UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Aurobindo Pharma USA Inc. Petitioners,

v.

Andrx Labs, LLC Patent Owner

Case IPR2018-00530 U.S. Patent No. 6,790,459

PATENT OWNER'S MANDATORY NOTICES UNDER 37 C.F.R. § 42.8



PATENT OWNER MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8, Patent Owner Andrx Labs, LLC, respectfully submits the following Mandatory Notices.

I. REAL PARTY IN INTEREST

Based on the Patent Owner's current understanding, the real parties-in-interest ("RPI") are Andrx Labs, LLC, Teva Pharmaceuticals USA Inc., and Shionogi Inc. The Patent Owner continues its investigation regarding entities which should be named as RPIs and will update these Mandatory Notices if and as needed.

II. RELATED MATTERS

IPR2017-01673 challenged claims in U.S. Patent No. 6,790,459. The Decision on Institution dated December 29, 2017, denied institution and the IPR is now terminated. Additionally, the Petitioner has filed IPR2017-01648 (currently pending) challenging claims in U.S. Patent No. 6,866,866. The Patent Owner identifies U.S. Patent No. 6,866,866 patent herein for the sake of completeness and does not concede that any matters identified below involving U.S. Patent No. 6,866,866 would affect or be affected by the outcome of this proceeding.



Patent Owner is unaware of any U.S. patent applications and issued patents that relate to U.S. Patent Application No. 09/705,625, which issued as U.S. Patent No. 6,790,459.

Additionally, Patent Owner identifies the following matters that relate or may relate to U.S. Patent Application No. 09/705,630, which issued as U.S. Patent No. 6,866,866 and U.S. Patent Application No. 09/705,625, which issued as U.S. Patent No. 6,790,459:

- U.S. Patent No. 6,866,866 was a patent-in-suit in *Sciele Pharma Inc.* et al. v. Lupin Ltd., et al., 1:09-cv-00037 (D. Del. Jan. 15, 2009), which is now closed;
- U.S. Patent No. 6,866,866 and U.S. Patent No. 6,790,459 were patents-in-suit in *Sciele Pharma, Inc. et al v. Lupin Ltd. et al.*, No. 1-09-cv-00105 (D. Md. Jan. 16, 2009), which is now closed;
- U.S. Patent No. 6,866,866 was a patent-in-suit in *Shionogi Pharma*Inc. et al. v. Mylan Inc., et al., 1:10-cv-00135 (D. Del. Feb. 18, 2010), which is now closed;
- U.S. Patent No. 6,866,866 and U.S. Patent No. 6,790,459 were patents-in-suit in *Takeda Pharmaceutical Company Limited et al v*.



- Mylan, Inc. et al., No. 1-12-cv-00024 (S.D. N.Y. Jan. 3, 2012), which is now closed;
- U.S. Patent No. 6,866,866 and U.S. Patent No. 6,790,459 were patents-in-suit in *Takeda Pharmaceutical Co., Ltd., et. al. v. Mylan, Inc., et. al.*, No. 2-12-cv-00026 (W.D. Pa. Jan. 6, 2012), which is now closed;
- U.S. Patent No. 6,866,866 and U.S. Patent No. 6,790,459 were patents-in-suit in *Takeda Pharmaceutical Company Limited et al v. Mylan, Inc. et al.*, No. 1-12-cv-02038 (S.D. N.Y. Mar. 20, 2012), which is now closed;
- U.S. Patent No. 6,866,866 was a patent-in-suit in *Sciele Pharma Inc.* et al. v. Lupin Ltd., et al., No. 2012-1228 (Fed. Cir. July 2, 2012), which is now closed;
- U.S. Patent No. 6,866,866 was a patent-in-suit in *Shionogi Inc. et al.*v. Nostrum Laboratories, Inc., et al., 1:12-cv-04402 (D. N.J. July 13, 2012), which is now closed;
- U.S. Patent No. 6,866,866 and U.S. Patent No. 6,790,459 were patents-in-suit in *Shionogi Inc. and Andrx Labs, L.L.C. v. Aurobindo Pharma Ltd. et al.*, Civ. Act. No. 1:17-cv-00072-MSG (D. Del. Jan. 25, 2017), which remains pending; and



• U.S. Patent No. 6,866,866 and U.S. Patent No. 6,790,459 were patents-in-suit in *Shionogi Inc. and Andrx Labs, L.L.C. v. Qingdao Baheal Pharmaceutical Co. Ltd.*, Civ. Act. No. 1:17-cv-1347-MSG (D. Del. Sept. 22, 2017), which remains pending.

III. COUNSEL

Lead Counsel:

David L. Cavanaugh, Reg. No. 36,476

Back-up Counsel:

Jonathan B. Roses, Reg. No. 61,115

David A. Chavous, Reg. No. 66,047

David A. Giordano, Reg. No. 64,480

IV. SERVICE INFORMATION

Electronic mail addresses:

David.Cavanaugh@wilmerhale.com

Jonathan.Roses@wilmerhale.com

dchavous@chavousiplaw.com

davidg@giordanolawllc.com

Electronic service on lead and back up counsel is approved and preferred.



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