UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC, PAR PHARMACEUTICAL, INC., and WOCKHARDT BIO AG
Petitioners,

v.

JAZZ PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2015-00547[1]
Patent 7,765,107 B2

PETITIONERS' REPLY TO PATENT OWNER'S RESPONSE

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[1] Case IPR2015-01820 has also been joined with this proceeding.

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TABLE OF ABBREVIATIONS

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

ACM = "Advisory Committee Meeting"—i.e., the June 6, 2001 meeting of the Peripheral and Central Nervous System Drugs Advisory Committee.

FACA = "Federal Advisory Committee Act"

FDA = "U.S. Food and Drug Administration"

IPR = "*inter partes* review proceeding"

OMI = "Orphan Medical, Inc." (predecessor to patent owner Jazz Pharmaceutical, Inc.)

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

I. INTRODUCTION

In its July 28, 2015 Institution Decision on U.S. Patent No. 7,765,107 ("the '107 patent"), the Board correctly found that the ACA was accessible to the public prior to the critical date and that there was a reasonable likelihood that the ACA rendered obvious each claim of the '107 patent. Paper No. 25 ("Decision") at 41. This is because, of course, the ACA is a public disclosure of the proposed risk management system for Xyrem—the very same system covered by the '107 patent. Faced with its own prior art, Jazz argues, with the barest of evidence, that the ACA somehow was *not* a printed publication, and that POSAs would not have been able to find it. Paper No. 46 ("Response") at 5-24. And as a last-ditch effort to save the '107 patent, Jazz argues that specific, preferred embodiments in the specification constitute limitations on the claims—something that has no basis in the patent specification, file history, or standards of claim construction. Response at 24-36. The Board should thus cancel each challenged claim of the '107 patent.

II. ARGUMENT

A. The ACA (Exs. 1003-1006) was publicly accessible prior to the critical date

As the Board noted, the key inquiry as to whether the ACA was publicly accessible as prior art is whether it "has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art exercising reasonable diligence, can locate it." Decision at 24

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