,303,482 (“the ’482 patent”), and 12,303,605 (“the ’605 patent”) (collectively, the “Patents-in-Suit”), and before the expiration dates of other patents listed in the Orange Book for CREXONT®.

**ANSWER:** Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs’ 25-cv-11981 First Amended Complaint purports to state a claim for alleged infringement of United States Patent Nos. 12,201,596 (“the ’596 patent”), 12,263,148 (“the ’148 patent”), 12,263,149 (“the ’149 patent”), 12,274,793 (“the ’793 patent”), 12,295,931 (“the ’931 patent”), 12,303,481 (“the ’481 patent”), 12,303,482 (“the ’482 patent”), and 12,303,605 (“the ’605 patent”). Further answering, Sandoz admits that it submitted Abbreviated New Drug Application (“ANDA”) No. 219989 seeking approval for carbidopa/levodopa capsules, extended release, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg strengths (collectively, “Sandoz’s ANDA Products”). Further answering, Sandoz admits that ANDA No. 219989 contains, inter alia, patent certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which state that the ’596, ’148, ’149, ’793, ’931, ’481, ’482, and ’605 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use,

or sale of Sandoz's ANDA Products. Sandoz denies any and all remaining allegations of Paragraph 1.

**RESPONSE TO "THE PARTIES"**

2. Plaintiff Impax is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Plaintiff Amneal is a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

**ANSWER:** Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz lacks knowledge or information sufficient to form a belief as to the truth of any and all remaining allegations of Paragraph 2, and therefore denies any and all remaining allegations of Paragraph 2.

3. On information and belief, Sandoz is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 100 College Road West, Princeton, New Jersey 08540-6604.

**ANSWER:** Paragraph 3 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it is a corporation organized and existing under the laws of the State of Delaware with a place of business at 100 College Road West, Princeton, NJ 08540. Sandoz denies any and all remaining allegations of Paragraph 3.

4. On information and belief, Sandoz is in the business of developing, preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including in the State of New Jersey.

**ANSWER:** Paragraph 4 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Sandoz denies any and all remaining allegations of Paragraph 4.

**RESPONSE TO “JURISDICTION AND VENUE”**

5. This Action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq.*, generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this Action under 28 U.S.C. §§ 1331 and 1338(a).

**ANSWER:** Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Plaintiffs’ 25-cv-11981 First Amended Complaint purports to state a claim under 35 U.S.C. § 271(e)(2). Further answering, Sandoz admits that subject matter jurisdiction is proper, if at all, solely for Plaintiffs’ alleged infringement claims against Sandoz under 35 U.S.C. § 271(e)(2)(A). Sandoz denies that subject matter jurisdiction is proper for any claims asserted against Sandoz under 35 U.S.C. § 271(a), (b), or (c). Sandoz denies any and all remaining allegations of Paragraph 5.

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

**ANSWER:** Paragraph 6 contains legal conclusions for which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only.

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

**ANSWER:** Paragraph 7 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 7.

8. On information and belief, Defendant directly or indirectly develops, manufactures,

imports, markets, distributes, and/or sells pharmaceutical products that are and/or will be manufactured and sold, pursuant to ANDA filings or other regulatory filings, throughout the United States, including in this Judicial District.

**ANSWER:** Paragraph 8 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 8.

9. On information and belief, Defendant develops and manufactures generic pharmaceutical products, which it then sells in the United States, the locations or operations of which are in, among other places, the State of New Jersey.

**ANSWER:** Paragraph 9 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 9.

10. On information and belief, this Judicial District will be a destination for the generic version of Impax's CREXONT® (carbidopa and levodopa) extended-release capsules for which Defendant seeks FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 219989.

**ANSWER:** Paragraph 10 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the

limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 10.

11. On information and belief, if the Sandoz ANDA (defined below) is approved, the Sandoz ANDA Products (defined below) will be marketed, distributed, and/or sold, directly or indirectly, by Defendant in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, on information and belief, if Defendant succeeds in obtaining FDA approval, Defendant will, directly or indirectly, market, distribute, and/or sell the Sandoz ANDA Products in the State of New Jersey.

**ANSWER:** Paragraph 11 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 11.

12. On information and belief, Sandoz is a corporation with its principal place of business in New Jersey and is qualified to do business in New Jersey.

**ANSWER:** Paragraph 12 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it has a place of business at 100 College Road West, Princeton, NJ 08540. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 12.

13. On information and belief, Sandoz is registered to do business in the State of New Jersey under Entity Identification Number 0100097265 and is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Number 5003732.

**ANSWER:** Paragraph 13 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100097265 (1979) and 0101056767 (2020), and that it is registered as a

manufacturer and wholesaler with the New Jersey Department of Health under Registration No. 5003732. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 13.

14. In view of the foregoing, Sandoz is subject to general personal jurisdiction in New Jersey.

**ANSWER:** Paragraph 14 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 14.

15. On information and belief, Sandoz is in the business of, *inter alia*: (a) developing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States, including throughout the State of New Jersey; (b) in concert with and/or through its affiliates, the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (c) alone or in concert with and/or through its affiliates, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

**ANSWER:** Paragraph 15 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 15.

16. On information and belief, Defendant intends to benefit directly if the Sandoz ANDA is approved by participating in the manufacture, importation, distribution, offer to sell, and/or sale of the generic drug products throughout the United States, including in the State of New Jersey, that are the subject of the Sandoz ANDA.

**ANSWER:** Paragraph 16 contains legal conclusions for which no answer is required.

To the extent an answer is required, Sandoz admits that it develops, manufactures, and sells pharmaceutical products in the United States, including quality generic medicines. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 16.

17. Sandoz has consented to and/or not contested personal jurisdiction in this Court in numerous recent actions arising out of its ANDA filings and has filed counterclaims in at least some of such cases. *See, e.g., AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civ. No. 3:25-cv-00231, Dkt. No. 12 (D.N.J. March 11, 2025); *Amneal Pharmaceuticals LLC et al v. Sandoz Inc.*, Civ. No. 3:25-cv-00181, Dkt. No. 34 (D.N.J. April 15, 2025); *Celgene Corporation v. Sandoz Inc.*, Civ. No. 3:18-11026, Dkt. No. 18 (D.N.J. Sept. 25, 2018); *Allergan Sales, LLC v. Sandoz, Inc.*, Civ. No. 2:17-10129, Dkt. No. 18 (D.N.J. Dec. 19, 2017); *Boehringer Ingelheim Pharms., Inc. v. Sandoz, Inc.*, Civ. No. 3:17-08825, Dkt. No. 14 (D.N.J. Jan. 23, 2018); *Mitsubishi Tanabe Pharma Corp. v. MSN Labs. Priv. Ltd.*, Civ. No. 1:17-05302, Dkt. No. 28 (D.N.J. Nov. 17, 2017) (collectively, the “Prior Actions”). Sandoz has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in this Court.

**ANSWER:** Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it was a named defendant in the complaints filed in Civil Action Nos. 3:25-cv-00231, 3:25-cv-00181, 3:18-11026, 2:17-10129, 3:17-08825, and 1:17-05302 in this judicial district. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 17.

