

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

MEDA PHARMACEUTICALS, INC. and CIPLA LTD.)	
)	
)	
Plaintiffs,)	Civil Action No. 14-1453 (LPS)
)	
v.)	
)	
APOTEX, INC. and APOTEX CORP.)	
)	
Defendants.)	

DEFENDANTS' PROPOSED FINDINGS OF FACT

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Defendants Apotex Corp. and Apotex Inc. (together, “Apotex”), respectfully submit the following proposed Findings of Fact. The clear and convincing evidence at trial showed that all asserted claims from the two patents-in-suit held by Cipla Ltd. (“Cipla”) and exclusively licensed to Meda Pharmaceuticals Inc. (“Meda”), are obvious. Alternatively, they are invalid under 35 U.S.C. § 112.

I. INTRODUCTION

1. The patents-in-suit cover nasal sprays that treat allergic rhinitis (*i.e.*, “hay fever”) with two long-known active ingredients: a steroid called fluticasone propionate (“fluticasone”), and an antihistamine called azelastine hydrochloride (“azelastine”), both of which were FDA-approved before the priority date. PTX 1. The claimed co-formulation also included known excipients for known uses. Tr. (Smyth) at 652:1–654:4; Tr. (Smyth) at 670:1-6. As every single physician who testified at trial—including Plaintiffs’ experts—conceded, doctors prescribed azelastine (branded as Astelin[®]) with fluticasone (branded as Flonase[®]) to treat allergic rhinitis (“AR”) before the time of the alleged invention in June 2002. Tr. (Accetta) at 46:12-14; Tr. (Wedner) at 76:20-77:6; Tr. (Kaliner) at 433:20-434:6; Tr. (Carr) at 574:10-13. There can be no question that combining these drugs was obvious.

2. Combining fluticasone and azelastine in a single nasal spray was also expressly disclosed and taught in the prior art. Two pharmaceutical companies expressly disclosed co-formulations with these two drugs in prior art patent applications. DTX 12 (“Cramer”); DTX 21 (“Segal”). Meda itself described combination fluticasone/azelastine nasal sprays in great detail before it knew anything about the work of its co-Plaintiff, Cipla, that led to the patents-in-suit—and even described this combination as “obvious” because “Fluticasone was the then best selling steroid, and Azelastine was the best antihistamine.” Tr. (Fuge) at 137:4-8, 138:19-25; DTX 313. Even Plaintiffs’ own expert conceded (through deposition testimony when impeached) that “a

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