

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 OBJECTIONS TO  
PETITIONER'S DEMONSTRATIVE EXHIBITS**

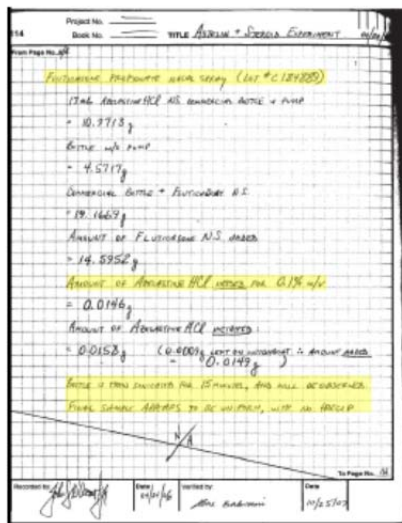
***Mail Stop "PATENT BOARD"***

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

Pursuant to the Board's Order of April 10, 2018 (Paper 40), the parties served objections on each other seven business days prior to Oral Argument, and subsequently met and conferred in a good-faith attempt to resolve their differences. The parties came to an agreement regarding some objections, but a few remain unresolved and are addressed here. The objections below "identify with particularity which portions of the demonstrative exhibits are subject to objection, include a copy of the objected-to portions, and include a one-sentence statement of the reason for each objection," as required by the Board. (Paper 40, 3).

**Objections to slide 19 (objected-to in its entirety)**

**Flonase® + Astelin® Combination Worked**



Meda Lab Notebook (CIP2061), 17; EX1145, ¶75; Reply, 26.

22. Beginning on April 24, 2006, Mr. John D'Acoti, an Assistant Formulation Scientist, began experiments under the direction of Mr. Balwani to create a combination nasal spray. At this time, Mr. D'Acoti had a bachelor's degree in pharmaceutical sciences and 3-4 years of formulation experience. He first conducted a screening experiment by combining Flonase®, a commercial fluticasone propionate nasal spray, with Astelin®, a commercial azelastine hydrochloride nasal spray. This experiment was designed to understand whether any gross formulation changes occurred with the combination of Flonase® and Astelin®. CIP2061, 17. The sample was sonicated for 15 minutes and then assessed by visual observation only. CIP2061, 17. No precipitation was observed. CIP2061, 17. As this was only a screening experiment, no further assessment of this sample was done. CIP2061, 17.

Dr. D'Addio (of Meda) (CIP2148), ¶22; EX1145, ¶75; Reply, 26.

Slide 19

Patent Owner objects to Petitioner's slide 19 because it presents new argument that was not raised in the Reply (Paper 30).

**Objections to slide 20 (objected-to portion boxed in purple)**

## Cramer Example III Worked

Component	Wgt %
triamcinolone acetonide	0.050
azelastine HCl	0.070
polysorbate 80	0.050
glycerin	2.000
hydroxypropyl methyl cellulose	1.000
sodium chloride	0.900
ethylenediamine tetraacetic acid	0.050
benzalkonium chloride	0.020
distilled water	q.s. to vol.

Dr. Govindarajan's Conclusions, Ex2030, 4 (¶13-14); Reply at 13-15.

"I concluded that Cramer Example III is a suspension that would be acceptable as a pharmaceutical product. There was some settling, but no settling or sedimentation in the product that would make it pharmaceutically unacceptable. I further concluded that the product could be delivered as a fine spray using a nasal spray pump."

Dr. Herpin's Observations, Ex2029, 53; Reply at 13-15

- formulation was uniformly dispersed

- Formulation was able to be sprayed

Slide 20

Patent Owner objects to Petitioner's slide 20 as misleading because it suggests that Dr. Govindarajan was a declarant in this proceeding.

