

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

designated exhibit number at that time; thus, Cipla's sole objection relating to that exhibit (*i.e.*, that it was an exhibit not described in the exhibit list and not filed) was unfounded and there could not have been any correction made at that time. At the reply stage, an article co-authored by Cipla's own expert, Dr. Carr, was designated as EX1037 and was then cited in Petitioner's Reply and Dr. Schleimer's second declaration (EX1144). However, Cipla failed to raise any objection to EX1037 or to portions of the Reply and declaration that cited to it. *See* Paper 32. Thus, the objections Cipla raises now are waived. *See* 37 C.F.R. 42.64(b)(1).

An error did occur during Petitioner's reply filing, such that EX1037 and EX1043 (another exhibit introduced for the first time on reply) were inadvertently not filed along with the Reply, which error was the result of confusion caused by using the lower exhibit numbers for these two exhibits. Concurrent with this filing, Petitioner is filing these two exhibits and an updated exhibit list providing a description and an indication these two exhibits have been filed. Petitioner regrets the filing oversight that occurred, but has now remedied the error.

In any event, Cipla cannot claim any prejudice regarding EX1037, as it is clearly identified in Dr. Schleimer's second declaration (EX1144, ¶ 90) in relation to Cipla's own EX2052 which itself cites EX1037. Dr. Schleimer even provides a quote *directly* from EX1037. EX1144, ¶ 90. And, EX1037 was also discussed during the *Apotex* trial during Dr. Carr's direct testimony. *See* EX2021, 538:10-

540:8. Given that EX1037 is a paper that Dr. Carr himself authored, there cannot be any surprise regarding EX1037, and Cipla clearly has a copy of it. Also, Cipla could have asked counsel for Petitioner or questioned Dr. Schleimer about the identity of this document if there were any confusion, but Cipla did not once ask about the exhibit, apparently content to sit on its earlier objections directed to exhibits that were nonexistent at the time. EX1037 should not be excluded.

IV. Petitioner’s Reply and Dr. Donovan’s Second Declaration (EX1145) Are Correctly Limited to Proper Reply Evidence and Argument

The Board has held that “[a] motion to exclude is neither a substantive surreply, nor a proper vehicle for arguing whether a reply or supporting evidence is of appropriate scope.” *Kyocera Corp. v. Softview LLC*, IPR2013-00007, Paper 51 at 34 (PTAB March 27, 2014). Yet here, Cipla’s motion does just that, seeking to exclude because “Petitioner and its declarant Dr. Donovan improperly supplement their obviousness arguments” and that “[t]hese arguments and evidence are newly raised to purportedly support obviousness and were available to Petitioner and Dr. Donovan at the time the Petition was filed.” Mot. 5, 7. These assertions are improper for a motion to exclude and should not be considered.

Further, the Federal Circuit has explained that a Petition is not required to preemptively address every possible argument, and that a Reply may counter arguments raised in the POR. *See Idemitsu Kosan Co., Ltd. v. SFC Co. Ltd.*, 870 F. 3d 1376, 1380-81 (Fed. Cir. 2017). This is precisely what Petitioner has done in

connection with its proper reply expert evidence, which is responsive to Cipla's Response; each bullet point at page 6 of the Motion is addressed below:

1) As discussed in her first declaration, it was well known to a POSA in 2002 that multi-dose nasal spray formulations must be preserved against microbial contamination. EX1004, ¶52. In addition, Dr. Donovan's discussion in ¶¶60-66 is responsive to Cipla's assertion that there was no design need or market pressure to use the claimed three-preservative combination (POR at 41-44).

2) The citation to *Remington's* is responsive to Cipla's assertions that a POSA would not focus on EDTA, BKC, and phenyl ethyl alcohol ("PEA") (POR, 41-44; EX2150, ¶¶53-54), and that preservatives would be avoided all together based on Segal (*id.*, ¶ 52). *Remington's* is cited in Segal (EX1012, 4:1-3), and Dr. Donovan uses it to illustrate why a POSA would have limited their preservative options, while finding EDTA, BKC, and PEA very promising (EX1145, ¶¶60-66).

3) Dr. Donovan's discussion of EDTA's chelating properties as further motivation for its use is responsive to Cipla's argument that a POSA would not have been motivated to use EDTA (*id.*) as well as Dr. Smyth's assertion that a POSA "would not have had a good reason" to include EDTA in a nasal spray suspension (EX2150, ¶ 54).

