UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NALOX-1 PHARMACEUTICALS, LLC, Petitioner,

v.

ADAPT PHARMA LIMITED, and OPIANT PHARMACEUTICALS, INC., Patent Owners.

Case IPR2019-00699 Patent 9, 775,838

PRELIMINARY RESPONSE OF PATENT OWNERS
ADAPT PHARMA LIMITED AND
OPIANT PHARMACEUTICALS, INC.



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TABLE OF AUTHORITIES

CASES

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