**Objections to slide 22 (objected-to portion boxed in purple)**

## Settling ≠ Unsuitable Nasal Spray

Cipla attempts to equate “settling” with “unsuitable for nasal administration,” e.g.,:

- “[A] POSA would have understood ‘nasal spray’ or ‘suitable for nasal administration’ to mean ‘pharmaceutical formulations that are ... homogeneous” (POR, 10);
- “Dr. Govindarajan’s recreations ... [were] unable to keep the formulation from settling” (POR, 35);
- “Dr. Herpin used a medium-viscosity grade HPMC, but also experienced significant settling” (POR, 35).  
Reply at 2-3, 14, 26.

Yet the Dymista® drug label indicates settling (CIP2066, 2):

**2.2 Important Administration Instructions**

Administer DYMISTA by the intranasal route only.

Shake the bottle gently before each use.

Reply at 26.

Flonase® drug label (Ex1010, 1): “SHAKE GENTLY BEFORE USE”

Cipla fails to provide reasonable clarity, deliberateness, and precision.

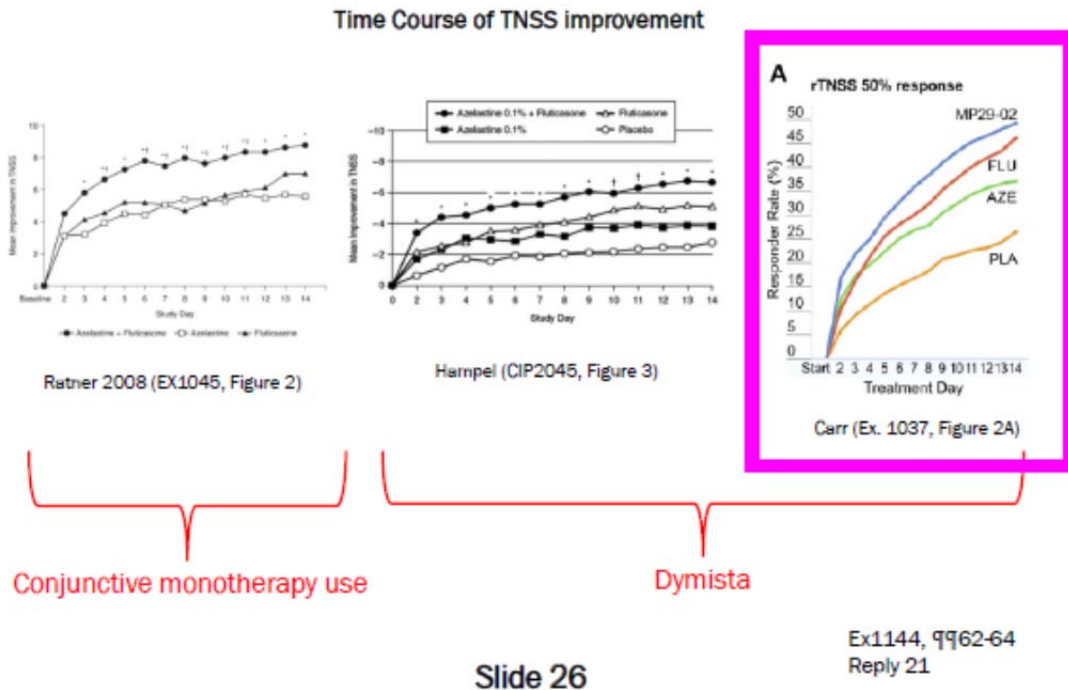
“Cipla does not describe how long the claimed compositions must be homogenous.” (Donovan Decl. (Ex1145) ¶9; Reply at 2-3)

### Slide 22

Patent Owner objects to Petitioner’s slide 22 because it presents new arguments that were not raised in the Petition or Reply, and relies on evidence that was used in the Petition and Reply to support different points (*see* Reply at 2-3, 26).

**Objections to slide 26 (objected-to portion boxed in purple)**

**Dymista® Shows No Increased Efficacy**



Patent Owner objects to Petitioner's slide 26 because the right-most figure presented in that slide appears nowhere in the Petition or Reply, is different from the figure that appears in EX1144 ¶¶ 62-64, and was not relied upon by Dr. Schleimer.

These objections are made within two business days of the May 16, 2018 oral hearing as required by the Board's Order. (Paper 40.) Patent Owner does not

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