IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 24-1208-RGA
	)	
v.	)	
	)	
SUN PHARMACEUTICALS INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC.,	)	
	)	
Defendants.	)	

DEFENDANTS' ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO THE COMPLAINT

Defendants Sun Pharmaceutical Industries Limited and Sun Pharmaceutical Industries, Inc. (collectively, "Sun" or "Defendants"), by and through their undersigned attorneys, provide the following answers, separate defenses, and counterclaims to the Complaint ("Complaint") (D.I. 1) of Plaintiff Exelixis, Inc. ("Exelixis" or "Plaintiff"). This pleading is based upon Sun's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Sun denies all allegations in Plaintiff's Complaint except those specifically admitted below. The headings in Plaintiff's complaint are copied herein for convenience only, and any allegations in such headings are denied.

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 U.S.C. §§ 100 et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), and Sun Pharmaceutical Industries, Inc. ("Sun Inc."), (collectively, "Sun" or "Defendants"). This action arises out of Sun Ltd.'s submission of Abbreviated New Drug Application ("ANDA") No. 214385, to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of CABOMETYX® (the "Sun ANDA Product") prior to the expiration of U.S. Patent Nos. 8,877,776; 11,091,439; 11,091,440; and 11,098,015 (the "Asserted Patents").

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that the Complaint purports to set forth claims for infringement of the U.S. Patent Nos. 8,877,776 ("the '776 patent"); 11,091,439 ("the '439 patent"); 11,091,440 ("the '440 patent"); and 11,098,015 ("the '015 patent") (collectively, the "Asserted Patents") against Sun. Sun further admits that the Complaint purports to set forth claims arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*. Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining allegations in Paragraph 1; therefore, denied.

PARTIES

2. Plaintiff Exelixis, Inc. ("Exelixis") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1851 Harbor Bay Parkway, Alameda, California 94502. Exelixis is engaged in the business of creating, developing, and bringing to market new medicines for difficult-to-treat cancers. Exelixis sells CABOMETYX® throughout the United States, including in Delaware.

ANSWER: Sun is without sufficient knowledge or information to form a belief as to the truth or falsity of the allegations in Paragraph 2; therefore, denied.

3. Upon information and belief, Sun Ltd. is a corporation organized under the laws of India, with its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai – 400 063, Maharashtra, India. Upon information and belief,Sun Ltd., itself and through its wholly-owned subsidiaries and agents, including Sun Inc., manufactures, distributes, and/or imports generic drugs for sale throughout the United States, including in Delaware.

ANSWER: Sun admits that Sun Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063, India. Sun further admits that Sun Inc. is a subsidiary of Sun Ltd. Sun further admits that certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market. Sun admits that certain Sun entities prepare, submit, and

file Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market and distribute pharmaceutical drug products in the United States. Otherwise, denied.

4. Upon information and belief, Sun Inc. is a corporation organized and existing under the laws of Delaware, with its principal place of business at 2 Independence Way, Princeton, NJ 08540. Upon information and belief, Sun Inc. is a wholly-owned subsidiary of Sun Ltd., and Sun Inc. is controlled and/or dominated by Sun Ltd. Upon information and belief, Sun Inc. manufactures, distributes, and/or imports generic drugs for sale and use throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of Sun Ltd.

ANSWER: Sun admits that Sun Inc. is a corporation organized and existing under the laws of Delaware, having a place of business at 2 Independence Way, Princeton, New Jersey 08540. Sun further admits that Sun Inc. is a subsidiary of Sun Ltd. Sun further admits that certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market, including pharmaceutical products for which Sun Ltd. is the named ANDA applicant. Sun admits that certain Sun entities prepare, submit, and file Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market and distribute pharmaceutical drug products in the United States. Otherwise, denied.

5. Upon information and belief, Sun Ltd. and Sun Inc. acted collaboratively in the preparation and submission of ANDA No. 214385.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Ltd. is the listed Applicant for ANDA No. 214385 and Sun Inc. is the listed Authorized U.S. Agent for ANDA No. 214385. Sun denies any remaining allegations in paragraph 5.

6. Upon information and belief, following any FDA approval of ANDA No. 214385, Defendants, themselves and through their subsidiaries and agents, will make, use, offer to sell, and/or sell the Sun ANDA Product that is the subject of ANDA No. 214385, throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

ANSWER: Paragraph 6 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Ltd. prepared and submitted ANDA No. 214385 to FDA with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Cabozantinib Tablets, 20 mg, 40 mg, and 60 mg ("Sun's Proposed ANDA Product") prior to the expiration of the Asserted Patents. Otherwise, denied.

JURISDICTION AND VENUE

7. This case arises under the patent laws of the United States of America, 35 U.S.C.§§ 100 et. seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that this court has subject matter jurisdiction for Exelixis' infringement claims under 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2201(b). Otherwise, denied.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest venue in this Court for purposes of this action only. Otherwise, denied.

9. This Court has personal jurisdiction over Defendants because Defendants, among other things, have committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and both intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b) and/or (c), including inDelaware. These acts have led and will lead to foreseeable harm and injury to Exelixis, a Delaware corporation, in Delaware. For example, on information and belief, following approval of ANDA No. 214385, Defendants will make, use, import, sell, and/or offer for sale the Sun ANDA Product in the United States, including in Delaware, prior to the expiration of the Asserted Patents.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Otherwise, denied.

