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)*
Ty W. Callahan *(Pro Hac Vice)*
Dylan G. Sacenti *(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.

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

AMNEAL PHARMACEUTICALS LLC, and IMPAX LABORATORIES LLC, Plaintiffs/Counterclaim-Defendants, v. SANDOZ, INC., Defendant/Counterclaim-Plaintiff.	Civil Action No. 3:25-cv-00181-GC-TJB *Document Filed Electronically*

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 April 1, 2025 First Amended Complaint for Patent Infringement (Dkt. No. 33) ("FAC") 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. 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"), 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"), and 12,194,150 ("the '150 patent") (collectively, the "Patents-in-Suit"), and before the expiration dates of these 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' FAC purports to state a claim for alleged infringement of 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"), 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"), and 12,194,150 ("the '150 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 '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '185, '141, '918, '919, and '150 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' FAC 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.*, *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. 3:18-11026, 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. In this Action, Sandoz has consented to and/or not contested personal jurisdiction in this Court and has filed counterclaims against Plaintiffs. *See* Defendant Sandoz Inc.'s Answer, Defenses and Counterclaims to Plaintiffs' Complaint for Patent Infringement, Dkt. No. 23 (March 11, 2025).

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it filed counterclaims against Plaintiffs in its March 11, 2025 Answer, Defenses and Counterclaims to Plaintiffs' Complaint for Patent Infringement (Dkt. No. 23). 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 18.

19. 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 19 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 19.

20. 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 20 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 20.

RESPONSE TO "BACKGROUND"

U.S. Patent No. 10,098,845

21. On October 16, 2018, the United States Patent & Trademark Office ("PTO"), duly and legally issued United States Patent No. 10,098,845 ("the '845 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '845 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 '845 patent is attached as **Exhibit 1**.

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 '845 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about October 16, 2018. Sandoz further admits that what purports to be a copy of the '844 patent is attached to Plaintiffs' FAC as Exhibit 1. Sandoz denies that the '845 patent was duly and legally issued, as well as any suggestion that the '845 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 21.

U.S. Patent No. 10,292,935

22. On May 21, 2019, the PTO duly and legally issued United States Patent No. 10,292,935 ("the '935 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '935 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 '935 patent is attached as **Exhibit 2**.

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 '935 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about May 21, 2019. Sandoz further admits that what purports to be a copy of the '935 patent is attached to Plaintiffs' FAC as Exhibit 2. Sandoz denies that the '935 patent was duly and legally issued, as well as any suggestion that the '935 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 22.

U.S. Patent No. 10,688,058

23. On June 23, 2020, the PTO duly and legally issued United States Patent No. 10,688,058 ("the '058 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '058 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 '058 patent is attached as **Exhibit 3**.

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 '058 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about June 23, 2020. Sandoz further admits that what purports to be a copy of the '058 patent is attached to Plaintiffs' FAC as Exhibit 3. Sandoz denies that the '058 patent was duly and legally issued, as well as any suggestion that the '058 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 23.

U.S. Patent No. 10,973,769

24. On April 13, 2021, the PTO duly and legally issued United States Patent No. 10,973,769 ("the '769 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '769 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 '769 patent is attached as **Exhibit 4**.

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 '769 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about April 13, 2021. Sandoz further admits that what purports to be a copy of the '769 patent is attached to Plaintiffs' FAC as Exhibit 4. Sandoz denies that the '769 patent was duly and legally issued, as well as any suggestion that the '769 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 24.

U.S. Patent No. 10,987,313

25. On April 27, 2021, the PTO duly and legally issued United States Patent No. 10,987,313 ("the '313 patent") entitled "Muco-adhesive, controlled release formulations of

levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '313 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 '313 patent is attached as **Exhibit 5**.

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 '313 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about April 27, 2021. Sandoz further admits that what purports to be a copy of the '313 patent is attached to Plaintiffs' FAC as Exhibit 5. Sandoz denies that the '313 patent was duly and legally issued, as well as any suggestion that the '313 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 25.

U.S. Patent No. 11,357,733

26. On June 14, 2022, the PTO duly and legally issued United States Patent No. 11,357,733 ("the '733 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '733 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 '733 patent is attached as **Exhibit 6**.

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 '733 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about June 14, 2022. Sandoz further admits that what purports to be a copy of the '733 patent is attached to Plaintiffs' FAC as Exhibit 6. Sandoz denies that the '733 patent was duly and legally issued, as well as any suggestion that the '733 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 26.

U.S. Patent No. 11,622,941

27. On April 11, 2023, the PTO duly and legally issued United States Patent No. 11,622,941 ("the '941 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '941 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 '941 patent is attached as **Exhibit 7**.

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 '941 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about April 11, 2023. Sandoz further admits that what purports to be a copy of the '941 patent is attached to Plaintiffs' FAC as Exhibit 7. Sandoz denies that the '941 patent was duly and legally issued, as well as any suggestion that the '941 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 27.

U.S. Patent No. 11,666,538

28. On June 6, 2023, the PTO duly and legally issued United States Patent No. 11,666,538 ("the '538 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '538 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 '538 patent is attached as **Exhibit 8**.

ANSWER: Paragraph 28 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 '538 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about June 6, 2023. Sandoz further admits that what purports to be a copy of the '538 patent is attached to Plaintiffs' FAC as Exhibit 8. Sandoz denies that the '538 patent was duly and legally issued, as well as any suggestion that the

'538 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 28.

U.S. Patent No. 11,986,449

29. On May 21, 2024, the PTO duly and legally issued United States Patent No. 11,986,449 ("the '449 patent") entitled "Levodopa dosing regimen" to inventors Richard D'Souza, Hester Visser, and Suneel Gupta. The '449 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 '449 patent is attached as **Exhibit 9**.

