IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC., Plaintiff, v. BIOCON PHARMA LIMITED, BIOCON LIMITED, and BIOCON PHARMA, INC., Defendants.	C.A. No. 1:25:cv-00452-RGA

DEFENDANTS BIOCON PHARMA LIMITED, BIOCON LIMITED, AND BIOCON PHARMA, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants BIOCON PHARMA LIMITED, BIOCON LIMITED, AND BIOCON PHARMA, INC. ("Biocon" or "Defendants"), by and through their undersigned counsel, hereby submit the following Answer, Affirmative Defenses, and Counterclaims in response to the Complaint for Patent Infringement ("Complaint") filed by Plaintiff EXELIXIS, INC. ("Exelixis").

Pursuant to Federal Rule of Civil Procedure 8(b)(3), Biocon denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. The numbered paragraphs below correspond to the numbered paragraphs in the Complaint. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculation that arguably follow from the admitted facts. Biocon denies that Plaintiffs are entitled to the relief requested or any other relief. Biocon responds to the Complaint as follows:

RESPONSE TO "COMPLAINT FOR PATENT INFRINGEMENT"

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 Biocon Pharma Limited ("BPL"), Biocon Limited ("BL"), and Biocon Pharma, Inc. ("BPI") (collectively, "Defendants" or "Biocon"). This action

arises out of Biocon's submission of Abbreviated New Drug Application ("ANDA") No. 220121 to the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell a generic version of CABOMETYX® (the "Biocon ANDA Product") prior to the expiration of U.S. Patent Nos. 8,877,776; 11,091,439; 11,091,440; 11,098,015; and 12,128,039 (the "Asserted Patents").

ANSWER: Paragraph 1 contains legal conclusions to which no response is required. To the extent a response is required, Biocon admits that the Plaintiff's Complaint purports to be a civil action alleging infringement of United States Patent Nos. 8,877,776; 11,091,439; 11,091,440; 11,098,015; and 12,128,039. Biocon further admits that it submitted ANDA No. 220121 to the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Biocon's proposed cabozantinib tablets prior to expiration of the Asserted Patents. Biocon denies any remaining allegations in this paragraph.

RESPONSE TO "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: Biocon lacks sufficient information to form a belief as to the truth of the allegations in this paragraph and therefore denies them.

3. Upon information and belief, BPL is a corporation organized under the laws of India, with its principal place of business at S20th KM, Hosur Road, Electronic City, Bangalore-560100, Karnataka, India. Upon information and belief, BPL, itself and through its parent company, BL, and wholly owned subsidiaries and agents (including BPI), manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware.

ANSWER: Biocon admits that Biocon Pharma Limited is a company incorporated under the laws of India, with its principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore-560100, Karnataka, India. Biocon admits that Biocon Pharma Limited is a

wholly owned subsidiary of Biocon Limited. Biocon further admits that Biocon Pharma Limited develops and manufactures generic drug products, Biocon Pharma Inc. engages in the commercialization of generic drug products, and that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon denies any remaining allegations in this paragraph.

4. Upon information and belief, BL is a corporation organized under the laws of India, with its principal place of business at S20th KM, Hosur Road, Electronic City, Bangolore-560100, Karnataka, India. Upon information and belief, BL, itself and through its wholly owned subsidiaries and agents (including BPL and BPI), manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware.

ANSWER: Biocon admits that Biocon Limited is a company incorporated under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangolore-560100, Karnataka, India. Biocon further admits that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon denies any remaining allegations in this paragraph.

5. Upon information and belief, BPI is a corporation organized under the laws of the State of Delaware, with its principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830. Upon information and belief, BPI, manufactures, distributes and/or imports generic drugs for sale throughout the United States, including in Delaware, at the direction, under the control, and for the direct benefit of its parent company, BPL, and BPL's parent company, BL.