10. The Court also has personal jurisdiction over Defendants because, among other things, this action arises from Defendants' actions directed toward Delaware, and because Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware, including through Sun Inc.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Otherwise, denied.

11. This Court has personal jurisdiction over Sun Inc. by virtue of, among other things, the fact that it is organized and exists under the laws of the State of Delaware.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Inc. is a corporation organized and existing under the laws of Delaware. Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Sun denies any remaining allegations in paragraph 11.

12. Upon information and belief, Sun Inc. currently manufactures and distributes for sale hundreds of drug products throughout the United States, including in Delaware.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent a response is required, Sun Inc. does not contest personal jurisdiction in this Court for the purposes of this action only. Sun denies any remaining allegations in paragraph 12.

13. Upon information and belief, Sun Ltd. directs the operations, management, and activities of Sun Inc. in the United States.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Inc. is a subsidiary of Sun Ltd. Sun denies any remaining allegations in paragraph 13.

14. Upon information and belief, Sun Ltd. and Sun Inc. collaborate in the manufacture, marketing, or sale of pharmaceutical products (including generic drug products manufactured and sold pursuant to approved ANDAs) throughout the United States, including in Delaware.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Inc. is a subsidiary of Sun Ltd. Sun further admits that certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical drug products, including, directly or indirectly, for the United States market, including pharmaceutical products for which Sun Ltd. is the named ANDA applicant. Sun denies any remaining allegations in paragraph 14.

15. Sun Ltd. has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Limited et al*, C.A. No. 24-726 (D. Del.); *Allergan Holdings Unlimited Company et al v. Sun Pharmaceutical Industries Limited*, C.A. No. 23-795 (D. Del.); *Vertex Pharmaceuticals Incorporated v. Sun Pharmaceutical Industries Limited*, C.A. No. 23-666 (D. Del.); *Novo Nordisk Inc. et al v. Sun Pharmaceutical Industries Ltd. et al*, C.A. No. 22-896 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Sun Pharmaceutical Industries Limited et al*, C.A. No. 21-1573 (D. Del.); *Sun Pharmaceuticals Industries Ltd. et al v. Saptalis Pharmaceuticals, LLC*, C.A. No. 18-648 (D. Del.).

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that it has been involved in litigations in the District of Delaware. Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Otherwise, denied.

16. Sun Inc. has previously availed itself of this forum by filing counterclaims in other actions pending before this Court, including *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Sun Pharmaceutical Industries Limited et al*, C.A. No. 21-1573 (D. Del.); *Galderma Laboratories, LP et al v. Sun Pharmaceutical Industries, Ltd*. et al, C.A. No. 18-1588 (D. Del.).

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that it has been involved in litigations in the District of Delaware. Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Otherwise, denied.

17. On information and belief, Sun Ltd.'s contacts with other states of the United States are no greater than its contacts with Delaware. Therefore, to the extent Sun Ltd. denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with

Delaware, this Court has personal jurisdiction over Sun Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest personal jurisdiction in this Court for the purposes of this action only. Otherwise, denied.

18. Venue is proper in this Court as to Sun Inc. under 28 U.S.C. § 1400(b) because, upon information and belief, it is incorporated under the state laws of Delaware and therefore resides in the District of Delaware.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest venue in this Court for the purposes of this action only. Otherwise, denied.

19. Venue is proper in this Court as to Sun Ltd. under 28 U.S.C. § 1391(c)(3), because, upon information and belief, it is not a resident of the United States and may thus be sued in any judicial district.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent a response is required, Sun does not contest venue in this Court for the purposes of this action only. Otherwise, denied.

BACKGROUND

20. U.S. Patent No. 8,877,776 (the "'776 Patent") ("Exhibit A"), entitled "(L)-malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide," was duly and legally issued on November 4, 2014. The '776 Patent willexpire on October 8, 2030. The claims of the '776 Patent are valid, enforceable, and not expired. All rights and interests in the '776 Patent are owned by and assigned to Exelixis.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Exhibit A to the Complaint is a copy of the '776 Patent. Sun admits that, according to the records of the United States Patent and Trademark Office ("PTO"), the PTO issued the '776 Patent titled "(L)-malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide" on November

4, 2014. Sun admits that the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the '776 Patent as having an expiration date of October 8, 2030. Sun admits that Exelixis is listed as the assignee on the face of the '776 Patent. Otherwise, denied.

21. U.S. Patent No. 11,091,439 (the "'439 Patent") ("Exhibit B"), entitled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms ther[e]of for the treatment of cancer" was duly and legally issued on August 17, 2021. The '439 Patent will expire on January 15, 2030. The claims of the '439 Patent are valid, enforceable, and not expired. All rights and interests in the '439 Patent are owned by and assigned to Exelixis.

