Loly Tor
(loly.tor@klgates.com)
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4000
(F) 973.848.4001

Anil H. Patel
(anil.patel@klgates.com)
(*pro hac vice* application submitted in consolidated case)
K&L GATES LLP
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Elizabeth Weiskopf
(elizabeth.weiskopf@klgates.com)
(*pro hac vice* application submitted in consolidated case)
Jenna Bruce
(Jenna.bruce@klgates.com)
(*pro hac vice* application submitted in consolidated case)
K&L GATES LLP
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.7022

Attorneys for Defendants/Counterclaim-Plaintiffs Cipla USA, Inc. and Cipla Limited

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH, *Plaintiffs*, v. CIPLA LIMITED and CIPLA USA, INC., *Defendants*.	Civil Action No. 3:24-cv-7346 **ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS** ***Document Electronically Filed***

Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants"), by and through their attorneys, respond to each of the numbered paragraphs in the Complaint by

Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH (collectively, "Plaintiffs") as follows[1]:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, which arises out of the submission by Cipla of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, prior to the expiration of U.S. Patent No. 8,859,562 ("the '562 patent"); U.S. Patent No. 11,970,530 (the "'530 patent"); U.S. Patent No. 11,975,001 (the "'001 patent"); U.S. Patent No. 8,475,842 ("the '842 patent"); and U.S. Patent No. 11,633,396 ("the '396 patent") (collectively, the "Patents-in-Suit").

ANSWER: Cipla admits that Plaintiffs' Complaint purports to be based upon the patent laws of the United States, 35 U.S.C. § 100 *et seq*. Cipla admits that Cipla Limited prepared and submitted Cipla's Abbreviated New Drug Application ("ANDA") No. 219410 ("Cipla's ANDA") to the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j), and that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of the product described in Cipla's ANDA ("Cipla's ANDA Product") prior to the expiration of U.S. Patent No. 8,859,562 (the "'562 patent"); U.S. Patent No. 11,970,530 (the "'530 patent"); U.S. Patent No. 11,975,001 (the "'001 patent"); U.S. Patent No. 8,475,842 (the "'842 patent"); and U.S. Patent No. 11,633,396 (the "'396 patent") (collectively, the "Patents-in-Suit"). Cipla denies the remaining allegations in paragraph 1.

2. Cipla notified Plaintiffs by letter dated May 21, 2024 ("Cipla's Notice Letter") that it had submitted to FDA ANDA No. 219410 ("Cipla's ANDA"), seeking approval from FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic

[1] This Answer reproduces the headings of the Complaint for convenience only. This reproduction of the headings should not be construed as an admission of any of the allegations in the Complaint. Pursuant to Federal Rule of Civil Procedure 8(b)(3), Defendants deny all allegations in the Complaint except those specifically admitted.

olaparib tablets, 100 mg and 150 mg ("Cipla's ANDA Product"), prior to the expiration of the '562, '842, and '396 patents.

ANSWER: Cipla admits that Cipla notified Plaintiffs by letter dated May 21, 2024 ("Cipla's Notice Letter") that Cipla had submitted Cipla's ANDA seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, or sale of Cipla's ANDA Product, prior to the expiration of the '562, '842, and '396 patents. Cipla denies any remaining allegations of paragraph 2.

The Parties

3. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558 for the manufacture and sale of LYNPARZA® (olaparib) tablets.

ANSWER: Cipla admits that New Drug Application No. 208558 is approved by the FDA. Cipla states that the FDA's electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") lists AstraZeneca Pharmaceuticals LP as the holder of New Drug Application No. 208558. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in this paragraph and therefore denies them.

4. Plaintiff AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 OAA, United Kingdom.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

5. Plaintiff AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

6. Plaintiff KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 OAA, United Kingdom.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

7. Plaintiff The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

8. Plaintiff MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

ANSWER: Cipla lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies them.

9. On information and belief, Defendant Cipla Limited is a corporation organized and existing under the laws of India, with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

ANSWER: Cipla admits that Cipla Limited is a company organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India. Cipla denies any remaining allegations of paragraph 9.

10. On information and belief, Defendant Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business in Warren, New Jersey. On information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market.

ANSWER: Cipla admits that Cipla USA, Inc. is a company organized and existing under the laws of the State of Delaware, with its principal place of business in Warren, New Jersey.

Cipla admits that Cipla USA, Inc. distributes pharmaceutical drug products, including generic drug products, for sale. Cipla denies the remaining allegations in paragraph 10.

11. On information and belief, Cipla USA, Inc. is a wholly owned subsidiary of Cipla Limited and is controlled by Cipla Limited.

ANSWER: Cipla admits that Cipla USA, Inc. is a wholly-owned subsidiary of InvaGen Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Cipla (EU Limited), which is a wholly-owned subsidiary of Cipla Limited. Cipla denies any remaining allegations of paragraph 11.

12. On information and belief, Cipla Limited and Cipla USA, Inc. acted in concert to prepare and submit Cipla's ANDA to the FDA.

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla Limited and Cipla USA, Inc. seek regulatory approval of pharmaceutical drug products, including generic drug products. Cipla denies the remaining allegations in paragraph 12.

13. On information and belief, Cipla Limited and Cipla USA, Inc. know and intend that upon approval of Cipla's ANDA, Cipla Limited will manufacture Cipla's ANDA Product and Cipla Limited and Cipla USA, Inc. will directly or indirectly market, sell, and distribute Cipla's ANDA Product throughout the United States, including in New Jersey.

ANSWER: Cipla admits that Cipla Limited and Cipla USA, Inc. prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j), and that Cipla seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of Cipla's ANDA Product. Cipla will decide whether to market its product in the United States upon FDA approval. Cipla denies the remaining allegations in paragraph 13.

14. On information and belief, following any FDA approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will act in concert to distribute and sell Cipla's ANDA Product throughout the United States, including in New Jersey.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 14 as phrased and affirmatively states that Cipla will decide whether to market its product in the United States upon FDA approval. Cipla denies any remaining allegations in paragraph 14.

Jurisdiction

15. Plaintiffs incorporate each of the preceding paragraphs 1-14 as if fully set forth herein.

ANSWER: In response to paragraph 15, Cipla repeats and realleges its responses to the allegations of paragraphs 1–14 of the Complaint as if fully set forth herein.

16. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. For the limited purpose of this action only, Cipla does not contest subject matter jurisdiction.

17. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Cipla Ltd. and Cipla USA, Inc.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 17.

18. Cipla Limited and Cipla USA, Inc. are subject to personal jurisdiction in New Jersey because, among other things, Cipla Limited and Cipla USA, Inc. have purposefully availed themselves of the benefits and protections of New Jersey's laws such that those entities would reasonably anticipate being haled into court here. On information and belief, Cipla Limited and Cipla USA, Inc. develop, manufacture, import, market, offer to sell, and/or sell generic drugs throughout the United States, including in the State of New Jersey, and therefore transact business within the State of New Jersey related to Plaintiffs' claims, and/or have engaged in systematic and continuous business contacts within the State of New Jersey.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc. markets, sells, and/or distributes pharmaceutical drug products, including generic drug products. Cipla admits that Cipla Limited is in the business of manufacturing pharmaceutical drug products, including generic pharmaceutical drug products. Cipla does not contest personal jurisdiction over Cipla USA, Inc. and Cipla Limited in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 18.

