IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME LLC, *Plaintiff,* BIOCON PHARMA LTD., BIOCON LTD., and BIOCON PHARMA, INC., *Defendants,*	C.A. No. _____

COMPLAINT

Plaintiff Merck Sharp & Dohme LLC ("Merck"), by its attorneys, for its Complaint, alleges as follows:

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and for a declaratory judgment of patent infringement under 28 U.S.C. §§ 2201 and 2202 and the patent laws of the United States, Title 35, United States Code, that arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 218441 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import versions of JANUVIA® (sitagliptin phosphate tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Biocon Pharma Inc. notified Merck by letter dated May 9, 2023 ("Biocon's Notice Letter") that Biocon Pharma limited had submitted to the FDA ANDA No. 218441 ("Biocon's ANDA"), seeking approval from the FDA to engage in the commercial

manufacture, use, offering for sale, sale, and/or importation of generic sitagliptin phosphate oral tablets ("Biocon's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Biocon's ANDA Product is a generic version of Merck's JANUVIA® product.

PARTIES

4. Plaintiff Merck is a company organized and existing under the laws of New Jersey, having its company offices and principal place of business at 126 East Lincoln Ave, P.O. Box 2000, Rahway, NJ 07065 USA.

5. Merck is the holder of New Drug Application ("NDA") No. 21995 for JANUVIA® (sitagliptin phosphate), which has been approved by the FDA.

6. On information and belief, Defendant Biocon Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India. On information and belief, Biocon Pharma Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

7. On information and belief, Defendant Biocon Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 20th KM, Hosur Road, Electronic City, Bangalore, 560100, India. On information and belief, Biocon Ltd. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

8. On information and belief, Defendant 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 Highway 1 S B305, Iselin, New Jersey 08830. On information and

belief, Biocon Pharma, Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

9. On information and belief, Defendant Biocon Pharma Ltd. is a wholly owned subsidiary of Defendant Biocon Ltd.

10. On information and belief, Defendant Biocon Pharma, Inc. is a wholly owned subsidiary of Defendant Biocon Pharma Ltd.

11. On information and belief, Defendants Biocon Pharma Ltd., Biocon Ltd., and Biocon Pharma, Inc. acted in concert to prepare and submit Biocon's ANDA to the FDA.

12. On information and belief, Defendants know and intend that upon approval of Biocon's ANDA, Biocon will manufacture, market, sell, and distribute Biocon's ANDA Product throughout the United States, including in Delaware. On information and belief, Defendants are agents of each other and/or operate in concert as integrated parts of the same business group, including with respect to Biocon's ANDA Product, and enter into agreements that are nearer than arm's length. On information and belief, Defendants participated, assisted, and cooperated in carrying out the acts complained of herein. Biocon Pharma Ltd., Biocon Ltd., and Biocon Pharma, Inc. are herein referred to collectively as "Biocon."

13. On information and belief, following any FDA approval of Biocon's ANDA, Defendants will act in concert to distribute and sell Biocon's ANDA Product throughout the United States, including within Delaware.

JURISDICTION

14. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

15. This Court has personal jurisdiction over Defendants.

16. Defendant Biocon Pharma, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Defendant Biocon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Biocon Pharma, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware related to Merck's claims, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

17. Defendant Biocon Pharma Ltd. is subject to personal jurisdiction in Delaware because, among other things, Defendant Biocon Pharma Ltd., itself and through its wholly owned subsidiary Biocon Pharma, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief Defendant Biocon Pharma Ltd., itself and through its wholly owned subsidiary Biocon Pharma, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Defendant Biocon Pharma Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Biocon Pharma, Inc., and therefore the activities of Biocon Pharma, Inc. in this jurisdiction are attributed to Defendant Biocon Pharma Ltd.

