## MEDA PHARMACEUTICALS AND CIPLA LTD.

V.

APOTEX C.A. No. 14-cv-1453



# Maureen Donovan, Ph.D.

**DIRECT EXAMINATION DEMONSTRATIVES** 



# Maureen Donovan, Ph.D. – Background and Educatio

#### **Curriculum Vitae**

Maureen D. Donovan, Ph.D.

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Education: University of Minnesota College of Pharmacy

Minneapolis, Minnesota

Bachelor of Science in Pharmacy, 1983

University of Michigan College of Pharmacy Horace H. Rackham School of Graduate Studies

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Ph.D. (Pharmaceutics), 1989

PROFESSIONAL EXPERIENCE

2013-present Associate Dean for Undergraduate Programs

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2008-2013 Division Head

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2008-present Professor

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1996-2008 Associate Professor

University of Iowa College of Pharmacy

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1989-1996 Assistant Professor

University of Iowa College of Pharmacy

**Division of Pharmaceutics** 

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1991 Visiting Scholar

SmithKline Beecham Pharmaceuticals

King of Prussia, PA

1986-88 Staff Pharmacist

Clark Professional Pharmacy

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Education: University of Minnesota College of Pharmacy

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DOCKET A L A R M

**DTX 293** 

# **Summary of Opinions**

A POSA formulator co-formulating a fluticasone/azelastine nasal spray would have started working from the Flonase® and Astelin® products.

The claimed combinations of fluticasone/azelasting in a nasal spray are obvious.



## **Framework for Analysis**

- Level of ordinary skill in the art.
- Assess the scope of the prior art.
- Assess any differences between the prior art and the claimed inventions.

• Were the claims obvious in light of any differences from the prior art?



## **Person of Ordinary Skill in the Art: Formulation**

The relevant art: pharmaceutical formulations of topical agents.

## Level of ordinary skill in the art:

- At least a bachelor's degree in chemistry, biology, chemical engineering or pharmaceutical science;
- 3-5 years of experience in formulation development of nasal dosage forms, and the ability to operate independently on formulation activities.
- Familiarity with pharmaceutical excipients and their uses.
- Could have advanced degree, with fewer years of experience
- Date of invention: June 2002



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