UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

CIPLA LTD.,
Patent Owner

CASE IPR2017-00807
Patent 8,168,620

CIPLA LTD.'S
MOTION FOR OBSERVATIONS ON CROSS-EXAMINATION OF PETITIONER'S REPLY WITNESSES: DR. ROBERT SCHLEIMER, DR. MAUREEN DONOVAN, AND JOHN C. STAINES, JR

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Patent Owner Cipla Ltd. ("Cipla") deposed Petitioner's reply witness, Dr. Maureen Donovan, on March 27, 2018, and files concurrently the deposition transcript and a previously unfiled exhibit as exhibits CIP2178 and CIP2177, respectively. Cipla deposed Petitioner's reply witness, Dr. Schleimer, on March 30, 2018, and files the deposition transcript concurrently as Exhibit CIP2179. Finally, Cipla deposed Petitioner's reply witness, Mr. Staines, on April 4, 2018, and files concurrently the deposition transcript as Exhibit CIP2180 and a previously unmarked exhibit that was marked by Petitioner as EX1171. Cipla files its Motion for Observations on Cross-Examination in accordance with Due Date 4 (Paper 36, 1). All emphasis is added unless otherwise noted.

I. Observation #1: Dr. Schleimer previously offered no evidence of a motivation to combine the four references listed in Ground 3.

In CIP2179, at 27:9-32:18, Dr. Schleimer testified that, with the exception of water, he "did not" discuss in his reply declaration (EX1144) any of the limitations in claims 42-44, *i.e.*, the claims of Ground 3. Dr. Schleimer further confirmed that footnote 1 of EX1144 is his sole response to Dr. Carr's testimony that Dr. Schleimer's first declaration (EX1003) failed to mention claims 42-44 or any motivation to combine the references of Petitioner's Ground 3. This testimony is relevant to Dr. Schleimer's obviousness conclusions pertaining to claims 42-44 and Petitioner's arguments because it undercuts their position that a motivation existed in 2002 for a person of ordinary skill to combine the art cited in Ground 3.

EX1144, ¶5, n.1; Reply, 15-18.

II. Observation #2: Petitioner and its declarant did not agree on the closest prior art.

In CIP2179, at 42:17-44:17, Dr. Schleimer, when asked if Cramer and Segal are the closest prior art, testified, "[n]o, that's not correct" but that he "was convinced that from a legal perspective that Segal and Cramer are perhaps more persuasive to a patent board than my view." This testimony is relevant to Dr. Schleimer's obviousness conclusions and Petitioner's arguments because it undercuts Dr. Schleimer's credibility and undermines his conclusions that Dymista® does not exhibit unexpected results compared to the closest prior art. EX1144, ¶¶52-60; Reply, 18-23. This is also relevant to the weight and credibility the Board should afford Dr. Schleimer's testimony.

III. Observation #3: Dr. Schleimer testified that multiple authors concluded that co-administration of antihistamines and steroids yielded no clinical benefit.

In CIP2179, at 58:3-74:15, Dr. Schleimer testified regarding the various co-administration studies he cited, as well as meta-analyses published before the invention date. He testified that Howarth (CIP2041) concluded that there was no "clinical benefit" to co-administration. He also testified that Nielsen (CIP2042) found that "[c]ombining antihistamines and intranasal corticosteroids in the treatment of allergic rhinitis does not provide any additional effect to intranasal corticosteroids." This testimony is relevant to Dr. Schleimer's obviousness

conclusions and Petitioner's arguments because it undermines Dr. Schleimer's credibility by contradicting his testimony regarding the views of skilled artisans before the invention date and further undermines his conclusions regarding how a POSA would interpret the co-administration studies he cites. EX1144, ¶¶ 10-39, 52-86; Reply, 3-10, 18-23.

IV. Observation #4: The clinical efficacy of co-administered azelastine and fluticasone was surprising in 2008.

In CIP2179, at 8:5-13, 80:15-19, and 93:9-98:12, Dr. Schleimer testified the authors of Ratner 2008 (EX1045) had concluded that co-administration of azelastine and fluticasone "produced an unanticipated magnitude of improvement in rhinitis symptoms." This testimony is relevant to Dr. Schleimer's obviousness conclusions and Petitioner's arguments because it undercuts Dr. Schleimer's conclusions regarding the clinical efficacy a POSA would have expected on the invention date because it confirms the independent views of skilled artisans years after the date of invention. EX1144, ¶¶ 52-67, 83-86; Reply, 18-21.

V. Observation #5: A POSA could not have known about Han and Corren "unless they had a time machine."

In CIP2179, at 103:13-104:6 and 107:4-109:13, Dr. Schleimer testified that he could not find any data from before the priority date to support a fast onset of azelastine, so he cited Han (EX1148) and Corren (EX1160). He further explained that a POSA as of the invention date could not have been aware of the data

conveyed in those two references "unless they had a time machine." This testimony is relevant to Dr. Schleimer's obviousness conclusions and Petitioner's arguments because Dr. Schleimer's reliance on post-invention publications to support his reading of onset undermines Dr. Schleimer's conclusion that POSA in 2002 would have expected Dymista®'s onset of action. EX1144, ¶¶68-73; Reply, 21-22.

VI. Observation #6: Dr. Donovan previously believed that sodium chloride and dextrose were obvious tonicity adjustors to use in an azelastine hydrochloride/fluticasone propionate combination formulation.

In CIP2178, at 46:7-55:6 and 56:20-57:14, Dr. Donovan stood by her trial demonstratives from the related proceedings before the the District Court for the District of Delaware that her trial demonstratives (*see* CIP2177) that "list as an obvious tonicity adjuster to use—to include in this combination formulation, dextrose and sodium chloride." According to Dr. Donovan, in CIP2178, at 58:17-59:4, "they [sodium chloride and dextrose] were all materials that – that were identified as obvious materials to include in a combination formulation" of azelastine hydrochloride and fluticasone propionate. Dr. Donovan's direct testimony demonstratives from the related proceeding are filed concurrently as CIP2177. CIP2177 and the above cited testimony in CIP2178 are relevant to Dr. Donovan's obviousness conclusions and Petitioner's Reply arguments because they directly contradict her testimony in the present proceeding that a POSA would

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