

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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ARGENTUM PHARMACEUTICALS LLC

Petitioner

v.

CIPLA LIMITED

Patent Owner

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Case No. IPR2017-00807

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

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

***Mail Stop "PATENT BOARD"***

Patent Trial and Appeal Board  
U.S. Patent and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450



## **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<sup>1</sup> 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

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<sup>1</sup> 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,



82-84, 90) imply that EX1037 was in fact filed. 37 C.F.R. § 42.63(a) states that “[a]ll evidence must be filed in the form of an exhibit” and subsection (e) provides that “[i]f the exhibit is not filed, the exhibit list should note that fact.” Because EX1037 was not filed and Petitioner’s Exhibit Lists fail to note that EX1037 was not filed, Petitioner violated both requirements. Accordingly, EX1037 and Petitioner’s Reply at pp. 5-7, 19-22, and 25, and EX1144 ¶¶16, 42, 61-63, 66-67, 77-79, 82-84, and 90, which cite EX1037, should be excluded.

**IV. PETITIONER’S REPLY AND EX1145 VIOLATE 37 C.F.R. § 42.23(b) BY RAISING NEW ISSUES.**

37 C.F.R. § 42.23(b) requires that “[a] reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, or patent owner response.” The Patent Trial Practice Guide provides examples of new issues that are improperly raised in reply: “new evidence necessary to make out a prima facie case for the [] unpatentability of a[] . . . claim,” or “new evidence that could have been presented in a prior filing.” Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012). Petitioner and its declarant Dr. Donovan improperly supplement their obviousness arguments by (1) raising new motivations for the POSA to use the preservatives and isotonicity adjustor recited in claims 42-44, and (2) raising new arguments for why a POSA would have had a reasonable expectation of successfully arriving at the invention of the challenged



claims. For example, for the first time in her reply declaration, Dr. Donovan:

- Asserts that a POSA would have been motivated to use the three claimed preservatives in order to pass a preservative challenge test (EX1145, ¶¶60-66);
- Cites *Remington: the Science of Practice of Pharmacy* as support of her opinions that the claimed preservatives were obvious (EX1145, ¶¶61-63);
- Asserts that EDTA’s use as a chelating agent would have motivated a POSA to use it (EX1145, ¶63);
- Asserts that a POSA would “have been motivated to *avoid*” using sodium chloride and dextrose—the tonicity adjusters used in the prior art Astelin® and Flonase® products (EX1145, ¶¶68-69) (emphasis in original);
- Asserts that a POSA would have been motivated to use glycerine to “add[] to the comfort of the nasal spray” (EX1145, ¶70); and
- Relies on Dr. Govindarajan’s recreations of Cramer Example III—recreations that Dr. Donovan relied on in the related district court proceeding months before the Petition was filed—to “support a POSA’s reasonable expectation of successfully combining azelastine hydrochloride and fluticasone propionate into an aqueous nasal spray” (EX1145, ¶¶12-17).



This testimony is also inconsistent with Dr. Donovan's opinions in the related Apotex litigation, where she testified that sodium chloride and dextrose were tonicity adjustors to include in an "obvious combination formulation," but now testifies that a POSA would have been "motivated to avoid" those agents. EX1145, ¶¶68-69; CIP2177, 33; EX2178, 54:3-7.

Petitioner's Reply is built on these same new issues and evidence. *See e.g.*, Reply, 13, 17-18. These 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. Petitioner therefore was required to submit these arguments and evidence in its case-in-chief. *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1369-70 (Fed. Cir. May 9, 2016); *Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1286 (Fed. Cir. April 4, 2017). Patent Owner timely objected. *See* Paper 32, 9-10. Petitioner is precluded from raising those issues in its reply papers, and therefore they should be excluded as contrary to 37 C.F.R. § 42.23(b).