ANSWER: Biocon admits that BPI is a corporation organized under the laws of the State of Delaware, with its principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830. Biocon admits that Biocon Pharma, Inc. engages in the commercialization of generic drug products. Biocon denies any remaining allegations in this paragraph.

6. Upon information and belief, BPL, BL, and BPI acted collaboratively in the preparation and submission of ANDA No. 220121.

ANSWER: Biocon admits that Biocon Pharma, Inc. is the U.S. Agent for ANDA No. 220121. Biocon further admits that Biocon Limited is the parent company of Biocon Pharma Limited. Biocon further admits that Biocon Pharma Limited develops and manufactures generic drug products, Biocon Pharma Inc. engages in the commercialization of generic drug products, and that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon admits that BPL and BPI collaborated in the submission of ANDA No. 220121. Biocon denies any remaining allegations in this paragraph.

7. Upon information and belief, following any FDA approval of ANDA No. 220121, Defendants, themselves and through their subsidiaries and agents, will make, use, offer to sell, and/or sell the Biocon ANDA Product that is the subject of ANDA No. 220121 throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

ANSWER: Biocon lack information sufficient to form a belief as to the truth of the allegations of paragraph 7, and denies them on that basis.

RESPONSE TO "JURISDICTION AND VENUE"

8. 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: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest subject matter jurisdiction.

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

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest personal venue for Biocon Pharma, Inc., Biocon Pharma Limited, and Biocon Limited.

10. 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 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. 220121, Defendants will make, use, import, sell, and/or offer for sale the Biocon ANDA Product in the United States, including in Delaware, prior to the expiration of the Asserted Patents.

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest personal jurisdiction for Biocon Pharma, Inc., Biocon Pharma Limited, and Biocon Limited.

11. 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 BPI.

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest personal jurisdiction for Biocon Pharma, Inc., Biocon Pharma Limited, and Biocon Limited.

12. This Court has personal jurisdiction over BPI because, upon information and belief, BPI currently manufactures and distributes for sale hundreds of drug products throughout the United States, including in Delaware.

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest personal jurisdiction for Biocon Pharma, Inc., Biocon Pharma Limited, and Biocon Limited.

13. Upon information and belief, BL directs the operations, management, and activities of BPL and BPI in the United States.

ANSWER: Denied.

14. Upon information and belief, BPL, BL, and BPI 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: Denied.

15. BPL has previously availed itself of this forum by affirmatively filing counterclaims in other actions pending before this Court, including Novo Nordisk Inc. et al. v. Biocon Pharma Ltd. et al., C.A. No. 22-00937 (D. Del.); Novo Nordisk Inc. et al. v. Biocon Pharma Ltd. et al., C.A. No. 22-00936 (D. Del.); and Novartis Pharmaceuticals Corp. v. Alkem Laboratories Ltd., C.A. 19-01979 (D. Del.).

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon states that the cited pleadings speak for themselves and denies any remaining portions of this paragraph. For purposes of this action only, Biocon does not contest personal jurisdiction for Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc.

16. BL has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including Novo Nordisk Inc. et al. v. Biocon Pharma Ltd. et al., C.A. No. 22-00937 (D. Del.); Novo Nordisk Inc. et al.

v. Biocon Pharma Ltd. et al., C.A. No. 22-00936 (D. Del.); Novartis Pharmaceuticals Corp. v. Alkem Laboratories Ltd., C.A. 19-01979 (D. Del.); Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc., et al., C.A. No. 18-01043 (D. Del.); Sanofi-Aventis U.S. LLC et al. v. Biocon Ltd., 17-00003 (D. Del.); Teva Pharmaceuticals USA, Inc. et al. v. Doctor Reddy's Laboratories Ltd. et al., C.A. No. 16- 01267 (D. Del.); and Teva Pharmaceutical USA, Inc. et al. v. Biocon Ltd. et al., C.A. No. 16-00278 (D. Del.).

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon states that the cited pleadings speak for themselves and denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest personal jurisdiction for Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc.