19. In addition, this Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because, among other things, on information and belief: (1) Cipla USA, Inc. filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla Limited and Cipla USA, Inc. will directly, or indirectly through subsidiaries, intermediaries, distributors, retailers, or others, market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc*., 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Cipla's ANDA, Cipla's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla admits that Cipla Limited prepared and submitted Cipla's ANDA to the FDA pursuant to 21 U.S.C. § 355(j). Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale of the Cipla's ANDA Product. Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 19.

20. This Court has personal jurisdiction over Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest personal jurisdiction in this District. *See, e.g., Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 20.

21. Additionally, this Court has personal jurisdiction over Cipla USA, Inc. because, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Cipla USA, Inc.'s principal place of business is in Warren, New Jersey. Cipla does not contest personal jurisdiction over Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 21.

22. For the above reasons, it would not be unfair or unreasonable for Cipla Limited and Cipla USA, Inc. to litigate this action in this District, and the Court has personal jurisdiction over those entities here.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest personal jurisdiction over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation, and denies the remaining allegations of paragraph 22.

Venue

23. Plaintiffs incorporate each of the preceding paragraphs 1-22 as if fully set forth herein.

ANSWER: In response to paragraph 23, Cipla repeats and realleges its responses to the allegations of paragraphs 1–22 of the Complaint as if fully set forth herein.

24. Venue is proper in this District as to Cipla Limited pursuant to 28 U.S.C. § 1391, at least because, on information and belief, Cipla Limited is a foreign corporation that may be sued in any judicial district in which it is subject to the Court's personal jurisdiction.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla Limited, Inc. in this Court for the limited purposes of this litigation. Cipla denies the remaining allegations of paragraph 24.

25. Venue is proper in this District as to Cipla USA, Inc. pursuant to 28 U.S.C. § 1400(b), at least because, on information and belief, Cipla USA, Inc. has committed, or will commit, an act of infringement in this District, and has a regular and established place of business in this District. On information and belief, among other things, (1) Cipla filed Cipla's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product in the United States, including in New Jersey; and (2) upon approval of Cipla's ANDA, Cipla will market, distribute, offer for sale, sell, and/or import Cipla's ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Cipla's ANDA Product in New Jersey. Further, on information and belief, Cipla USA, Inc. maintains its principal place of business in this District.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla USA, Inc. in this Court for the limited purposes of this litigation. Cipla admits that Cipla USA, Inc.'s principal place of business is in Warren, New Jersey. Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product. Cipla will decide whether to market, distribute, offer for sale, sell, and/or import its product in the United States upon FDA approval. Cipla denies the remaining allegations of paragraph 25.

26. Venue is proper in this District as to Cipla Limited and Cipla USA, Inc. because those entities (1) engage in patent litigation concerning Cipla's products in this District, and (2) do not contest that venue is proper in this District. *See, e.g., Cubist Pharms. LLC v. Cipla USA, Inc. and Cipla Limited*, Civ. No. 19-12920, Dkt. No. 15 (D.N.J. July 2, 2019).

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla does not contest venue over Cipla Limited and Cipla USA, Inc. in this Court for the limited purpose of this litigation. Cipla denies the remaining allegations of paragraph 26.

Factual Background

27. LYNPARZA® is approved by FDA for the treatment of certain ovarian, breast, pancreatic, and prostate cancers. The active pharmaceutical ingredient in LYNPARZA® is olaparib, a poly (ADP-ribose) polymerase (PARP) inhibitor.

ANSWER: Cipla admits that LYNPARZA® is approved by the FDA. Cipla admits that the prescribing information for LYNPARZA® dated 11/2023 available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/208558s028lbl.pdf ("Prescribing Information") lists certain types of ovarian, breast, pancreatic, and prostate cancer under the section titled "1 Indications and Usage." Cipla further admits that the Prescribing Information states under the section titled "12.1 Mechanism of Action" that "Olaparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes . . ." Cipla denies any remaining allegations of paragraph 27.

28. In Cipla's Notice Letter, Cipla states that the subject of Cipla's ANDA is olaparib tablets, 100 mg and 150 mg. In Cipla's Notice Letter, Cipla states that Cipla's ANDA was submitted under 21 U.S.C. § 355(j)(1) and § 355(j)(2)(A) and contends that Cipla's ANDA contains bioavailability and/or bioequivalence studies for Cipla's ANDA Product. On information and belief, Cipla's ANDA Product is a generic version of LYNPARZA®.

ANSWER: Cipla admits that in Cipla's Notice Letter, Cipla states that Cipla submitted an ANDA for Olaparib Tablets, 100 mg and 150 mg, to the FDA. Cipla admits that in Cipla's Notice Letter, Cipla states that Cipla's ANDA was submitted under 21 U.S.C. § 355(j)(1) and (j)(2)(A). Cipla admits that its Notice Letter states that Cipla's ANDA contains any required

bioavailability and/or bioequivalence data from studies on Cipla's ANDA product. Cipla denies the remaining allegations of paragraph 28.

29. The purpose of Cipla's submission of Cipla's ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product.

ANSWER: Cipla admits that Cipla submitted Cipla's ANDA to the FDA seeking approval to manufacture, use, and/or sale of Cipla's ANDA Product in the United States. Cipla denies the remaining allegations of paragraph 29.

30. In Cipla's Notice Letter, Cipla stated that it had submitted Paragraph IV Certifications to FDA alleging that the '562, '842, and '396 patents were invalid, unenforceable, and/or not infringed, and that Cipla is seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '562, '842, and '396 patents.

ANSWER: Cipla admits that in Cipla's Notice Letter, Cipla states that Cipla's ANDA includes paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Olaparib Tablets, 100 mg and 150 mg before the expiration of the '842 patent, '396 patent, and '562 patent. Cipla admits that its Notice Letter states that the patents subject to the paragraph IV certification are alleged to be invalid, and/or not infringed, and/or unenforceable. Cipla denies the remaining allegations of paragraph 30.

31. On April 10, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '530 patent. The '530 patent issued on April 30, 2024. On April 17, 2024, the U.S. Patent and Trademark Office issued an Issue Notification for the '001 patent. The '001 patent issued on May 7, 2024. LYNPARZA is covered by claims of the '530 and '001 patents, and the '530 and '001 patents have been listed in connection with LYNPARZA in the FDA's Orange Book.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that according to the online records of the United States Patent and Trademark Office ("USPTO"), an issue notification for the '530 patent was entered on April 10, 2024 and that, according to the face of the '530 patent, the issue

date is April 30, 2024. Cipla further admits that according to the online records of the USPTO, an issue notification for the '001 was entered on April 17, 2024, and that, according to the face of the '001 patent, the issue date is May 7, 2024. Cipla further admits that the Orange Book associates the '530 patent and the '001 patent with New Drug Application No. 208558. Cipla denies any remaining allegations of paragraph 31.

32. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit.

ANSWER: Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product prior to the expiration of the Patents-in-Suit. Cipla denies any remaining allegations in paragraph 32.