ANSWER: Paragraph 29 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 '449 patent, which is titled "Levodopa dosing regimen," issued on or about May 21, 2024. Sandoz further admits that what purports to be a copy of the '449 patent is attached to Plaintiffs' FAC as Exhibit 9. Sandoz denies that the '449 patent was duly and legally issued, as well as any suggestion that the '449 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 29.

U.S. Patent No. 12,064,521

30. On August 20, 2024, the PTO duly and legally issued United States Patent No. 12,064,521 ("the '521 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '521 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 '521 patent is attached as **Exhibit 10**.

ANSWER: Paragraph 30 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 '521 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about August 20, 2024. Sandoz further admits that what purports to be a copy of the '521 patent is attached to Plaintiffs' FAC as Exhibit 10. Sandoz denies that the '521 patent was duly and legally issued, as well as any suggestion that

the ’521 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 30.

U.S. Patent No. 12,109,185

31. On October 8, 2024, the PTO duly and legally issued United States Patent No. 12,109,185 (“the ’185 patent”) entitled “Levodopa dosing regimen” to inventors Richard D’Souza, Hester Visser, and Suneel Gupta. The ’185 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 ’185 patent is attached as **Exhibit 11**.

ANSWER: Paragraph 31 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 ’185 patent, which is titled “Levodopa dosing regimen,” issued on or about October 8, 2024. Sandoz further admits that what purports to be a copy of the ’185 patent is attached to Plaintiffs’ FAC as Exhibit 11. Sandoz denies that the ’185 patent was duly and legally issued, as well as any suggestion that the ’185 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 31.

U.S. Patent No. 12,128,141

32. On October 29, 2024, the PTO duly and legally issued United States Patent No. 12,128,141 (“the ’141 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 ’141 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 ’141 patent is attached as **Exhibit 12**.

ANSWER: Paragraph 32 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 ’141 patent, which is titled “Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof,” issued on or about October 29, 2024. Sandoz further admits that what purports to be a copy of the ’141 patent is attached to Plaintiffs’ FAC as Exhibit 12. Sandoz denies that the ’141 patent was duly and legally issued, as well as any suggestion that the

'141 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 32.

U.S. Patent No. 12,178,918

33. On December 31, 2024, the PTO duly and legally issued United States Patent No. 12,178,918 ("the '918 patent") entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof" to inventors Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta. The '918 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 '918 patent is attached as **Exhibit 13**.

ANSWER: Paragraph 33 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 '918 patent, which is titled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof," issued on or about December 31, 2024. Sandoz further admits that what purports to be a copy of the '918 patent is attached to Plaintiffs' FAC as Exhibit 13. Sandoz denies that the '918 patent was duly and legally issued, as well as any suggestion that the '918 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 33.

U.S. Patent No. 12,178,919

34. On December 31, 2024, the PTO duly and legally issued United States Patent No. 12,178,919 ("the '919 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 '919 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 '919 patent is attached as **Exhibit 14**.

ANSWER: Paragraph 34 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 '919 patent, which is titled "Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof," issued on or about December 31, 2024. Sandoz further admits that what purports to be a copy of the '919 patent is attached to Plaintiffs' FAC as Exhibit 14.

Sandoz denies that the '919 patent was duly and legally issued, as well as any suggestion that the '919 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 34.

U.S. Patent No. 12,194,150

35. On January 14, 2025, the PTO duly and legally issued United States Patent No. 12,194,150 ("the '150 patent") entitled "Levodopa dosing regimen" to inventors Richard D'Souza, Hester Visser, and Suneel Gupta. The '150 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 '150 patent is attached as **Exhibit 15**.

ANSWER: Paragraph 35 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 '150 patent, which is titled "Levodopa dosing regimen," issued on or about January 14, 2025. Sandoz further admits that what purports to be a copy of the '150 patent is attached to Plaintiffs' FAC as Exhibit 15. Sandoz denies that the '150 patent was duly and legally issued, as well as any suggestion that the '150 patent is valid and enforceable. Sandoz denies any and all remaining allegations of Paragraph 35.

RESPONSE TO "CREXONT®"

36. 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 36 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 36.

37. 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, and '150 patents are listed in the FDA "Orange Book" with respect to CREXONT®. Plaintiffs are owners by assignment of the Patents-in-Suit.

ANSWER: Paragraph 37 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, and '150 patents in connection with Crexont®. Sandoz denies any and all remaining allegations of Paragraph 37.

RESPONSE TO "ACTS GIVING RISE TO THIS ACTION"

38. 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.

39. 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 39 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 39.

40. 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 40 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 40.

41. On information and belief, in connection with the submission of the Sandoz ANDA, Defendant have provided written certifications to the FDA, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that claims of the '845, '935, '058, '769, '313, '733, '941, '538, '449, '521,'141, '185, '918, '919, and '150 patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products (the "Sandoz Paragraph IV Certifications").

ANSWER: Paragraph 41 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 '845, '935, '058, '769, '313, '733, '941, '538, '449, '521, '141, '185, '918, '919, and '150 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 41.

42. No earlier than November 25, 2024, Plaintiffs received written notice of the Sandoz ANDA and the Sandoz Paragraph IV Certifications from Defendant regarding the '845, '935, '058, '769, '313, '733, '941, '538, '449, and '521 patents ("Notice Letter"). The 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 ("Detailed Statement").

ANSWER: Paragraph 42 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" ("PIV Notice Letter"). Sandoz denies any and all remaining allegations of Paragraph 42.

43. No earlier than January 30, 2025, Plaintiffs received written notice of additional Sandoz Paragraph IV Certifications from Defendant regarding the '185, '141, '918, '919, and '150 patents ("Second Notice Letter"). The 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 ("Second Detailed Statement").

ANSWER: Paragraph 43 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 ("Second PIV Notice Letter)." Sandoz denies any and all remaining allegations of Paragraph 43.