18. Defendant Biocon Ltd. is subject to personal jurisdiction in Delaware because, among other things, Defendant Biocon Ltd., itself and through its wholly owned subsidiary Biocon Pharma, Inc., has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief Defendant Biocon Ltd., itself and through its wholly owned subsidiary Biocon Pharma, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Defendant Biocon Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Biocon Pharma, Inc., and therefore the activities of Biocon Pharma, Inc. in this jurisdiction are attributed to Defendant Biocon Pharma Ltd.

19. In addition, this Court has personal jurisdiction over Defendants because Biocon Pharma Ltd., Biocon Ltd., and Biocon Pharma, Inc. regularly engage in patent litigation concerning FDA-approved branded drug products in this district, do not contest personal jurisdiction in this district, and have purposefully availed themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g., Novo Nordisk Inc. et al v. Biocon Pharma Ltd. et al*, 22-856-CFC (D. Del. 2022); *Novartis Pharmaceuticals Corporation v. Torrent Pharma Inc., et al.*, 19-1979-RGA (D. Del. 2019).

20. On information and belief, if Biocon's ANDA is approved, Biocon will manufacture, market, sell, and/or distribute Biocon's ANDA Product within the United States, including in Delaware, consistent with Biocon's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Biocon regularly does

business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for distribution throughout the United States, including in Delaware. On information and belief, Biocon's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Biocon's ANDA Product will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Each of these activities would have a substantial effect within Delaware and would constitute infringement of Merck's patent in the event that Biocon's ANDA Product is approved before the patent expires.

21. On information and belief, Biocon derives substantial revenue from generic pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Biocon and/or for which Biocon is the named applicant on approved ANDAs. On information and belief, various products for which Biocon is the named applicant on approved ANDAs are available at retail pharmacies in Delaware.

VENUE

22. Merck incorporates each of the preceding paragraphs 1–21 as if fully set forth herein.

23. Venue is proper in this district as to Biocon Pharma, Inc. under 28 U.S.C. § 1400(b) because Biocon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

24. Venue is also proper in this district as to Biocon Pharma Ltd. and Biocon Ltd. under 28 U.S.C. § 1391 because Biocon Pharma Ltd. and Biocon Ltd. are corporations

organized and existing under the laws of India and are subject to personal jurisdiction in this judicial district.

THE '708 PATENT

25. Merck incorporates each of the preceding paragraphs 1–24 as if fully set forth herein.

26. The inventors named on the '708 patent are Stephen Howard Cypes, Alex Minhua Chen, Russell R. Ferlita, Karl Hansen, Ivan Lee, Vicky K. Vydra, and Robert M. Wenslow, Jr.

27. The '708 patent, entitled "Phosphoric Acid Salt of a Dipeptidyl Peptidase-IV Inhibitor" (attached as Exhibit A), was duly and legally issued on February 5, 2008.

28. Merck is the owner and assignee of the '708 patent.

29. The '708 patent claims, *inter alia*, a dihydrogenphosphate salt of 4-oxo-4-[3-(trifluoromethyl)-5,6-dihydro[1,2,4]triazolo[4,3-a]pyrazin-7(8H)-yl]-1-(2,4,5-trifluorophenyl)butan-2-amine of structural formula I, or a hydrate thereof, as recited in claim 1 of the '708 patent.

30. JANUVIA®, as well as methods of using JANUVIA®, are covered by one or more claims of the '708 patent, including claim 1 of the '708 patent, and the '708 patent has been listed in connection with JANUVIA® in the FDA's Orange Book.

COUNT I – INFRINGEMENT OF THE '708 PATENT

31. Merck incorporates each of the preceding paragraphs 1–30 as if fully set forth herein.

32. In Biocon's Notice Letter, Biocon notified Merck of the submission of Biocon's ANDA to the FDA. The purpose of this submission was to obtain approval under the

FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Biocon's ANDA Product prior to the expiration of the '708 patent.

33. In Biocon's Notice Letter, Biocon also notified Merck that, as part of its ANDA, Biocon had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '708 patent. On information and belief, Biocon submitted its ANDA to the FDA containing certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '708 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Product.

