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 MOTION TO EXCLUDE PETITIONER'S EVIDENCE UNDER 37 C.F.R. § 42.64

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I. INTRODUCTION AND STATEMENT OF RELIEF REQUESTED

Pursuant to 37 C.F.R. §§ 42.62 and 42.64(c), Patent Owner moves to exclude from the record inadmissible evidence submitted by Petitioner. Specifically, the Board should exclude Exhibits 1014, 1026-1032, 1034-1044, 1047-1049, 1051, 1052, 1054-1139, 1148-1150, 1152, 1153, 1159-1164, 1168, and 1171. In addition, the following paragraphs of Petitioner's expert declarations should be excluded: (1) paragraphs 1-11, 13-17, 21, 24-31, 42-44, 53, 55, 56, 62, 69-71, 77, 84-90, 95, 96, and 104-115 of EX1003; (2) paragraphs 1-13, 16-20, 27, 32-34, 40-42, 44-49, 59, and 72-77 of EX1004; (3) paragraphs 1, 20, 26, 32, 38, 41, 50, 56-66, 75-85, 87-111, 113, 114, 119, 120, 123, 124, 126, 130, 131, 133, 137-139, 142, 146, 149, 151-153 of EX1140; (4) exhibits 1, 2a, 5, and 7 of EX1140; (5) paragraphs 1-6, 10, 16, 42-44, 46-48, and 52-95 of EX1144; and (6) paragraphs 1-6, 12-17, 22, 23, 53, 54, 59-66, 68-70, and 72-84 of EX1145[1] because none of the above are cited in the Petition or Reply.

It is not enough for the Board to find that this Motion is moot if the Board does not rely on the inadmissible evidence in reaching its Final Written Decision. If the exhibits identified above remain in the record, Petitioner could continue to

[1] All objections to EX1145 apply equally to EX1165 because EX1165 is the public version of EX1145.

rely on them on appeal to the Federal Circuit, and Patent Owner would be unfairly forced to address them again.

Significant portions of the evidence submitted by Petitioner in support of its Petition and Reply should be excluded. For example, Petitioner relies on EX1055 as proof of the co-administration of azelastine and fluticasone before the invention date, but this exhibit: (1) is heavily modified; (2) was available to Petitioner before it filed its Petition, and thus is untimely; and (3) relies on a document that is, by definition, not a printed publication. Similarly, at pages 19 and 25 of its Reply, Petitioner relies on EX1037—purportedly, a "Carr" article—which is neither identified in its Exhibit List nor has it been entered in the record in this proceeding.

Petitioner also improperly attempts to use its Reply and reply declarations to cure the numerous deficiencies in its Petition. For example, Petitioner's formulation expert, Dr. Donovan, submitted new motivation arguments in her reply declaration. Her new testimony regarding selection of certain excipients and avoidance of others is (1) nowhere to be found in her original declaration; and (2) contradictory to her previous testimony in the related Apotex litigation.

The exhibits identified below should be excluded for the reasons that follow.

II. EX1055 AND ¶¶53-54 OF EX1144 SHOULD BE EXCLUDED UNDER FRE 801-802, AND 1002 AND 35 U.S.C. § 331(b).

Patent Owner moves to exclude EX1055 and paragraphs 53 and 54 of

EX1144. EX1055 is purportedly a patient record, but on its face, EX1055 is not the actual patient record but a modified imitation of it. First and foremost, as a doctor's patient record is subject to HIPAA confidentiality laws, so the underlying record is not a printed publication at the time of the invention. Petitioner has made no effort to show that this document, or the underlying source, was publicly available before the invention date.

FRE 1002 mandates that an "original writing, recording, or photograph is required in order to prove its contents unless these rules or a federal statute provides otherwise." The original (or at least an unmodified copy of it) is available from the prescribing clinician, Dr. Donald Accetta, or from the District Court for the District of Delaware, where it was entered into evidence *not* under seal. Petitioner, however, failed to submit the original record, or an unmodified copy, despite its availability.

Petitioner's failure to provide the original patient record is meaningful because Petitioner questioned Dr. Carr on EX1055 during his deposition but Dr. Carr repeatedly had difficulty testifying about EX1055 given the clear modifications from the original. EX1142, 13:6-7 ("Do you actually have the full document for me to review so that I can appropriately comment on it?") *and* 14:2-4 ("Well, perhaps, if I may, I could try to read the document behind rather than just what you've highlighted."). Even Petitioner's expert agreed that the modifications

impacted the ability to see the original content. CIP2179, 9:21-10:3 ("That's correct. It covers the writing underneath.").

Because EX1055 is not an original document, it is also double hearsay. Petitioner's reliance on EX1055 is not based on what EX1055 itself says, but instead relies on the out-of-court statements in the underlying, original patient record portrayed in EX1055. Petitioner and its declarant, Dr. Schleimer, rely on this document for the truth of the matter asserted, *i.e.*, that physicians did, in fact, co-prescribe azelastine and fluticasone before the invention date. EX1144, ¶¶53-54; Reply, 19. Petitioner has not shown that any exceptions apply under FRE 803 or that the residential exception under FRE 807 applies here.

Patent Owner timely objected to EX1055 both at Dr. Carr's deposition and in response to Petitioner's Reply. *See* EX1142, 12:21-22; Paper 32, 7. Accordingly, EX1055 should be excluded on either of these grounds.

III. EX1037 SHOULD BE EXCLUDED BECAUSE IT VIOLATES 37 C.F.R. § 42.63(a) AND (e).

Petitioner never submitted EX1037, and therefore it should be excluded. The entry for EX1037 in the Exhibit List submitted with the Petition was blank. Patent Owner timely raised this issue. *See* Paper 14, 3-4. The entry for EX1037 in Petitioner's current Exhibit List (served on March 27, 2018) is still blank. But Petitioner's Reply (pp. 5-7, 19-22, 25) and EX1144, ¶¶16, 42, 61-63, 66-67, 77-79,

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