44. 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 44 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 44.

45. This 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 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). With respect to the '185, '141, '918, '919, and '150 patents, this First Amended Complaint asserts infringement of those patents based on the Second Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. Sandoz admits that it sent the PIV 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. Sandoz denies any and all remaining allegations of Paragraph 45.

RESPONSE TO "COUNT I: INFRINGEMENT OF THE '845 PATENT BY SANDOZ"

46. 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.

47. 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 '845 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '845 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

48. 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 '845 patent constituted an act of infringement of one or more claims of the '845 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

49. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '845 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '845 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

50. Upon information and belief, Defendant intends to, and will, infringe at least claim 1 of the '845 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.

51. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '845 patent.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 51.

52. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-4, 6-8, 11-16, and 18-22. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '845 patent.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 52.

53. 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 '845 patent, including at least claim 17, 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 '845 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

54. 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 '845 patent.

ANSWER: Denied.

55. 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.

56. 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 '845 patent and will constitute infringement.

ANSWER: Denied.

57. 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 '845 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 '845 patent.

ANSWER: Denied.

58. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '845 patent, including at least claim 17, 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 '845 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 claims of the '845 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

59. 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 '845 patent, or any later expiration of exclusivity for the '845 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.

60. Defendant has had knowledge of the '845 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT II: INFRINGEMENT OF THE '935 PATENT BY SANDOZ"

62. 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.

63. 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 '935 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '935 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

64. 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 '935 patent constituted an act of infringement of one or more claims of the '935 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

65. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '935 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '935 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

66. Upon information and belief, Defendant intends to, and will, infringe at least claim 1 of the '935 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.

67. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '935 patent.

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 67.

68. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-17, 19, and 20. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '935 patent.

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 68.

69. 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 '935 patent, including at least claim 18, 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 the claims of the '935 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

70. 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 '935 patent.

ANSWER: Denied.

71. 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.

72. 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 '935 patent and will constitute infringement.

ANSWER: Denied.

73. 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 '935 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 '935 patent.

ANSWER: Denied.

74. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '935 patent, including at least claim 18, 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 '935 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 '935 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

75. 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 '935 patent, or any later expiration of exclusivity for the '935 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.

76. Defendant has had knowledge of the '935 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT III: INFRINGEMENT OF THE '058 PATENT BY SANDOZ"

78. 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.

79. 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 '058 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '058 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

80. 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 '058 patent constituted an act of infringement of one or more claims of the '058 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

81. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '058 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '058 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

82. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '058 patent.

ANSWER: Paragraph 82 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 82.

83. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '058 patent.

ANSWER: Denied.

84. 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 '058 patent, including at least claims 1 and 20, 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 '058 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

85. 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 '058 patent.

ANSWER: Denied.

86. 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.

87. 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 '058 patent and will constitute infringement.

ANSWER: Denied.

88. 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 '058 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 '058 patent.

ANSWER: Denied.

89. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '058 patent, including at least claims 1 and 20, 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 '058 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 '058 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

90. 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 '058 patent, or any later expiration of exclusivity for the '058 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.

91. Defendant has had knowledge of the '058 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT IV: INFRINGEMENT OF THE '769 PATENT BY SANDOZ"

93. 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.

94. 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 '769 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '769 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

95. 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 '769 patent constituted an act of infringement of one or more claims of the '769 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

96. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '769 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '769 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

97. Upon information and belief, Defendant intends to, and will, infringe at least claim 14 of the '769 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.

98. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '769 patent.

ANSWER: Paragraph 98 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 98.

99. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 14-16 and 18-27. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '769 patent.

ANSWER: Paragraph 99 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 99.

100. 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 '769 patent, including at least claims 1 and 10, 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 '769 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

101. 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 '769 patent.

ANSWER: Denied.

102. 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.

103. 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 '769 patent and will constitute infringement.

ANSWER: Denied.

104. 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 '769 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 '769 patent.

ANSWER: Denied.

105. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '769 patent, including at least claims 1 and 10, 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 '769 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 '769 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

106. 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 '769 patent, or any later expiration of exclusivity for the '769 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.

107. Defendant has had knowledge of the '769 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT V: INFRINGEMENT OF THE '313 PATENT BY SANDOZ"

109. 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.

110. 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 '313 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '313 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

111. 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 '313 patent constituted an act of infringement of one or more claims of the '313 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

112. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '313 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '313 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

113. Upon information and belief, Defendant intends to, and will, infringe at least claim 1 of the '313 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.

114. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '313 patent.

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 114.

115. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-5, and 7-19. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '313 patent.

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 115.

116. 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 '313 patent, including at least claim 20, 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 '313 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

117. 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 '313 patent.

ANSWER: Denied.

118. 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.

119. 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 '313 patent and will constitute infringement.

ANSWER: Denied.

120. 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 '313 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 '313 patent claims.

ANSWER: Denied.

121. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '313 patent, including at least claim 20, 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 '313 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 '313 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

122. 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 '313 patent, or any later expiration of exclusivity for the '313 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.

123. Defendant has had knowledge of the '313 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT VI: INFRINGEMENT OF THE '733 PATENT BY SANDOZ"

125. 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.

126. 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 '733 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '733 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

127. 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 '733 patent constituted an act of infringement of one or more claims of the '733 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

128. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '733 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '733 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

129. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 24, and 40 of the '733 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.

130. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '733 patent.

ANSWER: Paragraph 130 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 130.

131. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-6, 8-32, and 35-40. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '733 patent.

ANSWER: Paragraph 131 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 131.

132. 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 '733 patent, including at least claims 1, 24, and 40, 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 '733 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

133. 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.

134. 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 '733 patent and will constitute infringement.

ANSWER: Denied.

135. 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 '733 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 '733 patent.

ANSWER: Denied.

136. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '733 patent, including at least claims 1, 24, and 40, 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 '733 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 '733 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

137. 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 '733 patent, or any later expiration of exclusivity for the '733 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.

138. Defendant has had knowledge of the '733 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT VII: INFRINGEMENT OF THE '941 PATENT BY SANDOZ"

140. 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.

141. 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 '941 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '941 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

142. 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 '941 patent constituted an act of infringement of one or more claims of the '941 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

143. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '941 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '941 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

144. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 18, and 28 of the '941 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.

145. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '941 patent.

ANSWER: Paragraph 145 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 145.

146. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for non-infringement, other than invalidity, for any claim of the '941 patent. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '941 patent.

ANSWER: Paragraph 146 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 146.

147. 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 '941 patent, including at least claims 1, 18 and 28, 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 '941 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

148. 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.

149. 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 '941 patent and will constitute infringement.

ANSWER: Denied.

150. 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 '941 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 '941 patent.

ANSWER: Denied.

151. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '941 patent, including at least claims 1, 18, and 28, 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 '941 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 '941 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

152. 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 '941 patent, or any later expiration of exclusivity for the '941 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.

153. Defendant has had knowledge of the '941 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT VIII: INFRINGEMENT OF THE '538 PATENT BY SANDOZ"

155. 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.

156. 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 '538 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '538 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

157. 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 '538 patent constituted an act of infringement of one or more claims of the '538 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

158. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '538 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '538 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

159. Upon information and belief, Defendant intends to, and will, infringe at least claims 1 and 20 of the '538 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.

160. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '538 patent.

ANSWER: Paragraph 160 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 160.

161. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-9, 11-17, and 19-21. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '538 patent.

ANSWER: Paragraph 161 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449,

and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 161.

162. 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 '538 patent, including at least claim 18, 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 '538 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

163. 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 '538 patent.

ANSWER: Denied.

164. 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.

165. 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 '538 patent and will constitute infringement.

ANSWER: Denied.

166. 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 '538 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 '538 patent.

ANSWER: Denied.

167. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '538 patent, including at least claim 18, 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 '538 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 '538 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

168. 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 '538 patent, or any later expiration of exclusivity for the '538 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.

169. Defendant has had knowledge of the '538 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT IX: INFRINGEMENT OF THE '449 PATENT BY SANDOZ"

171. 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.

172. 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 '449 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '449 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

173. 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 '449 patent constituted an act of infringement of one or more claims of the '449 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

174. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '449 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '449 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

175. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '449 patent.

ANSWER: Paragraph 175 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 175.

176. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '449 patent.

ANSWER: Denied.

177. 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 '449 patent, including at least claims 1, 10, 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 '449 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

178. 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 '449 patent.

ANSWER: Denied.

179. 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.

180. 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 '449 patent and will constitute infringement.

ANSWER: Denied.

181. 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 '449 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 '449 patent claims.

ANSWER: Denied.

182. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '449 patent, including at least claims 1, 10 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 '449 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 '449 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

183. 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 '449 patent, or any later expiration of exclusivity for the '449 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.

184. Defendant has had knowledge of the '449 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT X: INFRINGEMENT OF THE '521 PATENT BY SANDOZ"

186. 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.

187. 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 '521 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '521 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

188. 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 '521 patent constituted an act of infringement of one or more claims of the '521 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

189. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '521 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '521 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

190. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 11, and 20 of the '521 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.

191. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '521 patent.

ANSWER: Paragraph 191 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 191.

192. In the Notice Letter and Detailed Statement, Defendant sets forth no grounds for non-infringement, other than invalidity, for any claim of the '521 patent. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe at least one claim of the '521 patent.

ANSWER: Paragraph 192 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the PIV 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 845, 935, 058, 769, 313, 733, 941, 538, 449, and 521 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 192.

193. 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 '521 patent, including at least claims 1, 11, and 20, 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 '521 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

194. 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.

195. 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 '521 patent and will constitute infringement.

ANSWER: Denied.

196. 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 '521 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 '521 patent.

ANSWER: Denied.

197. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '521 patent, including at least claims 1, 11 and 20, 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 '521 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 '521 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

198. 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 '521 patent, or any later expiration of exclusivity for the '521 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.

199. Defendant has had knowledge of the '521 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.

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

ANSWER: Denied.

RESPONSE TO "COUNT XI: INFRINGEMENT OF THE '185 PATENT BY SANDOZ"

201. 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.

202. 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 '185 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '185 patent under at least 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

203. 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 '185 patent constituted an act of infringement of one or more claims of the '185 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

204. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '185 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '185 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

205. Upon information and belief, by virtue of its listing in the Orange Book, Defendant has knowledge of the '185 patent.

ANSWER: Paragraph 205 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 205.

206. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '185 patent.

ANSWER: Denied.

207. 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 '185 patent, including at least claims 1, 10, and 17, 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 '185 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

208. 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 '185 patent.

ANSWER: Denied.

209. 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.

210. 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 '185 patent and will constitute infringement.

ANSWER: Denied.

211. 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 '185 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 '185 patent.

ANSWER: Denied.

212. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '185 patent, including at least claims 1, 10, and 17, 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 '185 patent. Upon information and belief, 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 '185 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

213. 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 '185 patent, or any later expiration of exclusivity for the '185 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.

214. Upon information and belief, Defendant had knowledge of the '185 patent from at least a time at or around the date the '185 patent was listed in the Orange Book.

ANSWER: Denied.

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

ANSWER: Denied.

RESPONSE TO "COUNT XII: INFRINGEMENT OF THE '141 PATENT BY SANDOZ"

216. 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.

217. 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 '141 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '141 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

218. 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 '141 patent constituted an act of infringement of one or more claims of the '141 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

219. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '141 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '141 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

220. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 11, and 13 of the '141 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.