18. For at least the foregoing reasons set forth above, this Court has personal jurisdiction over Defendant because, on information and belief, Defendant: (a) has substantial, continuous, and systematic contacts with the State of New Jersey; (b) has in the past and intends in the future to manufacture, market, import, offer to sell, sell, and/or distribute Defendant’s pharmaceutical products to residents of the State of New Jersey; (c) maintains a distributorship network within the State of New Jersey; (d) enjoys income from sales of their generic pharmaceutical products in the State of New Jersey; (e) is located in and/or has consented to and/or not contested personal jurisdiction in this Action and the Prior Actions; and (f) has availed itself of the jurisdiction of this Court by asserting counterclaims in this Action and at least one of the Prior Actions.

**ANSWER:** Paragraph 18 contains legal conclusions for which no answer is required.

To the extent an answer is required, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 18.

19. For at least the foregoing reasons, venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and/or 1400(b). Among other reasons, venue is proper in this Judicial District because, on information and belief, (a) Sandoz has a principal place of business in New Jersey, and has and will continue to engage in infringement activities in New Jersey, and (b) Sandoz has previously consented to and/or not contested venue in this Judicial District in this Action and at least one of the Prior Actions.

**ANSWER:** Paragraph 19 contains legal conclusions for which no answer is required.

To the extent an answer is required, Sandoz does not contest venue in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 19.

### **RESPONSE TO “BACKGROUND”**

#### **U.S. Patent No. 12,201,596**

20. On January 21, 2025, the United States Patent & Trademark Office (“PTO”), duly and legally issued United States Patent No. 12,201,596 (“the ’596 patent”) entitled “Levodopa Dosing Regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’596 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the ’596 patent is attached as **Exhibit 1**.

**ANSWER:** Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’596 patent, which is titled “Levodopa Dosing Regimen,” issued on or about January 21, 2025. Sandoz further admits that what purports to be a copy of the ’596 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 1. Sandoz denies that the ’596 patent was duly and legally issued, as well as any suggestion that the ’596 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 20.

**U.S. Patent No. 12,263,148**

21. On April 1, 2025, the PTO duly and legally issued United States Patent No. 12,263,148 (“the ’148 patent”) entitled “Levodopa Dosing Regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’148 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the ’148 patent is attached as **Exhibit 2**.

**ANSWER:** Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’148 patent, which is titled “Levodopa Dosing Regimen,” issued on or about April 1, 2025. Sandoz further admits that what purports to be a copy of the ’148 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 2. Sandoz denies that the ’148 patent was duly and legally issued, as well as any suggestion that the ’148 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 21.

**U.S. Patent No. 12,263,149**

22. On April 1, 2025, the PTO duly and legally issued United States Patent No. 12,263,149 (“the ’149 patent”) entitled “Levodopa Dosing Regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’149 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the ’149 patent is attached as **Exhibit 3**.

**ANSWER:** Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’149 patent, which is titled “Levodopa Dosing Regimen,” issued on or about April 1, 2025. Sandoz further admits that what purports to be a copy of the ’149 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 3. Sandoz denies that the ’149 patent was duly and legally issued, as well as any suggestion that the ’149 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 22.

**U.S. Patent No. 12,274,793**

23. On April 15, 2025, the PTO duly and legally issued United States Patent No.

12,274,793 (“the ’793 patent”) entitled “Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof” to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The ’793 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on October 7, 2034. A true and correct copy of the ’793 patent is attached as **Exhibit 4**.

**ANSWER:** Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’793 patent, which is titled “Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof,” issued on or about April 15, 2025. Sandoz further admits that what purports to be a copy of the ’793 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 4. Sandoz denies that the ’793 patent was duly and legally issued, as well as any suggestion that the ’793 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 23.

**U.S. Patent No. 12,295,931**

24. On May 13, 2025, the PTO duly and legally issued United States Patent No. 12,295,931 (“the ’931 patent”) entitled “Levodopa Dosing Regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’931 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the ’931 patent is attached as **Exhibit 5**.

**ANSWER:** Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’931 patent, which is titled “Levodopa Dosing Regimen,” issued on or about May 13, 2025. Sandoz further admits that what purports to be a copy of the ’931 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 5. Sandoz denies that the ’931 patent was duly and legally issued, as well as any suggestion that the ’931 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 24.

**U.S. Patent No. 12,303,481**

25. On May 20, 2025, the PTO duly and legally issued United States Patent No.

12,303,481 (“the ’481 patent”) entitled “Levodopa Dosing Regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’481 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the ’481 patent is attached as **Exhibit 6**.

**ANSWER:** Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’481 patent, which is titled “Levodopa Dosing Regimen,” issued on or about May 20, 2025. Sandoz further admits that what purports to be a copy of the ’481 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 6. Sandoz denies that the ’481 patent was duly and legally issued, as well as any suggestion that the ’481 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 25.

**U.S. Patent No. 12,303,482**

26. On May 20, 2025, the PTO duly and legally issued United States Patent No. 12,303,482 (“the ’482 patent”) entitled “Levodopa Dosing Regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’482 patent is owned by assignment by Amneal and per the FDA Orange Book patent data will expire on December 21, 2041. A true and correct copy of the ’482 patent is attached as **Exhibit 7**.

**ANSWER:** Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the ’482 patent, which is titled “Levodopa Dosing Regimen,” issued on or about May 20, 2025. Sandoz further admits that what purports to be a copy of the ’482 patent is attached to Plaintiffs’ 25-cv-11981 First Amended Complaint as Exhibit 7. Sandoz denies that the ’482 patent was duly and legally issued, as well as any suggestion that the ’482 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 26.

**U.S. Patent No. 12,303,605**

27. On May 20, 2025, the PTO duly and legally issued United States Patent No. 12,303,605 (“the ’605 patent”) entitled “Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof” to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The ’605 patent is owned by assignment by Impax and per the FDA

Orange Book patent data will expire on October 7, 2034. A true and correct copy of the '605 patent is attached as **Exhibit 8**.

**ANSWER:** Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to the online records of the PTO, the '605 patent, which is titled "Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof," issued on or about May 20, 2025. Sandoz further admits that what purports to be a copy of the '605 patent is attached to Plaintiffs' 25-cv-11981 First Amended Complaint as Exhibit 8. Sandoz denies that the '605 patent was duly and legally issued, as well as any suggestion that the '605 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 27.

**RESPONSE TO "CREXONT®"**

28. Impax is the holder of New Drug Application ("NDA") No. 217186 ("the NDA"), for carbidopa and levodopa extended-release capsules, for oral use, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg dosages, which is sold under the Proprietary Name CREXONT®.

**ANSWER:** Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that, according to FDA's online records, "IMPAX" is the holder of NDA No. 217186 for Crexont®, carbidopa/levodopa capsules, extended release, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg strengths. Sandoz denies any and all remaining allegations of Paragraph 28.

29. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, at least the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, '141, '918, '919, '150, '596, '148, '149, '793, '931, '481, '482, and '605 patents (defined above and below), are listed in the FDA "Orange Book" with respect to CREXONT®. Plaintiffs are owners by assignment of the Patents-in-Suit, and the other patents listed in the Orange Book for CREXONT® not at issue in this Action.