33. In Cipla's Notice Letter, Cipla included an Offer for Confidential Access to a redacted version of Cipla's ANDA. Cipla's Offer for Confidential Access was subject to various unreasonably restrictive conditions.

ANSWER: Cipla admits that in Cipla's Notice Letter, Cipla provided an Offer for Confidential Access to Cipla's ANDA pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8) ("OCA"). Cipla denies the remaining allegations in paragraph 33.

34. In an exchange of correspondence, counsel for Plaintiffs and counsel for Cipla discussed the terms of Cipla's Offer for Confidential Access. The parties did not agree on terms under which Plaintiffs could review, among other things, Cipla's ANDA and any Drug Master File referred to therein, as well as other material relevant to infringement.

ANSWER: Cipla admits that counsel for Plaintiffs and counsel for Cipla communicated regarding Cipla's OCA. Cipla denies the remaining allegations in paragraph 34.

35. This action is being commenced within forty-five days from the date Plaintiffs received Cipla's Notice Letter.

ANSWER: Admitted.

Count I —[Purported] Infringement of the '562 Patent Under 35 U.S.C. & 271(e)(2)

36. Plaintiffs incorporate each of the preceding paragraphs 1-35 as if fully set forth herein.

ANSWER: In response to paragraph 36, Cipla repeats and realleges its responses to the allegations of paragraphs 1–35 of the Complaint as if fully set forth herein.

37. On October 14, 2014, the USPTO duly and lawfully issued the '562 patent, entitled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer." A copy of the '562 patent is attached hereto as Exhibit A.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Exhibit A to the Complaint purports to be a copy of the '562 patent. Cipla admits that the '562 patent is titled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer" and lists October 14, 2014 as the issue date. Cipla denies the remaining allegations of paragraph 37.

38. Plaintiff The University of Sheffield is the assignee of the '562 patent. Plaintiffs collectively possess all exclusive rights and interests in the '562 patent.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, according to the face of the '562 patent, The University of Sheffield is listed as the assignee of the '562 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 38 and therefore denies them.

39. The '562 patent claims, *inter alia*, a method of treatment of cancer cells defective in homologous recombination (HR).

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that claim 1 of the '562 patent states:

> 1. A method of treatment of cancer cells defective in homologous recombination (HR), the method comprising:
>
> identifying a human patient with a familial predisposition to gene-linked hereditary cancer;

wherein said cancer comprises cancer cells defective in homologous recombination;

identifying a compound which inhibits PARP-1, and
administering to said human patient a therapeutically effective amount of said compound.

Cipla denies any remaining allegations of paragraph 39.

40. Methods of using LYNPARZA® are covered by one or more claims of the '562 patent, including at least claim 1 of the '562 patent, and the '562 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that FDA's Orange Book associates the '562 patent with New Drug Application No. 208558. Cipla denies any remaining allegations of paragraph 40.

41. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '562 patent was an act of infringement of the '562 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

42. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe claim 1 of the '562 patent.

ANSWER: Denied.

43. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '562 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '562 patent after approval of Cipla's ANDA.

ANSWER: Denied.

44. The foregoing actions by Cipla constitute and/or will constitute infringement of the '562 patent, active inducement of infringement of the '562 patent, and contribution to the infringement by others of the '562 patent.

ANSWER: Denied.

45. On information and belief, Cipla has acted with full knowledge of the '562 patent and without a reasonable basis for believing that it would not be liable for the infringement of the'562 patent, and contributing to the infringement by others of the '562 patent.

ANSWER: Denied.

46. In Cipla's Notice Letter, Cipla did not contest infringement of claim 1 of the '562 patent on any basis other than the alleged invalidity of that claim.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. Cipla's Notice Letter speaks for itself. Cipla denies any remaining allegations of paragraph 46.

47. Unless Cipla is enjoined from infringing the '562 patent, actively inducing the infringement of the '562 patent, and contributing to the infringement by others of the '562 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count II — Declaratory Judgment of [Purported] Infringement of the '562 Patent

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth herein.

ANSWER: In response to paragraph 48, Cipla repeats and realleges its responses to the allegations of paragraphs 1–47 of the Complaint as if fully set forth herein.

49. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding infringement and/or invalidity of the '562 patent.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '562 patent and the invalidity of the '562 patent. Cipla denies the remaining allegations of paragraph 49.

50. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '562 patent, will infringe, induce the

infringement of, and contribute to the infringement by others of the '562 patent, and that the claims of the '562 patent are valid and enforceable.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 50.

Count III — [Purported] Infringement of the '842 Patent Under 35 U.S.C. § 271(e)(2)

51. Plaintiffs incorporate each of the preceding paragraphs 1-50 as if fully set forth herein.

ANSWER: In response to paragraph 51, Cipla repeats and realleges its responses to the allegations of paragraphs 1–50 of the Complaint as if fully set forth herein.

52. On July 2, 2013, the USPTO duly and lawfully issued the '842 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One." A copy of the '842 patent is attached hereto as Exhibit B.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Exhibit B to the Complaint purports to be a copy of the '842 patent. Cipla admits that the '842 patent is titled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One" and lists July 2, 2013, as the issue date. Cipla denies the remaining allegations of paragraph 52.

53. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '842 patent. Plaintiffs collectively possess all exclusive rights and interests in the '842 patent.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla states that the face of the '842 patent lists AstraZeneca AB as the assignee of the '842 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 53 and therefore denies them.

54. The '842 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that claim 1 of the '842 patent states:

> 1. An immediate-release pharmaceutical composition in the form of a solid dispersion, the composition comprising:
>
> an active agent phase comprising 4-[3-(4-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluoro-benzyl]-2H-phthalazin-1-one (Compound 1) or a salt thereof; and
>
> a carrier phase comprising copovidone; and
>
> wherein the active agent phase is dispersed in the carrier phase:
>
> wherein the total concentration of Compound 1 in the composition is in the range of from 20% by weight to 30% by weight;
>
> wherein the total amount of Compound 1 in the composition is in the range of from 25 mg to 400 mg; and
>
> wherein the weight ratio of Compound 1 to copovidone is in the range of from 1:2 to 1:4.

Cipla denies any remaining allegations of paragraph 54.

55. LYNPARZA® is covered by one or more claims of the '842 patent, including at least claim 1 of the '842 patent, and the '842 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that FDA's Orange Book associates the '842 patent with New Drug Application No. 208558. Cipla denies any remaining allegations of paragraph 55.

56. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '842 patent was an act of infringement of the '842 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

57. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '842 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

58. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '842 patent.

ANSWER: Denied.

59. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '842 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

ANSWER: Denied.

60. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '842 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '842 patent after approval of Cipla's ANDA.

ANSWER: Denied.

61. The foregoing actions by Cipla constitute and/or will constitute infringement of the '842 patent, active inducement of infringement of the '842 patent, and contribution to the infringement by others of the '842 patent.

ANSWER: Denied.

62. On information and belief, Cipla has acted with full knowledge of the '842 patent and without a reasonable basis for believing that it would not be liable for infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent.

ANSWER: Denied.