221. Upon information and belief, by virtue of its listing in the Orange Book, Defendant has knowledge of the '141 patent.

ANSWER: Paragraph 221 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 221.

222. In the Second Notice Letter and Second Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-17. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '141 patent.

ANSWER: Paragraph 222 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Further answering, Sandoz admits that its Second 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 222.

223. 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 '141 patent, including at least claim 18, 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 '141 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

224. 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 '141 patent.

ANSWER: Denied.

225. 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.

226. 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 '141 patent and will constitute infringement.

ANSWER: Denied.

227. 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 '141 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 '141 patent.

ANSWER: Denied.

228. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '141 patent, including at least claim 18, 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 '141 patent. Upon information and belief, 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 '141 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

229. 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 '141 patent, or any later expiration of exclusivity for the '141 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.

230. Upon information and belief, Defendant had knowledge of the '141 patent from at least a time at or around the date the '141 patent was listed in the Orange Book.

ANSWER: Denied.

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

ANSWER: Denied.

RESPONSE TO "COUNT XIII: INFRINGEMENT OF THE '918 PATENT BY SANDOZ"

232. 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.

233. 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 '918 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '918 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

234. 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 '918 patent constituted an act of infringement of one or more claims of the '918 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

235. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '918 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '918 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

236. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 11, and 20 of the '918 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.

237. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Notice Letter and Detailed Statement, Defendant has knowledge of the '918 patent.

ANSWER: Paragraph 237 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 237.

238. In the Second Notice Letter and Second Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, any claims of the '918 patent. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '918 patent.

ANSWER: Paragraph 238 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Further answering, Sandoz admits that its Second 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 238.

239. 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 '918 patent, including at least claim 1, 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 '918 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

240. 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.

241. 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 '918 patent and will constitute infringement.

ANSWER: Denied.

242. 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 '918 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 '918 patent.

ANSWER: Denied.

243. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '918 patent, including at least claim 1, 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 '918 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 '918 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

244. 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 '918 patent, or any later expiration of exclusivity for the '918 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.

245. Upon information and belief, Defendant had knowledge of the '918 patent from at least a time at or around the date the '918 patent was listed in the Orange Book.

ANSWER: Denied.

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

ANSWER: Denied.

RESPONSE TO "COUNT XIV: INFRINGEMENT OF THE '919 PATENT BY SANDOZ"

247. 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.

248. 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 '919 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '919 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

249. 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 '919 patent constituted an act of infringement of one or more claims of the '919 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

250. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '919 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '919 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

251. Upon information and belief, Defendant intends to, and will, infringe at least claims 1, 13, and 16 of the '919 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.

252. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Second Notice Letter and Second Detailed Statement, Defendant has knowledge of the '919 patent.

ANSWER: Paragraph 252 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 252.

253. In the Second Notice Letter and Detailed Statement, Defendant sets forth no grounds for not directly infringing, other than invalidity, claims 1-21. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '919 patent.

ANSWER: Paragraph 253 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Further answering, Sandoz admits that its Second 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 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 drug products described in Sandoz's ANDA." Sandoz denies any and all remaining allegations of Paragraph 253.

254. 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 '919 patent, including at least claim 22, 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 '919 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

255. 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 or Parkinsonism. These uses will constitute direct infringement of one or more claims of the '919 patent.

ANSWER: Denied.

256. 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.

257. 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 '919 patent and will constitute infringement.

ANSWER: Denied.

258. 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 '919 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 '919 patent.

ANSWER: Denied.

259. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '919 patent, including at least claim 22, 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 '919 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 '919 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

260. 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 '919 patent, or any later expiration of exclusivity for the '919 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.

261. Upon information and belief, Defendant had knowledge of the '919 patent from at least a time at or around the date the '919 patent was listed in the Orange Book.

ANSWER: Denied.

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

ANSWER: Denied.

RESPONSE TO "COUNT XV: INFRINGEMENT OF THE '150 PATENT BY SANDOZ"

263. 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.

264. 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 '150 patent, in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Defendant's infringement of the '150 patent under 35 U.S.C. §§ 271(b) and/or (c).

ANSWER: Denied.

265. 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 '150 patent constituted an act of infringement of one or more claims of the '150 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

266. Defendant's commercial manufacture, use, offer for sale, sale, and/or importation of the Sandoz ANDA Products prior to expiration of the '150 patent, and Defendant's inducement of and/or contribution to such conduct, would further infringe at least one claim of the '150 patent, either literally or under the doctrine of equivalents, under at least 35 U.S.C. § 271(b) and/or (c).

ANSWER: Denied.

267. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Second Notice Letter and Second Detailed Statement, Defendant has knowledge of the '150 patent.

ANSWER: Paragraph 267 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that the Second Notice Letter stated, *inter alia*, that "[t]he ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and has been amended to contain 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 mg/350 mg, before the expiration of the 185, 141, 918, 919, and 150 patents . . . ." Sandoz denies any and all remaining allegations of Paragraph 267.

268. Upon information and belief, Defendant has knowledge that the Sandoz ANDA Products will infringe the '150 patent.

ANSWER: Denied.

269. 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 '150 patent, including at least claims 1, 5, and 6, 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 '150 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

270. 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 '150 patent.

ANSWER: Denied.

271. 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.

272. 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 '150 patent and will constitute infringement.

ANSWER: Denied.

273. 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 '150 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 '150 patent.

ANSWER: Denied.

274. Upon FDA approval of the Sandoz ANDA, Defendant will contributorily infringe one or more claims of the '150 patent, including at least claims 1, 5, and 6, 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 '150 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 '150 patent and are not suitable for substantial non-infringing use.

ANSWER: Denied.

275. 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 '150 patent, or any later expiration of exclusivity for the '150 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.

276. Upon information and belief, Defendant had knowledge of the '150 patent from at least a time at or around the date the '150 patent was listed in the Orange Book.

