UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MALLINCKRODT PHARMACEUTICALS IRELAND LIMITED,
PETITIONER,

v.

BIOVIE, INC.,

PATENT OWNER

CASE IPR2018-00974
PATENT 9,655,945 B2

PETITIONER'S OPPOSITION TO PATENT OWNER'S CONTINGENT MOTION TO AMEND

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I. INTRODUCTION

Petitioner, Mallinckrodt Pharmaceuticals Ireland Limited ("Petitioner"), provides this Opposition to BioVie Inc.'s ("Patent Owner") Contingent Motion to Amend filed on March 7, 2019 ("PO Mot."). *See also* Paper #14 at 1 (stipulation of due date for this Reply).

Patent Owner's Motion to Amend largely repeats the arguments in the Patent Owner's Response. This is because the only substantive amendment is to amend issued claim 1 to recite what Patent Owner improperly tries to read into claim 1 through claim construction – namely treating ascites. However, the Petition already addresses how the prior art renders obvious treating ascites.

In addition, the proposed amended claims are unpatentable under 35 U.S.C. 112 for lack of written description and enablement. There is no written description supporting the proposition that administering "about 1.0 mg [of telripressin]…per day to the patient for about one day" can treat ascites. In addition, the only written description for administering terlipressin to treat ascites in non-HRS or non-hospitalized patients is a research proposal which does not enable the claims reciting those limitations.

For these reasons, the Board should deny entry of Patent Owner's Motion to Amend and find that all substitute claims 15-28 are unpatentable.

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