**V. DOZENS OF EXHIBITS AND DECLARATION PARAGRAPHS WERE NOT CITED IN THE PETITION OR REPLY AND THEIR INCLUSION WOULD VIOLATE 37 C.F.R. § 42.24(c).**

Petitioner submitted dozens of exhibits that are cited nowhere in its Petition or its Reply. Exhibits 1014, 1026-1032, 1034-1044, 1047-1049, 1051, 1052, and 1054, as well as 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, and paragraphs 1-13, 16-20, 27, 32-34, 40-42, 44-49, 59, and 72-77 of EX1004 were submitted with the Petition, but are cited nowhere in the Petition itself. Similarly, the Reply fails to cite: (1) Exhibits 1055-1139, 1148-1150, 1152-1153, 1159-1165, and 1168; (2) 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, and 151-153 of EX1140; (3) Exhibits 1, 2a, 5, and 7 of declaration EX1140; (4) paragraphs 1-6, 10, 43-44, 46-48, 53-54, 72-74, 78, 80, and 94-95 of EX1144; and (5) paragraphs 1-6, 22-23, 53-54, 59, 66, 72-73, 78, and 80-81 of EX1145.

Petitioner's failure to cite these exhibits and paragraphs in its Petition or Reply demonstrates that these exhibits and paragraphs do not make any fact of consequence more or less probable. *See* FRE 401, 403. And to the extent that those uncited exhibits were cited in declaration paragraphs subsequently cited in the Petition or Reply, incorporation of the exhibits and/or declarations' discussion of these exhibits into either the Petition or Reply would result in either document exceeding the word limits set forth in 37 C.F.R. § 42.24(a) and (c). Patent Owner timely objected to these uncited exhibits and paragraphs as violating 35 U.S.C. § 331(b). Paper 14, 4-6; Paper 32, 3. The exhibits and declaration paragraphs identified above should thus be excluded for lack of relevance and/or exceeding the word limits of § 42.24.



**VI. PETITIONER’S OBJECTIVE INDICIA EVIDENCE WAS NOT TIMELY SUBMITTED.**

Petitioner’s objective indicia evidence and arguments in reply should be excluded because they were not timely submitted. 35 U.S.C. § 312(a)(3) required Petitioner to submit a petition that identified “with particularity” the grounds of its challenge and the evidence for the challenge. As Petitioner’s Ground 2 and Ground 3 are rooted in obviousness under 35 U.S.C. § 103, it is black-letter law that “[o]bjective indicia of nonobviousness must be considered in every case where present.” *Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (*en banc*).<sup>2</sup> This means that Petitioner needed to address *all* of the objective indicia of which it (and its experts) were, or should have been, aware.

Petitioner, however, was aware of a host of evidence and arguments that Patent Owner had publicly submitted and discussed less than two months before the Petition was filed. *See, e.g.*, CIP2127, 1; CIP2158, 94:10-96:10; CIP2159, 119:12-121:5, 123:7-126:13. Petitioner and its declarants knew of, but did not address: (1) Dymista<sup>®</sup>’s unexpectedly faster onset of action and reduction in side effects compared to existing fluticasone and azelastine products; (2) Dymista<sup>®</sup>’s satisfaction of the long-felt need in the U.S. for a more effective, faster, and safer

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<sup>2</sup> Indeed, both Petitioner’s declarants who submitted declarations with the Petition acknowledged this obligation. EX1003, ¶92; EX1004, ¶11.



treatment of allergic rhinitis; (3) FDA's and Meda's skepticism of the claimed invention; (4) industry praise for Dymista<sup>®</sup>; (5) failure by at least Meda to formulate an azelastine/fluticasone combination; (6) licensing of the '620 patent; (7) evidence of copying; or (8) Dymista<sup>®</sup>'s U.S. commercial success.<sup>3</sup> *See, e.g.*, CIP2127 ("Argentum attended the public portions of the trial and is using the same experts..."); CIP2158, 94:5-96:10 (Dr. Schleimer testifying that he recalled numerous objective indicia from trial that he did not opine on in his opening report); CIP2159, 121:8-124:4 (Dr. Donovan testifying that she was aware of Patent Owner's evidence of copycat formulations and Meda's failed efforts to develop an azelastine/fluticasone combination product); CIP2179, 101:4-102:8 and 106:7-107:3 (Dr. Schleimer testifying that he relied on the Greiff reference (EX1147) in the Apotex litigation for onset, yet did not cite it for the same proposition in his first declaration here).