**ANSWER:** Paragraph 29 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that the electronic version of FDA's Orange Book currently lists the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, '141, '918,

'919, '150, '596, '148, '149, 793, '931, '481, '482, and '605 patents in connection with Crexont®.

Sandoz denies any and all remaining allegations of Paragraph 29.

**RESPONSE TO “ACTS GIVING RISE TO THIS ACTION”**

30. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

31. On information and belief, Defendant submitted ANDA No. 219989 (the “Sandoz ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of carbidopa/levodopa extended-release capsules, for oral use, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg dosages (the “Sandoz ANDA Products”).

**ANSWER:** Paragraph 31 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that it submitted ANDA No. 219989 seeking approval for carbidopa/levodopa capsules, extended release, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg strengths. Sandoz denies any and all remaining allegations of Paragraph 31.

32. On information and belief, following any FDA approval of the Sandoz ANDA, Defendant intends to make, use, sell, or offer to sell the Sandoz ANDA Products throughout the United States, including in the State of New Jersey, and/or import that generic product into the United States, including into the State of New Jersey.

**ANSWER:** Paragraph 32 contains legal conclusions for which no answer is required. To the extent an answer is required, denied. Further answering, Sandoz does not contest personal jurisdiction in this judicial district solely for the limited purpose of this action only. Sandoz denies any and all remaining allegations of Paragraph 32.

33. No earlier than November 25, 2024, Plaintiffs received, as asserted in Amneal Pharmaceuticals LLC et al v. Sandoz Inc., Civ. No. 3:25-cv-00181 (D.N.J.) (“the cv-00181 Action”), written notice of the Sandoz ANDA and the Sandoz Paragraph IV Certifications from Defendant regarding United States Patent Nos. 10,098,845 (“the ’845 patent”), 10,292,935 (“the ’935 patent”), 10,688,058 (“the ’058 patent”), 10,973,769 (“the ’769 patent”), 10,987,313 (“the ’313 patent”), 11,357,733 (“the ’733 patent”), 11,622,941 (“the ’941 patent”), 11,666,538 (“the

'538 patent"), 11,986,449 ("the '449 patent"), and 12,064,521 ("the '521 patent") ("cv-00181 First Notice Letter"). The cv-00181 First Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that claims of the '845, '935, '058, '769, '313, '733, '941, '538, '449, and '521 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products ("cv-00181 First Detailed Statement").

**ANSWER:** Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent a letter dated November 22, 2024 to Impax Laboratories LLC and Amneal Pharmaceuticals LLC titled "Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg: Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. 10,098,845 B2, 10,292,935 B2, 10,688,058 B2, 10,973,769 B2, 10,987,313 B2, 11,357,733 B2, 11,622,941 B2, 11,666,538 B2, 11,986,449 B2, and 12,064,521 B2, Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act" ("cv-00181 First Notice Letter"). Sandoz denies any and all remaining allegations of Paragraph 33.

34. No earlier than January 30, 2025, Plaintiffs received, as asserted in the cv-00181 Action's First Amended Complaint (cv-00181 Action, Dkt. No. 33), written notice of additional Sandoz Paragraph IV Certifications from Defendant regarding United States Patent Nos. 12,109,185 ("the '185 patent"), 12,128,141 ("the '141 patent"), 12,178,918 ("the '918 patent"), 12,178,919 ("the '919 patent"), and 12,194,150 ("the '150 patent") ("cv-00181 Second Notice Letter"). The cv-00181 Second Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that claims of the '185, '141, '918, '919, and '150 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products ("cv-00181 Second Detailed Statement").

**ANSWER:** Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent a letter dated January 29, 2025 to Impax Laboratories LLC and Amneal Pharmaceuticals LLC titled "Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg: Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. 12,109,185 B2, 12,128,141 B1, 12,178,918 B2, 12,178,919 B2, and 12,194,150 B2

Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act” (“cv-00181 Second Notice Letter”). Sandoz denies any and all remaining allegations of Paragraph 34.

35. No earlier than May 15, 2025, Plaintiffs received, as asserted in this Action (“the cv-11981 Action”), written notice of additional Sandoz Paragraph IV Certifications from Defendant regarding the ’596, ’148, ’149, and ’793 patents (“cv-11981 First Notice Letter”). The cv-11981 First Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that claims of the ’596, ’148, ’149, and ’793 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products (“cv-11981 First Detailed Statement”).

**ANSWER:** Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent a letter dated May 14, 2025 to Impax Laboratories LLC and Amneal Pharmaceuticals LLC titled “Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg: Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S. Patent Nos. 12,201,596 B2, 12,263,148 B2, 12,263,149 B2, and 12,274,793 B2 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act” (“cv-11981 First Notice Letter”). Sandoz denies any and all remaining allegations of Paragraph 35.

36. No earlier than August 7, 2025, Plaintiffs received written notice of additional Sandoz Paragraph IV Certifications from Defendant regarding United States Patent Nos. 12,295,931 (“the ’931 patent”), 12,303,481 (“the ’481 patent”), 12,303,482 (“the ’482 patent”), and 12,303,605 (“the ’605 patent”) (“cv-11981 Second Notice Letter”). The cv-11981 Second Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that claims of the ’931, ’481, ’482, and ’605 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products (“cv-11981 Second Detailed Statement”).

**ANSWER:** Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent a letter dated August 6, 2025 to Impax Laboratories LLC and Amneal Pharmaceuticals LLC titled “Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg: Notification of Certification of Invalidity, Unenforceability, and/or Non-Infringement for U.S.

Patent Nos. 12,295,931, 12,303,481, 12,303,482, and 12,303,605 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act” (“cv-11981 Second Notice Letter”). Sandoz denies any and all remaining allegations of Paragraph 36.

37. On information and belief, in connection with the cv-11981 First Notice Letter, the cv-11981 Second Notice Letter, this Action, and the submission of the Sandoz ANDA, Defendant has provided written certifications to the FDA, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the ’596, ’148, ’149, ’793, ’931, ’481, ’482, and ’605 patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products.

**ANSWER:** Paragraph 37 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that ANDA No. 219989 contains, *inter alia*, patent certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), which state that the ’596, ’148, ’149, ’793, ’931, ’481, ’482, and ’605 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of Sandoz’s ANDA Products. Sandoz denies any and all remaining allegations of Paragraph 37.

38. By filing the Sandoz ANDA, Defendant represented to the FDA that the Sandoz ANDA Products have the same active ingredients as CREXONT®, have the same method of administration, dosage forms, and strengths, and are bioequivalent to CREXONT®, and would be sold under a label substantively the same as the label for CREXONT®.

**ANSWER:** Paragraph 38 contains legal conclusions for which no answer is required. To the extent an answer is required, Sandoz admits that ANDA No. 219989 meets all statutory requirements, including those of 21 U.S.C. §§ 355(j)(2)(A)(i), 355(j)(2)(A)(v), 355(j)(2)(ii)(A)(I), 21 C.F.R. §§ 314.94(a)(5), and 314.94(a)(8)(iv). Sandoz denies any and all remaining allegations of Paragraph 38.