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Exhibit B to the Complaint is a copy of the '439 Patent. Sun admits that, according to the records of the United States Patent and Trademark Office ("PTO"), the PTO issued the '439 Patent titled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms ther[e]of for the treatment of cancer" on August 17, 2021. Sun admits that the Orange Book lists the '439 Patent as having an expiration date of January 15, 2030. Sun admits that Exelixis is listed as the assignee on the face of the '439 Patent. Otherwise, denied.

22. U.S. Patent No. 11,091,440 (the "'440 Patent") ("Exhibit C"), entitled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)- N'-(4-fluorophenyl)cyclopropane-1,1 -dicarboxamide, and crystalline forms thereof for the treatment of cancer" was duly and legally issued on August 17, 2021. The '440 Patent will expire on January 15, 2030. The claims of the '440 Patent are valid, enforceable, and not expired. All rights and interests in the '440 Patent are owned by and assigned to Exelixis.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Exhibit C to the Complaint is a copy of the '440 Patent. Sun admits that, according to the records of the United States Patent and Trademark Office ("PTO"), the PTO issued the '440 Patent titled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-

4-yl]oxy}phenyl)- N′-(4-fluorophenyl)cyclopropane-1,1 -dicarboxamide, and crystalline forms thereof for the treatment of cancer" on August 17, 2021. Sun admits that the Orange Book lists the '440 Patent as having an expiration date of January 15, 2030. Sun admits that Exelixis is listed as the assignee on the face of the '440 Patent. Otherwise, denied.

23. U.S. Patent No. 11,098,015 (the "'015 Patent") ("Exhibit D"), entitled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms thereof for the treatment of cancer" was duly and legally issued on August 24, 2021. The '015 Patent will expire on January 15, 2030. The claims of the '015 Patent are valid, enforceable, and not expired. All rights and interests in the '015 Patent are owned by and assigned to Exelixis.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Exhibit D to the Complaint is a copy of the '015 Patent. Sun admits that, according to the records of the United States Patent and Trademark Office ("PTO"), the PTO issued the '015 Patent titled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms thereof for the treatment of cancer" on August 24, 2021. Sun admits that the Orange Book lists the '015 Patent as having an expiration date of January 15, 2030. Sun admits that Exelixis is listed as the assignee on the face of the '015 Patent. Otherwise, denied.

24. CABOMETYX® (cabozantinib) is a tyrosine kinase inhibitor, for oral administration, approved by the FDA for the treatment of patients with advanced kidney cancer (renal cell carcinoma) as a monotherapy and in combination with nivolumab. It is also approved to treat patients with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib, and adult and pediatric patients 12 years of age and older with locally advanced or metastatic thyroid cancer (differentiated thyroid cancer) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible. Exelixis sells CABOMETYX® in the United States pursuant to New Drug Application No. 208692, which was approved by the FDA in 2016.

ANSWER: Sun admits that the FDA-approved prescribing information for CABOMETYX® states that "CABOMETYX is indicated for the treatment of patients with advanced renal cell carcinoma (RCC)," and "CABOMETYX, in combination with nivolumab, is indicated for the first-line

treatment of patients with advanced RCC." Sun admits that the FDA-approved prescribing information for CABOMETYX® also states that "CABOMETYX is indicated for the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib." Sun admits that the FDA-approved prescribing information for CABOMETYX® also states that "CABOMETYX is indicated for the treatment of adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine-refractory or ineligible." Sun admits that, according to FDA's website, the FDA approved Exelixis' NDA No. 208692 on April 25, 2016 for CABOMETYX (cabozantinib) Tablets, 20 mg, 40 mg, and 60 mg. Sun is without sufficient knowledge or information to form a belief as to the truth of the remaining allegations and therefore denies them.

25. The '776, '439, '440, and '015 Patents have been listed in connection with CABOMETYX® in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, referred to as the "Orange Book."

ANSWER: Sun admits that, as of January 6, 2025, the '776, '439, '440, and '015 Patents are listed in the Orange Book for CABOMETYX® . Otherwise, denied.

26. By letter dated September 16, 2024, and received via FedEx on September 17, 2024 (the "Notice Letter"), Defendants notified Exelixis that Defendants had submitted ANDA No. 214385 to the FDA for Cabozantinib (*S*)-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

ANSWER: Sun admits that Sun Ltd. sent Exelixis a letter on September 16, 2024 with the subject line: "Notice of Certification Pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95) concerning ANDA No. 214385 (Cabozantinib Tablets, 20 mg, 40 mg and 60 mg)" ("Notice Letter"), "[p]ursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95." Sun admits that its Notice Letter was delivered to Exelixis Inc., 1851 Harbor

Bay Parkway, Alameda, CA, 94502 on September 17, 2024 and Exelixis, Inc., 210 East Grand Ave., South San Francisco, CA, 94080 on September 18, 2024. Otherwise, denied.

27. By submitting ANDA No. 214385, Defendants have necessarily represented to the FDA that the Sun ANDA Product has the same active ingredient as CABOMETYX®, has the same dosage forms and strengths as CABOMETYX®, and is bioequivalent to CABOMETYX®.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that the active ingredient in Sun's ANDA Product is Cabozantinib S Malate, that the dosage form is tablets, that the proposed strengths are 20 mg, 40 mg and 60 mg, and that Sun's ANDA reports that the fasting bioequivalence study it performed indicates that Sun's Cabozantinib Tablets, 60 mg is bioequivalent to CABOMETRYX® (cabozantinib) tablets, 60 mg and that Sun seeks a bio-waiver for its 20 mg and 40 mg proposed products. Otherwise, denied.