Petitioner opted to instead address some—but not all—of this evidence. Petitioner's Petition argues that "blocking patents" (EX1009, EX1007) negate any "commercial success" or "long-felt need." Petition, at 56-58. But because EX1009 and EX1007 are issued U.S. patents, they can only block U.S. commercial success

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<sup>3</sup> To the extent documents were marked as confidential, those documents were discussed in open court and were *not* submitted under seal.



or long-felt need—which is what Patent Owner presented in open court before the Petition was filed. Moreover, Petitioner argued in the Petition that EX1007 is not limited to medicaments consisting solely of azelastine and its physiologically acceptable salts. Petition, at 57. This argument only makes sense in view of Patent Owner’s public argument months before the Petition that the claims of EX1007 were limited to azelastine-only medicaments due to the presence of the Markush group in the claims of EX1007. EX2017, 117-118, 695. That is, Petitioner’s arguments confirm that it was aware of Patent Owner’s objective indicia arguments and evidence when it filed the Petition.

“Unlike district court litigation, where parties have greater freedom to revise and develop their arguments over time and in response to newly discovered material, the expedited nature of IPRs bring with it an obligation for petitioners to make their case in their petition to institute.” *Intelligent Bio-Sys.*, 821 F.3d at 1369. This obligation required Petitioner to address in its Petition objective indicia of nonobviousness it was aware of, rather than strategically avoiding those issues in the first instance, only to raise them in reply to Patent Owner’s prejudice. *See, e.g.*, CIP2158, 98:8-17 (Dr. Schleimer testifying that Petitioner did not address publicly available objective indicia for “strategic reasons”). Accordingly, because “[t]he Board will not attempt to sort proper from improper portions of the reply,” paragraphs 52-93 of EX1144, paragraphs 73-84 of EX1145, the entirety of



EX1140, Exhibits 1037, 1055-1138, 1147-1168, and pages 18-29 of Petitioner's Reply should be excluded. Office Patent Trial Practice Guide, 77 Fed. Reg. 48,756, 48,767 (Aug. 14, 2012). Patent Owner timely raised this objection. Paper 32, 9-11.

**VII. CROSS-EXAMINATION TESTIMONY OF PATENT OWNER'S DECLARANTS WAS OUTSIDE THE SCOPE OF THE DIRECT AND THEREFORE IS NOT RELEVANT.**

37 C.F.R. § 42.53(d)(5)(ii) states that "the scope of the [cross]-examination is limited to the scope of the direct testimony." Petitioner's Reply cites to the cross-examination testimony of Patent Owner's declarants Dr. Warner Carr (EX1142) and Dr. Alexander D'Addio (EX1141) which were not within the scope of their direct testimony, as follows:

- EX1142 at 6:8-11:15: relating to Dr. Carr's prescribing habits;
- EX1142 at 109:7-115:4, 114:16-121:20, and 196:22-198:1: relating to Dr. Carr's prescribing habits of Dymista<sup>®</sup> after it was commercially available in 2012;
- EX1141 at 44:13-45:8: relating to Dr. D'Addio's development of tannate pharmaceutical compositions which no declarant asserted as relevant to the challenged claims;
- EX1141 47:15-48:6: relating to Meda's (the exclusive licensee of the '620 patent) development times for drugs for which no declarant has asserted are relevant to the challenged claims; and



- EX1141 62:17-64:7: relating to work Meda and Patent Owner contemplated well after 2002.

This testimony does not make any fact of consequence more or less probable because it bears no relation to Dr. Carr's and Dr. D'Addio's direct testimony. Given its low probative value, this testimony is outweighed by the prejudice to Patent Owner of irrelevant and non-prior art information being used to invalidate the challenged claims, and the risk of confusing the issues. *See* FRE 401 and 403.