39. The cv-00181 Action, with respect to the ’845, ’935, ’058, ’769, ’313, ’733, ’941, ’538, ’449, and ’521 patents, was commenced before the expiration of forty-five (45) days from the date Plaintiffs received the cv-00181 First Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii) and thus triggered the thirty (30) month-stay under 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Paragraph 39 contains legal conclusions to which no answer is required. Sandoz admits that it sent its cv-00181 First Notice Letter on November 22, 2024 via Federal

Express to Impax Laboratories LLC and Amneal Pharmaceuticals LLC. Sandoz further avers that the '185, '141, '918, '919, and '150 patents were not listed in the Orange Book in connection with Crexont® as of the date Sandoz filed its ANDA, nor were U.S. Pat. Nos. 12,201,596, 12,263,148, 12,263,149, 12,274,793, 12,295,931, 12,303,481, 12,303,482, and 12,303,605. Sandoz denies any and all remaining allegations of Paragraph 39.

40. The First Amended Complaint in the cv-00181 Action additionally asserted infringement of the '185, '141, '918, '919, and '150 patents based on the cv-00181 Second Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent the cv-00181 Second Notice Letter via Federal Express to Impax Laboratories LLC and Amneal Pharmaceuticals LLC on January 29, 2025. Further answering, Sandoz admits that the First Amended Complaint in the cv-00181 Action purports to state a claim for alleged infringement of the '185, '141, '918, '919, and '150 patent. Sandoz denies any and all remaining allegations of Paragraph 40

41. This Action, with respect to the '596, '148, '149, and '793 patents, was commenced before the expiration of forty-five (45) days from the date Plaintiffs received the cv-11981 First Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent the cv-11981 First Notice Letter via Federal Express to Impax Laboratories LLC and Amneal Pharmaceuticals LLC on May 14, 2025. Sandoz further avers that the '596, '148, '149, and '793 patents were not listed in the Orange Book in connection with Crexont® as of the date Sandoz filed its ANDA. Sandoz denies any and all remaining allegations of Paragraph 41.

42. This First Amended Complaint in this Action additionally asserts infringement of the '931, '481, '482, and '605 patents based on the cv-11981 Second Notice Letter, under 21 U.S.C. § 355(j)(5)(B)(iii).

**ANSWER:** Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it sent the cv-11981 Second Notice Letter via Federal Express to Impax Laboratories LLC and Amneal Pharmaceuticals LLC on August 6, 2025. Sandoz further avers that the '931, '481, '482, and '605 patents were not listed in the Orange Book in connection with Crexont® as of the date Sandoz filed its ANDA. Sandoz denies any and all remaining allegations of Paragraph 42.

**RESPONSE TO “COUNT I: INFRINGEMENT OF THE '596 PATENT BY SANDOZ”**

43. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

44. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '596 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '596 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

45. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '596 patent constituted an act of infringement of one or more claims of the '596 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

46. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '596 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '596 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Denied.

47. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 First Notice Letter and cv-11981 First Detailed Statement, Defendant has knowledge of the '596 patent.

**ANSWER:** Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 First Notice Letter stated, *inter alia*, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 596, 148, 149, and 793 patents . . . .” Sandoz denies any and all remaining allegations of Paragraph 47.

48. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the ’596 patent.

**ANSWER:** Denied.

49. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the ’596 patent, including at least claims 1, 10, and 14, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the ’596 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

50. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson’s disease. These uses will constitute direct infringement of one or more claims of the ’596 patent.

**ANSWER:** Denied.

51. On information and belief, these direct infringing uses will occur with Defendant’s specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

52. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs’ rights under the ’596 patent and will constitute infringement.

**ANSWER:** Denied.

53. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '596 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '596 patent.

**ANSWER:** Denied.

54. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '596 patent, including at least claims 1, 10, and 14, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '596 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '596 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

55. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '596 patent, or any later expiration of exclusivity for the '596 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

56. Defendant has had knowledge of the '596 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications, and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

57. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO “COUNT II: INFRINGEMENT OF THE '148 PATENT BY SANDOZ”**

58. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

59. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '148 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '148 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

60. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '148 patent constituted an act of infringement of one or more claims of the '148 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

61. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '148 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '148 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Denied.

62. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 First Notice Letter and cv-11981 First Detailed Statement, Defendant has knowledge of the '148 patent.

**ANSWER:** Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 First Notice Letter stated, *inter alia*, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 596, 148, 149, and 793 patents . . . .” Sandoz denies any and all remaining allegations of Paragraph 62.

63. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '148 patent.

**ANSWER:** Denied.

64. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '148 patent, including at least claims 1 and 11, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '148 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

65. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, inter alia, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '148 patent.

**ANSWER:** Denied.

66. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

67. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '148 patent and will constitute infringement.

**ANSWER:** Denied.

68. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '148 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '148 patent.

**ANSWER:** Denied.

69. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '148 patent, including at least claims 1 and 11, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '148 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '148 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

70. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '148 patent, or any later expiration of exclusivity for the '148 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

71. Defendant has had knowledge of the '148 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications, and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

72. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO “COUNT III: INFRINGEMENT OF THE '149 PATENT BY SANDOZ”**

73. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

74. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '149 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '149 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

75. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '149 patent constituted an act of infringement of one or more claims of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

76. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '149 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '149 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Denied.

77. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 First Notice Letter and cv-11981 First Detailed Statement, Defendant has knowledge of the '149 patent.

**ANSWER:** Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 First Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 596, 148, 149, and 793 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 77.

78. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '149 patent.

**ANSWER:** Denied.

79. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '149 patent, including at least claims 1 and 11, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '149 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

80. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, reduce "off" time in treating Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '149 patent.

**ANSWER:** Denied.

81. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

82. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '149 patent and will constitute infringement.

**ANSWER:** Denied.

83. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '149 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '149 patent.

**ANSWER:** Denied.

84. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '149 patent, including at least claims 1 and 11, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '149 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '149 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

85. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '149 patent, or any later expiration of exclusivity for the '149 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

86. Defendant has had knowledge of the '149 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications, and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

87. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO “COUNT IV: INFRINGEMENT OF THE ’793 PATENT BY SANDOZ”**

88. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

89. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the ’793 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant’s infringement of the ’793 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

90. Defendant’s submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the ’793 patent constituted an act of infringement of one or more claims of the ’793 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

91. Defendant’s commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the ’793 patent, and Defendant’s inducement of and/or contribution to such conduct, would further infringe at least one claim of the ’793 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

92. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 9, and 16 of the ’793 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

**ANSWER:** Denied.

93. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 First Notice Letter and cv-11981 First Detailed Statement, Defendant has knowledge of the ’793 patent.

**ANSWER:** Paragraph 93 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 First Notice Letter stated, *inter alia*, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 596, 148, 149, and 793 patents . . . .” Sandoz denies any and all remaining allegations of Paragraph 93.

94. In the cv-11981 First Notice Letter and cv-11981 First Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-22. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the ’793 patent.

**ANSWER:** Denied.

95. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the ’793 patent, including at least claims 1, 9, and 16, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the ’793 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

96. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, *inter alia*, treat Parkinson’s disease. These uses will constitute direct infringement of one or more claims of the ’793 patent.