28. In Defendants' Notice Letter, Defendants stated that ANDA No. 214385 included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the '776, '439, '440,and '015 Patents and alleged that the '776, '439, '440, and '015 Patents are "invalid and/or would not be infringed by the commercial manufacture, use or sale" of the Sun ANDA Product. The Notice Letter also informed Exelixis that Defendants seek approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Sun ANDA Product before the '776, '439, '440, and '015 Patents expire.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that the Notice Letter stated that Sun Ltd. has submitted an ANDA "under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed Cabozantinib Tablets, 20 mg, 40 mg and 60 mg, [ ], prior to expiration of the Orange Book Patents, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') in association with NDA No. 208692." Sun admits that the Notice Letter stated that "[p]ursuant to

21 C.F.R. § 314.95(c)(6)," Sun notified Exelixis that the Asserted Patents were "not infringed, invalid and/or unenforceable…." Otherwise, denied.

29. Upon information and belief, Defendants had knowledge of the '776, '439, '440, and '015 Patents at least as of the time Defendants submitted the paragraph IV certification in ANDA No. 214385.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun submitted Paragraph IV certifications concerning the '776, '439, '440, and '015 Patents to FDA. Otherwise, denied.

30. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product immediately and imminently upon approval of ANDA No. 214385.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Ltd. had filed ANDA No. 214385 under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's Proposed ANDA Product prior to the expiration of the Asserted Patents. Otherwise, denied.

31. This action is being commenced before the expiration of forty-five days from the date of Exelixis' receipt of the Notice Letter.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that its Notice Letter was delivered to Exelixis Inc., 1851 Harbor Bay Parkway, Alameda, CA, 94502 on September 17, 2024 and Exelixis, Inc., 210 East Grand Ave., South San Francisco, CA, 94080 on September 18, 2024, and Exelixis, Inc. commenced this action on October 30, 2024. Otherwise, denied.

CLAIMS FOR RELIEF

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 8,877,776

32. Exelixis incorporates each of the preceding paragraphs 1-31 as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

33. Defendants' submission of ANDA No. 214385 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '776 Patent constituted an act of infringement of at least claims 1, 2, 3, and 5 of the '776 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

34. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the '776 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '776 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

35. Upon FDA approval of ANDA No. 214385, Defendants will infringe the '776 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '776 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Defendants have notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the SunANDA Product before the expiration of the '776 Patent.

ANSWER: Sun admits that its Notice Letter stated that Sun Ltd. has submitted an ANDA "under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed Cabozantinib Tablets, 20 mg, 40 mg and 60 mg, [ ], prior to expiration of the Orange Book Patents, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') in association with NDA No. 208692." Otherwise, denied.

36. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '776 Patent.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Plaintiff's allegation of infringement of the '776 Patent has merit or that Plaintiff is entitled to any relief on its claim.

37. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe the '776 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

38. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 214385, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '776 Patent. This is an exceptional case.

ANSWER: Denied.

39. Unless Defendants are enjoined from directly or indirectly infringing the '776 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

ANSWER: Denied.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 11,091,439

40. Exelixis incorporates each of the preceding paragraphs 1-39 as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

41. Defendants' submission of ANDA No. 214385 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '439 Patent constituted an act of infringement of at least claims 1, 3, and 4 of the '439 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

42. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the '439 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '439

Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

43. Upon FDA approval of ANDA No. 214385, Defendants will infringe the '439 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '439 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Defendants have notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '439 Patent.

ANSWER: Sun admits that its Notice Letter stated that Sun Ltd. has submitted an ANDA "under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed Cabozantinib Tablets, 20 mg, 40 mg and 60 mg, [ ], prior to expiration of the Orange Book Patents, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') in association with NDA No. 208692." Otherwise, denied.

44. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '439 Patent.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Plaintiff's allegation of infringement of the '439 Patent has merit or that Plaintiff is entitled to any relief on its claim.

45. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe the '439 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

46. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 214385, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '439 Patent. This is an exceptional case.

ANSWER: Denied.

47. Unless Defendants are enjoined from directly or indirectly infringing the '439 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

ANSWER: Denied.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 11,091,440

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

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

49. Defendants' submission of ANDA No. 214385 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '440 Patent constituted an act of infringement of at least claims 1 and 3 of the '440 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

50. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the '440 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '440 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

51. Upon FDA approval of ANDA No. 214385, Defendants will infringe the '440 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '440 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Defendants have notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '440 Patent.

ANSWER: Sun admits that its Notice Letter stated that Sun Ltd. has submitted an ANDA "under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed Cabozantinib Tablets, 20

mg, 40 mg and 60 mg, [ ], prior to expiration of the Orange Book Patents, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') in association with NDA No. 208692." Otherwise, denied.

52. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '440 Patent.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Plaintiff's allegation of infringement of the '440 Patent has merit or that Plaintiff is entitled to any relief on its claim.

53. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe the '440 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

54. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 214385, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '440 Patent. This is an exceptional case.

ANSWER: Denied.

55. Unless Defendants are enjoined from directly or indirectly infringing the '440 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

ANSWER: Denied.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 11,098,015

56. Exelixis incorporates each of the preceding paragraphs 1-55 as if fully set forth herein.

ANSWER: Sun incorporates by reference its prior answers to the paragraphs of this Complaint as if fully set forth herein.

57. Defendants' submission of ANDA No. 214385 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '015 Patent constituted an act of infringement of at least claims 1, 2, and 3 of the '015 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

58. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Sun ANDA Product and/or its active ingredient prior to expiration of the '015 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe the '015 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

59. Upon FDA approval of ANDA No. 214385, Defendants will infringe the '015 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Sun ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '015 Patent by others, under 35 U.S.C. § 271(a), (b), and/or (c), unless enjoined by the Court. Such infringement is imminent because, among other things, Defendants have notified Exelixis of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Sun ANDA Product before the expiration of the '015 Patent.

ANSWER: Sun admits that its Notice Letter stated that Sun Ltd. has submitted an ANDA "under 21 U.S.C. § 355(j) with paragraph IV certifications seeking to engage in the commercial manufacture, use, importation, offer for sale or sale of Sun's proposed Cabozantinib Tablets, 20 mg, 40 mg and 60 mg, [ ], prior to expiration of the Orange Book Patents, which are listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') in association with NDA No. 208692." Otherwise, denied.

60. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '015 Patent.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent a response is required, Sun denies that Plaintiff's allegation of infringement of the '015 Patent has merit or that Plaintiff is entitled to any relief on its claim.

61. Pursuant to 28 U.S.C. § 2201, Exelixis is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Sun ANDA Product, inducement thereof or contribution thereto, will infringe the '015 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

62. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 214385, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the ’015 Patent. This is an exceptional case.

ANSWER: Denied.

63. Unless Defendants are enjoined from directly or indirectly infringing the ’015 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

ANSWER: Denied.

ANSWER TO PLAINTIFF’S PRAYER FOR RELIEF

Sun denies that Exelixis is entitled to judgment or any of the relief sought against Sun in paragraphs (a)-(f) under the heading “PRAYER FOR RELIEF” in the Complaint. Sun demands judgment in its favor.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not expressly admitted, on information and belief, Sun asserts the following Separate Defenses to Exelixis’ Complaint without assuming the burden of proof on any such defense that would otherwise rest on Exelixis. Sun reserves the right to allege any and all defenses not presently known or revealed during discovery or other analysis.

FIRST SEPARATE DEFENSE

The submission of Sun’s ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun’s Proposed ANDA Product does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the ’776 Patent.

SECOND SEPARATE DEFENSE

The submission of Sun’s ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun’s Proposed ANDA Product does not and will not directly

infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '439 Patent.

THIRD SEPARATE DEFENSE

The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's Proposed ANDA Product does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '440 Patent.

FOURTH SEPARATE DEFENSE

The submission of Sun's ANDA and/or manufacture, use, sale, offer for sale and/or importation into the United States of Sun's Proposed ANDA Product does not and will not directly infringe, indirectly infringe, induce infringement of, or contribute to the infringement of, either literally or under the Doctrine of Equivalents, any valid and enforceable claim of the '015 Patent.

FIFTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '776 Patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated September 16, 2024.

SIXTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '439 Patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially created bases for invalidity

or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated September 16, 2024.

SEVENTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '440 Patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated September 16, 2024.

EIGHTH SEPARATE DEFENSE

Based on information and belief, each of the claims of the '015 Patent is invalid for failing to satisfy one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun's Notice Letter dated September 16, 2024.

NINETH SEPARATE DEFENSE

Exelixis has failed to state a proper claim for exceptional case under 35 U.S.C. § 285.

TENTH SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. §§ 271(a)-(c) against Sun because Exelixis has not pleaded with particularity facts regarding any post-ANDA-approval activities.

ELEVENTH SEPARATE DEFENSE

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

TWELFTH SEPARATE DEFENSE

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

THIRTEENTH SEPARATE DEFENSE

Exelixis is barred by 35 U.S.C. § 288 from recovering costs associated with this lawsuit.

RESERVATION OF ADDITIONAL SEPARATE AND/OR AFFIRMATIVE DEFENSES

Sun reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional separate and/or affirmative defenses are appropriate, including, but not limited to, under 35 U.S.C. §§ 116 and/or 120, inequitable conduct, unclean hands, laches, estoppel, patent misuse or any other defense of unenforceability.

