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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED THERAPEUTICS
CORPORATION,

Plaintiff,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 3:14-cv-5499
(PGS)(LHG)

PLAINTIFF'S OPENING CLAIM CONSTRUCTION BRIEF

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TABLE OF AUTHORITIES

CASES

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