**ANSWER:** Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 First Notice Letter stated, *inter alia*, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 596, 148, 149, and 793 patents . . . .” Further answering, Sandoz admits that its PIV Notice Letter stated, *inter alia*, that “Sandoz alleges,

and has certified to FDA, that in Sandoz's opinion and to the best of its knowledge, the 596, 148, 149, and 793 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 96.

97. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

98. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '793 patent and will constitute infringement.

**ANSWER:** Denied.

99. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '793 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '793 patent.

**ANSWER:** Denied.

100. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '793 patent, including at least claims 1, 9, and 16, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '793 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '793 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

101. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '793 patent, or any later expiration of exclusivity for the '793 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

102. Defendant has had knowledge of the '793 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

103. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO "COUNT V: INFRINGEMENT OF THE '931 PATENT BY SANDOZ"**

104. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

105. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '931 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '931 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

106. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '931 patent constituted an act of infringement of one or more claims of the '931 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

107. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '931 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '931 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Denied.

108. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 Second Notice Letter and cv-11981 Second Detailed Statement,

Defendant has knowledge of the '931 patent.

**ANSWER:** Paragraph 108 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 Second Notice Letter stated, inter alia, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 931, 481, 482, and 605 patents . . . .” Sandoz denies any and all remaining allegations of Paragraph 108.

109. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '931 patent.

**ANSWER:** Denied.

110. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '931 patent, including at least claims 1, 12, and 23, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '931 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

111. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to, inter alia, Parkinson's disease patients according to the dosing regimen claimed in the '931 patent. These uses will constitute direct infringement of one or more claims of the '931 patent.

**ANSWER:** Denied.

112. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

113. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '931 patent and will constitute infringement.

**ANSWER:** Denied.

114. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '931 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '931 patent.

**ANSWER:** Denied.

115. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '931 patent, including at least claims 1, 12, and 23, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '931 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '931 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

116. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '931 patent, or any later expiration of exclusivity for the '931 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

117. Defendant has had knowledge of the '931 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

118. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO “COUNT VI: INFRINGEMENT OF THE '481 PATENT BY SANDOZ”**

119. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

120. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '481 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '481 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

121. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '481 patent constituted an act of infringement of one or more claims of the '481 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

122. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '481 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '481 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(b), and/or (c).

**ANSWER:** Denied.

123. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 Second Notice Letter and cv-11981 Second Detailed Statement, Defendant has knowledge of the '481 patent.

**ANSWER:** Paragraph 123 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 Second Notice Letter stated, inter alia, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 931, 481, 482, and 605 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 123.

124. Upon information and belief, Defendant has knowledge that the Sandoz ANDA

Products will infringe the '481 patent.

**ANSWER:** Denied.

125. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '481 patent, including at least claims 1 and 15, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '481 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

126. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, inter alia, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '481 patent.

**ANSWER:** Denied.

127. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

128. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '481 patent and will constitute infringement.

**ANSWER:** Denied.

129. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '481 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '481 patent.

**ANSWER:** Denied.

130. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '481 patent, including at least claims 1 and 15, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '481 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '481 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

131. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '481 patent, or any later expiration of exclusivity for the '481 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

132. Defendant has had knowledge of the '481 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

133. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO “COUNT VII: INFRINGEMENT OF THE '482 PATENT BY SANDOZ”**

134. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

135. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the '482 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '482 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

**ANSWER:** Denied.

136. Defendant's submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the '482 patent constituted an act of infringement of one or more claims of the '482 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

137. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '482 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '482 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

**ANSWER:** Denied.

138. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 Second Notice Letter and cv-11981 Second Detailed Statement, Defendant has knowledge of the '482 patent.

**ANSWER:** Paragraph 138 contains legal conclusions to which no answer is required.

To the extent an answer is required, Sandoz admits that the cv-11981 Second Notice Letter stated, inter alia, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 931, 481, 482, and 605 patents . . . ."

Sandoz denies any and all remaining allegations of Paragraph 138.

139. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '482 patent.

**ANSWER:** Denied.

140. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the '482 patent, including at least claims 1, 11, and 21, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the '482 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

141. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, inter alia, treat Parkinson's disease. These uses will constitute direct infringement of one or more claims of the '482 patent.

**ANSWER:** Denied.

142. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will

occur.

**ANSWER:** Denied.

143. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '482 patent and will constitute infringement.

**ANSWER:** Denied.

144. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '482 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '482 patent.

**ANSWER:** Denied.

145. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '482 patent, including at least claims 1, 11, and 21, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '482 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '482 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

146. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '482 patent, or any later expiration of exclusivity for the '482 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

147. Defendant has had knowledge of the '482 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

148. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

**RESPONSE TO “COUNT VIII: INFRINGEMENT OF THE ’605 PATENT BY SANDOZ”**

149. Plaintiffs reallege all preceding paragraphs as if fully set forth herein.

**ANSWER:** Sandoz restates its answers to all preceding paragraphs as if fully set forth herein.

150. By submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA and notice to Plaintiffs of the same, Defendant declared its intent to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to the expiration of the ’605 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant’s infringement of the ’605 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

151. Defendant’s submission of the Sandoz ANDA with the Sandoz Paragraph IV Certifications to the FDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products before expiration of the ’605 patent constituted an act of infringement of one or more claims of the ’605 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

152. Defendant’s commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the ’605 patent, and Defendant’s inducement of and/or contribution to such conduct, would further infringe at least one claim of the ’605 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

**ANSWER:** Denied.

153. Upon information and belief, Defendant intends to, and will, infringe at least claims 1 and 14 of the ’605 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Sandoz ANDA Products, either literally or under the doctrine of equivalents, upon FDA approval of the Sandoz ANDA, unless enjoined by this Court.

**ANSWER:** Denied.

154. Upon information and belief, by virtue of its listing in the Orange Book and identification in the cv-11981 Second Notice Letter and cv-11981 Second Detailed Statement, Defendant has knowledge of the ’605 patent.

**ANSWER:** Paragraph 154 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 Second Notice Letter stated, inter alia, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 931, 481, 482, and 605 patents . . . .” Sandoz denies any and all remaining allegations of Paragraph 154.

155. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the ’605 patent.

**ANSWER:** Denied.

156. Unless enjoined by this Court, upon FDA approval of the Sandoz ANDA, Defendant intends to, and will, actively induce infringement of one or more claims of the ’605 patent, including at least claims 1 and 14, under 35 U.S.C. § 271(b). On information and belief, Defendant will do so by marketing the Sandoz ANDA Products and encouraging healthcare professionals and patients to use them in a manner that constitutes direct infringement of one or more of the claims of the ’605 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

157. For example, on information and belief, the Sandoz ANDA Products, if approved by the FDA, will be prescribed and administered to human patients to, inter alia, treat Parkinson’s disease. These uses will constitute direct infringement of one or more claims of the ’605 patent.

**ANSWER:** Paragraph 157 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the cv-11981 Second Notice Letter stated, inter alia, that “[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of Carbidopa and Levodopa Extended-Release Capsules, 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5/350 mg, before the expiration of the 931, 481, 482, and 605 patents . . . .” Further answering, Sandoz admits that its PIV Notice Letter stated, inter alia, that “Sandoz alleges, and has certified to FDA, that in Sandoz’s opinion and to the best of its knowledge, the 931, 481,

482, and 605 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 157.