17. BPI has previously availed itself of this forum by affirmatively filing claims and counterclaims in other actions pending before this Court, including Novo Nordisk Inc. et al. v. Biocon Pharma Ltd. et al., C.A. No. 22-00937 (D. Del.); Novo Nordisk Inc. et al. v. Biocon Pharma Ltd. et al., C.A. No. 22-00936 (D. Del.); Novartis Pharmaceuticals Corp. v. Alkem Laboratories Ltd., C.A. 19-01979 (D. Del.); and Novartis Pharmaceuticals Corp. v. Accord Healthcare Inc., et al., C.A. No. 18-01043 (D. Del.).

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon states that the cited pleadings speak for themselves and denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest personal jurisdiction for Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc.

18. On information and belief, BPL and BL's contacts with other states of the United States are no greater than their contacts with Delaware. Therefore, to the extent BPL and BL deny that this Court has personal jurisdiction over them because of a purported lack of systematic and continuous contacts with Delaware, this Court has personal jurisdiction over BPL pursuant to Federal Rule of Civil Procedure 4(k)(2)(A).

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action

only, Biocon does not contest personal jurisdiction for Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc.

19. Venue is proper in this Court as to BPI 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: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest venue.

20. Venue is proper in this Court as to BPL and BL under 28 U.S.C. § 1391(c)(3) because, upon information and belief, they are not residents of the United States and may thus be sued in any judicial district.

ANSWER: Biocon provides no answers to the portions of this paragraph that contain conclusions of law. To the extent an answer is required, Biocon denies those portions of this paragraph. Biocon denies any remaining allegations in this paragraph. For purposes of this action only, Biocon does not contest venue.

RESPONSE TO "BACKGROUND"

21. 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 by the U.S. Patent and Trademark Office on November 4, 2014. The '776 Patent will expire 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: Biocon admits that the '776 patent is entitled "(L)-malate salt of N-(4-{[6,7-bis(methyloxy) quinolin-4-yl]oxy}phenyl)-N'-(4-fluorophenyl)cyclopropane-1,1-dicarboxamide" and indicates on its face that it issued on November 4, 2014 and that it was assigned to Exelixis. Biocon denies that the '776 patent was duly and legally issued and further

denies that the claims of the '776 patent are valid and enforceable. Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

22. 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 by the U.S. Patent and Trademark Office 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: Biocon admits that the '439 patent is 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" and indicates on its face that it issued on August 17, 2021 and that it was assigned to Exelixis. Biocon denies that the '439 patent was duly and legally issued and further denies that the claims of the '439 patent are valid and enforceable. Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

23. 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 by the U.S. Patent and Trademark Office 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: Biocon admits that the '440 patent is 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" and indicates on its face that it issued on August 17, 2021 and that it was assigned to Exelixis. Biocon denies that the '440 patent was duly and legally issued and further denies that the claims of the '440 patent are valid and

enforceable. Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

24. 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 by the U.S. Patent and Trademark Office 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: Biocon admits that the '015 patent is 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" and indicates on its face that it issued on August 24, 2021 and that it was assigned to Exelixis. Biocon denies that the '015 patent was duly and legally issued and further denies that the claims of the '015 patent are valid and enforceable. Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

25. U.S. Patent No. 12,128,039 ("the '039 Patent") (Exhibit E), 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: Biocon admits that the '039 patent is entitled "Processes for preparing quinoline compounds and pharmaceutical compositions containing such compounds" and indicates on its face that it issued on October 29, 2024 and that it was assigned to Exelixis. Biocon denies that the '039 patent was duly and legally issued and further denies that the claims of the '039 patent are valid and enforceable. Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

26. 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: Biocon admits that the Orange Book identifies Exelixis as holder of NDA No. 208692 directed to the product sold under the trade name CABOMETYX®. Biocon admits that the current Highlight of Prescribing Information for CABOMETYX® states that CABOMETYX® tablets are "for oral use," and that "CABOMETYX is a kinase inhibitor indicated for the treatment of: patients with advanced renal cell carcinoma"; "patients with advanced renal cell carcinoma, as a first-line treatment in combination with nivolumab"; "patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib"; "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"; adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET)"; and "adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated extra-pancreatic neuroendocrine tumors (epNET). Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

27. The Asserted 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: Paragraph 27 contains legal conclusions to which no response is required. To the extent a response is required, Biocon admits that the Orange Book entry for CABOMETYX® lists the Asserted Patents.

