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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, LLC.,	Honorable Evelyn Padin, U.S.D.J.
Plaintiff,	Civil Action No. 25 CV 1968 (EP)(CLW)
v.	
BIOCON PHARMA LTD., BIOCON LTD., and BIOCON PHARMA, INC.,	**DEFENDANTS' ANSWER TO THE COMPLAINT, AFFIRMATIVE DEFENSES AND COUNTERCLAIMS**
Defendants.	

Defendants Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc., (collectively, "Biocon"), by and through the undersigned attorneys, answer the Complaint for Patent Infringement ("Complaint") of Impax Laboratories, LLC, ("Impax" or "Plaintiff") as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Biocon denies all allegations in Plaintiff's Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the food and drug laws and patent laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising

from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Impax's RYTARY® (Carbidopa/Levodopa) extended-release capsules prior to the expiration of United States Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively, the "Patents-in-Suit"), and other patents listed in the Orange Book for RYTARY®.

Answer: Biocon admits that the Complaint purports to be based on the patent laws of the United States, but denies that Plaintiff is entitled to any relief. Biocon further admits that Biocon Pharma Limited submitted ANDA No. 220119 ("Biocon's ANDA") seeking U.S. Food and Drug Administration ("FDA") approval for proposed generic carbidopa/levodopa capsules, 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/245mg dosages, ("Biocon's ANDA Products") prior to the expiration of U.S. Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively, the "Patents-in-Suit"). Biocon denies any remaining allegations in this paragraph.

THE PARTIES

2. Plaintiff Impax Laboratories, LLC is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal Pharmaceuticals LLC. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Amneal Pharmaceuticals LLC is a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

Answer: Biocon lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

3. On information and belief, Defendant BPL is a corporation organized and existing under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, Karnataka, India.

Answer: Biocon admits that Biocon Pharma Limited is a company incorporated under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India. Biocon denies any remaining allegations in this paragraph.

4. On information and belief, Defendant BL is a corporation organized and existing under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, Karnataka, India.

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, Bangalore, 560100, India. Biocon denies any remaining allegations in this paragraph.

5. On information and belief, Defendant BPI is a corporation organized and existing under the laws of Delaware, having a principal place of business at 485 US Highway 1 South Ste B305, Iselin, New Jersey 08830.

Answer: Biocon admits that Biocon Pharma, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830. Biocon denies any remaining allegations in this paragraph.

6. On information and belief, BPI is a wholly-owned subsidiary of BPL.

Answer: Admitted.

7. On information and belief, BPL is a wholly-owned subsidiary of BL.

Answer: Admitted.

8. On information and belief, BL is the parent company of BPL.

Answer: Admitted.

9. On information and belief, Defendants BL and BPL conduct business in the United States and in the State of New Jersey, including through and using the offices of BPI.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

10. On information and belief, Defendants are in the business of developing, preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the State of New Jersey.

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

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon does not contest subject matter jurisdiction for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

12. On information and belief, Defendants purposefully have conducted and continue to conduct business in this Judicial District.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

13. On information and belief, Defendants are in the business of, among other things, manufacturing, marketing, importing, distributing, offering for sale, and/or selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

Answer: Biocon admits that Biocon Pharma Limited develops and manufactures generic drug products. Biocon admits that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon admits that Biocon Pharma, Inc., engages in the commercialization of generic drug products. Biocon denies any remaining allegations in this paragraph. Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

14. On information and belief, Defendants directly or indirectly develop, manufacture, import, market, distribute, and/or sell pharmaceutical products that are and/or will be manufactured and sold, pursuant to ANDA filings or other regulatory filings, throughout the United States, including in this Judicial District.

Answer: Biocon admits that Biocon Pharma Limited develops and manufactures generic drug products. Biocon admits that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon admits that Biocon Pharma, Inc., engages in the commercialization of generic drug products. Biocon denies any remaining allegations in

this paragraph. Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

15. On information and belief, Defendants develop and manufacture generic pharmaceutical products, which they then sell in the United States, the locations or operations of which are in, among other places, the State of New Jersey.

Answer: Biocon admits that Biocon Pharma Limited develops and manufactures generic drug products. Biocon admits that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon admits that Biocon Pharma, Inc., engages in the commercialization of generic drug products. Biocon denies any remaining allegations in this paragraph. Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

16. On information and belief, this Judicial District will be a destination for the generic version of Impax's RYTARY® (Carbidopa/Levodopa) extended-release capsules for which Defendants seek FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 220119.

Answer: Denied.

17. On information and belief, if the Biocon ANDA (defined below) is approved, the Biocon ANDA Products (defined below) will be marketed, distributed, and/or sold, directly or indirectly, by Defendants in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, on information and belief, if Defendants succeed in obtaining FDA approval, Defendants will, directly or indirectly, market, distribute, and/or sell the Biocon ANDA Products in the State of New Jersey.

Answer: Denied.

18. BPI is a corporation with its principal and regular and established place of business at 485 US Highway 1 South, Woodbridge Corp. Plaza, Suite B305, Iselin, New Jersey 08830 and is qualified to do business in the State of New Jersey. On information and belief, BL and BPL conduct business in the State of New Jersey through BPI and its offices in the State of New Jersey.

