Filed: February 22, 2019

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC.

and

DR. REDDY'S LABORATORIES, INC.,

Petitioners

v.

HORIZON PHARMA USA, INC. and NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY,

Patent Owners.

Case No. IPR2017-01995[1]
U.S. Patent No. 9,220,698

RESPONSE TO PATENT OWNERS' MOTION TO TERMINATE

[1] Petitioner Dr. Reddy's Laboratories, Inc. ("DRL"), from IPR2018-00894, has been joined as a Petitioner to this proceeding.

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

CASES **PAGE**

OTHER AUTHORITIES

Patent Owners' motion to terminate ('698 IPR Paper 66) rests on the district court's indefiniteness finding—a finding they are appealing—and a supposed resultant inability of Mylan and Dr. Reddy's Laboratories ("Petitioners") to now prove unpatentability. Patent Owners have waived that position. Their argument should be rejected for that reason as well as their misapprehension of the law, their own patents, and the prior art. Although the patents fail to provide clear boundaries, unpatentability can still be found because the prior art does not fall near these undefined edges; it falls *dead-center* in the claims.

BACKGROUND

The '698 and '208 patents ("patents") claim methods of administering a drug formulation combining naproxen with esomeprazole. The patent claims recite steps for administering that formulation and the intended pharmacokinetic ("PK") and pharmacodynamic ("PD") results. The patents claim a particular PK/PD profile, reciting a range of PK/PD values "±20%." The claimed formulations, however, need not *produce* any particular results. Importantly, the claims require only that the ranges are "target[ed]." Thus, while a formulation actually producing the recited values may "target" the recited range, the claims also envision one merely "*target[ing]*" that range, even if one does not achieve the claimed results.

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