28. By letter dated March 3, 2025, and received via Federal Express on March 4, 2025 (the "Notice Letter"), Defendants notified Exelixis that Defendants had submitted ANDA No. 220121 to the FDA for Cabozantinib (S)-Malate Tablets, 20 mg, 40 mg, and 60 mg, a generic version of CABOMETYX®.

ANSWER: Biocon admits that by letter dated March 3, 2025, BPL sent Exelixis written notice of the Paragraph IV certifications contained in ANDA No. 220121. Biocon lacks information sufficient to form a belief as to the remaining allegations in this paragraph, and on this basis denies them.

29. By submitting ANDA No. 220121, Defendants have necessarily represented to the FDA that the Biocon ANDA Product has the same active ingredient as CABOMETYX®, has the same dosage forms and strengths as CABOMETYX®, and is bioequivalent to CABOMETYX®.

ANSWER: Biocon admits that BPL submitted ANDA No. 220121 seeking FDA approval to market the products that are the subject of that ANDA. Biocon denies any remaining allegations in this paragraph.

30. In Defendants' Notice Letter, Defendants stated that ANDA No. 220121 included a Paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the Asserted Patents and alleged that the Asserted Patents are "unenforceable, invalid, and/or not infringed … by the manufacture, use, sale, offer for sale, and/or importation of the" Biocon 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 Biocon ANDA Product before the Asserted Patents expire.

ANSWER: Biocon admits that BPL sent Exelixis written notice of the Paragraph IV certifications contained in ANDA No. 220121. The Notice Letter speaks for itself. Biocon admits that the Notice Letter states that the asserted patents are "unenforceable, invalid, and/or not infringed … by the manufacture, use, sale, offer for sale, and/or importation of the" Biocon ANDA Product. Biocon admits that BPL's notice letter also stated that ANDA No. 220121 seeks approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the Biocon ANDA Product before the Asserted Patents expire. Otherwise denied.

31. Upon information and belief, Defendants had knowledge of the Asserted Patents at least as of the time Defendants submitted the Paragraph IV certification in ANDA No. 220121.

ANSWER: Admitted.

32. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product immediately and imminently upon approval of ANDA No. 220121.

ANSWER: Biocon lacks information sufficient to form a belief as to the allegations in this paragraph, and on this basis denies them.

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

ANSWER: Admitted.

RESPONSE TO "CLAIMS FOR RELIEF COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,877,776"

34. Exelixis incorporates each of the preceding paragraphs 1-33 as if fully set forth herein.

ANSWER: Biocon repeats and realleges its responses to the preceding paragraphs as if fully set forth herein.

35. Defendants' submission of ANDA No. 220121 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon 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.

36. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Biocon 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.

37. Upon FDA approval of ANDA No. 220121, 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 Biocon 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 their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product before the expiration of the '776 Patent.

ANSWER: Denied.

38. Counsel for Exelixis obtained and reviewed portions of ANDA No. 220121 produced by Defendants pursuant to an agreed Offer of Confidential Access. Materials provided to Plaintiffs by Defendants support the conclusion that Cabozantinib (S)-Malate Form N-2 may be present in the Biocon ANDA Product and, at the very least, are insufficient to demonstrate that Cabozantinib (S)-Malate Form N-2 is not present in the Biocon ANDA Product.

ANSWER: Biocon lacks information sufficient to form a belief as to whether counsel for Exelixis obtained and reviewed portions of ANDA No. 220121, and therefore denies that allegation. Biocon denies the remaining allegations in this paragraph.

