IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	C.A. No. 25-423-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 ("Sun Ltd.") and Sun Pharmaceutical Industries, Inc. ("Sun 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, 35 U.S.C. §§ 100 et seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, against Defendants Sun Pharmaceutical Industries Ltd. ("Sun Ltd."), and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively, "Defendants" or "Sun"). 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 No. 12,128,039 (the "Asserted Patent" or "'039 Patent").

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit 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 and 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: Defendants are 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: Defendants admit that Sun Ltd. is a company organized under the laws of India, with a principal place of business at Sun House, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai – 400 063, Maharashtra, India. Defendants further admit that Sun Inc. is a subsidiary of Sun Ltd. Defendants further admit 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. Defendants further admit that certain Sun entities prepare, submit, and file Abbreviated New Drug Applications ("ANDAs") to the FDA seeking approval to market such 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, New Jersey 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: Defendants admit that Sun Inc. is a corporation organized under the laws of Delaware with a place of business at 2 Independence Way, Princeton, New Jersey 08540, and that it is a subsidiary of Sun Ltd. Defendants further admit that certain Sun entities are in the business of manufacturing, marketing, and/or selling pharmaceutical products, including, directly or indirectly, for the United States market, including pharmaceutical products for which Sun Ltd. is the named ANDA applicant. Defendants further admit that certain Sun entities prepare, submit, and file ANDAs seeking FDA approval to market and distribute pharmaceutical 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 response is required. To the extent a response is required, Defendants admit that Sun Ltd. is the applicant for ANDA No. 214385 and that Sun Inc. is the listed Authorized U.S. Agent for the ANDA. Defendants deny the remaining allegations in this paragraph.

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 response is required. To the extent a response is required, Defendants admit that Sun Ltd. prepared and submitted ANDA No. 214385 to FDA with a paragraph IV certification seeking approval 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 '039 Patent. 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 Judgement 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 response is required. To the extent a response is required, Defendants admit that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 for Plaintiff's infringement claims. 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 response is required. To the extent a response is required, Defendants do not contest venue in this District for purposes of this action only. Otherwise, denied.

9. This Court 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 in Delaware. 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 Patent.

ANSWER: Paragraph 9 contains legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction for 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 response is required. To the extent a response is required, Defendants do not contest personal jurisdiction in this Court for 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 response is required. To the extent a response is required, Defendants admit that Sun Inc. is incorporated under the laws of the State of Delaware. Defendants do not contest personal jurisdiction for purposes of this action only. Otherwise, denied.

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

ANSWER: Paragraph 12 contains legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest personal jurisdiction in this Court for purposes of this action only. Otherwise, denied.

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 response is required. To the extent a response is required, Defendants admit that Sun Inc. is a subsidiary of Sun Ltd. and deny the remaining allegations in this paragraph.

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

ANSWER: Paragraph 14 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit 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. Otherwise, denied.

15. Sun Ltd. has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including *Exelixis, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 24-1208 (D. Del.); *Veloxis Pharmaceuticals, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 24-726 (D. Del.); *Allergan Holdings Unlimited Co. et al. v. Sun Pharmaceutical Industries Ltd.*, C.A. No. 23-795 (D. Del.); *Vertex Pharmaceuticals Inc. v. Sun Pharmaceutical Industries Ltd.*, 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 Ltd. et al.*, C.A. No. 21-1573 (D. Del.); *Sun Pharmaceutical Industries Ltd. et al. v. Saptalis Pharmaceuticals, LLC*, C.A. No. 18-648 (D. Del.).

ANSWER: Paragraph 15 contains legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Sun Ltd. has been involved in litigation in this District. Sun Ltd. does not contest personal jurisdiction for 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 *Exelixis, Inc. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 24-1208 (D. Del.); *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 response is required. To the extent a response is required, Defendants admit that Sun Inc. has been involved in litigation in this District. Sun Inc. has asserted counterclaims in actions in this District, including the cited cases. Sun Inc. does not contest personal jurisdiction for 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 a purported lack of 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 response is required. To the extent a response is required, Sun Ltd. does not contest personal jurisdiction in this Court for 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 response is required. To the extent a response is required, Defendants do not contest venue in this Court for 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 response is required. To the extent a response is required, Defendants do not contest venue in this Court for purposes of this action only. Otherwise, denied.

