UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

Case No. IPR2017-00807

U.S. Patent No. 8,168,620

PATENT OWNER'S REPLY TO OPPOSITION TO MOTION TO EXCLUDE EVIDENCE

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I. Petitioner's objective indicia response was not timely.

In view of the Board's admonition to "develop a more complete record during trial," Paper 11, 24, Cipla's discovery revealed that Petitioner and its declarants knew of Cipla's objective indicia arguments and evidence before filing its Petition, but did not address them for "strategic reasons." *See* Paper 43 at 9-10; POR at 53-55. Petitioner doesn't dispute this. Without an opportunity to substantively respond, Cipla is prejudiced.

Petitioner's sole rebuttal—that it could not access many of the documents Cipla relied upon in the Apotex trial—belies the facts. Almost all of these documents were publicly available from peer-reviewed journals that Petitioner could find using the public exhibit list from trial. CIP2017, 257-354. Even so, Petitioner could have addressed the publicly available arguments and evidence, but failed to meet that low threshold. *cf. Amneal Pharm. Inc. v. Supernus Pharm. Inc.*, IPR2013-00368, Paper 2, at 47-48 (June 20, 2013). In any event, EX1174 shows that Petitioner didn't contact the Court until February **2018**, which does not show unavailability in February **2017** when the Petition was filed.

II. Petitioner's Reply and EX1145 Should be Excluded.

Petitioner claims that its new arguments and evidence are meant to "counter arguments raised in the POR." Opp. at 6. But that is not what occurred in Petitioner's Reply or EX1145. The Petition and Dr. Donovan's first declaration

(EX1004) offered only broad, non-specific motivations for why a POSA would use the excipients recited in claims 42-44. Pet., 42; EX1004, ¶¶ 57-68. Cipla deconstructed these arguments, so Petitioner belatedly offered in its Reply and EX1145 new motivations for a POSA to use those same claimed excipients.[1] That Cipla overcame Petitioner's and Dr. Donovan's original motivations in the POR is not a license to offer brand new motivations in Reply when those new motivations could, and should, have been raised in the Petition. Allowing Petitioner to inject these new arguments in Reply renders meaningless 37 C.F.R. § 42.23(b).

Petitioner and Dr. Donovan raised Dr. Govindarajan's non-confidential testing (CIP2030) in Reply as "support[ing]" an expectation of success. EX1145, ¶¶30-40. That is a far cry from rebutting Cipla's reliance on this same information, which Dr. Donovan attempted separately. EX1145, ¶¶41-49.

Finally, the Federal Circuit has implicitly endorsed inclusion of Rule 42.23(b) arguments in motions to exclude. *See Genzyme Therapeutic Prods. Ltd. Partnership v. Biomarin Pharm. Inc.*, 825 F.3d 1360, 1368-69 (Fed. Cir. 2016).

III. Certain cross examination testimony was outside the scope.

Petitioner's *post hoc* justifications for claiming that certain testimony from

[1] Petitioner's attempt to connect its general disclosure of glycine's "humectant" properties to its new "comfort" argument is untimely and impermissible in a motion to exclude.

Drs. Carr and D'Addio was within the scope of their declaration fails. First, Petitioner concedes that Dr. Carr didn't raise the issue of his Astelin and Flonase prescribing habits in his declaration. Petitioner also implies that Dr. Carr's testimony was directed to whether co-administration of Astelin and Flonase provided a meaningful benefit. But nowhere in EX1142, 6:8-11:15, did Petitioner question Dr. Carr about such a meaningful benefit.[2] Nor did Dr. Carr's declaration mention his Dymista® prescribing habits. And the relationship between Dr. Carr's prescribing habits and Dymista®'s status as the "gold standard" is tenuous at best, especially in view of Dr. Carr's testimony that poor insurance coverage often prevents more patients from receiving Dymista®. EX1142, 114:16-115:4; 117:3-11; 117:18-118:7.

As for Dr. D'Addio's testimony, Petitioner makes no attempt to justify how Meda's development work with orally administered non-allergy drugs was within the scope of Dr. D'Addio's narrowly focused testimony on the facts surrounding Meda's azelastine/fluticasone nasal spray formulation work, except to say that it is "relevant." This testimony is therefore out of scope.

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[2] Petitioner gratuitously adds to the record by asserting "why would Dr. Carr have regularly prescribed such a combination?" The answer is: "[t]he practice was not to administer [Astelin and Flonase] together." CIP1142, 6:21-7:4.

IV. EX1171 should be excluded.

Petitioner failed to respond to several bases for exclusion—that EX1171 was (1) substantive testimony belatedly filed after the deadline to do so, (2) taking Petitioner's viewpoint that the revisions in EX1171 are "clerical," not relevant because the revisions "don't affect the opinions or evidence," and (3) not properly introduced on redirect—and therefore has waived them. *See* Paper 43, 13-15. Petitioner's only substantive rebuttal—that citation to 37 C.F.R. § 42.53(d)(3) was improper—bolsters Cipla's grounds for exclusion. If EX1171 was not direct evidence, as Petitioner argues, then it could only have been properly entered on redirect (it was not). As for prejudice, an additional hour of examination does not offset the need to restrategize Mr. Staines's deposition and review at least 237 additional pages of exhibits in the last few hours of the one day Mr. Staines was available for deposition. *See* CIP2180, 167:8-15.

V. EX1055 and Paragraphs 53-43 of EX1144 should be excluded.

Petitioner doesn't dispute that (1) Cipla timely objected to EX1055 as incomplete, and (2) EX1055 obscures much of the underlying document. This missing information is important because that the obscured information likely contradicts Petitioner. In fact, Dr. Schleimer conceded that "Dr. Accetta's records actually frequently said 'take as needed'" (*See* CIP2179, 94, 4-7), which, as Dr. Carr explained, is wholly inconsistent with a fixed-dose combination formulation

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