Answer: Biocon admits that Biocon Pharma, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 485 US Highway 1 S B305, Iselin, New Jersey 08830. Biocon denies any remaining allegations in this paragraph.

19. BL has a registered agent for service of process in the State of New Jersey at 485 US Highway 1 South, Woodbridge Corp. Plaza, Suite B305, Iselin, New Jersey 08830.

Answer: Admitted.

20. BPI is registered with the New Jersey Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0450071685.

Answer: Admitted.

21. BPI is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under registration number 5004931.

Answer: Admitted.

22. On information and belief, Defendants are in the business of, *inter alia*: (a) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (b) in concert with each other and/or through their various affiliates, the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (c) in concert with each other

and/or through their various affiliates, the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

Answer: Biocon admits that Biocon Pharma Limited develops and manufactures generic drug products. Biocon admits that Biocon Limited directly or indirectly develops, manufactures, distributes, sells, and/or imports drug products. Biocon admits that Biocon Pharma, Inc., engages in the commercialization of generic drug products. Biocon denies any remaining allegations in this paragraph. Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

23. On information and belief, Defendants intend to benefit directly if the Biocon ANDA is approved by participating in the manufacture, importation, distribution, offer to sell, and/or sale of the generic drug products throughout the United States, including in the State of New Jersey, that are the subject of the Biocon ANDA.

Answer: Denied.

24. Defendants have previously submitted to the jurisdiction of this Court and/or have further previously availed themselves of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Bristol-Myers Squibb Company v. Biocon Pharma Limited et al*, C.A. No. 22-03505, Dkt. No. 8 (D.N.J. Sept. 15, 2022); *Celgene Corporation v. Biocon Pharma Limited et al,* C.A. No. 21-11261, Dkt. No. 7 (D.N.J. Jun. 11, 2021); *Sanofi-Aventis U.S. LLC et al v. Mylan et al* C.A. No. 17-09105, Dkt. No. 177 (D.N.J. Sept. 14, 2018) (collectively, "Prior Actions").

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon does not contest that this Court has personal

jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

25. For at least the foregoing reasons set forth above, this Court has personal jurisdiction over Defendants because, on information and belief, Defendants: (a) have substantial, continuous, and systematic contacts with the State of New Jersey; (b) have in the past and intend in the future to manufacture, market, import, offer to sell, sell, and/or distribute Defendants' pharmaceutical products to residents of the State of New Jersey; (c) maintain a distributorship network within the State of New Jersey; (d) enjoy income from sales of their generic pharmaceutical products in the State of New Jersey; (e) are located in and/or have consented to and/or not contested personal jurisdiction in the Prior Actions; and (f) have availed themselves of the jurisdiction of this Court by asserting counterclaims in at least one of the Prior Actions.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon does not contest that this Court has personal jurisdiction over Biocon for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

26. For at least the foregoing reasons set forth above, venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and/or 1400(b). Among other reasons, venue is proper in this Judicial District because: (a) BL and BPL are incorporated in India and may be sued in any judicial district in which BL and BPL are subject to the Court's personal jurisdiction, and further operates in the United States through or in concert with BPI, which has its principal and regular and established place of business in the State of New Jersey; and (b) Defendants have previously consented to and/or not contested venue in this Judicial District in the Prior Actions.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon does not contest that this Court has personal jurisdiction over Biocon or that venue is proper for purposes of this action only. Biocon denies any remaining allegations in this paragraph.

BACKGROUND

U.S. Patent No. 8,557,283

27. On October 15, 2013, the United States Patent & Trademark Office ("PTO"), duly and legally issued United States Patent No. 8,557,283 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '283 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '283 patent is attached as **Exhibit 1**.

Answer: Biocon admits Exhibit 1 purports to be a copy of the '283 patent. Biocon further admits the '283 patent is titled "Controlled Release Formulations of Levodopa and Uses Thereof" and lists inventors Ann Hsu, Jim H. Kou, and Laman Lynn Alani. Biocon admits that the '283 patent lists an issue date of October 15, 2013. Biocon admits that FDA's Orange Book lists the expiry as December 26, 2028. Biocon denies any remaining allegations in this paragraph.

U.S. Patent No. 9,089,608

28. On July 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,608 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou, and Laman Lynn Alani. The '608 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '608 patent is attached as **Exhibit 2**.

Answer: Biocon admits Exhibit 2 purports to be a copy of the '608 patent. Biocon further admits the '608 patent is titled "Controlled Release Formulations of Levodopa and Uses Thereof"

and lists inventors Ann Hsu, Jim H. Kou, and Laman Lynn Alani. Biocon admits that the '608 patent lists an issue date of July 28, 2015. Biocon admits that FDA's Orange Book lists the expiry as December 26, 2028. Biocon denies any remaining allegations in this paragraph.

U.S. Patent No. 9,463,246

29. On October 11, 2016, the PTO duly and legally issued United States Patent No. 9,463,246 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '246 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '246 patent is attached as **Exhibit 3**.

