UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

NOVARTIS AG,
Patent Owner

Inter Partes Review No. IPR2017-01063
U.S. Patent No. 9,006,224 B2

PETITION FOR *INTER PARTES* REVIEW OF
US PATENT NO. 9,006,224
CHALLENGING CLAIMS 1-3
UNDER 35 U.S.C. §§ 311-319 AND 37 C.F.R. § 42.100 *et seq*.

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TABLE OF AUTHORITIES

CASES

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