BACKGROUND

20. U.S. Patent No. 12,128,039 ("the '039 Patent") (Exhibit A), entitled "Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds," was duly and legally issued by the U.S. Patent and Trademark Office on October 29, 2024. The '039 Patent will expire on February 10, 2032. The claims of the '039 Patent are valid, enforceable, and not expired. All rights and interests in the '039 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, Defendants admit that Exhibit A to the Complaint is a copy of the '039 Patent. Sun admits that, according to the records of the United States Patent and Trademark Office ("PTO"), the PTO issued the '039 Patent titled "Processes for Preparing

Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds," on October 29, 2024. Sun admits that the FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the '039 Patent as having an expiration date of February 10, 2032. Sun admits that Exelixis is listed as the assignee on the face of the '039 Patent. Otherwise, denied.

21. 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), patients with liver cancer (hepatocellular carcinoma) who have been previously treated with the medicine sorafenib, and patients with advanced or metastatic thyroid cancer (differentiated thyroid cancer) who have 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: Defendants admit the contents of 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.

22. CABOMETYX® is covered by at least, inter alia, claims 1-5 of the '039 Patent.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent a response is required, Sun is without sufficient knowledge or information to form a belief as to the truth of the allegations and therefore denies them.

23. The '039 Patent has 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: Defendants admit that, as of May 29, 2025, the '039 Patent is listed in the Orange Book for CABOMETYX®. Otherwise, denied.

24. By letter dated February 25, 2025, and received via Federal Express on February 27, 2025 (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: Defendants admit that Sun Ltd. sent Exelixis a letter on February 25, 2025 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 February 27, 2025. Otherwise, denied.

25. 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 25 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.

26. 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 '039 Patent and alleged that the '039 Patent is "invalid, unenforceable, and/or will not be infringed by" 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 '039 Patent expires.

ANSWER: Paragraph 26 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 certification 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 is 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 Patent was "not infringed, invalid and/or unenforceable…." Otherwise, denied.

27. Upon information and belief, Defendants had knowledge of the '039 Patent at least as of the time they submitted their Paragraph IV certification.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun submitted a Paragraph IV certification concerning the '039 Patent to FDA. Otherwise, denied.

28. 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 28 contains legal conclusions to which no answer is required. To the extent a response is required, Sun admits that Sun Ltd. filed a paragraph IV certification 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 '039 Patent. Otherwise, denied.

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

ANSWER: Paragraph 29 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. on February 27, 2025, and Exelixis Inc. commenced this action on April 4, 2025. Otherwise, denied.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 12,128,039

30. Exelixis incorporates each of the preceding paragraphs 1-29 as if fully set forth herein.

ANSWER: Defendants incorporate their responses to Paragraphs 1–29.

31. 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 '039 Patent constituted an act of infringement of at least claim 1 of the '039 Patent (the "'039 Asserted Claims") under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Defendants have not contested the infringement of any claim of the '039 Patent to the extent that the patent's claims are valid.

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 stated that Sun Ltd. has submitted an ANDA "under 21 U.S.C. § 355(j) with paragraph IV certification 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 Patent, which is listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange

Book') in association with NDA No. 208692." Sun further admits that its Notice Letter included a factual and legal basis for Sun's certification that the '039 Patent "will not be infringed, is invalid, and/or is unenforceable. There is no requirement that this document provides an exhaustive list of Sun's factual and legal bases. Sun reserves the right to change or add to these bases for any reason..." Otherwise, denied.

32. 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 '039 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe at least the '039 Asserted Claims, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Denied.