Answer: Biocon admits Exhibit 3 purports to be a copy of the '246 patent. Biocon further admits the '246 patent is titled "Controlled Release Formulations of Levodopa and Uses Thereof" and lists inventors Ann Hsu, Jim H. Kou, and Laman Lynn Alani. Biocon admits that the '246 patent lists an issue date of October 11, 2016. Biocon admits that FDA's Orange Book lists the expiry as December 26, 2028. Biocon denies any remaining allegations in this paragraph.

U.S. Patent No. 9,533,046

30. On January 3, 2017, the PTO duly and legally issued United States Patent No. 9,533,046 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim Kou and Laman Alani. The '046 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '046 patent is attached as **Exhibit 4**.

Answer: Biocon admits Exhibit 4 purports to be a copy of the '046 patent. Biocon further admits the '046 patent is titled "Controlled Release Formulations of Levodopa and Uses Thereof" and lists inventors Ann Hsu, Jim Kou, and Laman Alani. Biocon admits that the '046 patent lists

an issue date of January 3, 2017. Biocon admits that FDA's Orange Book lists the expiry as December 26, 2028. Biocon denies any remaining allegations in this paragraph.

U.S. Patent No. 9,901,640

31. On February 27, 2018, the PTO duly and legally issued United States Patent No. 9,901,640 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim Kou and Laman Alani. The '640 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '640 patent is attached as **Exhibit 5**.

Answer: Biocon admits Exhibit 5 purports to be a copy of the '640 patent. Biocon further admits the '640 patent is titled "Controlled Release Formulations of Levodopa and Uses Thereof" and lists inventors Ann Hsu, Jim Kou, and Laman Alani. Biocon admits that the '640 patent lists an issue date of February 27, 2018. Biocon admits that FDA's Orange Book lists the expiry as December 26, 2028. Biocon denies any remaining allegations in this paragraph.

RYTARY®

32. Impax Laboratories, LLC is the holder of New Drug Application ("NDA") No. 203312 ("the NDA") for carbidopa and levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the Proprietary Name RYTARY®.

Answer: Biocon admits FDA's website lists IMPAX LABORATORIES LLC as the company associated with NDA No. 203312 for carbidopa/levodopa extended-release capsules, for oral use, in 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/245mg dosages. Biocon admits FDA's website lists the proprietary name of the product associated with NDA No. 203312 as RYTARY. Biocon denies any remaining allegations in this paragraph.

33. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '283, '608, '246, '046, and '640 patents, among others, are listed in the FDA "Orange Book" with respect to RYTARY®.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

ACTS GIVING RISE TO THIS ACTION

34. Impax realleges all preceding paragraphs as if fully set forth herein.

Answer: Biocon repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

35. BPL, on information and belief with the active involvement and participation of the other Defendants, submitted ANDA No. 220119 (the "Biocon ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of carbidopa/levodopa capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the "Biocon ANDA Products").

Answer: Biocon admits that Biocon Pharma Limited submitted Biocon's ANDA seeking FDA approval for proposed generic carbidopa/levodopa capsules, 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/245mg. Biocon denies any remaining allegations in this paragraph.

36. On information and belief, following FDA approval of the Biocon ANDA, Defendants intend to make, use, sell, or offer to sell the Biocon ANDA Products throughout the United States, including in the State of New Jersey, and/or import that generic product into the United States, including into the State of New Jersey.

Answer: Denied.

37. On information and belief, in connection with the submission of the Biocon ANDA, Defendants provided written certification to the FDA, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the Biocon ANDA Products (the "Biocon Paragraph IV Certifications").

Answer: Biocon admits that in connection with the Biocon ANDA, Biocon Pharma Limited provided written certification that the claims of the Patents-in-Suit are invalid, unenforceable, and/or not infringed by, *inter alia*, the manufacture, use, or sale of Biocon's ANDA Products.

38. No earlier than February 5, 2025, Impax received written notice of the Biocon ANDA and the Biocon Paragraph IV Certifications from Defendants ("Notice Letter"). The Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that, *inter alia*, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Biocon ANDA Products ("Detailed Statement").

Answer: Biocon admits that by letter dated February 3, 2025, Biocon Pharma Limited provided a "Notice Letter" to, *inter alia*, Impax, which contained a detailed statement of the factual and legal bases for Biocon Pharma Limited's Paragraph IV Certification to FDA. Biocon denies any remaining allegations in this paragraph.

39. By filing the Biocon ANDA, Defendants represented to the FDA that the Biocon ANDA Products have the same active ingredients as RYTARY®, have the same method of

administration, dosage forms, and strengths, and are bioequivalent to RYTARY®, and would be sold under a label substantively the same as the label for RYTARY®.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

40. Pursuant to the Notice Letter, Biocon offered confidential access to portions of the Biocon ANDA for the sole purpose of permitting Impax to determine whether to file an infringement action under 35 U.S.C. § 271(e)(2) (the "OCA").

Answer: Biocon admits that the Notice Letter included an Offer of Confidential Access ("OCA"). Biocon denies any remaining allegations in this paragraph.

