UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Hetero Drugs Limited, Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc., Defendants.	Civil Action No. 17-cv-04421 **AMENDED COMPLAINT**

Plaintiffs, Kowa Company, Ltd. ("KCL"), Kowa Pharmaceuticals America, Inc. ("KPA") (collectively, "Kowa"), and Nissan Chemical Industries, Ltd. ("NCI") (Kowa and NCI, collectively, "Plaintiffs"), by their undersigned counsel, for their Complaint against defendants Hetero Drugs Limited, Hetero Labs Limited, Hetero Labs Limited Unit-V, and Hetero USA Inc. (collectively, "Hetero" or "Defendants"), allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2), and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c). Personal jurisdiction over Defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a), because Defendants are doing business in this jurisdiction, and/or under Fed. R. Civ. P. 4(k)(2).

Parties

2. KCL is a Japanese corporation having its corporate headquarters and principal place of business in Aichi, Japan. KPA is a wholly owned U.S. subsidiary of KCL. KPA has its corporate headquarters and principal place of business in Montgomery, Alabama and is organized under the laws of Delaware.

3. NCI is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan.

4. KCL and NCI are engaged in the business of research, developing, manufacturing, and marketing of a broad spectrum of innovative pharmaceutical products, including Livalo®.

5. Upon information and belief, Hetero Drugs Limited ("Hetero Drugs") is a company organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

6. Upon information and belief, Hetero Labs Limited ("Hetero Labs") is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500018, Telangana, India.

7. Upon information and belief, Hetero Labs Limited Unit-V is a division of Hetero Labs, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad - 500018, Telangana, India.

8. Upon information and belief, Hetero USA Inc. ("Hetero USA") is a company organized and existing under the laws of Delaware, having its principal place of business at 1035

Centennial Avenue, Piscataway, NJ 08854. Upon information and belief, Hetero USA is a wholly-owned subsidiary of Hetero Drugs.

9. Upon information and belief, Hetero USA is the "U.S. Regulatory Agent" with respect to ANDA No. 205977 (the "Hetero ANDA"), which is the subject of this action.

10. Upon information and belief, Hetero sells generic drugs throughout the United States, including at least in New York.

11. Upon information and belief, Hetero is currently transacting business in the Southern District of New York, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Upon information and belief, Hetero engages in such conduct with respect to its drug products throughout the United States, including at least in the State of New York. Upon information and belief, Hetero derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and the Southern District of New York. By filing its ANDA, Hetero has committed, and unless enjoined, will continue to commit a tortious act without the State of New York, which Hetero expects or should reasonably expect to have consequences in the State of New York, including in this Judicial District.

The New Drug Application

12. KPA sells drug products containing pitavastatin calcium (the "pitavastatin drug product") under the trade name Livalo® in the United States pursuant to the United States Food and Drug Administration's approval of a New Drug Application ("NDA") held by KCL (NDA No. 22-363).

13. Livalo® is approved for use as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia.

14. The approval letter for Livalo®, with approved labeling, was issued by the FDA on August 3, 2009.

15. Certain amendments to the approved labeling for Livalo® have subsequently been approved.

The Patent in Suit

16. United States Patent No. 8,557,993 ("the '993 patent"), entitled "Crystalline Forms of Pitavastatin Calcium," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 15, 2013 to inventors Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening, and ultimately was assigned to plaintiff NCI. The '993 patent claims, inter alia, crystalline polymorphs or the amorphous form of pitavastatin or processes for preparing the same.

17. Plaintiff NCI has been and still is the owner through assignment of the '993 patent, which expires on February 2, 2024. KCL is NCI's licensee for the '993 patent and KPA holds a license from KCL for the '993 patent.

18. In accordance with its license, KPA sells the pitavastatin drug product under the trade name Livalo® in the United States. Sales of Livalo® are made pursuant to approval by the FDA of NDA No. 22-363.

19. Plaintiff KCL manufactures the Livalo® drug products as sold by KPA.

20. Plaintiffs Kowa and NCI will be substantially and irreparably harmed by infringement of the '993 patent. There is no adequate remedy at law.

COUNT I

INFRINGEMENT OF THE '993 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

21. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

22. Upon information and belief, Hetero filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j) (the Hetero ANDA) seeking approval to market 1 mg, 2 mg, and 4 mg tablets comprising pitavastatin calcium.

23. By this ANDA filing, Hetero has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, importation, use, offer for sale, and/or sale, or inducement thereof, of Plaintiffs' patented pitavastatin drug product immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Hetero has indicated that its pitavastatin drug product is bioequivalent to Plaintiffs' pitavastatin drug product.

24. By its ANDA filing, Hetero seeks to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' Livalo® pitavastatin drug product prior to the expiration date of the '993 patent.

25. By a letter dated April 27, 2017 (the "Notice Letter"), Hetero informed Kowa and NCI that Hetero had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I). On or about April 28, 2017, KPA received the Notice Letter, on or about May 1, 2017, KCL received the Notice Letter, and on or about May 2, 2017, NCI received the Notice Letter.

26. The Notice Letter, purporting to be Hetero's Notice of Certification under 21 U.S.C.§ 355(j)(2)(B)(ii), indicates that Hetero intends to manufacture, use, sell, or offer for sale, its proposed pitavastatin drug product prior to the expiration of the '993 patent.

27. The Notice Letter asserts that in Hetero's opinion, "the manufacture, import, marketing, and use of Hetero's Pitavastatin Product will not infringe any valid claim of the '993 patent." Hetero's Notice Letter purports to dispute infringement, but does not assert any basis for challenging validity of any claim of the '993 patent.

28. Hetero's filing of the Hetero ANDA for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or the inducement thereof, of its proposed pitavastatin drug product before the expiration of the '993 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

29. On information and belief, Hetero's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed pitavastatin drug product would directly infringe or induce infringement of at least one claim of the '993 patent under 35 U.S.C. § 271(e)(2)(A).

30. Unless Hetero is enjoined from infringing the '993 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Hetero's pitavastatin drug product for which it seeks FDA approval or any drug product containing pitavastatin will infringe at least one claim of the '993 patent;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any

FDA approval for Hetero to commercially make, use, sell, offer to sell or import its pitavastatin drug product or any drug product containing pitavastatin be no earlier than the date following the expiration date of the '993 patent;

(c) a permanent injunction restraining and enjoining against any infringement by Defendants, their officers, agents, attorneys, employees, successors or assigns, or those acting in privity or concert with them, of the '993 patent, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Hetero's pitavastatin drug product or any drug product containing pitavastatin, and/or any inducement of the same;

(d) attorneys' fees in this action under 35 U.S.C. § 285; and

(e) such further and other relief in favor of Plaintiffs and against Defendants as this Court may deem just and proper.

Dated: New York, New York
June 13, 2017

Kowa Company, Ltd.,
Kowa Pharmaceuticals America, Inc., and
Nissan Chemical Industries, Ltd.,

By their attorneys,

s/Jennifer L. Dereka

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