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

ANSWER: Paragraph 39 contains legal conclusions to which no response is required.

40. 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 Biocon 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.

41. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 220121 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '776 Patent.

ANSWER: Denied.

42. 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.

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

43. Exelixis incorporates each of the preceding paragraphs 1-42 as if fully set forth herein.

ANSWER: Biocon repeats and realleges its responses to the preceding paragraphs as if fully set forth herein.

44. Defendants' submission of ANDA No. 220121 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon 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). In the Notice Letter, Defendants have not contested the infringement of any claim of the '439 Patent to the extent that the patent's claims are valid.

ANSWER: Denied.

45. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Biocon 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.

46. Upon FDA approval of ANDA No. 220121, 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 Biocon 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 their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product before the expiration of the '439 Patent.

ANSWER: Denied.

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

ANSWER: Paragraph 47 contains legal conclusions to which no response is required.

48. 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 Biocon 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.

49. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 220121 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '439 Patent.

ANSWER: Denied.

50. 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.

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

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

ANSWER: Biocon repeats and realleges its responses to the preceding paragraphs as if fully set forth herein.

52. Defendants' submission of ANDA No. 220121 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon 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). In the Notice

Letter, Defendants have not contested the infringement of any claim of the '440 Patent to the extent that the patent's claims are valid.

ANSWER: Denied.

53. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Biocon 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.

54. Upon FDA approval of ANDA No. 220121, 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 Biocon 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 their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product before the expiration of the '440 Patent.

ANSWER: Denied.

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

ANSWER: Paragraph 55 contains legal conclusions to which no response is required.

56. 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 Biocon 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.

57. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 220121 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '440 Patent.

ANSWER: Denied.

58. 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.

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

59. Exelixis incorporates each of the preceding paragraphs 1-58 as if fully set forth herein.

ANSWER: Biocon repeats and realleges its responses to the preceding paragraphs as if fully set forth herein.

60. Defendants' submission of ANDA No. 220121 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon 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). In the Notice Letter, Defendants have not contested the infringement of any claim of the '015 Patent to the extent that the patent's claims are valid.

ANSWER: Denied.

61. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Biocon 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.

62. Upon FDA approval of ANDA No. 220121, 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 Biocon 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 their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product before the expiration of the '015 Patent.

ANSWER: Denied.

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

ANSWER: Paragraph 63 contains legal conclusions to which no response is required.

64. 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 Biocon

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.

65. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 220121 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '015 Patent.

ANSWER: Denied.

66. 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.

RESPONSE TO "COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 12,128,039

67. Exelixis incorporates each of the preceding paragraphs 1–66 as if fully set forth herein.

ANSWER: Biocon repeats and realleges its responses to the preceding paragraphs as if fully set forth herein.

68. Defendants' submission of ANDA No. 220121 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product before the expiration of the '039 Patent constituted an act of infringement of at least claim 1 of the '039 Patent 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: Denied.

69. Defendants' commercial manufacture, use, offer for sale, sale and/or importation of the Biocon 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 the '039 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

70. Upon FDA approval of ANDA No. 220121, Defendants will infringe at least the '039 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the Biocon ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '039 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 their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Biocon ANDA Product before the expiration of the '039 Patent.

ANSWER: Denied.

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

ANSWER: Paragraph 71 contains legal conclusions to which no response is required.

72. 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 Biocon 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.

73. Upon information and belief, Defendants acted, and upon FDA approval of ANDA No. 220121 will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '039 Patent.

ANSWER: Denied.

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

ANSWER: Denied.

RESPONSE TO "PRAYER FOR RELIEF"

Biocon denies that Plaintiff is entitled to the judgment of any of the relief requested in its prayer for relief or otherwise.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in this Answer, Biocon further responds to the Complaint with the defenses set forth below. Biocon expressly reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned

through discovery and further factual investigation in this case. Biocon does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST AFFIRMATIVE DEFENSE

Each purported claim in the complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the '776, '439, '440, '015, or '039 patents are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or based on other judicially created bases for invalidation.