63. Unless Cipla is enjoined from infringing the '842 patent, actively inducing infringement of the '842 patent, and contributing to the infringement by others of the '842 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count IV — Declaratory Judgment of [Purported] Infringement of the '842 Patent

64. Plaintiffs incorporate each of the preceding paragraphs 1-63 as if fully set forth herein.

ANSWER: In response to paragraph 64, Cipla repeats and realleges its responses to the allegations of paragraphs 1–63 of the Complaint as if fully set forth herein.

65. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the '842 patent.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '842 patent and the validity of the '842 patent. Cipla denies the remaining allegations of paragraph 65.

66. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '842 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '842 patent, and that the claims of the '842 patent are valid and enforceable.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 66.

Count V — [Purported] Infringement of the '396 Patent Under 35 U.S.C. § 271(e)(2)

67. Plaintiffs incorporate each of the preceding paragraphs 1-66 as if fully set forth herein.

ANSWER: In response to paragraph 67, Cipla repeats and realleges its responses to the allegations of paragraphs 1–66 of the Complaint as if fully set forth herein.

68. On April 25, 2023, the USPTO duly and lawfully issued the '396 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One." A copy of the '396 patent is attached hereto as Exhibit C.

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Exhibit C to the Complaint purports to be a copy of the '396 patent. Cipla admits that the '396 patent is titled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One" and lists April 25, 2023 as the issue date. Cipla denies the remaining allegations of paragraph 68.

69. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '396 patent. Plaintiffs collectively possess all exclusive rights and interests in the '396 patent.

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that according to the face of the '396 patent, KuDOS Pharmaceuticals Limited is listed as the assignee of the '396 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 69 and therefore denies them.

70. The '396 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising olaparib and certain excipients.

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that claim 1 of the '396 patent states:

> 1. An immediate-release pharmaceutical composition comprising:
>
> a core composition comprising
>
> a solid dispersion comprising
>
> (i) 4-[3-(4-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluoro-benzyl]-2H-phthalazin-1-one (Compound 1); and
>
> (ii) at least one matrix polymer, wherein one of said at least one matrix polymers is copovidone; and

> wherein the total concentration of Compound 1 in the core composition is in the range of from 10% by weight to 40% by weight;
>
> wherein the weight ratio of Compound 1 to copovidone in the core composition is in the range of from 1:1 to 1:4.

Cipla denies any remaining allegations of paragraph 70.

71. LYNPARZA® is covered by one or more claims of the '396 patent, including at least claim 1 of the '396 patent, and the '396 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that FDA's Orange Book associates the '396 patent with New Drug Application No. 208558. Cipla denies any remaining allegations of paragraph 71.

72. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '396 patent was an act of infringement of the '396 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

73. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '396 patent, recited above, either literally or under the doctrine of equivalents.

ANSWER: Denied.

74. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '396 patent.

ANSWER: Denied.

75. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '396 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

ANSWER: Denied.

76. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '396 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '396 patent after approval of Cipla's ANDA.

ANSWER: Denied.

77. The foregoing actions by Cipla constitute and/or will constitute infringement of the '396 patent, active inducement of infringement of the '396 patent, and contribution to the infringement by others of the '396 patent.

ANSWER: Denied.

78. On information and belief, Cipla has acted with full knowledge of the '396 patent and without a reasonable basis for believing that it would not be liable for infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent.

ANSWER: Denied.

79. Unless Cipla is enjoined from infringing the '396 patent, actively inducing infringement of the '396 patent, and contributing to the infringement by others of the '396 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count VI — Declaratory Judgment of [Purported] Infringement of the '396 Patent

80. Plaintiffs incorporate each of the preceding paragraphs 1-79 as if fully set forth herein.

ANSWER: In response to paragraph 80, Cipla repeats and realleges its responses to the allegations of paragraphs 1–79 of the Complaint as if fully set forth herein.

81. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the '396 patent.

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy

exists between Plaintiffs and Cipla with respect to the alleged infringement of the '396 patent and the validity of the '396 patent. Cipla denies the remaining allegations of paragraph 81.

82. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '396 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '396 patent, and that the claims of the '396 patent are valid and enforceable.

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 82.

Count VII — [Purported] Infringement of the '001 Patent Under 35 U.S.C. § 271(e)(2)

83. Plaintiffs incorporate each of the preceding paragraphs 1-82 as if fully set forth herein.

ANSWER: In response to paragraph 83, Cipla repeats and realleges its responses to the allegations of paragraphs 1–82 of the Complaint as if fully set forth herein.

84. On May 7, 2024, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '001 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-l-Carbony1)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One." A copy of the '001 patent is attached hereto as Exhibit D.

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Exhibit D to the Complaint purports to be a copy of the '001 patent. Cipla admits that the '001 patent is titled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-l-Carbony1)-4-Fluoro-Benzyl-]-211-Phthalazin-1-One" and lists May 7, 2024, as the issue date. Cipla denies the remaining allegations of paragraph 84.

85. Plaintiff KuDOS Pharmaceuticals Limited is the assignee of the '001 patent. Plaintiffs collectively possess all exclusive rights and interests in the '001 patent.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that according to the face of the '001

patent, KuDOS Pharmaceuticals Limited is listed as the assignee of the '001 patent. Cipla lacks sufficient information or knowledge to admit or deny the remaining allegations in paragraph 85 and therefore denies them.

86. The '001 patent claims, *inter alia*, an immediate-release pharmaceutical composition in the form of a solid dispersion comprising 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzyl-]-2H-Phthalazin-1-One, known by the international nonproprietary name olaparib, and certain excipients.

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that claim 1 of the '001 patent states:

> 1. An immediate-release pharmaceutical composition comprising a solid dispersion comprising:
>
> (i) 100 mg to 200 mg of 4-[3-(4-cyclopropanecarbonyl-piperazine-1-carbonyl)-4-fluorobenzyl]-2H-phthalazin-1-one (Compound 1); and
>
> (ii) at least one polymer chosen from copovidone, povidone, hypromellose phthalate, hypromellose acetate succinate, 2-hydroxypropyl-β-cyclodextrin, hypromellose, polymethacrylates, hydroxypropyl cellulose, and cellulose acetate phthalate;
>
> wherein the weight ratio of Compound 1 to the at least one polymer in the solid dispersion is in the range of from 1:1 to 1:9, and
>
> wherein the total concentration of Compound 1 in the solid dispersion is in the range of from 10% by weight to 50% by weight.

Cipla denies any remaining allegations of paragraph 86.

87. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

ANSWER: Cipla admits that according to the Prescribing Information, LYNPARZA® contains olaparib as its active ingredient. Cipla denies any remaining allegations of paragraph 87.

88. LYNPARZA® is covered by one or more claims of the '001 patent, including at least claim 1 of the '001 patent, and the '001 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent a response is required, Cipla admits that FDA's Orange Book associates the '001 patent with New Drug Application No. 208558. Cipla denies any remaining allegations of paragraph 88.

89. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '001 patent.

ANSWER: Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product prior to the expiration of the '001 patent. Cipla denies any remaining allegations of paragraph 89.

90. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '001 patent was an act of infringement of the '001 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

91. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '001 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

92. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '001 patent.

ANSWER: Denied.

93. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '001 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

ANSWER: Denied.

94. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '001 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing

use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the ’001 patent after approval of Cipla’s ANDA.

ANSWER: Denied.

95. The foregoing actions by Cipla constitute and/or will constitute infringement of the ’001 patent, active inducement of infringement of the ’001 patent, and contribution to the infringement by others of the ’001 patent.

ANSWER: Denied.

96. On information and belief, Cipla has acted with full knowledge of the ’001 patent and without a reasonable basis for believing that it would not be liable for infringing the ’001 patent, actively inducing infringement of the ’001 patent, and contributing to the infringement by others of the ’001 patent.

ANSWER: Denied.

97. Unless Cipla is enjoined from infringing the ’001 patent, actively inducing infringement of the ’001 patent, and contributing to the infringement by others of the ’001 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count VIII — Declaratory Judgment of [Purported] Infringement of the ’001 Patent

98. Plaintiffs incorporate each of the preceding paragraphs 1-97 as if fully set forth herein.

ANSWER: In response to paragraph 98, Cipla repeats and realleges its responses to the allegations of paragraphs 1–97 of the Complaint as if fully set forth herein.

99. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding validity and/or infringement of the ’001 patent.

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the ’001 patent and the validity of the ’001 patent. Cipla denies the remaining allegations of paragraph 99.

100. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '001 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '001 patent, and that the claims of the '001 patent are valid and enforceable.

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 100.

Count IX — [Purported] Infringement of the '530 Patent Under 35 U.S.C. § 271(e)(2)

101. Plaintiffs incorporate each of the preceding paragraphs 1-100 as if fully set forth herein.

ANSWER: In response to paragraph 101, Cipla repeats and realleges its responses to the allegations of paragraphs 1–100 of the Complaint as if fully set forth herein.

102. On April 30, 2024, the United States Patent and Trademark Office (the "USPTO") duly and lawfully issued the '530 patent, entitled "Methods of Treating Homologous Recombination Deficient Cancer." A copy of the '530 patent is attached hereto as Exhibit E.

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that Exhibit E to the Complaint purports to be a copy of the '530 patent. Cipla admits that the '530 patent is titled "Methods of Treating Homologous Recombination Deficient Cancer" and lists April 30, 2024 as the issue date. Cipla denies the remaining allegations of paragraph 102.

103. Plaintiff AstraZeneca AB is the assignee of the '530 patent. Plaintiffs collectively possess all exclusive rights and interests in the '530 patent.

ANSWER: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that according to the face of the '530 patent, AstraZeneca AB is listed as the assignee of the '530 patent. Cipla lacks sufficient

information or knowledge to admit or deny the remaining allegations in paragraph 103 and therefore denies them.

104. The '530 patent claims, *inter alia*, a method for treating ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and/or pancreatic cancer in a subject, the method comprising administering to the subject a therapeutically effective amount of bevacizumab, and a therapeutically effective amount of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1 -Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One (olaparib).

ANSWER: Paragraph 104 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that claim 1 of the '530 patent states:

> 1. A method for treating ovarian cancer, fallopian tube cancer, primary peritoneal cancer, breast cancer, and/or pancreatic cancer in a subject, the method comprising:
>
> administering to the subject a therapeutically effective amount of bevacizumab, and
>
> administering to the subject a therapeutically effective amount of 4-[(3-{[4-(cyclopropane-carbonyl)piperazine-1-yl]carbonyl}-4-fluorophenyl)methyl]-2H-phthalazin-1-one (olaparib), or a hydrate, solvate, or prodrug thereof,
>
> wherein the therapeutically effective amount of bevacizumab is in the range of about 10 to 20 mg/kg of body weight every 3 weeks;
>
> wherein the therapeutically effective amount of olaparib is about 300 mg twice daily;
>
> wherein the therapeutically effective amount of olaparib reduces Common Terminology Criteria for Adverse Events (CTCAE) Grade 2, Grade 3, or Grade 4 hypertension in the subject as compared to hypertension in the subject when the subject receives bevacizumab alone; and
>
> wherein the progression free survival is at least about 4 months greater than for subjects receiving bevacizumab alone.

Cipla denies any remaining allegations in paragraph 104.

105. LYNPARZA® contains olaparib as its active pharmaceutical ingredient.

ANSWER: Cipla admits that according to the Prescribing Information for LYNPARZA®, LYNPARZA® contains olaparib as its active ingredient. Cipla denies any remaining allegations of paragraph 105.

106. Methods of using LYNPARZA® are covered by one or more claims of the '530 patent, including at least claim 1 of the '530 patent, and the '530 patent has been listed in connection with LYNPARZA® in the FDA's Orange Book.

ANSWER: Paragraph 106 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Cipla admits that FDA's Orange Book associates the '530 patent with New Drug Application No. 208558. Cipla denies any remaining allegations of paragraph 106.

107. On information and belief, Cipla intends to seek approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '530 patent.

ANSWER: Cipla admits that Cipla's ANDA seeks approval from the FDA to engage in the commercial manufacture, use, and/or sale, of Cipla's ANDA Product prior to the expiration of the '530 patent. Cipla denies any remaining allegations of paragraph 107.

108. Cipla's submission of Cipla's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA Product prior to the expiration of the '530 patent was an act of infringement of the '530 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

109. On information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Cipla's ANDA Product would infringe at least claim 1 of the '530 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

110. On information and belief, the use of Cipla's ANDA Product in accordance with and as directed by Cipla's proposed labeling for Cipla's ANDA Product would infringe at least claim 1 of the '530 patent.

ANSWER: Denied.

111. On information and belief, Cipla plans and intends to, and will, actively induce infringement of the '530 patent when Cipla's ANDA is approved, and plans and intends to, and will, do so after approval of Cipla's ANDA.

ANSWER: Denied.

112. On information and belief, Cipla knows that Cipla's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '530 patent and that Cipla's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Cipla plans and intends to, and will, contribute to infringement of the '530 patent after approval of Cipla's ANDA.

ANSWER: Denied.

113. The foregoing actions by Cipla constitute and/or will constitute infringement of the '530 patent, active inducement of infringement of the '530 patent, and contribution to the infringement by others of the '530 patent.

ANSWER: Denied.

114. On information and belief, Cipla has acted with full knowledge of the '530 patent and without a reasonable basis for believing that it would not be liable for infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent.

ANSWER: Denied.

115. Unless Cipla is enjoined from infringing the '530 patent, actively inducing infringement of the '530 patent, and contributing to the infringement by others of the '530 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

ANSWER: Denied.

Count X — Declaratory Judgment of [Purported] Infringement of the '530 Patent

116. Plaintiffs incorporate each of the preceding paragraphs 1-115 as if fully set forth herein.

ANSWER: In response to paragraph 116, Cipla repeats and realleges its responses to the allegations of paragraphs 1–115 of the Complaint as if fully set forth herein.

117. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case or actual controversy between Plaintiffs on the one hand and Cipla on the other regarding the validity and/or infringement of the '530 patent.

ANSWER: Paragraph 117 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla admits that an actual case or controversy exists between Plaintiffs and Cipla with respect to the alleged infringement of the '530 patent and the validity of the '530 patent. Cipla denies the remaining allegations of paragraph 117.

118. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Cipla's ANDA Product with its proposed labeling, or any other Cipla drug product that is covered by or whose use is covered by the '530 patent, will infringe, induce the infringement of, and contribute to the infringement by others of the '530 patent, and that the claims of the '530 patent are valid and enforceable.

ANSWER: Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, Cipla denies the allegations of paragraph 118.

PLAINTIFFS' PRAYER FOR RELIEF

The remainder of the Complaint is a prayer for relief and does not require a response. To the extent any response is required Cipla denies that Plaintiffs are entitled to any remedy or relief sought in paragraphs (1) through (9) on pages 19 through 20 of the Complaint. Should Plaintiffs receive any of their requested relief, no such relief should prevent Cipla from obtaining a Pre-Launch Activities Importation Request from the FDA, or acting under it, in connection with Cipla's ANDA Product. All other allegations in the Complaint not specifically admitted or denied are hereby denied.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its responses to paragraphs 1 through 118 of the Complaint, Cipla alleges the following Separate Defenses to the Complaint. Cipla expressly

reserves the right to allege additional defenses as they become known through the course of discovery or other factual investigation. Cipla does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

First Defense
(Invalidity and Ineligibility of the '562 Patent)

Each claim of the '562 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Second Defense
(Noninfringement of the '562 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '562 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '562 patent, either literally or under the doctrine of equivalents.

Third Defense
(Invalidity and Ineligibility of the '842 Patent)

Each claim of the '842 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fourth Defense
(Noninfringement of the '842 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '842 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '842 patent, either literally or under the doctrine of equivalents.

Fifth Defense
(Invalidity and Ineligibility of the '396 Patent)

Each claim of the '396 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Sixth Defense
(Noninfringement of the '396 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '396 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '396 patent, either literally or under the doctrine of equivalents.

Seventh Defense
(Invalidity and Ineligibility of the '001 Patent)

Each claim of the '001 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Eighth Defense
(Noninfringement of the '001 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '001 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '001 patent, either literally or under the doctrine of equivalents.

Ninth Defense
(Invalidity and Ineligibility of the '530 Patent)

Each claim of the '530 patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Tenth Defense
(Noninfringement of the '530 Patent)

Cipla has not, does not, and will not infringe any valid and enforceable claim of the '530 patent. The manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claim of the '530 patent, either literally or under the doctrine of equivalents.

Eleventh Defense
(Waiver)

Plaintiffs have waived any defect in the manner in which Cipla served Cipla's Notice Letter and/or are estopped from contesting any alleged defect in service of Cipla's Notice Letter.

Twelfth Defense
(Estoppel)

Plaintiffs are estopped from asserting infringement by the doctrine of prosecution history estoppel, equitable estoppel, unclean hands, waiver, implied waiver, acquiescence, disclaimer, judicial estoppel, and/or other equitable doctrines.

Thirteenth Defense
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

Fourteenth Defense
(No Exceptional Case)

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

Fifteenth Defense
(Safe Harbor Under 35 U.S.C. §271(e)(1))

Pursuant to 35 U.S.C. § 271(e)(1), Cipla's actions do not constitute infringement.

Sixteenth Defense
(Ensnarement)

To the extent Plaintiffs claims infringement of one or more claims of the Patents-in-Suit under the doctrine of equivalents, Plaintiffs' claims are barred under the ensnarement doctrine, which prohibits Plaintiffs from asserting an infringement theory under the doctrine of equivalents that encompasses or ensnares the prior art.

Seventeenth Defense
(Lack of Standing)

To the extent that Plaintiffs did not, or do not, hold all substantial rights, title, and interest to the Patents-in-Suit, Plaintiffs lack standing to bring, or maintain, this lawsuit in connection with such patent.

Eighteenth Defense
(Reservation of Defenses)

Defendants reserve all affirmative defenses under Rule 8(c) of the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defenses at law or in equity that may exist now or that may be available in the future, including, but not limited to, those related to the unenforceability of any claim of the Patents-in-Suit based on inequitable conduct, as may be determined through discovery and further factual investigation in this action.

COUNTERCLAIMS

Without admitting the allegations of Plaintiffs AstraZeneca Pharmaceuticals LP, AstraZeneca UK Limited, AstraZeneca AB, Kudos Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH (collectively, "Plaintiffs" or "Counterclaim Defendants"), other than those expressly admitted herein, Defendants Cipla USA, Inc. and Cipla Limited (collectively, "Cipla" or "Defendants" or "Counterclaim Plaintiffs") bring the following Counterclaims against Plaintiffs/Counterclaim Defendants for declaratory judgment that U.S. Patent No. 8,859,562 (the "'562 patent"); U.S. Patent No. 11,975,001 (the "'001 patent"); U.S. Patent No. 8,475,842 (the "'842 patent"); and U.S. Patent No. 11,633,396 (the "'396 patent") (collectively, the "Counterclaim Patents") are invalid and/or not infringed by Cipla and the product as described in Cipla's Abbreviated New Drug Application ("ANDA") No. 219410 ("Cipla's ANDA Product"):

The Parties

1. Counterclaim Plaintiff Cipla Limited is an entity organized and existing under the laws of India, having a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

2. Counterclaim Plaintiff Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

3. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca Pharmaceuticals LP is a limited partnership organized and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803.

4. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca UK Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 OAA, United Kingdom.

5. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant AstraZeneca AB is a limited company organized and existing under the laws of Sweden, whose registered office is at SE-151 85, Södertälje, Sweden.

6. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant KuDOS Pharmaceuticals Limited is a private company limited by shares organized and existing under the laws of England and Wales, whose registered office is at 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 OAA, United Kingdom. Based on the allegations in the Complaint, Kudos Pharmaceuticals Limited purports to be the assignee of the ’842 patent, the ’396 patent, and the ’001 patent.

7. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant The University of Sheffield is a Royal Charter company organized and existing under the laws of England and Wales, whose address is Western Bank, Sheffield S10 2TN, United Kingdom. Based on the allegations in the Complaint, The University of Sheffield purports to be the assignee of the ’562 patent.

8. Upon information and belief, based on the allegations in the Complaint, Counterclaim Defendant MSD International Business GmbH is a company with limited liability organized and existing under the laws of Switzerland, whose registered office is at Tribschenstrasse, 60, 6005 Lucerne, Switzerland.

9. Upon information and belief, and based on the U.S. Food and Drug Administration's ("FDA's") electronic *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") Counterclaim Defendant AstraZeneca Pharmaceuticals LP is the holder of New Drug Application No. 208558.

10. Upon information and belief, Counterclaim Defendants currently promote and market LYNPARZA® in the United States.

11. Based on the allegations in the Complaint, Counterclaim Defendants purport to possess all exclusive rights and interests in the Counterclaim Patents.

Jurisdiction and Venue

12. This court has subject matter jurisdiction over the Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201, 2202, 1331, 1338(a), and 1367, based on an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*

13. 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 Cipla in this judicial district.

14. Venue is proper in this district for the purposes of these Counterclaims because Counterclaim Defendants filed the present action in this district.