41. On February 13, 2025, Impax's outside counsel sent a modestly revised OCA to Defendants for discussion. Defendants ignored that communication, did not communicate with Impax on the OCA, and did not produce any portions of the Biocon ANDA to Impax.

Answer: Biocon admits the parties did not reach agreement on the terms of the OCA. Biocon denies any remaining allegations in this paragraph.

42. Defendants' decision to not produce any portions of the Biocon ANDA has severely limited Impax's ability to assess Defendants' non-infringement assertions in the Notice Letter and Detailed Statement. Once Defendants produce the full Biocon ANDA, Impax will be able to assess whether it has a basis to assert additional claims of patent infringement.

Answer: Denied.

43. This action is being commenced before the expiration of forty-five (45) days from the date Impax received the Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii) and thus triggers the thirty (30) month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

COUNT I - INFRINGEMENT OF THE '283 PATENT BY BIOCON

44. Impax realleges all preceding paragraphs as if fully set forth herein.

Answer: Biocon repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

45. By submission of the Biocon ANDA with the Biocon Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '283 patent, in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '283 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Answer: Denied.

46. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '283 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

47. In the Notice Letter and Detailed Statement, Defendants set forth no grounds for invalidity of any claim of the '283 patent. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe is a claim construction argument.

Answer: Denied.

48. A justiciable controversy exists regarding Defendants' infringement of the '283 patent.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

49. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '283 patent, including at least claim 1, which can be further assessed upon production by Defendants of the full Biocon ANDA.

Answer: Denied.

50. For example, in addition to the act of infringement stemming from the filing of the Biocon ANDA and the Biocon Paragraph IV Certifications, based on a review of the full Biocon ANDA, Impax believes that it can show after discovery and analysis that the Biocon ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 1 of the '283 patent either literally or under the doctrine of equivalents. For example, on information and belief, the Biocon ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '283 patent under 35 U.S.C. § 271(e)(2)(A), Defendants will also indirectly infringe one or more claims of the '283 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

Answer: Denied.

51. On information and belief, the Biocon ANDA Products, if approved by FDA, will be prescribed and administered to human patients to reduce motor fluctuations in a patient suffering from Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '283 patent.

Answer: Denied.

52. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

Answer: Denied.

53. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '283 patent and will constitute infringement.

Answer: Denied.

54. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will induce others to infringe one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Biocon ANDA Products to reduce motor fluctuations in a patient suffering from Parkinson's disease in a manner that meets the limitations of claims in the '283 patent, including at least claim 1.

Answer: Denied.

55. On information and belief, upon FDA approval of the Biocon ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '283 patent, by at least their promotional activities and package

inserts for the Biocon ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

Answer: Denied.

56. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will contributorily infringe one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the Biocon ANDA Products constitute a material part of at least one of the claims of the '283 patent; are especially made or adapted for use in infringing the '283 patent; and that the Biocon ANDA Products are not suitable for substantial non-infringing use.

Answer: Denied.

57. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Biocon ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Biocon ANDA be a date that is not earlier than the expiration date of the '283 patent, or any later expiration of exclusivity for the '283 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

Answer: Denied.

58. Defendants have had knowledge of the '283 patent since at least the date Defendants submitted the Biocon ANDA and the Biocon Paragraph IV Certifications and were

aware that submission of the Biocon ANDA and the Biocon Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

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

Answer: Denied.

COUNT II - INFRINGEMENT OF THE '608 PATENT BY BIOCON

60. Impax realleges all preceding paragraphs as if fully set forth herein.

Answer: Biocon repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

61. By submission of the Biocon ANDA with the Biocon Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '608 patent, in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '608 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Answer: Denied.

62. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '608 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

63. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe claims 1-21 is a claim construction argument. Defendants set forth no grounds for invalidity of claims 1-15 of the '608 patent, and Defendants' only basis for invalidity of claims 16-21 is indefiniteness.

Answer: Denied.

64. A justiciable controversy exists regarding Defendants' infringement of the '608 patent.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

65. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will infringe, literally or under the doctrine of equivalents, one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Biocon ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Biocon ANDA and the Biocon Paragraph IV Certifications, based on a review of the full Biocon ANDA, Impax believes that it can show after discovery and analysis that the Biocon ANDA Products practice all the limitations of at least claims 1 and/or 21 of the '608 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, on information and belief, in addition to literal infringement, the Biocon ANDA Products perform substantially

the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

Answer: Denied.

66. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will also induce others to infringe one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '608 patent, by at least their promotional activities and package inserts for the Biocon ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

Answer: Denied.

67. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will contributorily infringe one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and have had and continue to have knowledge that the Biocon ANDA Products constitute a material part of at least one of the claims of the '608 patent; are especially made or adapted for use in infringing the '608 patent; and that the Biocon ANDA Products are not suitable for substantial non-infringing use.

Answer: Denied.

68. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Biocon ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C.

§§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Biocon ANDA be a date that is not earlier than the expiration date of the '608 patent, or any later expiration of exclusivity for the '608 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

Answer: Denied.