THIRD AFFIRMATIVE DEFENSE

Biocon has not infringed, is not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid claim of the '776, '439, '440, '015, or '039 patents.

WHEREFORE, Biocon respectfully requests the Court enter judgment in its favor granting the following relief:

A. Dismissing Plaintiff's complaint with prejudice and denying each request for relief made by Plaintiff;

B. Denying Plaintiff any award of damages, costs, or fees;

C. Granting Biocon judgment in its favor;

D. Declaring that this is an exceptional case in favor of Biocon under 35 U.S.C. § 285;

E. Declaring that Biocon is the prevailing party and awarding its fees, costs, and expenses in this action pursuant to 35 U.S.C. § 285 or any other applicable statute; and

F. Awarding Biocon such other and further relief as this Court deems just and proper.

COUNTERCLAIMS

Counterclaim-Plaintiffs Biocon Limited, Biocon Pharma Limited ("BPL"), and Biocon Pharma, Inc. (collectively "Biocon"), for their Counterclaims against Plaintiffs/Counterclaim-Defendants Exelixis Inc., allege as follows:

NATURE OF THE ACTION

1. This is a counterclaim action for declaratory judgment of noninfringement and/or invalidity of United States 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"); and 12,128,039 (the "'015 patent") (collectively the "asserted patents" or "patents-in-suit").

PARTIES

2. Counterclaim-Plaintiff Biocon Pharma Limited is a company incorporated under the laws of India, having a principal place of business in Bangalore, India.

3. Counterclaim-Plaintiff Biocon Limited is a corporation organized and existing under the laws of India, having a principal place of business in Bangalore, India.

4. Counterclaim-Plaintiff Biocon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Iselin, New Jersey.

5. On information and belief, based on Exelixis' allegations in its complaint, Exelixis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Alameda, California.

6. On information and belief, Exelixis, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, developing, manufacturing, and obtaining regulatory approval of branded pharmaceutical products for distribution and sale throughout the United States, including within this judicial district.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. § 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Exelixis based on, *inter alia*, its filing of this lawsuit in this jurisdiction.

9. Venue is proper in this judicial district based on 28 U.S.C. § 1391(b) and (c).

FACTUAL BACKGROUND FOR COUNTERCLAIMS

10. Biocon submitted its Abbreviated New Drug Application ("ANDA") No. 220121 to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale, and/or importation into the United States of cabozantinib tablets ("the Biocon ANDA Product").

11. On information and belief, the FDA lists Plaintiff as the holder of New Drug Application ("NDA") No. 208692.

12. On information and belief, NDA No. 208692 covers cabozantinib tablets, sold in the United States under the trademark CABOMETYX®.

13. On information and belief, the '776, '439, '440, '015, and '039 patents are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 208692.

14. Plaintiff has alleged in the present action that Biocon has infringed and will infringe the '776, '439, '440, '015, and '039 patents by the filing of ANDA No. 220121 with the FDA and/or by manufacturing, using, selling, offering for sale, and/or importing the products described in that ANDA.

15. As a consequence of the foregoing, there is an actual and justiciable controversy between Biocon and Plaintiff as to whether the claims of the '776, '439, '440, '015, and '039 patents are infringed or will be infringed by Biocon's ANDA No. 220121 or by the manufacture, use, sale, offer for sale, and/or importation of the products described therein, and as to whether the claims of those patents are invalid.

FIRST COUNTERCLAIM

(Declaratory Judgment of Non-Infringement and/or Invalidity of the '776 patent)

16. Biocon incorporates and re-alleges paragraphs 1-15 of its Counterclaims as if fully set forth herein.

17. Biocon does not, has not, and would not, if the products described in ANDA No. 220121 are marketed, directly or indirectly infringe any valid claim of the '776 patent.

18. Biocon's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Biocon ANDA will not infringe, directly or indirectly, any valid claim of the '776 patent.