158. On information and belief, these direct infringing uses will occur with Defendant's specific intent and encouragement and will be uses that Defendant knows or should know will occur.

**ANSWER:** Denied.

159. On information and belief, Defendant will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Plaintiffs' rights under the '605 patent and will constitute infringement.

**ANSWER:** Denied.

160. On information and belief, upon FDA approval of the Sandoz ANDA, Defendant will intentionally encourage direct infringement, either literally or under the doctrine of equivalents, with knowledge of the '605 patent. Defendant will do so through its promotional activities and package inserts for the Sandoz ANDA Products, by encouraging healthcare professionals and patients to use the products in a manner that infringes the '605 patent.

**ANSWER:** Denied.

161. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '605 patent, including at least claims 1 and 14, under 35 U.S.C. § 271(c), unless enjoined by this Court. On information and belief, Defendant will contribute to the direct infringement by others, either literally or under the doctrine of equivalents, with knowledge that the Sandoz ANDA Products constitute a material part of at least one of the claims of the '605 patent. Defendant has had and continues to have knowledge that the Sandoz ANDA Products are especially made or adapted for use in infringing one or more of the claims of the '605 patent and are not suitable for substantial non-infringing use.

**ANSWER:** Denied.

162. Plaintiffs will be substantially and irreparably harmed if Defendant is permitted to make, use, sell, offer to sell, and/or import the Sandoz ANDA Products and is not enjoined from doing so. Plaintiffs are entitled to relief, including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, such as an order from this Court that the effective date of approval of the Sandoz ANDA be a date that is not earlier than the expiration date of the '605 patent, or any later expiration of exclusivity for the '605 patent to which Plaintiffs are or become entitled, and an injunction against such infringement. Plaintiffs do not have an adequate remedy at law.

**ANSWER:** Denied.

163. Defendant has had knowledge of the '605 patent since at least the date it submitted the Sandoz ANDA and the Sandoz Paragraph IV Certifications and was aware that the submission of the Sandoz ANDA and the Sandoz Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

164. This is an exceptional case within the meaning of 35 U.S.C. § 285.

**ANSWER:** Denied.

### **SEPARATE DEFENSES**

Without prejudice to the denials set forth in its Answer, without admitting any allegations in the 25-cv-11981 First Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on the Plaintiffs, Sandoz asserts the following separate defenses:

#### **First Defense**

The 25-cv-11981 First Amended Complaint fails to state a claim upon which relief can be granted.

#### **Second Defense**

The claims of the '596 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

#### **Third Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '596 patent, either literally or under the doctrine of equivalents.

#### **Fourth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid

and/or enforceable claim of the '596 patent.

**Fifth Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '596 patent.

**Sixth Defense**

The claims of the '148 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Seventh Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '148 patent, either literally or under the doctrine of equivalents.

**Eighth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '148 patent.

**Ninth Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '148 patent.

**Tenth Defense**

The claims of the '149 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Eleventh Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '149 patent, either literally or under the doctrine of equivalents.

**Twelfth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '149 patent.

**Thirteenth Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '149 patent.

**Fourteenth Defense**

The claims of the '793 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Fifteenth Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '793 patent, either literally or under the doctrine of equivalents.

**Sixteenth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '793 patent.

**Seventeenth Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '793 patent.

**Eighteenth Defense**

The claims of the '931 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Nineteenth Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '931 patent, either literally or under the doctrine of equivalents.

**Twentieth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '931 patent.

**Twenty-First Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '931 patent.

**Twenty-Second Defense**

The claims of the '481 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Twenty-Third Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's

ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '481 patent, either literally or under the doctrine of equivalents.

**Twenty-Fourth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '481 patent.

**Twenty-Fifth Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '481 patent.

**Twenty-Sixth Defense**

The claims of the '482 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Twenty-Seventh Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '482 patent, either literally or under the doctrine of equivalents.

**Twenty-Eighth Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '482 patent.

**Twenty-Ninth Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '482 patent.

**Thirtieth Defense**

The claims of the '605 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, and/or for double-patenting.

**Thirty-First Defense**

The manufacture, use, sale, offer for sale, importation, and/or marketing of Sandoz's ANDA Products have not infringed, do not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claim of the '605 patent, either literally or under the doctrine of equivalents.

**Thirty-Second Defense**

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '605 patent.

**Thirty-Third Defense**

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '605 patent.

**Thirty-Fourth Defense**

The Court lacks subject lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

**Thirty-Fifth Defense**

The First Amended Complaint fails to state a claim for willful infringement and/or exceptional case.

**Thirty-Sixth Defense**

Any additional defenses or counterclaims that discovery may reveal, including unenforceability.

## **COUNTERCLAIMS**

Defendant/Counterclaim-Plaintiff Sandoz Inc. (“Sandoz”), for its Counterclaims against Plaintiffs/Counterclaim-Defendants Amneal Pharmaceuticals LLC (“Amneal”) and Impax Laboratories, LLC (“Impax”), (collectively, “Counterclaim-Defendants”), alleges as follows.

### **The Parties**

1. Sandoz is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 100 College Road West, Princeton, New Jersey 08540.

2. Counterclaim-Defendant Impax purports to be a limited liability company organized and existing under the laws of the State of Delaware that is wholly-owned by Amneal. Impax’s registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

3. Counterclaim-Defendant Amneal purports to be a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

### **Jurisdiction and Venue**

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Counterclaim-Defendants because Counterclaim-Defendants have availed themselves of the rights and privileges—and subjected themselves to the jurisdiction—of this forum by suing Sandoz in this District, and/or because

Counterclaim-Defendants conduct substantial business in, and have regular systemic contact with, this District.

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

**Crexont®**

8. According to the United States Food and Drug Administration's ("FDA") website, Impax holds approved New Drug Application ("NDA") No. 217186, under which the FDA granted approval for Crexont®, carbidopa/levodopa capsules, extended release, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg strengths.

9. At the time the Complaint in this action ("25-cv-11981 Complaint") was filed, the electronic version of U.S. Food and Drug Administration's ("FDA") publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (a/k/a FDA's Orange Book) ("Orange Book"), listed United States Patent Nos. 10,098,845 ("the '845 patent"), 10,292,935 ("the '935 patent"), 10,688,058 ("the '058 patent"), ("the '769 patent"), 10,987,313 ("the '313 patent"), 11,357,733 ("the '733 patent"), 11,622,941 ("the '941 patent"), 11,666,538 ("the '538 patent"), 11,986,449 ("the '449 patent"), 12,064,521 ("the '521 patent"), 12,109,185 ("the '185 patent"), 12,128,141 ("the '141 patent"), 12,178,918 ("the '918 patent"), 12,178,919 ("the '919 patent"), 12,194,150 ("the '150 patent"), 12,201,596 ("the '596 patent"), 12,263,148 ("the '148 patent"), 12,263,149 ("the '149 patent"), and 12,274,793 ("the '793 patent"), 12,295,931 ("the '931 patent"), 12,303,481 ("the '481 patent"), 12,303,482 ("the '482 patent"), 12,303,605 ("the '605 patent") in connection with NDA No. 217186.