69. Defendants have had knowledge of the '608 patent since at least the date Defendants submitted the Biocon ANDA and the Biocon Paragraph IV Certifications and were aware that submission of the Biocon ANDA and the Biocon Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A), as evidenced by the fact that the Notice Letter and Detailed Statement offer no basis for non-infringement of claim 21 in the '608 patent.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

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

Answer: Denied.

COUNT III - INFRINGEMENT OF THE '246 PATENT BY BIOCON

71. Impax realleges all preceding paragraphs as if fully set forth herein.

Answer: Biocon repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

72. By submission of the Biocon ANDA with the Biocon Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '246 patent, in the event that the FDA

approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '246 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Answer: Denied.

73. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '246 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

74. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe includes a claim construction argument.

Answer: Denied.

75. A justiciable controversy exists regarding Defendants' infringement of the '246 patent.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

76. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '246 patent, including at least claim 26, which can be further assessed upon production by Defendants of the full Biocon ANDA.

Answer: Denied.

77. For example, in addition to the act of infringement stemming from the filing of the Biocon ANDA and the Biocon Paragraph IV Certifications, based on a review of the full Biocon ANDA, Impax believes that it can show after discovery and analysis that the Biocon ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 26 of the '246 patent either literally or under the doctrine of equivalents. For example, on information and belief, the Biocon ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '246 patent under 35 U.S.C. § 271(e)(2)(A), Defendants will also indirectly infringe one or more claims of the '246 patent, including without limitation claim 26, by inducing at least healthcare professionals and patients to directly infringe that claim.

Answer: Denied.

78. On information and belief, the Biocon ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '246 patent.

Answer: Denied.

79. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

Answer: Denied.

80. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '246 patent and will constitute infringement.

Answer: Denied.

81. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will induce others to infringe one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Biocon ANDA Products to treat aspects of Parkinson's disease in a manner that meets the limitations of claims in the '246 patent, including at least claim 26.

Answer: Denied.

82. On information and belief, upon FDA approval of the Biocon ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '246 patent, by at least their promotional activities and package inserts for the Biocon ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

Answer: Denied.

83. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will contributorily infringe one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the Biocon ANDA Products constitute a material part of at least one of the claims of the '246 patent; are especially made or adapted for use in infringing the '246 patent; and that the Biocon ANDA Products are not suitable for substantial non-infringing use.

Answer: Denied.

84. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Biocon ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Biocon ANDA be a date that is not earlier than the expiration date of the '246 patent, or any later expiration of exclusivity for the '246 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

Answer: Denied.

85. Defendants have had knowledge of the '246 patent since at least the date Defendants submitted the Biocon ANDA and the Biocon Paragraph IV Certifications and were aware that submission of the Biocon ANDA and the Biocon Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

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

Answer: Denied.

COUNT IV - INFRINGEMENT OF THE '046 PATENT BY BIOCON

87. Impax realleges all preceding paragraphs as if fully set forth herein.

Answer: Biocon repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

88. By submission of the Biocon ANDA with the Biocon Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the

Biocon ANDA Products prior to the expiration of the '046 patent, in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '046 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Answer: Denied.

89. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '046 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

90. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe includes a claim construction argument.

Answer: Denied.

91. A justiciable controversy exists regarding Defendants' infringement of the '046 patent.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

92. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '046 patent, including at least claim 1, which can be further assessed upon production by Defendants of the full Biocon ANDA.

Answer: Denied.

93. For example, in addition to the act of infringement stemming from the filing of the Biocon ANDA and the Biocon Paragraph IV Certifications, based on a review of the full Biocon ANDA, Impax believes that it can show after discovery and analysis that the Biocon ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 1 of the '046 patent either literally or under the doctrine of equivalents. For example, on information and belief, the Biocon ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '046 patent under 35 U.S.C. § 271(e)(2)(A), Defendants will also indirectly infringe one or more claims of the '046 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

Answer: Denied.

94. On information and belief, the Biocon ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '046 patent.

Answer: Denied.

95. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

Answer: Denied.

96. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '046 patent and will constitute infringement.

Answer: Denied.

97. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will induce others to infringe one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Biocon ANDA Products to treat aspects of Parkinson's disease in a manner that meets the limitations of claims in the '046 patent, including at least claim 1.

Answer: Denied.

98. On information and belief, upon FDA approval of the Biocon ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '046 patent, by at least their promotional activities and package inserts for the Biocon ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

Answer: Denied.

99. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will contributorily infringe one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the Biocon ANDA Products constitute a material part of at least one of the claims of the '046 patent; are

especially made or adapted for use in infringing the '046 patent; and that the Biocon ANDA Products are not suitable for substantial non-infringing use.

Answer: Denied.

100. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Biocon ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Biocon ANDA be a date that is not earlier than the expiration date of the '046 patent, or any later expiration of exclusivity for the '046 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

Answer: Denied.

101. Defendants have had knowledge of the '046 patent since at least the date Defendants submitted the Biocon ANDA and the Biocon Paragraph IV Certifications and were aware that submission of the Biocon ANDA and the Biocon Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

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

Answer: Denied.