4) Dr. Donovan's assertions regarding the use of sodium chloride and dextrose as tonicity agents respond to Dr. Smyth's assertion that there was a "clear

preference in the art for sodium chloride and dextrose” and that “there was no reason for a POSA to pursue glycerin” (EX2150, ¶¶ 56, 58), as well as Cipla’s assertion that there was no “good reason to pursue glycerine” (POR at 46).

5) In the Petition and in Dr. Donovan’s first declaration, the use of glycerine as a humectant and the use of humectants to provide nasal formulations comfortable for the use is expressly described. Pet. at 44; EX1004, ¶¶ 56, 72. Because humectants “effect moisturization” (EX1004, ¶ 56, EX1012, 4:8-10) among other things, Dr. Donovan’s assertion is not new to the Reply. Petitioner and Dr. Donovan’s discussion of using glycerine to add to the comfort of a nasal spray is also responsive to Cipla’s assertion that a POSA would not have been motivated to use glycerine (POR at 3, 40, 44-46; EX2150, ¶ 55).

6) Dr. Donovan’s discussion of Dr. Govindarajan’s successful examples (which were submitted by Cipla to begin with) is directly responsive to Cipla and Dr. Smyth’s false assertion that those examples “failed” and were “(i) unacceptably acidic; (ii) unstable, leading to significant caking of azelastine; and (iii) unable to consistently deliver proper doses” (POR at 34; EX2150, ¶¶ 37-41).

Not only is none of the foregoing inconsistent with Dr. Donovan’s trial testimony, even if it were that would not justify exclusion from the proceeding. Thus, neither the portions of Dr. Donovan’s second declaration identified by Cipla nor Petitioner’s Reply are improper.

V. Evidence Need Not Be Cited In Papers To Remain In The Record

The Board has held that “[i]t is better to have a complete record of the evidence submitted by the parties than to exclude particular pieces of evidence.” *Biomarin Pharm. Inc. v. Genzyme Therapeutic Prods. L.P.*, IPR2013-00537, Paper 79 at 25 (PTAB February 23, 2015). With that policy in mind, while certain of Petitioner’s exhibits are not referenced directly in the Petition or the Reply, the vast majority of the exhibits identified by Cipla that were not intentionally blank or a public version of another exhibit are cited in at least one of Petitioner’s expert declarations (112 of 117).³ Further, Cipla’s motion provides no explanation of how the Board would be prejudiced by the identified exhibits, particularly given their content such as EX1014 (a U.S. patent publication), EX1051 (Dr. Schleimer’s CV), and EX1139 (Mr. Staines’ CV). *See Hughes Network Systems, LLC, et al. v.*

³ Exhibits 1062-63, 1080, and 1086 were provided by Mr. Staines, but were ultimately not cited in his declaration (a copy of his CV (EX1139) is appended to Mr. Staines’ declaration). However, exhibits 1030-31, 1034-43, 1047, 1051, 1055, 1148, 1150, and 1159-1164 were cited by Dr. Schleimer; exhibits 1014, 1027, 1048-49, 1052, 1054, 1056, 1149, 1152-53, and 1168 were cited by Dr. Donovan; and exhibits 1057-61, 1064-1079, 1081-1085, 1087-1138 were cited by Mr. Staines. Exhibits 1026, 1028-29, 1032, and 1044 were intentionally left blank/unused. Exhibit 1165 is simply a public version of 1145.

Cal. Inst. of Tech., IPR2015-00059, Paper 42 at 40 (PTAB April 21, 2016)

(denying motion to exclude where “the listed exhibits are all discussed, relied upon and cited either in the Petition, Reply or supporting declarations” and where movant had failed to identify any prejudice).

The fact that certain paragraphs of the expert declarations are not cited in the Petition or the Reply also does not support their exclusion from the record.⁴ This is demonstrated by their actual content, such as paragraphs 1-11 of EX1003 – Dr. Schleimer’s first declaration – which describes his retention and expert qualifications. Similar to the non-declaration exhibits, Cipla only cursorily addresses alleged irrelevancy and lack of probative value, and fails to identify any actual prejudice, which the Board has found insufficient to support exclusion from the record. *See Cisco Systems, Inc. v. TQ Delta, LLC*, IPR2016-01760, Paper 35 at