15. Based on the allegations in the Complaint, Counterclaim Defendants purport and claim to have the right to enforce the Counterclaim Patents. One or more of the Counterclaim Defendants listed each of the Counterclaim Patents in the Orange Book. By maintaining the listing of the Counterclaim Patents in the Orange Book for NDA No. 208558 for LYNPARZA®, Counterclaim Defendants have represented that the Counterclaim Patents cover olaparib tablets,

and that a claim of patent infringement may reasonably be asserted against any ANDA applicant, including Cipla, who is not licensed by Counterclaim Defendants and who files an ANDA seeking approval to market olaparib tablets before the expiration of the Counterclaim Patents.

16. Further, on or about June 28, 2024, Counterclaim Defendants filed a civil action in this judicial district against Cipla alleging infringement of the Counterclaim Patents. There is a dispute between the parties concerning whether the Counterclaim Patents are not infringed and/or invalid. The dispute between the parties would be redressed by a finding of non-infringement or invalidity of the Counterclaim Patents.

17. Further, by listing the Counterclaim Patents in the Orange Book, Counterclaim Defendants created a hurdle for FDA approval of Cipla's ANDA product and/or injected uncertainty and insecurity into Cipla's pursuit of regulatory approval and commercialization of Cipla's ANDA product. A favorable judgment in this action would eliminate a potential for Counterclaim Patents to exclude or delay Cipla from the drug market. Cipla, therefore, seeks a resolution to eliminate a barrier to FDA approval and/or the potential for substantial lost revenue. A judgment from this Court through an adjudication or consent decree can alleviate the harm to Cipla.

18. To the extent Counterclaim Defendants no longer contend that Cipla's ANDA product infringes any claim of the '842 or '396 patents, there is still a substantial and continuing controversy between the parties and a declaration of rights is both necessary and appropriate. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.,* 527 F.3d 1278, 1285 (Fed. Cir. 2008). Cipla is under reasonable apprehension of suit and lacks certainty concerning the dispute over whether the Counterclaim Patents are not infringed and/or invalid because Counterclaim Defendants could bring or maintain suit against Cipla at a later time.

19. There is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding Cipla and Cipla's ANDA Product's non-infringement of the Counterclaim Patents and the invalidity of the Counterclaim Patents.

The Counterclaim Patents

20. Based on the allegations in the Complaint, the '562 patent, entitled "Use of RNAi Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer" was issued on October 14, 2014. The face of the patent lists The University of Sheffield as the assignee.

21. Based on the allegations in the Complaint, the '842 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One" was issued on July 2, 2013. Based on the allegations in the Complaint, KuDOS Pharmaceuticals Limited is the assignee of the '842 patent.

22. Based on the allegations in the Complaint, the '396 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-1-Carbony1)-4-Fluoro-Benzy1]-2H-Phthalazin-1-One," was issued on April 25, 2023. The face of the '396 patent lists KuDOS Pharmaceuticals Limited as assignee.

23. Based on the allegations in the Complaint, the '001 patent, entitled "Immediate Release Pharmaceutical Formulation of 4-[3-(4-Cyclopropanecarbonyl-Piperazine-l-Carbony1)-4-Fluoro-Benzyl]-2H-Phthalazin-1-One," was issued on May 7, 2024. The face of the '001 patent lists KuDOS Pharmaceuticals Limited as assignee.

24. The Counterclaim Patents are listed in the Orange Book in association with LYNPARZA®.

25. On May 21, 2024, pursuant to 21 U.S.C. § 355(j)(2)(B)(i)–(iv) and 21 C.F.R. § 314.95, Cipla sent Plaintiffs notification of Cipla's paragraph IV certification for the '562 patent, the '396 patent, and the '842 patent with respect to Cipla's ANDA No. 219410 ("Cipla's ANDA"), which seeks approval from the FDA to engage in the commercial manufacture, distribution, use, offer for sale, sale, and/or import of Cipla's ANDA Product ("Cipla's First Notice Letter").

26. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Cipla's First Notice Letter included, among other things, Cipla's detailed factual and legal basis for the paragraph IV certification regarding the '562 patent, the '396 patent, and the '842 patent as it pertains to Cipla's ANDA Product and an offer of confidential access ("Cipla's First OCA").

27. On or about June 28, 2024, Counterclaim Defendants brought this present action alleging infringement of the Counterclaim Patents.

28. On June 28, 2024, pursuant to 21 U.S.C. § 355(j)(2)(B)(i)–(iv) and 21 C.F.R. § 314.95, Cipla sent Plaintiffs notification of Cipla's paragraph IV certification for the '001 patent with respect to Cipla's ANDA which seeks approval from the FDA to engage in the commercial manufacture, distribution, use, offer for sale, sale, and/or import of Cipla's ANDA product ("Cipla's Second Notice Letter").

29. In accordance with 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Cipla's Second Notice Letter included, among other things, Cipla's detailed factual and legal basis for the paragraph IV certification regarding the '001 patent as it pertains to Cipla's ANDA Product and an offer of confidential access ("Cipla's Second OCA").

First Counterclaim
(Declaratory Judgment of Noninfringement of the '562 Patent)

30. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 29 of the Counterclaims as if fully set forth herein.

31. Counterclaim Defendants have accused Cipla of infringing the '562 patent.

32. Cipla denies infringement of the '562 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '562 patent.

33. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '562 patent.

34. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '562 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of the '562 Patent)

35. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 34 of the Counterclaims as if fully set forth herein.

36. The claim of the '562 patent is invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

37. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, any claim of the '562 patent is not infringed by Cipla's ANDA Product and/or is invalid.

38. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claim of the '562 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

39. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of any claim of the '562 patent.

40. Cipla is entitled to a judicial declaration that the claim of the '562 patent is invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Third Counterclaim
(Declaratory Judgment of Noninfringement of the '842 Patent)

41. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 40 of the Counterclaims as if fully set forth herein.

42. Counterclaim Defendants have accused Cipla of infringing the '842 patent.

43. Cipla denies infringement of the '842 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '842 patent.

44. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of

sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '842 patent.

45. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '842 patent.

Fourth Counterclaim
(Declaratory Judgment of Invalidity of the '842 Patent)

46. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 45 of the Counterclaims as if fully set forth herein.

47. The claims of the '842 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 including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

48. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '842 patent are not infringed by Cipla's ANDA Product and/or are invalid.

49. Upon information and belief, Cipla believes that Counterclaim Defendants can continue to assert that Cipla's ANDA Product is infringing the claims of the '842 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

50. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '842 patent.

51. Cipla is entitled to a judicial declaration that all claims of the '842 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Fifth Counterclaim
(Declaratory Judgment of Noninfringement of the '396 Patent)

52. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 51 of the Counterclaims as if fully set forth herein.

53. Counterclaim Defendants have accused Cipla of infringing the '396 patent.

54. Cipla denies infringement of the '396 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '396 patent.

55. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '396 patent.

56. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '396 patent.

Sixth Counterclaim
(Declaratory Judgment of Invalidity of the '396 Patent)

57. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 56 of the Counterclaims as if fully set forth herein.

58. The claims of the '396 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 including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

59. For at least the reasons stated in Cipla's First Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '396 patent are not infringed by Cipla's ANDA Product and/or are invalid.