COUNT V - INFRINGEMENT OF THE '640 PATENT BY BIOCON

103. Impax realleges all preceding paragraphs as if fully set forth herein.

Answer: Biocon repeats and reincorporates by reference its answers to the preceding paragraphs as if fully set forth herein.

104. By submission of the Biocon ANDA with the Biocon Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '640 patent, in the event that the FDA approves the Biocon ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '640 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

Answer: Denied.

105. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Biocon ANDA Products prior to the expiration of the '640 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

106. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe includes a claim construction argument.

Answer: Denied.

107. A justiciable controversy exists regarding Defendants' infringement of the '640 patent.

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

108. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will infringe, literally or under the doctrine of equivalents, one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Biocon ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Biocon ANDA and the Biocon Paragraph IV Certifications, based on a review of the full Biocon ANDA, Impax believes that it can show after discovery and analysis that the Biocon ANDA Products practice all the limitations of at least claim 15 of the '640 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, on information and belief, in addition to literal infringement, the Biocon ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

Answer: Denied.

109. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will also induce others to infringe one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '640 patent, by at least their promotional activities and package inserts for the Biocon ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

Answer: Denied.

110. Unless enjoined by this Court, upon FDA approval of the Biocon ANDA, Defendants will contributorily infringe one or more claims of the '640 patent, including at least

claim 15, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Biocon ANDA, Defendants will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and have had and continue to have knowledge that the Biocon ANDA Products constitute a material part of at least one of the claims of the '640 patent; are especially made or adapted for use in infringing the '640 patent; and that the Biocon ANDA Products are not suitable for substantial non-infringing use.

Answer: Denied.

111. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Biocon ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Biocon ANDA be a date that is not earlier than the expiration date of the '640 patent, or any later expiration of exclusivity for the '640 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

Answer: Denied.

112. Defendants have had knowledge of the '640 patent since at least the date Defendants submitted the Biocon ANDA and the Biocon Paragraph IV Certifications and were aware that submission of the Biocon ANDA and the Biocon Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

Answer: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Biocon denies them. Biocon denies any remaining allegations in this paragraph.

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

Answer: Denied.

PRAYER FOR RELIEF

Biocon denies that Plaintiff is entitled to any of the relief requested in its Prayer for Relief or to any relief whatsoever, including the relief specifically requested against Biocon in paragraph (a) through (h).

BIOCON'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Biocon asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Biocon reserves the right to amend this Answer with additional defenses as further information is obtained in discovery. Biocon asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted herein.

FIRST AFFIRMATIVE DEFENSE

Each claim of the Patents-in-Suit is invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE

Biocon has not, does not, and will not infringe any valid and enforceable claim of the Patents-in-Suit. The manufacture, use, sale, offer for sale, and/or importation of Biocon's ANDA Product has not, does not, and will not infringe, directly or indirectly, any valid and enforceable claims of the Patents-in-Suit, either literally or under the doctrine of equivalents.

THIRD AFFIRMATIVE DEFENSE

The Complaint fails to adequately state a claim for relief against Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc.

FOURTH AFFIRMATIVE DEFENSE

Plaintiff is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim for relief against Biocon for an exceptional case under 35 U.S.C. § 285.

SIXTH AFFIRMATIVE DEFENSE

Biocon has not willfully infringed any claim of the Patents-in-Suit.

SEVENTH AFFIRMATIVE DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Biocon respectfully requests that Plaintiff take nothing by way of its Complaint, that judgment be entered in favor of Biocon, and that Biocon be awarded its attorneys' fees and costs and all other just and proper relief.

BIOCON'S COUNTERCLAIMS FOR DECLARATORY JUDGMENT

Without admitting the allegations of Plaintiff Impax Laboratories, LLC, ("Impax" or "Plaintiff" or "Counterclaim Defendant"), other than those expressly admitted herein, Defendants Biocon Pharma Limited, Biocon Limited, and Biocon Pharma, Inc., (collectively, "Biocon" or "Counterclaim Plaintiff") bring the following counterclaims against Plaintiff for declaratory judgment that U.S. Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively, the "Patents-in-Suit") are invalid and/or not infringed by Biocon or the product as described in ANDA No. 220119 ("Biocon's ANDA Products").

PARTIES

1. Counterclaim Plaintiff Biocon Limited is a company incorporated under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India.

2. Counterclaim Plaintiff Biocon Pharma Limited is a company incorporated under the laws of India having a principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India

3. 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 at 485 US Highway 1 S B305, Iselin, New Jersey 08830.

4. Upon information and belief, and based on allegations in the Complaint, Counterclaim Defendant Impax Laboratories, LLC, is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal Pharmaceuticals LLC. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater,

New Jersey 08807. Amneal Pharmaceuticals LLC is a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

JURISDICTION AND VENUE

5. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Counterclaim Defendant on the basis of, *inter alia*, their contacts with New Jersey relating to the subject matter of this action, including having filed suit against Biocon.

