

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ARGENTUM PHARMACEUTICALS LLC,
Petitioner

v.

CIPLA LTD.,
Patent Owner.

Patent No. 8,168,620
Issue Date: May 1, 2012
Title: COMBINATION OF AZELASTINE AND STEROIDS

Inter Partes Review No.: IPR2017-00807

**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO
EXCLUDE PETITIONER'S EVIDENCE UNDER 37 C.F.R. § 42.64**

I. Introduction

Petitioner opposes Cipla's motion to exclude certain evidence (Paper 41, hereafter "Mot."). In sum, Cipla's motion fails to identify any rule or statutory basis for the requested exclusions, and similarly fails to identify any prejudice.

II. EX1055 and ¶¶ 53 and 54 of Dr. Schleimer's Second Declaration (EX1144) Should Not Be Excluded

Exhibit 1055 is an excerpted demonstrative slide from the *Apotex* trial. It is the only such record that is available to Petitioner. The sponsoring witness at trial, Dr. Accetta, described the underlying, original patient record (DTX-2) in great detail during the *Apotex* trial, and Cipla had ample opportunity to cross-examine him on this document. *See* EX2018, 48:11-50:17 (direct testimony); 62:14-65:4 (cross-examination). The trial court then allowed exhibit DTX-2 into evidence. *Id.* at 58:21. Despite this, the original patient record underlying EX1055 remained unavailable to Petitioner, contrary to Cipla's contention (Mot., 2-3). First, the District Court denied a request for copies of the *Apotex* trial exhibits. EX1174 (Decl. of Tyler Liu), ¶ 2. Petitioner then requested a copy of the exhibit from Cipla, but Cipla refused. *See* EX1175 (Email From Adam LaRock to Michael Houston). Because EX1055 is the only evidence of the patient record available to Petitioner, it should not be excluded, especially where Cipla has the underlying document.

As for timeliness, Cipla fails to identify any reason why EX1055 is not

proper reply evidence.¹ *See* Mot., 2. Exhibit 1055 is responsive at least to Dr. Carr’s opinions that the closest prior art is monotherapy, ignoring the prevalent practice in the art of co-prescribing the two drugs together. *See* EX1144, ¶¶ 53-54.

As for relevance, which is already waived,² Cipla misstates Dr. Schleimer’s use of the exhibit; his declaration identifies EX1055 to support the fact that “[c]onjunctive use of a fluticasone propionate nasal spray and an azelastine hydrochloride nasal spray was confirmed in the prior *Apotex* trial” well before the filing date of the ’620 patent. *See* EX1144, ¶53. Dr. Schleimer is not advancing EX1055 as a printed publication, but instead as evidence to show that doctors did in fact co-prescribe azelastine and fluticasone for adjunctive administration well before the priority date, thus corroborating his testimony regarding the prior art.

Turning next to Cipla’s arguments based on FRE 1002, Cipla offers no explanation of how “modification” of the underlying patient record to focus in on

¹ This scope argument is improper in a motion to exclude. *See* section IV, below.

² EX1055 was first served on Cipla at the deposition of Dr. Carr on Feb. 7, 2018.

Cipla did not make a relevance or hearsay objection, so both have been waived.

See Office Trial Practice Guide, 77 Fed. Reg. 48,756, 48,772 (Aug. 14, 2012).

Cipla’s later filed objections of Mar. 13, 2018 – more than 5 business days after initial service – are untimely as to this exhibit. *See* 37 C.F.R. § 42.64(b)(1).

the details relating to co-administration actually affects the probative value of the exhibit. *See* Mot., 3. The fact that Dr. Carr did not have access to the original patient record during his deposition is not a reason to exclude EX1055, as Dr. Carr was an expert witness in the *Apotex* trial and had *more* access to the original patient record than Petitioner. EX1142, 11:22-12:8 (“I was there for pretty much the whole trial...I do remember [Dr. Accetta] testifying.”).

Regarding hearsay, another waived objection, the crux of Cipla’s argument is that Dr. Schleimer “relies on the out-of-court statements in the underlying, original patent record portrayed in EX1055.” Mot., 4. As a patient record, the original underlying document falls within the exception of FRE 803(4) – “Statement Made for Medical Diagnosis or Treatment.” Here, the statement in the original document was “made for—and is reasonably pertinent to—medical diagnosis or treatment” and “describes medical history; past or present symptoms or sensations; their inception; or their general cause.” FRE 803(4). As for the “second level” of hearsay resulting from EX1055 not being the original document itself, there are no allegations of actual modification of any of the text from the original patient record. That is, Cipla does not contend that the portions of the original patient record shown in EX1055 are anything but that—a copy of at least a portion of the actual record. Thus, this is not a hearsay-within-hearsay situation. Even if it were, because the underlying document is just being reproduced, it “has

equivalent circumstantial guarantees of trustworthiness” and otherwise meets subparts (2)-(4) of FRE 807. *See* FRE 807; 805 (exception of hearsay within hearsay).

Further, EX1055 has non-hearsay relevance in terms of corroborating Dr. Accetta’s trial testimony regarding the original patient record, DTX-2, and his prescribing practices in general. That testimony is the primary evidence Petitioner relies on for the underlying facts, as supported by Dr. Schleimer. *See* EX1144, ¶ 41; EX1170, ¶ 2.

As for any prejudice to Cipla, there can be none at least because Cipla itself put Dr. Accetta’s testimony in evidence in this proceeding, and Cipla was a party in the *Apotex* trial where EX1055 was used, and where the original patient record, DTX-2, was admitted into evidence. Cipla also had ample opportunity to cross-examine Dr. Accetta at deposition and during the trial. There simply can be no surprise or prejudice in connection with EX1055.

As for declaration paragraphs 53 and 54, Cipla seeks to exclude them wholesale even though their content does not exclusively rely on EX1055. *See e.g.*, EX1144, ¶ 53 (discussion of closest prior art); ¶ 54 (discussion of Dr. Carr prior admissions). In any event, FRE 703 allows Dr. Schleimer to rely on the contents of EX1055, even if it suffers from the evidentiary flaws alleged by Cipla.

III. EX1037 Should Not Be Excluded

No exhibit numbered 1037 was cited in the Petition, and 1037 was not a

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