60. Upon information and belief, Cipla believes that Counterclaim Defendants can continue to assert that Cipla's ANDA Product is infringing the claims of the '396 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

61. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '396 patent.

62. Cipla is entitled to a judicial declaration that all claims of the '396 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Seventh Counterclaim
(Declaratory Judgment of Noninfringement of the '001 Patent)

63. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 62 of the Counterclaims as if fully set forth herein.

64. Counterclaim Defendants have accused Cipla of infringing the '001 patent.

65. Cipla denies infringement of the '001 patent and alleges that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe, induce infringement of or contribute to infringement of, either literally or under the doctrine of equivalents, any valid and enforceable claims of the '001 patent.

66. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding infringement of any valid and enforceable claim of the '001 patent.

67. Cipla is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the '001 patent.

Eighth Counterclaim
(Declaratory Judgment of Invalidity of the '001 Patent)

68. Cipla incorporates by reference the allegations set forth in paragraphs 1 through 67 of the Counterclaims as if fully set forth herein.

69. The claims of the '001 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 including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

70. For at least the reasons stated in Cipla's Second Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '001 patent are not infringed by Cipla's ANDA Product and/or are invalid.

71. Upon information and belief, Cipla believes that Counterclaim Defendants will continue to assert that Cipla's ANDA Product is infringing the claims of the '001 patent and will continue to try to interfere with Cipla's business with respect to Cipla's ANDA Product.

72. Therefore, there is an actual, substantial, and continuing justiciable case or controversy between Cipla and Counterclaim Defendants having adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of all claims of the '001 patent.

73. Cipla is entitled to a judicial declaration that all claims of the '001 patent are invalid for failure to satisfy one or more of the requirements of Title 35 of the United States Code including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, 116, 120 and/or double patenting and the defenses recognized in 35 U.S.C. § 282(b) and/or other judicially created bases for invalidity.

Request for Relief

WHEREFORE, Cipla requests that this Court enter judgment against Counterclaim Defendants:

A. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA Product does not and will not directly or indirectly infringe any claim of the Patents-in-Suit and Counterclaim Patents, either literally or under the doctrine of equivalents;

B. Declaring that the claims of the Patents-in-Suit and Counterclaim Patents are invalid and/or unenforceable;

C. Ordering that Counterclaim Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Cipla;

D. Preliminarily and permanently enjoining Counterclaim Defendants, its employees and agents, and any other person acting in concert with any of them, from asserting or threatening to assert any alleged rights arising under the Patents-in-Suit and Counterclaim Patents against Cipla or any person or entity working in concert with Cipla;

E. Awarding Cipla its costs and expenses incurred in this action;

F. Declaring that this is an exceptional case in favor of Cipla and awarding Cipla its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

G. Awarding Cipla such other and further relief as the Court may deem proper.

DATED: September 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

Loly G. Tor
(loly.tor@klgates.com)
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4000
(F) 973.848.4001

Of Counsel:

Anil H. Patel
(anil.patel@klgates.com)
(*pro hac vice* application submitted in consolidated case)
K&L GATES LLP
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Elizabeth Weiskopf
(elizabeth.weiskopf@klgates.com)
(*pro hac vice* application submitted in consolidated case)
Jenna Bruce
(Jenna.bruce@klgates.com)
(*pro hac vice* application submitted in consolidated case)
K&L GATES LLP
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.7022

Attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that, to the best of my knowledge, the following actions involve some of the same patents as the Patents-in-Suit and Counterclaim Patents:

- *AstraZeneca Pharmaceuticals LP et al. v. Natco Pharma, Ltd. et al.*, No 3:23-cv-00796, pending before the United States District Court for the District of New Jersey, involves certain Patents-in-Suit and Counterclaim Patents.
- *AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc.*, No. 3:24-cv-00641, pending before the United States District Court for the District of New Jersey, involves certain Patents-in-Suit and Counterclaim Patents;
- *AstraZeneca Pharmaceuticals LP et al. v. Natco Pharma Ltd., et al.*, No. 3:24-cv-05887, pending before the United States District Court for the District of New Jersey, involves certain Patents-in-Suit and Counterclaim Patents; and
- *AstraZeneca Pharmaceuticals LP et al. v. Sandoz Inc.*, No. 3:24-cv-05889, pending before the United States District Court for the District of New Jersey, involves certain Patents-in-Suit and Counterclaim Patents.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: September 3, 2024

Respectfully submitted,

K&L GATES LLP

By: /s/ *Loly G. Tor*

Loly G. Tor
(loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4000
(F) 973.848.4001

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Cipla Limited and Cipla USA, Inc. hereby certifies that this action seeks declaratory judgement and therefore this action is not appropriate for compulsory arbitration.

Dated: September 3, 2024

Respectfully submitted,

K&L GATES LLP

By: *s/ Loly G. Tor*

Loly G. Tor
(loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4000
(F) 973.848.4001

Loly Tor
(loly.tor@klgates.com)
K&L GATES LLP
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4026
(F) 973.848.4001

Anil H. Patel
(anil.patel@klgates.com)
(*pro hac vice* application submitted in consolidated case)
K&L GATES LLP
609 Main Street, Suite 4150
Houston, TX 77002
(T) 713.815.7300
(F) 713.815.7301

Elizabeth Weiskopf
(elizabeth.weiskopf@klgates.com)
(*pro hac vice* application submitted in consolidated case)
Jenna Bruce
(Jenna.bruce@klgates.com)
(*pro hac vice* application submitted in consolidated case)
K&L GATES LLP
925 Fourth Avenue, Suite 2900
Seattle, WA 98104
(T) 206.623.7580
(F) 206.623.702

Attorneys for Defendants/Counterclaim-Plaintiffs Cipla USA, Inc. and Cipla Limited

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA UK LIMITED, ASTRAZENECA AB, KUDOS PHARMACEUTICALS LIMITED, THE UNIVERSITY OF SHEFFIELD, and MSD INTERNATIONAL BUSINESS GMBH, *Plaintiffs*, v. CIPLA LIMITED and CIPLA USA, INC., *Defendants*.	Civil Action No. 3:24-cv-7346 **CERTIFICATE OF SERVICE** ***Document Electronically Filed***

LOLY G. TOR, of full age, hereby certifies as follows:

1. I am an attorney-at-law of the State of New Jersey and admitted to practice before the United States District Court for the District of New Jersey and partner with the law firm of K&L Gates LLP, attorneys for Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.

2. I hereby certify that on the date indicated below, I caused a copy of Defendants/Counterclaim-Plaintiffs Cipla Limited and Cipla USA, Inc.'s Answer, Separate Defenses, and Counterclaims, Fed. R. Civ. P. 7.1 Corporate Disclosure Statement, and this certificate of service to be served upon all counsel of record by CM/ECF.

3. I certify under penalty of perjury that the foregoing is true and correct.

Dated: September 3, 2024

Respectfully submitted,

K&L GATES LLP

By: s/ *Loly G. Tor*

Loly G. Tor
(loly.tor@klgates.com)
One Newark Center, 10th Floor
Newark, NJ 07102
(T) 973.848.4000
(F) 973.848.4001