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

BACKGROUND

8. Upon information and belief, and based on allegations in the Complaint, Impax Laboratories, LLC, is the holder of New Drug Application ("NDA") No. 203312 for carbidopa/levodopa extended-release capsules, for oral use, in 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/24 mg dosages, which is sold under the name RYTARY®.

9. Upon information and belief, and based on allegations in the Complaint, RYTARY® contains 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/245mg dosages of the active ingredients carbidopa/levodopa.

10. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a

claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2).

11. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

12. Based on allegations in the Complaint, the '283 patent, titled "Controlled Release Formulations of Levodopa and Uses Thereof," was issued on October 15, 2013. Based on the allegations in the Complaint, Impax owns the '283 patent. A purported copy of the '283 patent was attached to the Complaint as Exhibit 1.

13. Based on allegations in the Complaint, the '608 patent, titled "Controlled Release Formulations of Levodopa and Uses Thereof," was issued on July 28, 2015. Based on the allegations in the Complaint, Impax owns the '608 patent. A purported copy of the '608 patent was attached to the Complaint as Exhibit 2.

14. Based on allegations in the Complaint, the '346 patent, titled "Controlled Release Formulations of Levodopa and Uses Thereof," was issued on October 11, 2016. Based on the allegations in the Complaint, Impax owns the '246 patent. A purported copy of the '246 patent was attached to the Complaint as Exhibit 3.

15. Based on allegations in the Complaint, the '046 patent, titled "Controlled Release Formulations of Levodopa and Uses Thereof," was issued on January 2, 2017. Based on the allegations in the Complaint, Impax owns the '046 patent. A purported copy of the '046 patent was attached to the Complaint as Exhibit 4.

16. Based on allegations in the Complaint, the '640 patent, titled "Controlled Release Formulations of Levodopa and Uses Thereof," was issued on February 27, 2018. Based on the allegations in the Complaint, Impax owns the '640 patent. A purported copy of the '640 patent was attached to the Complaint as Exhibit 5.

17. Upon information and belief, Counterclaim Defendant caused the Patents-in-Suit to be listed in the Orange Book as patents that claim a pharmaceutical composition comprising and/or a method of using a drug pursuant to NDA No. 203312.

18. Biocon Pharma Limited submitted Abbreviated New Drug Application No. 220119 to obtain FDA approval of carbidopa/levodopa capsules, 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/245mg 120 mg, prior to the expiration of the Patents-in-Suit.

19. ANDA No. 220119 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit (among other patents) are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products.

20. By letter dated February 3, 2025, ("Biocon's Notice Letter"), Biocon Pharma Limited notified Counterclaim Defendant that it had submitted ANDA No. 220119 to FDA for approval of carbidopa/levodopa capsules, 23.75mg/95mg, 36.25mg/145mg, 48.75mg/195mg, 61.25mg/245mg 120 mg, a generic version of RYTARY®.

21. Biocon's Notice Letter included, among other things, detailed factual and legal bases for the Paragraph IV certification regarding the Patents-in-Suit as they pertain to Biocon's ANDA Products.

22. On March 19, 2025, Counterclaim Defendant filed the instant lawsuit alleging infringement of the Patents-in-Suit.

COUNT I
(Declaratory Judgment of Non-Infringement of the '283 Patent)

23. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

24. Counterclaim Defendant has accused Biocon of infringing the '283 patent.

25. The manufacture, use, sale, offer for sale, and/or importation of Biocon's ANDA Products does not and will not infringe any valid or enforceable claim of the '283 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

26. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '283 patent are not infringed by Biocon's ANDA Products and/or are invalid.

27. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '283 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

28. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '283 patent.

29. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '283 patent.

30. Biocon is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Biocon's ANDA Products will not infringe any valid and enforceable claim of the '238 patent.

COUNT II
(Declaratory Judgment of Invalidity the '283 Patent)

31. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

32. One of more claims of the '283 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

33. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '283 patent are not infringed by Biocon's ANDA Product and/or are invalid.

34. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '283 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

35. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '283 patent.

36. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '283 patent.

37. Biocon is entitled to a declaration that all claims of the '283 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

COUNT III
(Declaratory Judgment of Non-Infringement of the '608 Patent)

38. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

39. Counterclaim Defendant has accused Biocon of infringing the '608 patent.

40. The manufacture, use, sale, offer for sale, and/or importation of Biocon's ANDA Products does not and will not infringe any valid or enforceable claim of the '608 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

41. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '608 patent are not infringed by Biocon's ANDA Products and/or are invalid.

42. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '608 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

43. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '608 patent.

44. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '608 patent.

45. Biocon is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Biocon's ANDA Products will not infringe any valid and enforceable claim of the '608 patent.

COUNT IV
(Declaratory Judgment of Invalidity the '608 Patent)

46. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

47. One of more claims of the '608 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

48. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '608 patent are not infringed by Biocon's ANDA Product and/or are invalid.

49. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '608 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

50. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '608 patent.

51. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '608 patent.

