

Filed on behalf of Patent Owner Merck Patentgesellschaft by:

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,

Petitioner,

v.

MERCK PATENTGESELLSCHAFT,

Patent Owner.

Case IPR2018-00423

Patent 8,673,921

PATENT OWNER'S PRELIMINARY RESPONSE

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<i>In re Depomed</i> , No. 13-cv-4507, 2016 WL 7163647 (D. N.J. Sept. 30, 2016).....	30, 31, 37
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<i>In re Hellsund</i> , 474 F.2d 1307 (C.C.P.A. 1973)	24
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<i>In re Lee</i> , 277 F.3d 1338 (Fed. Cir. 2002).....	41
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