34. In Biocon's Notice Letter, Biocon stated that Biocon's ANDA Product contains sitagliptin phosphate as an active ingredient.

35. Biocon's ANDA Product, and the use of Biocon's ANDA Product, is covered by one or more claims of the '708 patent, including at least claim 1 of the '708 patent, because claim 1 of the '708 patent covers the sitagliptin phosphate contained in Biocon's ANDA Product.

36. Biocon's submission of Biocon's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Biocon's ANDA Product before the expiration of the '708 patent was an act of infringement of the '708 patent under 35 U.S.C. § 271(e)(2)(A).

37. On information and belief, Biocon will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Biocon's ANDA Product immediately and imminently upon approval of its ANDA.

38. The manufacture, use, sale, offer for sale, or importation of Biocon's ANDA Product would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

39. On information and belief, the manufacture, use, sale, offer for sale, or importation of Biocon's ANDA Product in accordance with, and as directed by, its proposed product labeling would infringe one or more claims of the '708 patent, including at least claim 1 of the '708 patent.

40. On information and belief, Biocon plans and intends to, and will, actively induce infringement of the '708 patent when Biocon's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval. Biocon's activities will be done with knowledge of the '708 patent and specific intent to infringe that patent.

41. On information and belief, Biocon knows that Biocon's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '708 patent, that Biocon's ANDA Product is not a staple article or commodity of commerce, and that Biocon's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. On information and belief, Biocon plans and intends to, and will, contribute to infringement of the '708 patent immediately and imminently upon approval of Biocon's ANDA.

42. Notwithstanding Biocon's knowledge of the claims of the '708 patent, Biocon has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import Biocon's ANDA Product with its product labeling following FDA approval of Biocon's ANDA prior to the expiration of the '708 patent.

43. The foregoing actions by Biocon constitute and/or will constitute infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and contribution to the infringement by others of the ’708 patent.

44. On information and belief, Biocon has acted with full knowledge of the ’708 patent and without a reasonable basis for believing that it would not be liable for infringement of the ’708 patent; active inducement of infringement of the ’708 patent; and/or contribution to the infringement by others of the ’708 patent.

45. Merck will be substantially and irreparably damaged by infringement of the ’708 patent.

46. Unless Biocon is enjoined from infringing the ’708 patent, actively inducing infringement of the ’708 patent, and contributing to the infringement by others of the ’708 patent, Merck will suffer irreparable injury. Merck has no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’708 PATENT

47. Merck incorporates each of the preceding paragraphs 1–46 as if fully set forth herein.

48. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Merck on the one hand and Biocon on the other regarding Biocon’s infringement, active inducement of infringement, and contribution to the infringement by others of the ’708 patent.

49. The Court should declare that the commercial manufacture, use, sale, offer for sale or importation of Biocon’s ANDA Product with its proposed labeling, or any other Biocon drug product that is covered by or whose use is covered by the ’708 patent, will infringe,

induce the infringement of, and contribute to the infringement by others of the ’708 patent, and that the claims of the ’708 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Merck requests the following relief:

(a) A judgment that the ’708 patent has been infringed under 35 U.S.C. § 271(e)(2) by Biocon’s submission to the FDA of Biocon’s ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Biocon’s ANDA Product, or any other drug product that infringes or the use of which infringes the ’708 patent, be not earlier than the latest of the expiration date of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Biocon, and all persons acting in concert with Biocon, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Biocon’s ANDA Product, or any other drug product covered by or whose use is covered by the ’708 patent, prior to the expiration of the ’708 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that the commercial manufacture, use, sale, offer for sale or importation of Biocon’s ANDA Product, or any other drug product that is covered by or whose use is covered by the ’708 patent, prior to the expiration of the ’708 patent, will infringe, induce the infringement of, and contribute to the infringement by others of, the ’708 patent;

(e) A declaration that this is an exceptional case and an award of attorney’s fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: June 23, 2023

Respectfully submitted,

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