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Novartis AG and LTS Lohmann Therapie-Systeme AG

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVEN PHARMACEUTICALS INC.,
Petitioner

v.

NOVARTIS AG AND LTS LOHMANN THERAPIE-SYSTEME AG,
Patent Owners

Inter Partes Review No. 2014-00549

U.S. Patent 6,316,023

PRELIMINARY RESPONSE BY PATENT OWNERS PURSUANT TO 37 C.F.R. § 42.107

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Novartis AG and LTS Lohmann Therapie-Systeme AG ("Patent Owners") respectfully submit this Preliminary Response to the Petition of Noven Pharmaceuticals Inc. ("Noven") seeking *inter partes* review ("IPR") of U.S. Patent No. 6,316,023 ("'023 patent").

I. 35 U.S.C. § 315(a) Bars Noven's Petition

35 U.S.C. § 315(a) provides that "[a]n inter partes review may not be instituted if, before the date on which the petition for such a review is filed, the petitioner . . . filed a civil action challenging the validity of a claim of the patent." Noven effectively filed a civil action challenging the validity of a claim of the '023 patent before the date of its petition. Its petition thus is barred by 35 U.S.C. § 315(a).

Noven is seeking approval from the United States Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j) of the Hatch-Waxman Act to market a generic copy of Novartis's Exelon® Patch rivastigmine transdermal device, which is indicated for the treatment of mild to moderate dementia associated with Alzheimer's disease and Parkinson's disease. On April 2, 2014, Noven filed the instant petition challenging the validity of claims 1, 2, 4, 5, 7 and 8 of the '023 patent. More than one year before, and prior to February 18, 2013, Noven filed with the FDA a certification

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