COUNTERCLAIMS

Without admitting any of the allegations of Plaintiff/Counter Defendant, Exelixis, Inc. ("Plaintiff/Counter Defendant") other than those expressly admitted herein, and without prejudice to Defendants/Counterclaimants, Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun, Inc.") (collectively "Counterclaimants"), to plead additional counterclaims as the facts of the matter warrant, Counterclaimants assert the following counterclaims against Counter Defendant:

NATURE OF THE ACTION

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and seek a declaratory judgment that Sun Ltd.'s proposed products in Abbreviated New Drug Application ("ANDA") No. 214385 ("Sun's ANDA") do not and will not infringe any valid and enforceable claim of U.S. Patent Nos. 8,877,776 ("the '776 patent"); 11,091,439 ("the '439 patent"); 11,091,440 ("the '440 patent"); 11,098,015 ("the '015 patent"); 9,724,342 (the "'342 patent"); 10,034,873 (the "'873 patent"); 10,039,757 (the "'757 patent"); and 11,298,349 (the "'349 patent") (collectively, the

"Orange Book Patents"), and that each and every claim of the Orange Book Patents are invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103 and/or 112, and/or based on other judicially created bases for invalidation.

PARTIES

2. Counterclaimant Sun Ltd. is a company organized and existing under the laws of the Republic of India with its principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India.

3. Counterclaimant Sun Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

4. On information and belief, and based on Counter Defendant's allegations, Counter Defendant is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1851 Harbor Bay Parkway, Alameda, California 94502.

5. Counter Defendant purports to be the lawful owner of the Orange Book Patents.

JURISDICTION AND VENUE

6. This action arises under and the Court has jurisdiction over these counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201(a), 2201(b) and 35 U.S.C. § 271 based on an actual controversy between Counterclaimants and Counter Defendant arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

7. This Court may declare the rights and legal relation of the parties pursuant to §§ 2201 and 2202 of Title 28 of the United States Code and § 271(e)(5) of Title 35 of the United

States Code because the Counterclaims present an actual controversy within the Court's jurisdiction.

8. This Court has personal jurisdiction over the Counter Defendant based, *inter alia*, on the filing by Counter Defendant of this lawsuit in this jurisdiction.

9. Venue is proper in this judicial district based on 28 U.S.C. §§ 1391 and 1400(b), and by Counter Defendant's choice of forum.

BACKGROUND

10. According to the United States Food & Drug Administration ("FDA") publication titled Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), Counter Defendant holds an approved New Drug Application ("NDA") No. 208692 for Cabozantinib S-Malate 20 mg, 40 mg and 60 mg tablets, sold under the brand name CABOMETYX®.

11. Under 21 U.S.C. § 355(b)(1), an NDA holder must provide to FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes "claims the drug for which the applicant submitted the [NDA]" or which "claims a method of using such drug." FDA ministerially publishes these patents in the Orange Book.

12. Upon information and belief, and as stated in the Complaint in this matter, Counter Defendant is the owner of the '776, '439, '440, and '015 Patents ("Asserted Patents").

13. Upon information and belief, Counter Defendant is the owner of the '873, '342, '757, and '349 Patents.

14. Upon information and belief, the Counter Defendant itself or through its agents, caused the Orange Book Patents to be listed in connection with CABOMETYX® in the Food and

Drug Administration's ("FDA") publication, Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book").

15. The '776 Patent, on its face, is titled "(L)-malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide," and has an issue date of November 4, 2014. Upon information and belief, a true and complete copy of the '776 patent is attached to the Complaint (D.I. 1) as Exhibit A.

16. The'439 Patent, on its face, is titled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms ther[e]of for the treatment of cancer," and has an issue date of August 17, 2021. Upon information and belief, a true and complete copy of the '439 patent is attached to the Complaint (D.I. 1) as Exhibit B.

17. The '440 Patent, on its face, is titled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)- N′-(4-fluorophenyl)cyclopropane-1,1 -dicarboxamide, and crystalline forms thereof for the treatment of cancer," and has an issue date of August 17, 2021. Upon information and belief, a true and complete copy of the '440 patent is attached to the Complaint (D.I. 1) as Exhibit C.

18. The '015 Patent, on its face, is titled "Malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N′-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide, and crystalline forms thereof for the treatment of cancer," and has an issue date of August 24, 2021. Upon information and belief, a true and complete copy of the '015 patent is attached to the Complaint (D.I. 1) as Exhibit D.

19. The ’342 Patent, on its face, is titled “C-met Modulator Pharmaceutical Compositions,” and has an issue date of August 8, 2017. Upon information and belief, a true and complete copy of the ’342 Patent is attached to Sun’s Counterclaims as Exhibit E.

20. The ’873 Patent, on its face, is titled “C-met Modulator Pharmaceutical Compositions,” and has an issue date of July 31, 2018. Upon information and belief, a true and complete copy of the ’873 Patent is attached to Sun’s Counterclaims as Exhibit F.

21. The ’757 Patent, on its face, is titled “C-met Modulator Pharmaceutical Compositions,” and has an issue date of August 7, 2018. Upon information and belief, a true and complete copy of the ’757 Patent is attached to Sun’s Counterclaims as Exhibit G.

22. The ’349 Patent, on its face, is titled “Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds,” and has an issue date of April 12, 2022. Upon information and belief, a true and complete copy of the ’349 Patent is attached to Sun’s Counterclaims as Exhibit H.

23. Sun Ltd., listing its Authorized U.S. Agent, Sun Inc., submitted Sun’s ANDA to the FDA seeking approval to market the products described therein (“Sun’s Proposed ANDA Product”) in the United States.

24. Sun’s ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Orange Book Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sun’s Proposed ANDA Product.