ANSWER: Denied.

277. 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 FAC 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 FAC fails to state a claim upon which relief can be granted.

Second Defense

The claims of the ’845 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 ’845 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 ’845 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 ’845 patent.

Sixth Defense

The claims of the ’935 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 '935 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 '935 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 '935 patent.

Tenth Defense

The claims of the '058 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 '058 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 '058 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 '058 patent.

Fourteenth Defense

The claims of the ’769 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 ’769 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 ’769 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 ’769 patent.

Eighteenth Defense

The claims of the ’313 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 ’313 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 ’313 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 ’313 patent.

Twenty Second Defense

The claims of the ’733 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 ’733 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 ’733 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 ’733 patent.

Twenty Sixth Defense

The claims of the ’941 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 '941 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 '941 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 '941 patent.

Thirtieth Defense

The claims of the '538 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 '538 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 '538 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 ’538 patent.

Thirty Fourth Defense

The claims of the ’449 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 Fifth 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 ’449 patent, either literally or under the doctrine of equivalents.

Thirty Sixth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ’449 patent.

Thirty Seventh Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’449 patent.

Thirty Eighth Defense

The claims of the ’521 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 Ninth 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 '521 patent, either literally or under the doctrine of equivalents.

Fortieth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '521 patent.

Forty First Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '521 patent.

Forty Second Defense

The claims of the '185 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.

Forty 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 '185 patent, either literally or under the doctrine of equivalents.

Forty Fourth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '185 patent.

Forty Fifth Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’185 patent.

Forty Sixth Defense

The claims of the ’141 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.

Forty 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 ’141 patent, either literally or under the doctrine of equivalents.

Forty Eighth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ’141 patent.

Forty Ninth Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’141 patent.

Fiftieth Defense

The claims of the ’918 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.

Fifty 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 '918 patent, either literally or under the doctrine of equivalents.

Fifty Second Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '918 patent.

FiftyThird Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '918 patent.

Fifty Fourth Defense

The claims of the '919 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.

Fifty Fifth 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 '919 patent, either literally or under the doctrine of equivalents.

Fifty Sixth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '919 patent.

Fifty Seventh Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’919 patent.

Fifty Eighth Defense

The claims of the ’150 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.

Fifty Ninth 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 ’150 patent, either literally or under the doctrine of equivalents.

Sixtieth Defense

Sandoz has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the ’150 patent.

Sixty First Defense

Sandoz has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the ’150 patent.

Sixty Second 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).

Sixty Third Defense

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

Sixty Fourth 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 is 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 First Amended Complaint for Patent Infringement ("FAC") 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"), and 12,201,596 ("the '596 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.

Patents-in-Suit

U.S. Patent No. 10,098,845

26. On or about October 16, 2018, the United States Patent & Trademark Office ("PTO"), issued the '845 patent, entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof."

27. The face of the '845 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

28. The face of the '845 patent identifies Impax Laboratories, LLC as the purported assignee.

29. By listing the '845 patent in the Orange Book, Counterclaim-Defendants maintain that an infringement suit could reasonably be asserted against any generic Abbreviated New Drug Application ("ANDA") applicant—including Sandoz—that attempts to seek approval for, and market, a generic version of Crexont® before patent expiration.

U.S. Patent No. 10,292,935

30. On or about May 21, 2019, the PTO issued the '935 patent, entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof."

31. The face of the ’935 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

32. The face of the ’935 patent identifies Impax Laboratories, LLC as the purported assignee.

33. By listing the ’935 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. 10,688,058

34. On or about June 23, 2020, the PTO issued the ’058 patent, entitled “Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof.”

35. The face of the ’058 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

36. The face of the ’058 patent identifies Impax Laboratories, LLC as the purported assignee.

37. By listing the ’058 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. 10,973,769

38. On or about April 13, 2021, the PTO issued the ’769 patent, entitled “Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof.”

39. The face of the '769 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

40. The face of the '769 patent identifies Impax Laboratories, LLC as the purported assignee.

41. By listing the '769 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. 10,987,313

42. On or about April 27, 2021, the PTO issued the '313 patent, entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof."

43. The face of the '313 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

44. The face of the ' 313 patent identifies Impax Laboratories, LLC as the purported assignee.

45. By listing the '313 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. 11,357,733

46. On or about June 14, 2022, the PTO issued the '733 patent, entitled "Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof."

47. The face of the ’733 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

48. The face of the ’733 patent identifies Impax Laboratories, LLC as the purported assignee.

49. By listing the ’733 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. 11,622,941

50. On or about April 11, 2023, the PTO issued the ’941 patent, entitled “Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof.”

51. The face of the ’941 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

52. The face of the ’941 patent identifies Impax Laboratories, LLC as the purported assignee.

53. By listing the ’941 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. 11,666,538

54. On or about June 6, 2023, the PTO issued the ’538 patent, entitled “Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof.”

55. The face of the ’538 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

56. The face of the ’538 patent identifies Impax Laboratories, LLC as the purported assignee.

57. By listing the ’538 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. 11,986,449

58. On or about May 21, 2024, the PTO issued the ’449 patent, entitled “Levodopa dosing regimen.”

59. The face of the ’449 patent identifies Richard D’Souza, Hester Visser, and Suneel Gupta as the purported inventors.

60. The face of the ’449 patent identifies Amneal Pharmaceuticals LLC as the purported assignee.

61. By listing the ’449 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. 12,064,521

62. On or about August 20, 2024, the PTO issued the ’521 patent, entitled “Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof.”

