

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Sawai USA Inc., and Sawai Pharmaceutical Co., Ltd,
Petitioners,

v.

Nissan Chemical Industries, Ltd.,
Patent Owner

U.S. Patent No. 5,856,336

Issue Date: January 5, 1999

Title: Quinoline Type Mevalonolactones

Inter Partes Review No. IPR2015-01648

DECLARATION OF THOMAS H. WINTNER

I, Thomas H. Wintner, do hereby declare:

1. I am a member in the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo P.C. (“Mintz Levin”). Lead counsel in this *inter partes* review proceeding is David G. Conlin, who is also a member at Mintz Levin. Back up counsel is Kathleen B. Carr who is also a member at Mintz Levin. Mr. Conlin and Ms. Carr are registered to practice before the United States Patent and Trademark Office and hold Registration Nos. 27,026 and 41,658 respectively. With respect to this proceeding, I will work closely with Mr. Conlin and Ms. Carr.

2. I am a member in good standing of the Bar of the Commonwealth of Massachusetts (see current Certificate, appended hereto). My Massachusetts Bar membership is 667329. I am admitted to practice before the Supreme Court of the United States, the United States Courts of Appeals for the Federal, First, Fourth, Sixth, and Ninth Circuits, and the United States District Court for the District of Massachusetts.

3. In my almost ten years of litigation practice I currently represent or have represented clients in numerous chemical and pharmaceutical patent litigation cases in various United States courts. Those actions include:

- *Kowa Company, Ltd., et al. v. Aurobindo Pharma Limited, et al.* (S.D.N.Y. No. 14-2497)
- *Kowa Company, Ltd., et al. v. Amneal Pharmaceuticals LLC* (S.D.N.Y. No. 14-2758)

- *Kowa Company, Ltd., et al. v. Mylan Inc., et al.* (S.D.N.Y. No. 14-2647)
- *Kowa Company, Ltd., et al. v. Orient Pharma Co., Ltd.* (S.D.N.Y. No. 14-2759)
- *Kowa Company, Ltd., et al. v. Sawai USA, Inc., et al.* (S.D.N.Y. No. 14-5575)
- *Kowa Company, Ltd., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.* (S.D.N.Y. No. 14-2760)
- *Kowa Company, Ltd., et al. v. Apotex, Inc., et al.* (S.D.N.Y. No. 14-7934)
- *Kowa Company, Ltd., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.* (S.D.N.Y. 15-07136)
- *Takeda Pharmaceutical Co. v. Mylan, Inc., et al.,* (S.D.N.Y. No. 12-00024)
- *Mitsubishi Chemical Corp. v. Barr Laboratories, Inc.,* 718 F. Supp. 2d 382 (S.D.N.Y. 2010), *affirmed*, No. 2010-1432, 2011 WL 3288394 (Fed. Cir. Aug. 2, 2011).
- *Roquette Frères v. SPI Pharma, Inc.,* No. 06-540 (D. Del. Oct. 4, 2010)

4. In addition to my J.D. obtained from the University of Virginia School of Law, I hold a B.A. in chemistry, *summa cum laude*, from Williams College, and an M.A. in bioorganic chemistry from Harvard University, where I was a National Science Foundation Fellow. Accordingly, I am comfortable and experienced with technically and legally complex matters such as those raised in this *inter partes* review proceeding. In particular, I am experienced with technically and legally complex matters in the fields of synthetic organic chemistry and biochemistry.

5. I am familiar with U.S. Patent No. 5,856,336 (“the ‘336 patent”), its prosecution history, and the legal subject matter, technical subject matter, and prior art discussed in Petitioner’s request for *inter partes* review of the ‘336 patent.

6. I am also familiar with Livalo[®], the FDA-approved drug product for which the ‘336 patent is listed in the Orange Book.

7. I am currently serving as trial counsel in the co-pending district court litigation involving Patent Owner Nissan Chemical Industries, Ltd. (“NCI”) and Petitioners, Sawai USA Inc. and Sawai Pharmaceutical Co., Ltd (“Sawai”). That litigation involves the ‘336 patent, and I have been actively involved throughout that litigation, including investigating and analyzing infringement and validity issues raised by Sawai in connection with that litigation. In connection with my work in relation to the ‘336 patent and Livalo[®], I have become familiar with the prior art references that are the subject of this *inter partes* review proceeding. I was substantially involved with the preparation of the Patent Owner’s Preliminary Response in connection with this IPR 2015-01648 proceeding.

8. I have never been suspended or disbarred from practice before any court or administrative body, nor has a court or administrative body denied my application for admission to practice. I have not been sanctioned or cited for contempt by any court or administrative body.

9. I have read and will comply with the Patent Office Trial Practice Guide and the Board's Rules of Practice for Trials set forth in Part 42 of 37 C.F.R.

10. I agree to be subject to the United States Patent and Trademark Office Rules of Professional Conduct set forth in 37 C.F.R. §§ 11.101 et seq., and disciplinary jurisdiction under 37 C.F.R. § 11.19(a).

11. I am simultaneously applying to appear *pro hac vice* in two additional proceedings before the U.S. Patent and Trademark Office, both involving the same claims of the same '336 patent: *Sawai USA Inc. and Sawai Pharmaceutical Co., Ltd v. Nissan Chemical Industries, Ltd.*, IPR2015-01647, and *Mylan Pharmaceuticals Inc. v. Nissan Chemical Industries, Ltd.*, IPR2015-01069.

12. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

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