

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC and PAR
PHARMACEUTICAL, INC.,
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-01903
Patent 8,731,963

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

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TABLE OF ABBREVIATIONS

ACA = “Advisory Committee Art”— i.e., Exs. 1003–1006.

FDA = “U.S. Food and Drug Administration”

IPR = “*inter partes* review proceeding”

POSA = “person of ordinary skill in the art at the time of the alleged invention”

I. INTRODUCTION

U.S. Patent No. 8,731,963 (“the ’963 patent”) is directed to restricted drug distribution systems, which relate to Patent Owner’s Xyrem (sodium oxybate) drug product. The Board has already reviewed six other such restricted drug distribution patents held by Patent Owner in related IPRs 2015-00545, -546, -547, -548, -551, and -554 (the “related IPRs”), and the Board held that the claims at issue in those IPRs were obvious.¹ Patent Owner advances the *same arguments* here in its effort to preserve claims 24, 26 and 27 (the “challenged claims”) of the ’963 patent. For the same reasons as in the related IPRs, the challenged claims are obvious.

¹ *Par Pharmaceutical, Inc., et al. v. Jazz Pharmaceuticals, Inc.*, IPR2015-00548, Paper 69, at 59 (P.T.A.B July 27, 2016); *Par Pharmaceutical, Inc., et al. v. Jazz Pharmaceuticals, Inc.*, IPR2015-00546, Paper 70, at 52 (P.T.A.B July 27, 2016); *Amneal Pharmaceuticals, LLC, et al. v. Jazz Pharmaceuticals, Inc.*, IPR2015-00545, Paper 69, at 47–48 (P.T.A.B July 27, 2016); *Par Pharmaceutical, Inc., et al. v. Jazz Pharmaceuticals, Inc.*, IPR2015-00551, Paper 70, at 61 (P.T.A.B July 27, 2016); *Par Pharmaceutical, Inc., et al. v. Jazz Pharmaceuticals, Inc.*, IPR2015-00554, Paper 68, at 61 (P.T.A.B July 27, 2016); *Par Pharmaceutical, Inc., et al. v. Jazz Pharmaceuticals, Inc.*, IPR2015-00547, Paper 70, at 53 (P.T.A.B July 27, 2016).

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