25. On or around September 16, 2024, Sun Ltd. sent a notice letter providing Counter Defendant notice of submission of Sun’s ANDA to FDA (“the Notice Letter”). The Notice Letter contains notification of Sun’s Paragraph IV Certification to FDA that the Orange Book Patents are

invalid, unenforceable, and/or not infringed by Sun's Proposed ANDA Product and the factual and legal bases in support thereof. The Notice Letter also contained an offer of confidential access to Sun's ANDA in accordance with 21 U.S.C. § 355(j)(5)(C).

26. On or around October 30, 2024, Plaintiff/Counter Defendant filed a lawsuit, alleging, *inter alia*, infringement of the Asserted Patents based on Sun Ltd.'s filing of Sun's ANDA.

27. Plaintiff/Counter Defendant did not allege infringement of the '873, '342, '757, and '349 Patents in its Complaint against Sun despite receiving Sun's Notice Letter that included these patents.

28. Counterclaimants deny they infringe any valid claim of the Orange Book Patents.

29. Absent a ruling from this Court finding the Orange Book Patents are invalid, unenforceable, and/or not infringed by Counterclaimants or Sun's Proposed ANDA Product, Plaintiff/Counter Defendant will continue to assert the Asserted Patents against Counterclaimants, hindering the ability of Counterclaimants to obtain regulatory approval and to market in the United States Sun's Proposed ANDA Product, causing irreparable harm to Counterclaimants' businesses and denying Counterclaimants patent certainty.

30. Absent a ruling from this Court finding the Orange Book Patents are invalid, unenforceable, and/or not infringed by Counterclaimants or Sun's Proposed ANDA Product, Plaintiff/Counter Defendant may later assert the '873, '342, '757, and '349 Patents against Counterclaimants, hindering the ability of Counterclaimants to obtain regulatory approval and to market in the United States Sun's Proposed ANDA Product, causing irreparable harm to Counterclaimants' businesses and denying Counterclaimants patent certainty.

31. Plaintiff/Counter Defendant has requested both injunctive relief and damages against Counterclaimants. Counterclaimants have invested significant financial and other resources into the development of Sun's Proposed ANDA Product and in seeking FDA approval. Plaintiff/Counter Defendant's threats against Counterclaimants will continue as long as the disputes identified with respect to the infringement and validity of the Orange Book Patents remain.

32. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Counter Defendant and Counterclaimants regarding the Orange Book Patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

COUNT I
(Declaratory Judgment of Invalidity of the '776 Patent)

33. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 32 of the Counterclaims as though fully set forth herein.

34. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '776 Patent.

35. Counter Defendant has asserted the '776 Patent against Counterclaimants.

36. One or more of the claims of the '776 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for

invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

37. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '776 Patent is/are invalid.

COUNT II
(Declaratory Judgment of Invalidity of the '439 Patent)

38. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 37 of the Counterclaims as though fully set forth herein.

39. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '439 Patent.

40. Counter Defendant has asserted the '439 Patent against Counterclaimants.

41. One or more of the claims of the '439 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

42. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '439 Patent is/are invalid.

COUNT III
(Declaratory Judgment of Invalidity of the '440 Patent)

43. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 42 of the Counterclaims as though fully set forth herein.

44. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '440 Patent.

45. Counter Defendant has asserted the '440 Patent against Counterclaimants.

46. One or more of the claims of the '440 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

47. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '440 Patent is/are invalid.

COUNT IV
(Declaratory Judgment of Invalidity of the '015 Patent)

48. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 47 of the Counterclaims as though fully set forth herein.

49. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '015 Patent.

50. Counter Defendant has asserted the '015 Patent against Counterclaimants.

51. One or more of the claims of the '015 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

52. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '015 Patent is/are invalid.

COUNT V
(Declaratory Judgment of Invalidity of the '342 Patent)

53. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 52 of the Counterclaims as though fully set forth herein.

54. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '342 Patent.

55. One or more of the claims of the '342 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

56. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '342 Patent is/are invalid.

COUNT VI
(Declaratory Judgment of Invalidity of the '873 Patent)

57. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 56 of the Counterclaims as though fully set forth herein.

58. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '873 Patent.

59. One or more of the claims of the '873 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

60. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '873 Patent is/are invalid.

COUNT VII
(Declaratory Judgment of Invalidity of the '757 Patent)

61. Counterclaimants incorporate by reference and realleges their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 60 of the Counterclaims as though fully set forth herein.

62. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '757 Patent.

63. One or more of the claims of the '757 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

64. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '757 Patent is/are invalid.

COUNT VIII
(Declaratory Judgment of Invalidity of the '349 Patent)

65. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 64 of the Counterclaims as though fully set forth herein.

66. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the invalidity of the '349 Patent.

67. One or more of the claims of the '349 Patent are invalid for failure to comply with one or more of the conditions of patentability set forth in Title 35 of the United States Code, including at least 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially-created bases for invalidity or unenforceability, for example, for at least the reasons set forth in Sun Ltd.'s Notice Letter.

68. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. §§ 2201 *et seq.*, Counterclaimants are entitled to a declaratory judgment that one or more claims of the '349 Patent is/are invalid.