⁴ Cipla misrepresents the record regarding many of the challenged expert declaration paragraphs. Mot., 7-8. For example, paragraph 53 of EX1003 is cited in the Petition at page 37. A listing of all such citations is as follows: ***Petition:***

EX1003, ¶¶53(37), 55(37), 70(36), 84(37,43), 88-90(56), 95(56), 115(40);

EX1004, ¶¶27(12,14), 41(49), 44-45(23), 59(18,45,47); ***Reply:*** EX1003, ¶¶53(8),

62(8), 84-90(6); EX1004, ¶¶27(15), 32(2,15), 34(15), 59(10); EX1140, ¶¶50(25),

114(25), 137(27), 149(26); EX1144, ¶¶53-54(19), 72-73,78,80(21-22); EX1145,

¶¶22-23(10-12,17), 53-54(10-11,17), 59(17), 72(17-18), 73,78,80,81(26).

42 (PTAB March 12, 2018) (“We are not persuaded by Patent Owner’s cursory argument that evidence not cited in Petitioner’s Reply is irrelevant or lacks probative value outweighed by its prejudice.”). Similarly, Cipla has failed to explain how the uncited paragraphs would result in confusion, delay, or wasted time, and would not instead just cause confusion by selectively excluding some paragraphs from the declarations for no apparent benefit. *See id.*

Lastly, as to the allegations regarding page lengths and incorporation by reference, the Board has previously held that “not every statement made by an expert need be repeated in a brief to avoid incorporation by reference; otherwise, separate expert declarations would be unnecessary.” *Sumitomo Elec. Indus., Ltd. v. United Technologies Corp.*, IPR2017-00966, Paper 7 at 11 (PTAB Sept. 13, 2017). The Board has also recognized that uncited portions of expert declarations can provide context and support for testimony elsewhere in the declaration. *See Google Inc. v. Intellectual Ventures II LLC*, IPR2014-01031, Paper 41 at 13-14 (PTAB December 7, 2015).

VI. Petitioner’s Rebuttal Evidence on Secondary Considerations Is Timely

Petitioner’s ability to address secondary considerations evidence has already been addressed by the Board. *See* Paper 11, 22-26. The Board recognized many distinctions over the *Robert Bosch* IPR, including that “Petitioner was not a party to the [] trial and therefore did not have an opportunity in that case to response to

Patent Owner's evidence" and that "the Board relied upon the Administrative Judge's determination in the corresponding ITC proceeding." *Id.*, 25. The Board further noted that the prosecution history was the only fixed record at that time, and that the POPR offered "testimony and evidence from different declarants" to which "Petitioner has not yet had an opportunity to respond." *Id.*, 25-26.

Thus, the Board held that "a better course of action is to permit the parties to develop a more complete record during trial before considering Patent Owner's evidence of objective indicia of nonobviousness" (*id.*, 24), which is precisely what Petitioner did with its timely submissions directed to secondary considerations raised in the POR. This makes logical sense because the traditional way to develop such a record is for a Patent Owner to first raise the issues it intends to raise, and then allow Petitioner to appropriately respond. *See Petroleum Geo-Services Inc. v. Westerngeco LLC*, IPR2014-01477, Paper 18 at 32 (PTAB March 17, 2015) (finding Petition not deficient where Petitioner was not a named defendant in a prior litigation, and stating "evidence of secondary indicia of non-obviousness must be first developed in this proceeding by Patent Owner").

This approach is even more critical here because, as noted above, Petitioner attempted to gain access to the *Apotex* trial record and was denied by both the District Court and Cipla. EX1174, ¶ 2; EX1175. Thus, Petitioner did not know at the Petition stage which arguments from the prior litigation Cipla would raise here,

nor did Petitioner have access to the evidence underlying those arguments.

Moreover, Dr. Donovan explained in her deposition that some litigation materials were subject to a protective order that barred her from discussing such information in this proceeding. *See* EX2159, 125:16-19.

Cipla should not be allowed to exclude evidence and arguments that Petitioner could realistically only have submitted in its Reply papers. Requiring anything more from Petitioner beyond addressing the arguments from the prosecution history would simply be unfair and not in the interests of justice, especially given that Cipla could have requested to file a sur-reply, but chose not to. *See, e.g., Campbell Soup Co., et al. v. Gamon Plus, Inc.*, IPR2017-00087, Paper 37 at 3-4 (PTAB Nov. 17, 2017) (granting sur-reply on secondary considerations).