52. Biocon is entitled to a declaration that all claims of the '608 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

COUNT V
(Declaratory Judgment of Non-Infringement of the '246 Patent)

53. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

54. Counterclaim Defendant has accused Biocon of infringing the '246 patent.

55. The manufacture, use, sale, offer for sale, and/or importation of Biocon's ANDA Products does not and will not infringe any valid or enforceable claim of the '246 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

56. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '246 patent are not infringed by Biocon's ANDA Products and/or are invalid.

57. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '246 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

58. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '246 patent.

59. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '246 patent.

60. Biocon is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Biocon's ANDA Products will not infringe any valid and enforceable claim of the '246 patent.

COUNT VI
(Declaratory Judgment of Invalidity the '246 Patent)

61. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

62. One of more claims of the '246 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

63. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '246 patent are not infringed by Biocon's ANDA Product and/or are invalid.

64. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '246 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

65. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '246 patent.

66. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '283 patent.

67. Biocon is entitled to a declaration that all claims of the '246 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

COUNT VII
(Declaratory Judgment of Non-Infringement of the ’046 Patent)

68. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

69. Counterclaim Defendant has accused Biocon of infringing the ’046 patent.

70. The manufacture, use, sale, offer for sale, and/or importation of Biocon’s ANDA Products does not and will not infringe any valid or enforceable claim of the ’046 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

71. For at least the reasons stated in Biocon’s Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the ’046 patent are not infringed by Biocon’s ANDA Products and/or are invalid.

72. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon’s ANDA Products are infringing the claims of the ’046 patent and will continue to try to interfere with Biocon’s business with respect to Biocon’s ANDA Products.

73. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon’s ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the ’046 patent.

74. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the ’283 patent.

75. Biocon is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Biocon’s ANDA Products will not infringe any valid and enforceable claim of the ’046 patent.

COUNT VIII
(Declaratory Judgment of Invalidity the '046 Patent)

76. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

77. One of more claims of the '046 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

78. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '046 patent are not infringed by Biocon's ANDA Product and/or are invalid.

79. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '046 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

80. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '046 patent.

81. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '046 patent.

82. Biocon is entitled to a declaration that all claims of the '046 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

COUNT IX
(Declaratory Judgment of Non-Infringement of the '640 Patent)

83. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

84. Counterclaim Defendant has accused Biocon of infringing the '640 patent.

85. The manufacture, use, sale, offer for sale, and/or importation of Biocon's ANDA Products does not and will not infringe any valid or enforceable claim of the '640 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

86. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '640 patent are not infringed by Biocon's ANDA Products and/or are invalid.

87. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '640 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

88. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '640 patent.

89. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '640 patent.

90. Biocon is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of Biocon's ANDA Products will not infringe any valid and enforceable claim of the '640 patent.

COUNT X
(Declaratory Judgment of Invalidity the '640 Patent)

91. Biocon realleges and incorporates by reference the allegations in the preceding paragraphs of its Counterclaims.

92. One of more claims of the '640 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

93. For at least the reasons stated in Biocon's Notice Letter, which is hereby incorporated by reference in its entirety, the claims of the '640 patent are not infringed by Biocon's ANDA Product and/or are invalid.

94. Upon information and belief, Biocon believes that Counterclaim Defendant will continue to assert that Biocon's ANDA Products are infringing the claims of the '640 patent and will continue to try to interfere with Biocon's business with respect to Biocon's ANDA Products.

95. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of ANDA No. 220119 and/or the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Products infringes, has infringed, and/or will infringe a valid and enforceable claim of the '640 patent.

96. The parties have adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding infringement of any valid claim of the '640 patent.

97. Biocon is entitled to a declaration that all claims of the '640 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. 282(b), and/or under other judicially created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Biocon requests judgment in its favor and against Counterclaim Defendant as follows:

a. Declaring that all claims of the Patents-in-Suit are invalid;

b. Declaring that the filing of ANDA No. 220119 has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the Patent-in-Suit, directly or indirectly and literally or under the doctrine of equivalents;

c. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Biocon's ANDA Products does not, and will not, if marketed, infringe any valid and enforceable claim of the Patents-in-Suit, directly or indirectly and literally or under the doctrine of equivalents;

d. Ordering that Counterclaim Defendant's Complaint be dismissed with prejudice and judgment entered in favor of Biocon;

e. Declaring this an exceptional case in favor of Biocon and awarding its attorneys' fees pursuant to 35 U.S.C. § 285;

f. Awarding costs and expenses; and

g. Awarding any and all such other relief as the Court determines to be just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendants,
Biocon Pharma Ltd., Biocon Ltd.,
and Biocon Pharma, Inc.

By: *s/ James S. Richter*
James S. Richter
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Dated: June 18, 2025

OF COUNSEL:

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following action currently pending in this District:

- *Impax Laboratories, LLC v. Qilu Pharmaceutical Co., Ltd., et al., 25 CV 1962 (D.N.J.)*

Biocon is not aware of any other action in any court or any pending arbitration or administrative proceeding related to this matter

s/ James S. Richter
James S. Richter

Dated: June 18, 2025

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

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

s/ James S. Richter
James S. Richter

Dated: June 18, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Biocon's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on June 18, 2025.

s/James S. Richter
James S. Richter

Dated: June 18, 2025