33. Upon FDA approval of ANDA No. 214385, Defendants will infringe at least the '039 Asserted Claims, 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 '039 Asserted Claims 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, Sun has notified Exelixis of the submission of Sun's 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 '039 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 certification 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 Patent, which is listed in Approved Drug Products with Therapeutic Equivalence Evaluation ('Orange Book') in association with NDA No. 208692." Otherwise, denied.

34. A substantial and justiciable controversy exists between the parties hereto as to the infringement of the '039 Patent.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny that Plaintiff's allegation of infringement of the '039 Patent has merit or that Plaintiff is entitled to any relief on its claim.

35. 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 '039 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

36. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 214385 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '039 Patent. This is an exceptional case.

ANSWER: Denied.

37. Unless Sun is enjoined from directly or indirectly infringing the '039 Patent, Exelixis will suffer irreparable injury. Exelixis has no adequate remedy at law.

ANSWER: Denied.

PRAYER FOR RELIEF

Sun denies that Plaintiff 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 OF DEFENDANTS

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's 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 '039 Patent.

SECOND SEPARATE DEFENSE

Based upon information and belief, each of the claims of the '039 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 February 25, 2025.

THIRD SEPARATE DEFENSE

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

FOURTH 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.

FIFTH SEPARATE DEFENSE

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

SIXTH SEPARATE DEFENSE

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

SEVENTH 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 No. 12,128,039 ("the '039 Patent"), and that each and every claim of the Orange Book Patent is invalid for failure to satisfy one or more provisions of Title 35 of United States Code, including but not limited to, 35 U.S.C. §§ 102, 103, 112, and/or based on other judicially created bases for invalidation.

PARTIES

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

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

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

5. Counter Defendant purports to be a lawful owner of the '039 Patent.

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.

FACTUAL 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, 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 '039 Patent ("'039 Patent").

13. Upon information and belief, 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").

14. The '039 Patent, on its face, is titled "Processes for Preparing Quinoline Compounds and Pharmaceutical Compositions Containing Such Compounds," and has an issue date of October 29, 2024. Upon information and belief, a true and complete copy of the '039 Patent is attached to the Complaint (D.I. 1) as Exhibit A.

15. On or around April 4, 2025, Plaintiff/Counter Defendant filed a lawsuit alleging, *inter alia*, infringement of the '039 Patent based on Sun Ltd.'s filing of Sun's ANDA.

16. Absent a ruling from this Court finding the '039 Patent is invalid, unenforceable, and/or not infringed by Counterclaimants or Sun's Proposed ANDA Product, Plaintiff/Counter

Defendant will continue to assert the '039 Patent 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 Counterclaimant's businesses and denying Counterclaimants patent certainty.

17. 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.

18. 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.

DECLATORY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 12,128,039

19. Sun incorporates by reference paragraphs 1 through 18 of these Counterclaims as if fully set forth herein.

20. 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 '039 Patent.

21. Counter Defendant has asserted the '039 Patent against Sun.

22. Counter Defendant alleges, and Sun denies, that the '039 Patent is valid.

23. One or more of the claims of the '039 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.

24. 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 '039 Patent is/are invalid.

EXCEPTIONAL CASE

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

PRAYER FOR RELIEF

WHEREFORE, Sun respectfully requests the Court enter judgement in its 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 '039 Patent is invalid;

C. An order declaring that no valid and enforceable claim of the '039 Patent 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 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/ Sara M. Metzler

Kelly E. Farnan (#4395)
Sara M. Metzler (#6509)
Richards, Layton & Finger, P.A.
One Rodney Square
920 North King Street
Wilmington, DE 19801
(302) 651-7700
farnan@rlf.com
metzler@rlf.com

Attorneys for Defendants

Of Counsel:

Samuel T. Lockner
Jennell C. Bilek
CARLSON, CASPERS, VANDENBURGH & LINDQUIST, P.A.
225 S. Sixth Street, Suite 4200
Minneapolis, MN 55402
(612) 436-9600
slockner@carlsoncaspers.com
jbilek@carlsoncaspers.com

Dated: June 9, 2025