**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| MERCK SHARP & DOHME CORP.,<br><br>*Plaintiff,*<br><br>v.<br><br>INVENTIA HEALTHCARE LTD., and INVENTIA HEALTHCARE LLC,<br><br>*Defendants*. | C.A. No. _____ |

**COMPLAINT**

Plaintiff Merck Sharp & Dohme Corp. ("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. 215411 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a version of JANUMET® (metformin hydrochloride; sitagliptin phosphate tablets) prior to the expiration of U.S. Patent No. 7,326,708 ("the '708 patent").

2. Inventia Healthcare Limited ("Inventia Ltd.") notified Merck by letter dated January 15, 2021 ("Inventia's Notice Letter") that it had submitted to the FDA ANDA No. 215411 ("Inventia's ANDA"), seeking approval from the FDA to engage in the commercial manufacture, use, offering for sale, sale, and/or importation of generic metformin hydrochloride

and sitagliptin phosphate oral tablets ("Inventia's ANDA Product") prior to the expiration of the '708 patent.

3. On information and belief, Inventia's ANDA Product is a generic version of Merck's JANUMET®.

**PARTIES**

4. Plaintiff Merck is a corporation organized and existing under the laws of New Jersey, having its corporate offices and principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

5. Merck is the holder of NDA No. 022044 for JANUMET® (metformin hydrochloride; sitagliptin phosphate), which has been approved by the FDA.

6. On information and belief, Defendant Inventia Healthcare Limited ("Inventia Ltd.") is a corporation organized and existing under the laws of India, with a principal place of business at Unit 703 and 704, 7th Floor, Hubtown Solaris, N S Phadke Marg, Andheri (East), Mumbai, 400 069, Maharashtra India. Upon information and belief, Inventia Ltd. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs.

7. On information and belief, Defendant Inventia Healthcare LLC ("Inventia LLC") is a limited liability company organized and existing under the laws of the State of Delaware, with registered agent Incorp Services, Inc. located at 919 North Market Street, Suite 950, Wilmington, Delaware 19801. On information and belief, Inventia LLC is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for the U.S. market.

8. On information and belief, Inventia LLC is a wholly owned subsidiary of Inventia Ltd. Inventia Ltd. and Inventia LLC are collectively referred to herein as "Inventia."

9. On information and belief, Inventia Ltd. and Inventia LLC acted in concert to prepare and submit Inventia's ANDA to the FDA.

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

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

## JURISDICTION

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

13. This Court has personal jurisdiction over Inventia.

14. Inventia Ltd. is subject to personal jurisdiction in Delaware because, among other things, Inventia Ltd., itself and through its wholly owned subsidiary Inventia LLC, 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, Inventia Ltd., itself and through its wholly owned subsidiary Inventia LLC, 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, Inventia Ltd. is subject to personal jurisdiction in Delaware because, on information and belief, it controls and dominates Inventia LLC and therefore the activities of Inventia LLC in this jurisdiction are attributed to Inventia Ltd.

15. Inventia LLC 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. Inventia LLC is a limited liability company 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, Inventia LLC 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.

16. In addition, this Court has personal jurisdiction over Inventia because Inventia Ltd. engages in patent litigation concerning FDA-approved branded drug products in this district, does not contest personal jurisdiction in this district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *Adare Pharma, Inc. v. Inventia Healthcare Ltd.*, No. 18-1079-MSG, D.I. 17 (D. Del. Sept. 24, 2018); *Vanda Pharma Inc. v. Inventia Healthcare Ltd.*, No. 15-921-CFC, D.I. 10 (D. Del. Jan. 11, 2016); *Vanda Pharma Inc. v. Inventia Healthcare Ltd.*, No. 15-362-CFC, D.I. 24 (D. Del. Oct. 9, 2015).

17. On information and belief, if Inventia's ANDA is approved, Inventia will manufacture, market, sell, and/or distribute Inventia's ANDA Product within the United States, including in Delaware, consistent with Inventia's practices for the marketing and distribution of other generic pharmaceutical products. On information and belief, Inventia 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, Inventia's generic pharmaceutical products are used and/or consumed within and throughout the United States, including in Delaware. On information and belief, Inventia'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 Inventia's ANDA Product is approved before the patent expires.

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

## VENUE

19. Merck incorporates each of the preceding paragraphs 1–18 as if fully set forth herein.

20. Venue is proper in this district as to Inventia Ltd. under 28 U.S.C. § 1391 because Inventia Ltd. is a corporation organized and existing under the laws of India and is subject to personal jurisdiction in this judicial district.

21. Venue is proper in this district as to Inventia LLC under 28 U.S.C. § 1400(b) because Inventia LLC is a limited liability company organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

**THE '708 PATENT**

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

23. 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.

24. 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.

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

26. 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.

27. JANUMET®, as well as methods of using JANUMET®, 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 JANUMET® in the FDA's Orange Book.

**COUNT I – INFRINGEMENT OF THE '708 PATENT**

28. Merck incorporates each of the preceding paragraphs 1–27 as if fully set forth herein.

29. In Inventia's Notice Letter, Inventia notified Merck of the submission of Inventia'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 Inventia's ANDA Product prior to the expiration of the '708 patent.

30. In Inventia's Notice Letter, Inventia also notified Merck that, as part of its ANDA, Inventia 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, Inventia 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 Inventia's ANDA Product.

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

32. Inventia's ANDA Product, and the use of Inventia's ANDA Product, are 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 Inventia's ANDA Product.

33. Inventia's submission of its ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Inventia'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).

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

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

36. On information and belief, the manufacture, use, sale, offer for sale, or importation of Inventia'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.

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

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

39. Notwithstanding Inventia's knowledge of the claims of the '708 patent, Inventia has continued to assert its intent to manufacture, offer for sale, sell, distribute, and/or import

Inventia's ANDA Product with its product labeling following FDA approval of Inventia's ANDA prior to the expiration of the '708 patent.

40. The foregoing actions by Inventia 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.

41. On information and belief, Inventia 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.

42. Merck will be substantially and irreparably damaged by infringement of the '708 patent.

43. Unless Inventia 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**

44. Merck incorporates each of the preceding paragraphs 1–43 as if fully set forth herein.

45. 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 Inventia on the other regarding Inventia's infringement, active inducement of infringement, and contribution to the infringement by others of the '708 patent.

46. The Court should declare that the commercial manufacture, use, sale, offer for sale, or importation of Inventia's ANDA Product with its proposed labeling, or any other

Inventia 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 Inventia's submission to the FDA of Inventia's ANDA;

(b) A judgment ordering that the effective date of any FDA approval of the commercial manufacture, use, or sale of Inventia'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 Inventia, and all persons acting in concert with Inventia, from the commercial manufacture, use, sale, offer for sale, or importation into the United States of Inventia'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 Inventia'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: February 10, 2021

Respectfully submitted,

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