As the above citations show, Patent Owner objected to this testimony at the time it occurred and subsequently filed formal objections. Paper 32, 8-9. Accordingly, this testimony should be excluded as irrelevant.

**VIII. EX1171 IS UNTIMELY, OUTSIDE THE SCOPE OF THE CROSS-EXAMINATION, AND IRRELEVANT.**

Seventeen hours before the deposition of Petitioner's declarant, John C. Staines, Petitioner's counsel emailed to Patent Owner's counsel a list of errata to Mr. Staines's declaration (EX1140). *See* CIP2180, at 105:16-106:8. This exhibit was brought into the record by Petitioner's counsel, in direct contravention of the requirement that, "[i]n the case of direct testimony," Petitioner was required to serve a copy of this document "at least ten days prior to the deposition." 37 C.F.R. § 42.53(d)(3). Petitioner failed to meet this deadline.

Despite the deadline for Petitioner to file declaration evidence passing 29



days earlier, Petitioner attempted to make substantive changes to Mr. Staines's testimony. For example, one of Mr. Staines's revisions is to change "corticosteroids" to "*oral* corticosteroids," a change Mr. Staines testified was made because his prior testimony was "inaccurate or vague." EX1171 (emphasis added), EX1140, ¶49 FN. 97; CIP2180, 123:13-124:3. Further, Mr. Staines sought to change the language "It does address the relevant..." to "It does *not* address the relevant..." because without the change his prior testimony was "misleading." EX1171 (emphasis added), EX1140, ¶121; CIP2180, 124:21-125:21.

EX1171 also modifies the factual support to several statements. EX1171, entries for pages 16, 51, 61, 73, 90, 91, 92, 98, 99, 101, 110, 112, 113, 114. Regarding the revisions to Mr. Staines's cited exhibits, he testified that these revisions were not errors, but instead that he had found exhibits that "gave better support, more—not better, but more support". CIP2179, at 143:18-145:21.

Petitioner's testimonial evidence is untimely as it was filed well after the March 6, 2018 deadline for filing reply evidence. Paper 26, 2. Had Petitioner wanted to file EX1171, it needed to follow the protocol for filing supplemental information by obtaining authorization from the Board, explaining why the information reasonably could not have been obtained earlier, and showing that the interests-of-justice favored considering the information. *See* 37 C.F.R § 42.123(c).

EX1171 should also be excluded because it was marked as an exhibit on

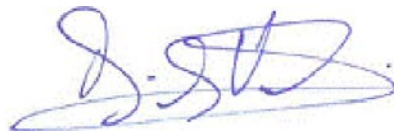


redirect when the witness had not been asked about EX1171, nor had the witness referred to it during his cross-examination. Because EX1171 had no bearing on the questions or answers in cross-examination, marking EX1171 during redirect was outside the scope of the cross-examination, and should therefore be excluded. 37 C.F.R. § 42.53 (d)(5)(ii).

Finally, EX1171 is not relevant. Petitioner's counsel characterized the changes reflected in EX1171 as "clerical" CIP2180, at 91:17-20, 94:21-95:7. Indeed, Mr. Staines testified that EX1171 "do[es]n't affect the opinions or the evidence, but [] make them more accurate." CIP2180, at 132:11-14. Thus, pursuant to FRE 401 and 403 and 37 C.F.R. § 42.53(d)(3), EX1171 does not make any fact more or less probable and is untimely, especially given the prejudice caused to Patent Owner's deposition preparation efforts. Patent Owner timely objected to EX1171. CIP2180, 90:10-16, 94:6-20, 104:17-119:2.

Respectfully submitted,

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**CERTIFICATE OF SERVICE (37 C.F.R. § 42.6(e))**

The undersigned hereby certifies that the above-captioned “Motion to Exclude Petitioner’s Evidence Under 37 C.F.R. § 42.64” was served in its entirety on April 10, 2018, upon the following parties via electronic mail upon the following counsel of record for the Petitioner:

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