UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

LUPIN LTD. AND LUPIN PHARMACEUTICALS INC.,

Petitioner

v.

HORIZON THERAPEUTICS, LLC,

Patent Owner

Case IPR2017-01159

Patent 9,254,278

PATENT OWNER'S SUR-REPLY TO PETITIONER'S REPLY

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I. HORIZON IS NOT COLLATERALLY ESTOPPED FROM ARGUING UNPATENTABILITY

A. Lupin Ignores Precedent Requiring Exhaustion of Appeal Rights

Lupin argues that Horizon should be collaterally estopped from contesting the unpatentability of U.S. Patent No. 9,254,278 ("the '278 patent") in light of the Board's Final Written Decision ("FWD") in IPR2016-00829 regarding U.S. Patent 9,095,559 ("the '559 FWD"), now on appeal (*see* IPR2016-00829, Paper 43), and that certain findings in that FWD are entitled to preclusive effect. But, such argument fails because it ignores applicable precedent requiring the exhaustion of appeal rights before any potential preclusive effect attaches to PTAB findings.

37 C.F.R. § 42.73(d)(3) governs patent owner estoppel in an IPR and states, "A patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent: (i) A claim that is not patentably distinct from a finally refused or cancelled claim . . ." However, this rule does not support estopping Horizon here at least because, as Lupin admits, the Board has refused to use it to attach preclusion to FWDs before termination of all appeal rights. (Paper 23 at 3, n.2.) For instance, in *SDI Technologies, Inc. v. Bose Corp.*, the Board refused to bar a patent owner from raising arguments previously rejected in an IPR involving the same patent and art, finding "Rule 42.73(d)(3) does not apply . . . at least because Patent Owner's appeal rights [in the earlier IPR]

have not been exhausted." IPR2014-00343, Paper 32 at 7-10 (June 11, 2015) (The rule applies "against a party whose claim has been cancelled and not merely held unpatentable") (citing 77 Fed. Reg. 48,612, 48,625 (Aug. 14, 2012)); *ABS Global, Inc. v. XY, LLC*, IPR2017-02184, Paper 10 at 4-5 (Apr. 13, 2018). "[U]nder 35 U.S.C. § 318(b), a claim is not cancelled until all appeal rights have terminated." IPR2014-00343, Paper 32 at 9. Lupin does not even address this governing IPR rule and instead improperly focuses only on common-law collateral estoppel.

Moreover, other applicable Federal Circuit precedent shows that estoppel is improper here, where the '559 FWD remains on appeal. The sole case cited by Lupin in support of applying collateral estoppel in administrative contexts is easily distinguished from the instant facts, as it finds estoppel attached to the reversal of the PTAB's claim construction on appeal, *not* to the PTAB's unreviewed decision itself. *Nestle USA, Inc. v. Steuben Foods, Inc.*, 884 F.3d 1350, 1351-52 (Fed. Cir. 2018) (applying estoppel to reverse the same construction made in a subsequent IPR, noting the patent owner "had a full and fair opportunity to litigate the issue of claim construction during the prior appeal."); *Maxlinear, Inc. v. CF CRESPE LCC*, 880 F.3d 1373, 1375-1377 (Fed. Cir. 2018) ("[T]hose prior decisions, *having been affirmed by our court*, are binding in this proceeding, as a matter of collateral estoppel …") (emphasis added); *Apple v. Papst Licensing GMBH & Co.*, IPR2016-01863, Paper 35 at 46 (Apr. 13, 2018). Faced with this problem, Lupin asserts the

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