63. The face of the ’521 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

64. The face of the ’521 patent identifies Impax Laboratories, LLC as the purported assignee.

65. By listing the ’521 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. 12,109,185

66. On or about October 8, 2024, the PTO issued the ’185 patent,” entitled “Levodopa dosing regimen.”

67. The face of the ’185 patent identifies Richard D’Souza, Hester Visser, and Suneel Gupta as the purported inventors.

68. The face of the ’185 patent identifies Amneal Pharmaceuticals, LLC as the purported assignee.

69. By listing the ’185 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. 12,128,141

70. On or about October 29, 2024, PTO issued the ’141 patent, entitled “Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof.”

71. The face of the ’141 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

72. The face of the ’141 patent identifies Impax Laboratories, LLC as the purported assignee.

73. By listing the ’141 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. 12,178,918

74. On or about December 31, 2024, the PTO issued the ’918 patent, entitled “Muco-adhesive, controlled release formulations of levodopa and/or esters of levodopa and uses thereof.”

75. The face of the ’918 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

76. The face of the ’918 patent identifies Impax Laboratories, LLC as the purported assignee.

77. By listing the ’918 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. 12,178,919

78. On or about December 31, 2024, the PTO issued the ’919 patent, entitled “Muco-adhesive, controlled release formulation of levodopa and/or esters of levodopa and uses thereof.”

79. The face of the ’919 patent identifies Ann Hsu, Liang Dong, Amy Ding, and Suneel Gupta as the purported inventors.

80. The face of the ’919 patent identifies Impax Laboratories, LLC as the purported assignee.

81. By listing the ’919 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. 12,194,150

82. On or about January 14, 2025, the PTO issued the ’150 patent, entitled “Levodopa dosing regimen.”

83. The face of the ’150 patent identifies Richard D’Souza, Hester Visser, and Suneel Gupta as the purported inventors.

84. The face of the ’150 patent identifies Amneal Pharmaceuticals LLC as the purported assignee.

85. By listing the ’150 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

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

87. 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, and ’150 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 patents.

88. On January 7, 2025, Plaintiffs filed the above-captioned action against Sandoz, asserting infringement of the ’845, ’935, ’058, ’769, ’313, ’733, ’941, ’538, ’449, ’521, ’185 and ’141 patents.

89. On April 1, 2025, Plaintiffs filed the FAC, asserting infringement of the ’845, ’935, ’058, ’769, ’313, ’733, ’941, ’538, ’449, ’521, ’185, ’141, ’918, ’919, and ’150 patents.

COUNT I

Declaration of Noninfringement of the ’845 Patent

90. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-89 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 ’845 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 ’845 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 ’845 patent.

COUNT II

Declaration of Invalidity of the '845 Patent

94. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-93 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 '845 patent.

96. The '845 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 '845 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 '845 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 '845 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 '845 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 ’935 Patent

100. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-99 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 ’935 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 ’935 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 ’935 patent.

COUNT IV

Declaration of Invalidity of the ’935 Patent

104. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-103 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 ’935 patent.

106. The ’935 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 ’935 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 ’935 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 ’935 patent and would have had a reasonable expectation of success in doing so.

108. The subject matter claimed in the ’935 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 ’935 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 ’058 Patent

110. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-109 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 ’058 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 '058 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 '058 patent.

COUNT VI

Declaration of Invalidity of the '058 Patent

114. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-113 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 '058 patent.

116. The '058 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 '058 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 '058 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 '058 patent and would have had a reasonable expectation of success in doing so.

118. The subject matter claimed in the '058 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 ’058 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 ’769 Patent

120. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-119 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 ’769 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 ’769 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 ’769 patent.

COUNT VIII

Declaration of Invalidity of the ’769 Patent

124. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-123 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 '769 patent.

126. The '769 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 '769 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 '769 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 '769 patent and would have had a reasonable expectation of success in doing so.

128. The subject matter claimed in the '769 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 '769 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 '313 Patent

130. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-129 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 '313 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 '313 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 '313 patent.

COUNT X

Declaration of Invalidity of the '313 Patent

134. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-133 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 '313 patent.

136. The '313 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 '313 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 '313 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 '313 patent and would have had a reasonable expectation of success in doing so.

138. The subject matter claimed in the '313 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 '313 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 '733 Patent

140. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-139 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 '733 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 '733 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 '733 patent.

COUNT XII

Declaration of Invalidity of the '733 Patent

144. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-143 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 '733 patent.

146. The '733 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 '733 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 '733 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 '733 patent and would have had a reasonable expectation of success in doing so.

148. The subject matter claimed in the '733 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 '733 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 ’941 Patent

150. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-149 as if fully set forth herein.

151. 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 ’941 patent.

152. 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 ’941 patent, either literally or under the doctrine of equivalents.

153. 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 ’941 patent.

COUNT XIV

Declaration of Invalidity of the ’941 Patent

154. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-153 as if fully set forth herein.

155. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the ’941 patent.

156. The ’941 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.

157. The alleged invention of the '941 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 '941 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 '941 patent and would have had a reasonable expectation of success in doing so.

158. The subject matter claimed in the '941 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.

159. Sandoz is entitled to a judicial declaration that the claims of the '941 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 '538 Patent

160. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-159 as if fully set forth herein.

161. 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 '538 patent.

162. 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 '538 patent, either literally or under the doctrine of equivalents.

163. 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 '538 patent.

COUNT XVI

Declaration of Invalidity of the '538 Patent

164. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-163 as if fully set forth herein.

165. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '538 patent.

166. The '538 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.

167. The alleged invention of the '538 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 '538 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 '538 patent and would have had a reasonable expectation of success in doing so.

168. The subject matter claimed in the '538 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.

169. Sandoz is entitled to a judicial declaration that the claims of the ’538 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XVII

Declaration of Noninfringement of the ’449 Patent

170. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-169 as if fully set forth herein.

171. 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 ’449 patent.

172. 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 ’449 patent, either literally or under the doctrine of equivalents.

173. 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 ’449 patent.

COUNT XVIII

Declaration of Invalidity of the ’449 Patent

174. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-173 as if fully set forth herein.

175. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '449 patent.

176. The '449 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.

177. The alleged invention of the '449 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 '449 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 '449 patent and would have had a reasonable expectation of success in doing so.

178. The subject matter claimed in the '449 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.

179. Sandoz is entitled to a judicial declaration that the claims of the '449 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XIX

Declaration of Noninfringement of the '521 Patent

180. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-179 as if fully set forth herein.

181. 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 '521 patent.

182. 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 '521 patent, either literally or under the doctrine of equivalents.

183. 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 '521 patent.

COUNT XX

Declaration of Invalidity of the '521 Patent

184. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-183 as if fully set forth herein.

185. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '521 patent.

186. The '521 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.

187. The alleged invention of the '521 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 '521 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 '521 patent and would have had a reasonable expectation of success in doing so.

188. The subject matter claimed in the '521 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.

189. Sandoz is entitled to a judicial declaration that the claims of the '521 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XXI

Declaration of Noninfringement of the '185 Patent

190. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-189 as if fully set forth herein.

191. 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 '185 patent.

192. 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 '185 patent, either literally or under the doctrine of equivalents.

193. 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 '185 patent.

COUNT XXII

Declaration of Invalidity of the '185 Patent

194. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-193 as if fully set forth herein.

195. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '185 patent.

196. The '185 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.

197. The alleged invention of the '185 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 '185 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 '185 patent and would have had a reasonable expectation of success in doing so.

198. The subject matter claimed in the '185 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.

199. Sandoz is entitled to a judicial declaration that the claims of the '185 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XXIII

Declaration of Noninfringement of the ’141 Patent

200. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-199 as if fully set forth herein.

201. 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 ’141 patent.

202. 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 ’141 patent, either literally or under the doctrine of equivalents.

203. 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 ’141 patent.

COUNT XXIV

Declaration of Invalidity of the ’141 Patent

204. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-203 as if fully set forth herein.

205. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the ’141 patent.

206. The ’141 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.

207. The alleged invention of the '141 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 '141 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 '141 patent and would have had a reasonable expectation of success in doing so.

208. The subject matter claimed in the '141 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.

209. Sandoz is entitled to a judicial declaration that the claims of the '141 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XXV

Declaration of Noninfringement of the '918 Patent

210. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-209 as if fully set forth herein.

211. 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 '918 patent.

212. 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 '918 patent, either literally or under the doctrine of equivalents.

213. 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 '918 patent.

COUNT XXVI

Declaration of Invalidity of the '918 Patent

214. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-213 as if fully set forth herein.

215. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '918 patent.

216. The '918 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.

217. The alleged invention of the '918 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 '918 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 '918 patent and would have had a reasonable expectation of success in doing so.

218. The subject matter claimed in the '918 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.

219. Sandoz is entitled to a judicial declaration that the claims of the ’918 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XXVII

Declaration of Noninfringement of the ’919 Patent

220. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-219 as if fully set forth herein.

221. 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 ’919 patent.

222. 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 ’919 patent, either literally or under the doctrine of equivalents.

223. 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 ’919 patent.

COUNT XXVIII

Declaration of Invalidity of the ’919 Patent

224. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-223 as if fully set forth herein.

225. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '919 patent.

226. The '919 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.

227. The alleged invention of the '919 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 '919 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 '919 patent and would have had a reasonable expectation of success in doing so.

228. The subject matter claimed in the '919 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.

229. Sandoz is entitled to a judicial declaration that the claims of the '919 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT XXIX

Declaration of Noninfringement of the '150 Patent

230. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-229 as if fully set forth herein.

231. 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 '150 patent.

232. 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 '150 patent, either literally or under the doctrine of equivalents.

233. 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 '150 patent.

COUNT XXX

Declaration of Invalidity of the '150 Patent

234. Sandoz realleges and incorporates by reference the allegations in the preceding Paragraphs 1-233 as if fully set forth herein.

235. A present, genuine, and justiciable controversy exists between Counterclaim-Defendants and Sandoz regarding, *inter alia*, the invalidity of the '150 patent.

236. The '150 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.

237. The alleged invention of the '150 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 '150 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 '150 patent and would have had a reasonable expectation of success in doing so.

238. The subject matter claimed in the '150 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.

239. Sandoz is entitled to a judicial declaration that the claims of the '150 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 '845 patent;

(b) declaring that the claims of the '845 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 '935 patent;

(d) declaring that the claims of the '935 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 '058 patent;

(f) declaring that the claims of the '058 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 '769 patent;

(h) declaring that the claims of the '769 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 '313 patent;

(j) declaring that the claims of the '313 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 '733 patent;

(l) declaring that the claims of the '733 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 ’941 patent;

(n) declaring that the claims of the ’941 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 ’538 patent;

(p) declaring that the claims of the ’538 patent are invalid;

(q) 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 ’449 patent;

(r) declaring that the claims of the ’449 patent are invalid;

(s) 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 ’521 patent;

(t) declaring that the claims of the ’521 patent are invalid;

(u) 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 ’185 patent;

(v) declaring that the claims of the ’185 patent are invalid;

(w) 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 '141 patent;

(x) declaring that the claims of the '141 patent are invalid;

(y) 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 '918 patent;

(z) declaring that the claims of the '918 patent are invalid;

(aa) 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 '919 patent;

(bb) declaring that the claims of the '919 patent are invalid;

(cc) 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 '150 patent;

(dd) declaring that the claims of the '150 patent are invalid;

(ee) 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

(ff) 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: April 15, 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)
Ty W. Callahan (tcallahan@rmmslegal.com)
Dylan G. Sacenti (dsacenti@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 April 15, 2025, I caused a true and correct copy of the foregoing document to be served via electronic mail on counsel of record in this matter.

Dated: April 15, 2025

Respectfully submitted,

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