IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS LLC AND AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, and MYLAN PHARMACEUTICALS INC.,
Petitioners,

v.

ALMIRALL, LLC,
Patent Owner.

Case IPR2019-00207
Patent 9,517,219 B2

[REDACTED] PETITIONERS' SUPPLEMENTAL BRIEF ADDRESSING NEW EVIDENCE FROM ADDITIONAL DISCOVERY

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TABLE OF CONTENTS

INTRODUCTION

Dr. David Osborne is the ***only*** Almirall expert has alleging unexpected results in this proceeding. Dr. Osborne's ***only*** evidence and basis for alleging unexpected results is the declaration submitted by co-inventor Dr. Kevin Warner during prosecution (the "Warner Declaration" AMN1017, 289-293). EX2057, ¶¶173-194 (citing AMN1017, 289-293). Dr. Osborne has no personal knowledge of the experiments Dr. Warner described. AMN1040, 76:23-82:8, 108:11-15; AMN1043, ¶¶70-71. Nor did Dr. Osborne know who actually conducted the testing or what their level of skill was. *See* AMN1040, 107:15-108:15. Importantly, Dr. Osborne conceded that he would have liked to have had additional information about the Warner Declaration. *See* AMN1040, 108:11-15.

Accordingly, Petitioner Amneal tried for months to secure Dr. Warner's deposition in this IPR, which Almirall repeatedly refused, until his deposition was ordered by the Board. Paper 39, 8-9. Even then, Almirall failed to comply with that order. Paper 44, 2-3. Dr. Warner was, however, previously deposed in a related district court litigation, *Almirall LLC v. Taro Pharmas. Indus. Ltd.*, 17-663 (D. Del.), (the "*Taro* action") involving the '219 patent at issue here.

After Amneal finally received the *Taro* action transcript, the reason for Almirall's steadfast refusal to make Dr. Warner available and to produce his litigation transcript soon became apparent. Dr. Warner made critical admissions in the *Taro* action that (1) further confirm Petitioner Amneal's obviousness case and

(2) entirely disproves any unexpected results alleged by Almirall and Dr. Osborne.

These admissions are additional reasons the Board should find that the '219 patent's claims are unpatentable as obvious.

I. DR. WARNER'S *TARO* ACTION TESTIMONY FURTHER CONFIRMS THE '219 PATENT IS *PRIMA FACIE* OBVIOUS.

At his deposition in the *Taro* action, Dr. Warner provided critical admissions that support Amneal's obviousness case and undercut Almirall's defenses. [redacted]

Dr. Warner's approach is precisely what the prior art taught. As Dr. Michniak-Kohn explained, Garrett taught that an amount between 5% and 10% w/w dapsone could be used once- or twice- daily. AMN1043, ¶19; AMN1004, 12:20-30. Further, Dr. Michniak-Kohn explained that because the prior art Aczone Gel 5% product was administered twice-daily, a POSA would have been motivated

to optimize to once-daily dosing. AMN1043, ¶19. [redacted] This testimony shows that a POSA would have been motivated to use amounts of ethoxydiglycol greater than 25%, defeating Almirall's assertion of teaching away. [redacted] As explained by Dr. Michniak-Kohn, these qualities of Sepineo were all previously known in the art from at least Nadau-Fourcade (AMN1005, 48:5-9), Bonacucina (AMN1015, 2, 7), the Sepineo brochure (AMN1026, 1), and Andersson (AMN 1055, 4). Dr. Michniak-Kohn also explained that these qualities would have motivated a POSA to use Sepineo. AMN1043, ¶¶55-69. Thus, Dr. Warner's testimony confirms a POSA's reasons to select Sepineo as a thickener. [redacted]

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