19. The claims of the '776 patent are invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112.

20. Because Biocon has not infringed and will not infringe any valid claim of the '776 patent, Biocon is entitled to a declaratory judgment of invalidity and non-infringement.

SECOND COUNTERCLAIM

(Declaratory Judgment of Non-Infringement and/or Invalidity of the '439 Patent)

21. Biocon incorporates and re-alleges paragraphs 1-20 of its Counterclaims as if fully set forth herein.

22. Biocon does not, has not, and would not, if the products described in ANDA No. 220121 are marketed, directly or indirectly infringe any valid claim of the '439 patent.

23. Biocon's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Biocon ANDA will not infringe, directly or indirectly, any valid claim of the '439 patent.

24. The claims of the '439 patent are invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112.

25. Because Biocon has not infringed and will not infringe any valid claim of the '439 patent, Biocon is entitled to a declaratory judgment of invalidity and non-infringement.

THIRD COUNTERCLAIM

(Declaratory Judgment of Non-Infringement and/or Invalidity of the '440 patent)

26. Biocon incorporates and re-alleges paragraphs 1-25 of its Counterclaims as if fully set forth herein.

27. Biocon does not, has not, and would not, if the products described in ANDA No. 220121 are marketed, directly or indirectly infringe any valid claim of the '440 patent.

28. Biocon's manufacture, use, offer for sale, sale in the United States, and/or importation into the United States of the Biocon ANDA will not infringe, directly or indirectly, any valid claim of the '440 patent.

29. The claims of the '440 patent are invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112.

30. Because Biocon has not infringed and will not infringe any valid claim of the '440 patent, Biocon is entitled to a declaratory judgment of invalidity and non-infringement.

FOURTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '015 patent)

31. Biocon incorporates and re-alleges paragraphs 1-30 of its Counterclaims as if fully set forth herein.

32. The claims of the '015 patent are invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or double patenting, and/or based on other judicially-created bases for invalidation.

33. Biocon is entitled to a declaratory judgment of invalidity of the claims of the '015 patent.

FIFTH COUNTERCLAIM

(Declaratory Judgment of Invalidity of the '039 patent)

34. Biocon incorporates and re-alleges paragraphs 1-33 of its Counterclaims as if fully set forth herein.

35. The claims of the '039 patent are invalid for failure to comply with one or more of the requirements of Title 35, United States Code, including, without limitation, §§ 101, 102, 103, and/or 112, and/or double patenting, and/or based on other judicially-created bases for invalidation.

36. Biocon is entitled to a declaratory judgment of invalidity of the claims of the '039 patent.

EXCEPTIONAL CASE

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

PRAYER FOR RELIEF

WHEREFORE, Biocon respectfully requests that the Court enter judgment in its favor against Plaintiffs that:

A. dismisses Plaintiff's complaint with prejudice and denies each request for relief made by Plaintiff;

B. declares that the claims of the asserted patents are invalid;

C. declares that the submission of BPL's ANDA seeking FDA approval to market Biocon's ANDA Products prior to the expiration of the asserted patents has not infringed and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid claim of the asserted patents;

D. declares that the manufacture, use, sale, offer for sale, and/or importation of Biocon's ANDA Products will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid claim of the asserted patents;

E. declares that Plaintiffs/Counterclaim-Defendants are not entitled to injunctive relief;

F. grants Biocon judgment in its favor on Plaintiff's claims;

G. grants Biocon judgment in favor of its own Counterclaims;

H. declares that this is an exceptional case in favor of Biocon pursuant to 35 U.S.C. § 285;

I. declares that Biocon is the prevailing party and awards Biocon its fees, costs, and expenses in this action pursuant to 35 U.S.C. § 285 or any other applicable statute; and

J. awards Biocon such other and further relief as this Court deems just and proper.

Dated: June 19, 2025

PHILLIPS, MCLAUGHLIN & HALL, P.A.

/s/ John C. Phillips, Jr.

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