Lastly, Cipla requests to exclude numerous exhibits for which an objection as to timeliness was not asserted. *See* Paper 32, 9-11 (not identifying exhibits 1037, 1057-1138, 1147-48, 1150, 1157-58, and 1163-65).

VII. Cross-Examination Questioning Was Properly Within The Scope

Petitioner's cross-examination questioning of Drs. Carr and D'Addio was within the scope of their declarations; each of Cipla's points raised at pages 12-13 of the Motion are addressed below:

1) Cross-examination relating to Dr. Carr's prescribing habits of Astelin and Flonase administered sequentially was within the scope of his opinion that "a

POSA would have known that co-administration of antihistamines and steroids provided no meaningful benefit as compared to steroids alone” and that “the art did not motivate a POSA to combine azelastine and fluticasone into a fixed dose combination.” *See* EX2147, ¶¶ 45-64 and 80-95. That is, if there were no meaningful benefits, and there was otherwise no motivation, why would Dr. Carr have regularly prescribed such a combination?

2) Cross-examination relating to Dr. Carr’s prescribing habits of Dymista® was within the scope of his opinions that Dymista® is “the new gold standard for the treatment of AR” and has “unexpectedly reduced side effects as compared to either azelastine or fluticasone monotherapies.” *See* EX2147, ¶¶ 148-49, 122-29. That is, Dr. Carr’s frequency and conditions of prescription are relevant to whether Dymista really is “the gold standard,” and his experiences with side-effects are relevant to his opinion regarding “unexpectedly reduced side effects.”

3), 4), and 5) Cross-examination that identified (i) the **months**-long efforts to develop compositions in the ’206 patent, (ii) general new product development times of “probably **months**,” and (iii) further formulation work that took **days** just to make a “minor variation” to the final Cipla formula was relevant to and within the scope of Dr. D’Addio’s testimony regarding Meda’s alleged “efforts” to formulate a composition of azelastine and fluticasone that hardly spanned more than a day (*see* EX2148, ¶¶ 20-25), which Cipla characterizes as a “failure by

others” (POR at 60-61).

VIII. EX1171 Should Not Be Excluded

While Cipla characterizes the corrections Mr. Staines identified in EX1171 as Petitioner’s, they were clearly those independently identified by Mr. Staines during his deposition preparation efforts. EX2180, 119:7-121:8, 166:9-20. Cipla’s reference to 37 C.F.R. § 42.53(d)(3) is misplaced, as that rule is not directed to the situation here where a declarant has already submitted direct testimony in a declaration. Cipla was afforded the opportunity to question Mr. Staines about EX1171, including time to review notes and assistance in printing any exhibits needed. *See* EX2180, 121:9-14; 167:1-20. Notably, while Cipla’s Counsel claimed there were five “new exhibits” cited in EX1171 (*i.e.*, 1069, 1092, 1133, and 1136-37), all of those exhibits were cited in Mr. Staines’ original declaration. *See*, EX1140, FN 240 (EX1069); FN 122 (EX1092); FN 252 (EX1133); FN 286 (EX1136); FN 289 (EX1137). Cipla’s additional examination lasted one-hour, and only covered two of the five “new exhibits.” *See* EX2180, 121:18 (start time of 2:57pm); 167:21 (end time of 3:56pm); 4:14-15. Thus, Cipla cannot claim any real prejudice, and EX1171 should thus not be excluded from the record.

Respectfully submitted,

Dated: April 24, 2018

By: /Michael R. Houston/
Michael Houston
Registration No. 58,486
FOLEY & LARDNER LLP

321 North Clark Street, Suite 2800
Chicago, Illinois 60654
Telephone: 312-832-4500
Facsimile: 312-832-4700
mhouston@foley.com

*Counsel for Petitioner
Argentum Pharmaceuticals LLC*

CERTIFICATION OF SERVICE

The undersigned hereby certifies that a copy of the foregoing
**PETITIONER'S OPPOSITION TO PATENT OWNER'S MOTION TO
EXCLUDE PETITIONER'S EVIDENCE UNDER 37 C.F.R. § 42.64** was
served on April 24, 2018, on Counsel for Patent Owner via electronic mail to the
following:

dvarughe-PTAB@skgf.com
dsterlin-PTAB@skgf.com
alarock-PTAB@skgf.com
ueverett-PTAB@skgf.com

Dated: April 24, 2018

By: /Michael R. Houston/
Michael Houston
Registration No. 58,486
Counsel for Petitioner