10. The electronic version of FDA's Orange Book lists the "Submission Date" for the '845 patent as August 12, 2024.

11. The electronic version of FDA's Orange Book lists the "Submission Date" for the '935 patent as August 12, 2024.

12. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’058 patent as August 12, 2024.

13. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’769 patent as August 12, 2024.

14. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’313 patent as August 12, 2024.

15. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’733 patent as August 12, 2024.

16. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’941 patent as August 12, 2024.

17. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’538 patent as August 12, 2024.

18. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’449 patent as August 12, 2024.

19. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’521 patent as August 21, 2024.

20. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’185 patent as October 11, 2024.

21. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’141 patent as November 13, 2024.

22. The electronic version of FDA’s Orange Book lists the “Submission Date” for the ’918 patent as January 8, 2025.

23. The electronic version of FDA's Orange Book lists the "Submission Date" for the '919 patent as January 8, 2025.

24. The electronic version of FDA's Orange Book lists the "Submission Date" for the '150 patent as January 22, 2025.

25. The electronic version of FDA's Orange Book lists the "Submission Date" for the '596 patent as February 5, 2025.

26. The electronic version of FDA's Orange Book lists the "Submission Date" for the '148 patent as April 17, 2025.

27. The electronic version of FDA's Orange Book lists the "Submission Date" for the '149 patent as April 17, 2025.

28. The electronic version of FDA's Orange Book lists the "Submission Date" for the '793 patent as May 6, 2025.

29. The electronic version of FDA's Orange Book lists the "Submission Date" for the '931 patent as June 12, 2025.

30. The electronic version of FDA's Orange Book lists the "Submission Date" for the '482 patent as June 12, 2025.

31. The electronic version of FDA's Orange Book lists the "Submission Date" for the '605 patent as June 12, 2025.

32. The electronic version of FDA's Orange Book lists the "Submission Date" for the '481 patent as June 20, 2025.

U.S. Patent No. 12,201,596

33. On or about January 21, 2025, the PTO issued the '596 patent, entitled "Levodopa Dosing Regimen."

34. The face of the '596 patent identifies Richard D'Souza, Hester Visser, and Suneel Gupta as the purported inventors.

35. The face of the '596 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

36. By listing the '596 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,263,148

37. On or about April 1, 2025, the PTO issued the '148 patent, entitled “Levodopa Dosing Regimen.”

38. The face of the '148 patent identifies Richard D'Souza, Hester Visser, and Suneel Gupta as the purported inventors.

39. The face of the '148 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

40. By listing the '148 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,263,149

41. On or about April 1, 2025, the PTO issued the '149 patent, entitled “Levodopa Dosing Regimen.”

42. The face of the '149 patent identifies Richard D'Souza, Hester Visser, and Suneel Gupta as the purported inventors.

43. The face of the '149 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

44. By listing the '149 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,274,793

45. On or about April 15, 2025, the PTO issued the '793 patent, entitled “Muco-Adhesive, Controlled Release Formulation of Levodopa and/or Esters of Levodopa and Uses Thereof.”

46. The face of the '793 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

47. The face of the '793 patent identifies Impax Laboratories, LLC as the purported assignee.

48. By listing the '793 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,295,931

49. On or about May 13, 2025, the PTO issued the '931 patent, entitled “Levodopa Dosing Regimen.”

50. The face of the '931 patent identifies Richard D'Souza, Hester Visser, and Suneel Gupta as the purported inventors.

51. The face of the '931 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

52. By listing the '931 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,303,481

53. On or about May 20, 2025, the PTO issued the '481 patent, entitled “Levodopa Dosing Regimen.”

54. The face of the '481 patent identifies Richard D'Souza, Hester Visser, and Suneel Gupta as the purported inventors.

55. The face of the '481 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

56. By listing the '481 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,303,482

57. On or about May 20, 2025, the PTO issued the '482 patent, entitled “Levodopa Dosing Regimen.”

58. The face of the '482 patent identifies Richard D'Souza, Hester Visser, and Suneel Gupta as the purported inventors.

59. The face of the '482 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

60. By listing the '482 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 12,303,605

61. On or about May 20, 2025, the PTO issued the '605 patent, entitled “Muco-Adhesive, Controlled Release Formulation of Levodopa and/or Esters of Levodopa and Uses Thereof.”

62. The face of the '605 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

63. The face of the '605 patent identifies Impax Laboratories, LLC as the purported assignee.

64. By listing the '605 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic ANDA applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

**Sandoz's ANDA Product**

65. Sandoz has filed ANDA No. 219989 (“Sandoz’s ANDA”) with the FDA.

66. Because Sandoz’s ANDA seeks FDA approval to engage in the commercial manufacture, use or sale of carbidopa/levodopa capsules, extended release, in 35 mg/140 mg, 52.5 mg/210 mg, 70 mg/280 mg, and 87.5 mg/350 mg strengths (collectively, “Sandoz’s ANDA Products”) prior to the expiration of the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521,

'185, '141, '918, '919, '150, '596, '148, '149, and '793 patents, Sandoz's ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, '141, '918, '919, and '150, '596, '148, '149, and '793 patents.

67. On January 7, 2025, Plaintiffs filed Civil Action No. 3:25-cv-00181-GC-TJB ("the cv-00181 action") against Sandoz, asserting infringement of the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185 and '141 patents.

68. On April 1, 2025, Plaintiffs filed the First Amended Complaint in the cv-00181 Action asserting infringement of the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, '141, '918, '919, and '150 patents.

69. On June 20, 2025, Plaintiffs filed the Complaint in the above-captioned action asserting infringement of the '596, '148, '149, and '793 patents.

## **COUNT I**

### **Declaration of Noninfringement of the '596 Patent**

70. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

71. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '596 patent.

72. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '596 patent, either literally or under the doctrine of equivalents.

73. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '596 patent.

## **COUNT II**

### **Declaration of Invalidity of the '596 Patent**

74. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

75. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '596 patent.

76. The '596 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

77. The alleged invention of the '596 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '596 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

78. The subject matter claimed in the '596 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

79. Sandoz is entitled to a judicial declaration that the claims of the '596 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

### **COUNT III**

#### **Declaration of Noninfringement of the '148 Patent**

80. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

81. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '148 patent.

82. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '148 patent, either literally or under the doctrine of equivalents.

83. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '148 patent.

### **COUNT IV**

#### **Declaration of Invalidity of the '148 Patent**

84. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

85. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '148 patent.

86. The '148 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

87. The alleged invention of the '148 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '148 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

88. The subject matter claimed in the '148 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

89. Sandoz is entitled to a judicial declaration that the claims of the '148 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

## **COUNT V**

### **Declaration of Noninfringement of the '149 Patent**

90. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

91. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or

importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '149 patent.

92. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '149 patent, either literally or under the doctrine of equivalents.

93. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '149 patent.

## **COUNT VI**

### **Declaration of Invalidity of the '149 Patent**

94. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

95. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '149 patent.

96. The '149 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

97. The alleged invention of the '149 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '149 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

98. The subject matter claimed in the '149 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

99. Sandoz is entitled to a judicial declaration that the claims of the '149 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

## **COUNT VII**

### **Declaration of Noninfringement of the '793 Patent**

100. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

101. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '793 patent.

102. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '793 patent, either literally or under the doctrine of equivalents.

103. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '793 patent.

## **COUNT VIII**

### **Declaration of Invalidity of the '793 Patent**

104. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

105. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '793 patent.

106. The '793 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

107. The alleged invention of the '793 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '793 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

108. The subject matter claimed in the '793 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

109. Sandoz is entitled to a judicial declaration that the claims of the '793 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT IX**

**Declaration of Noninfringement of the '931 Patent**

110. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

111. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '931 patent.

112. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '931 patent, either literally or under the doctrine of equivalents.

113. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '931 patent.

**COUNT X**

**Declaration of Invalidity of the '931 Patent**

114. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

115. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '931 patent.

116. The '931 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

117. The alleged invention of the '931 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '931 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

118. The subject matter claimed in the '931 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

119. Sandoz is entitled to a judicial declaration that the claims of the '931 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

## **COUNT XI**

### **Declaration of Noninfringement of the '481 Patent**

120. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

121. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '481 patent.

122. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '481 patent, either literally or under the doctrine of equivalents.

123. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '481 patent.

## **COUNT XII**

### **Declaration of Invalidity of the '481 Patent**

124. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

125. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '481 patent.

126. The '481 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

127. The alleged invention of the '481 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '481 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

128. The subject matter claimed in the '481 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was

made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

129. Sandoz is entitled to a judicial declaration that the claims of the '481 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

### **COUNT XIII**

#### **Declaration of Noninfringement of the '482 Patent**

130. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

131. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, inter alia, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '482 patent.

132. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '482 patent, either literally or under the doctrine of equivalents.

133. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '482 patent.

### **COUNT XIV**

#### **Declaration of Invalidity of the '482 Patent**

134. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

135. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '482 patent.

136. The '482 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

137. The alleged invention of the '482 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '482 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

138. The subject matter claimed in the '482 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

139. Sandoz is entitled to a judicial declaration that the claims of the '482 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

## **COUNT XV**

### **Declaration of Noninfringement of the '605 Patent**

140. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

141. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, whether the manufacture, use, offer for sale, sale or importation of Sandoz's ANDA Product would infringe any valid and enforceable claim of the '605 patent.

142. The manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not directly or indirectly infringe any valid and enforceable claim of the '605 patent, either literally or under the doctrine of equivalents.

143. Sandoz is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product would not infringe any valid and enforceable claim of the '605 patent.

#### **COUNT XVI**

##### **Declaration of Invalidity of the '605 Patent**

144. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs as if fully set forth herein.

145. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '605 patent.

146. The '605 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

147. The alleged invention of the '605 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '605 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to

combine the teachings of the prior art to achieve the alleged invention of the '845 patent and would have had a reasonable expectation of success in doing so.

148. The subject matter claimed in the '605 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

149. Sandoz is entitled to a judicial declaration that the claims of the '605 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

#### **PRAYER FOR RELIEF**

WHEREFORE, Sandoz respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim-Defendants as follows:

(a) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '596 patent;

(b) declaring that the claims of the '596 patent are invalid;

(c) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '148 patent;

(d) declaring that the claims of the '148 patent are invalid;

(e) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '149 patent;

(f) declaring that the claims of the '149 patent are invalid;

(g) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '793 patent;

(h) declaring that the claims of the '793 patent are invalid;

(i) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '931 patent;

(j) declaring that the claims of the '931 patent are invalid;

(k) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '481 patent;

(l) declaring that the claims of the '481 patent are invalid;

(m) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of

equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '482 patent;

(n) declaring that the claims of the '482 patent are invalid;

(o) declaring that the manufacture, sale, offer for sale, use or importation of Sandoz's ANDA Products does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '605 patent;

(p) declaring that the claims of the '605 patent are invalid;

(q) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Sandoz its attorneys' fees, costs, and expenses in this action; and

(r) awarding Sandoz any further and additional relief as the Court deems just and proper.

### **DEMAND FOR JURY TRIAL**

Sandoz hereby demands a jury trial on all issues so triable.

Dated: October 2, 2025

Respectfully submitted,

s/ Eric I. Abraham

Eric I. Abraham (eabraham@hillwallack.com)  
William P. Murtha (wmurtha@hillwallack.com)  
Kristine L. Butler (kbutler@hillwallack.com)  
**HILL WALLACK LLP**  
21 Roszel Road  
Princeton, NJ 08540  
(609) 734-6358 (telephone)

Of Counsel (admitted *pro hac vice*)

William A. Rakoczy (wrakoczy@rmmslegal.com)  
Rachel Pernic Waldron (rwaldron@rmmslegal.com)  
Steven J. Birkos (sbirkos@rmmslegal.com)  
Scott Beall (sbeall@rmmslegal.com)  
Rebecca L. Neubauer (rneubauer@rmmslegal.com)

Dylan G. Sacenti (dsacenti@rmmslegal.com)  
Claude J. Vandevender (cvandevender@rmmslegal.com)  
Sarah M.L. Wilkening (swilkening@rmmslegal.com)  
**RAKOCZY MOLINO MAZZOCHI SIWIK LLP**  
6 West Hubbard Street, Suite 500  
Chicago, IL 60654  
(312) 527-2157

*Attorneys for Defendant/Counterclaim-Plaintiff Sandoz Inc.*

**LOCAL RULE 11.2 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this action is related to the following actions:

- *Amneal Pharms. LLC v. Sandoz Inc.*, Civil Action No. 3:25-cv-00181 (D.N.J.)

**LOCAL RULE 201.1 CERTIFICATION**

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: October 2, 2025

Respectfully submitted,

s/ Eric I. Abraham

Eric I. Abraham (eabraham@hillwallack.com)  
William P. Murtha (wmurtha@hillwallack.com)  
Kristine L. Butler (kbutler@hillwallack.com)  
**HILL WALLACK LLP**  
21 Roszel Road  
Princeton, NJ 08540  
(609) 734-6358 (telephone)

Of Counsel (admitted *pro hac vice*)

William A. Rakoczy (wrakoczy@rmmslegal.com)  
Rachel Pernic Waldron (rwaldron@rmmslegal.com)  
Steven J. Birkos (sbirkos@rmmslegal.com)  
Rebecca L. Neubauer (rneubauer@rmmslegal.com)  
Dylan G. Sacenti (dsacenti@rmmslegal.com)  
Claude J. Vandevender (cvandevender@rmmslegal.com)  
Sarah M.L. Wilkening (swilkening@rmmslegal.com)  
**RAKOCZY MOLINO MAZZOCHI SIWIK LLP**  
6 West Hubbard Street, Suite 500  
Chicago, IL 60654

(312) 527-2157

*Attorneys for Defendant/Counterclaim-Plaintiff Sandoz Inc.*

**CERTIFICATE OF SERVICE**

I hereby certify that on October 2, 2025, I caused a true and correct copy of the foregoing document to be served by notice of electronic filing and via electronic mail on counsel of record in this matter.

By: s/ Eric I. Abraham  
Eric I. Abraham