COUNT IX
(Declaratory Judgment of Noninfringement of the '776 Patent)

69. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 68 of the Counterclaims as though fully set forth herein.

70. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '776 Patent.

71. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '776 Patent, either literally or under the doctrine of equivalents, at least because the claims of the '776 Patent are invalid, and an invalid claim cannot be infringed.

72. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '776 Patent, either literally or under the doctrine of equivalents.

73. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '776 Patent, either literally or under the doctrine of equivalents.

COUNT X
(Declaratory Judgment of Noninfringement of the '439 Patent)

74. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 73 of the Counterclaims as though fully set forth herein.

75. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '439 Patent.

76. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '439 Patent, either literally or under the doctrine of equivalents, at least because the claims of the '439 Patent are invalid, and an invalid claim cannot be infringed.

77. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '439 Patent, either literally or under the doctrine of equivalents.

78. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly

or indirectly, any valid and enforceable claim of the '439 Patent, either literally or under the doctrine of equivalents.

COUNT XI
(Declaratory Judgment of Noninfringement of the '440 Patent)

79. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 78 of the Counterclaims as though fully set forth herein.

80. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '440 Patent.

81. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '440 Patent, either literally or under the doctrine of equivalents, at least because the claims of the '440 Patent are invalid, and an invalid claim cannot be infringed.

82. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '440 Patent, either literally or under the doctrine of equivalents.

83. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '440 Patent, either literally or under the doctrine of equivalents.

COUNT XIII
(Declaratory Judgment of Noninfringement of the '342 Patent)

84. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 83 of the Counterclaims as though fully set forth herein.

85. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '342 Patent.

86. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '342 Patent, either literally or under the doctrine of equivalents, at least because the claims of the '342 Patent are invalid, and an invalid claim cannot be infringed.

87. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or

will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '342 Patent, either literally or under the doctrine of equivalents.

88. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '342 Patent, either literally or under the doctrine of equivalents.

COUNT XIV
(Declaratory Judgment of Noninfringement of the '873 Patent)

89. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 88 of the Counterclaims as though fully set forth herein.

90. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '873 Patent.

91. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '873 Patent, either literally or under the doctrine of equivalents, at least because the claims of the '873 Patent are invalid, and an invalid claim cannot be infringed.

92. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation

into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '873 Patent, either literally or under the doctrine of equivalents.

93. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '873 Patent, either literally or under the doctrine of equivalents.

COUNT XIV
(Declaratory Judgment of Noninfringement of the '757 Patent)

94. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 93 of the Counterclaims as though fully set forth herein.

95. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '757 Patent.

96. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '757 Patent, either literally or under the doctrine of equivalents, at least because the claims of the '757 Patent are invalid, and an invalid claim cannot be infringed.

97. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '757 Patent, either literally or under the doctrine of equivalents.

98. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '757 Patent, either literally or under the doctrine of equivalents.

COUNT XIV
(Declaratory Judgment of Noninfringement of the '349 Patent)

99. Counterclaimants incorporate by reference and reallege their responses to the Complaint and each of its allegations set forth in Paragraphs 1 through 98 of the Counterclaims as though fully set forth herein.

100. This Counterclaim arises under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counter Defendant concerning the non-infringement of the '349 Patent.

101. Neither the submission of Sun's ANDA nor any future manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '349 Patent, either literally or under the

doctrine of equivalents, at least because the claims of the '349 Patent are invalid, and an invalid claim cannot be infringed.

102. Additionally, for at least the reasons set forth in Sun Ltd.'s Notice Letter, neither the submission of Sun's ANDA nor the manufacture, use, sale, offer for sale, and/or importation into the United States of Sun's Proposed ANDA Product infringes (or will infringe), induces (or will induce) infringement of, or contributes (or will contribute) to the infringement of any valid or enforceable claim of the '349 Patent, either literally or under the doctrine of equivalents.

103. Pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201 *et seq.*, Sun is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '349 Patent, either literally or under the doctrine of equivalents.

EXCEPTIONAL CASES

This case is an exceptional one, and Counterclaimants are entitled to an award of their reasonable attorney fees, expenses, and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Defendants/Counterclaimants respectfully request the Court enter judgment in their favor, granting the following relief:

A. An order dismissing the Complaint, with prejudice, and denying Plaintiff/Counter Defendant the relief requested in the Complaint and any relief whatsoever;

B. An order declaring, pursuant to one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, that each claim of the Orange Book Patents is invalid;

C. An order declaring that no valid and enforceable claim of the Orange Book Patents is infringed by the submission of Sun's ANDA No. 214385 or by the making, use, sale, offer for sale, marketing, or importation into the United States of a drug product subject to Sun's ANDA;

D. Denying Plaintiff/Counter Defendant any award of damages, costs, or fees;

E. An order declaring this case exceptional under 35 U.S.C. § 285 and awarding Defendants/Counterclaimants their reasonable attorneys' fees, and costs under 35 U.S.C. § 285 and all other applicable statutes and rules in common law that would be appropriate, with pre- and post-judgment interest thereon;

F. Awarding Defendants/Counterclaimants such other and further relief as this Court may deem just and proper.

/s/ Kelly E. Farnan

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