IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

KOWA COMPANY, LTD., KOWA PHARMACEUTICALS AMERICA, INC., and NISSAN CHEMICAL INDUSTRIES, LTD., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	Civil Action No. 14-cv-2647-PAC ECF Case **DOCUMENT ELECTRONICALLY FILED**

MYLAN PHARMACEUTICALS INC.'S AND MYLAN INC.'S
ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS

Defendants Mylan Pharmaceuticals Inc. ("Mylan Pharms") and Mylan Inc. (collectively, "Mylan") hereby answer the Complaint of Plaintiffs Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc. (collectively, "Kowa") and Nissan Chemical Industries, Ltd. ("Nissan") (Kowa and Nissan, collectively, "Plaintiffs") as follows:

Jurisdiction and Venue

1. Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that this action purports to be an action for alleged patent infringement. Further answering, Mylan admits that subject matter jurisdiction is proper only for the claims directed solely against Mylan Pharms under 35 U.S.C § 271(e)(2)(A). Mylan denies that subject matter jurisdiction is proper as to Mylan Inc., and for any claims asserted under 35 U.S.C. §§ 271(b), (c) and 281-83. Mylan denies that Mylan Inc. is a proper party to this action. Solely to conserve the resources of the parties and the Court, Mylan does not contest

personal jurisdiction or venue in this judicial District for the limited purpose of this action only. Mylan denies all remaining allegations in Paragraph 1.

Parties

2. Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 2, and therefore denies the same.

3. Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 3, and therefore denies the same.

4. Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 4, and therefore denies the same.

5. Mylan admits that Mylan Pharms is a West Virginia corporation with a place of business in Morgantown, West Virginia. Mylan further admits that Mylan Pharms is a wholly-owned subsidiary of Mylan Inc. Mylan further admits that Mylan Pharms submitted an Abbreviated New Drug Application ("ANDA"), No. 206070, to the U.S. Food and Drug Administration ("FDA") seeking approval for Pitavastatin Calcium Tablets, 1 mg, 2 mg, and 4 mg. Mylan denies all remaining allegations in Paragraph 5.

6. Paragraph 6 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that Mylan Inc. is a Pennsylvania corporation having its corporate headquarters in Canonsburg, Pennsylvania. Mylan denies all remaining allegations in Paragraph 6.

7. Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

8. Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the current electronic records of the New York State Department of State, Division of Corporations, identify Mylan Pharms and Mylan Inc. as

"active" entities in the Corporation and Business Entity Database. Further answering, Mylan admits that Mylan Inc. is listed on the NASDAQ Global Select Market. Mylan also admits that Mylan Inc. identifies American Stock Transfer & Trust Company, LLC as its transfer agent. Mylan denies all remaining allegations in Paragraph 8.

The New Drug Application

9. Mylan admits that the electronic version of the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"), identifies "KOWA CO" as the purported holder of New Drug Application ("NDA") No. 022363 for LIVALO® (Pitavastatin Calcium) Tablets, 1 mg, 2 mg and 4 mg. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 9, and therefore denies the same.

10. Mylan admits that according to FDA's electronic searchable catalog of approved drugs, the current approved Prescribing Information for LIVALO® provides, in relevant part, that LIVALO® is "indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia." Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 10, and therefore denies the same.

11. Mylan admits that the electronic version of FDA's Orange Book identifies August 3, 2009 as the approval date for LIVALO®. Mylan is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11, and therefore denies the same.

12. Mylan is without knowledge and information sufficient to form a belief as to the truth of the allegations in Paragraph 12, and therefore denies the same.

The Patents in Suit

13. Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, according to the electronic records of the U.S. Patent and Trademark Office ("PTO"), on or about January 5, 1999, the PTO issued U.S. Patent No. 5,856,336 ("the '336 patent"), entitled "QUINOLINE TYPE MEVALONOLACTONES," to Yoshiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita and Masaki Kitahara; that the electronic records of the PTO identify "Nissan Chemical Industries Ltd." as the purported "assignee" to the '336 patent; and that what purports to be a copy of the '336 patent is attached to the Complaint as Exhibit A. Mylan denies that the '336 patent was "duly issued," and any suggestion or implication that the '336 patent is valid or enforceable. Mylan denies all remaining allegations in Paragraph 13.

14. Paragraph 14 contains legal conclusions to which no answer is required. Mylan lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 14, and therefore denies all such allegations.

15. Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, according to the electronic records of the PTO, on or about October 15, 2002, the PTO issued U.S. Patent No. 6,465,477 B1 ("the '477 patent"), entitled "STABLE PHARMACEUTICAL COMPOSITION," to Toyojiro Muramatsu, Katsumi Mashita, Yasuo Shinoda, Hironori Sassa, Hiroyuki Kawashima, Yoshio Tanizawa and Hideatsu Takeuchi; that the electronic records of the PTO identify "Kowa Company, Ltd." and "Nissan Chemical Industries Ltd." as the purported "assignees" to the '477 patent; and that what purports to be a copy of the '477 patent is attached to the Complaint as Exhibit B. Mylan denies that the '477 patent was "duly issued," and any suggestion or implication that the '477 patent is valid or enforceable. Mylan denies all remaining allegations in Paragraph 15.

16. Paragraph 16 contains legal conclusions to which no answer is required. Mylan lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 16, and therefore denies all such allegations.

17. Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that, according to the electronic records of the PTO, on or about October 15, 2013, the PTO issued U.S. Patent No. 8,557,993 B2 ("the '993 patent"), entitled "CRYSTALLINE FORMS OF PITAVASTATIN CALCIUM," to Paul Adriaan Van der Schaaf, Fritz Blatter, Martin Szelagiewicz and Kai-Uwe Schoening; that the electronic records of the PTO identify "Nissan Chemical Industries Ltd." as the purported "assignee" to the '993 patent; and that what purports to be a copy of the '993 patent is attached to the Complaint as Exhibit C. Mylan denies that the '993 patent was "duly issued," and any suggestion or implication that the '993 patent is valid or enforceable. Mylan denies all remaining allegations in Paragraph 17.

18. Paragraph 18 contains legal conclusions to which no answer is required. Mylan lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 18, and therefore denies all such allegations.

19. Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Mylan admits that the electronic version of the FDA's Orange Book identifies NDA No. 022363 in connection with LIVALO® (Pitavastatin Calcium) Tablets 1 mg, 2 mg and 4 mg. Mylan lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 19, and therefore denies all such allegations.

20. Mylan lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 20, and therefore denies all such allegations.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.