

Paper No. ____
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ACRUX DDS PTY LTD. & ACRUX LIMITED
Petitioners,

v.

KAKEN PHARMACEUTICAL CO., LTD. and VALEANT
PHARMACEUTICALS INTERNATIONAL, INC.,
Patent Owner and Licensee

Case: IPR2017-00190
U.S. Patent No. 7,214,506

PETITIONER'S REPLY TO PATENT OWNER'S RESPONSE

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TABLE OF AUTHORITIES

Cases

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<i>In re Sasse</i> , 629 F.2d 675 (C.C.P.A. 1980)	7
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<i>Pharmastem Therapeutics, Inc. v. ViaCell, Inc.</i> , 491 F.3d 1342 (Fed. Cir. 2007)	20
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