

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

MEDA PHARMACEUTICALS INC. and)
CIPLA LTD.,)
)
 Plaintiffs,)
)
 v.)
)
 APOTEX INC. and APOTEX CORP.,)
)
 Defendants.)
)

C.A. No. 14-01453-LPS

**PLAINTIFFS' POST-TRIAL SUR-REPLY BRIEF
ON OBJECTIVE INDICIA OF NONOBVIOUSNESS**

STERNE, KESSLER, GOLDSTEIN & FOX
P.L.L.C.
Dennies Varughese
Mark Fox Evens
Uma N. Everett
Adam C. LaRock
Joshua I. Miller
Josephine J. Kim
1100 New York Ave., N.W., Suite 800
Washington, DC 20005-3934
(202) 371-2600

RICHARDS, LAYTON & FINGER, P.A.
Frederick L. Cottrell, III (#2555)
Selena E. Molina (#5936)
920 North King Street,
Wilmington, DE 19801
(302) 651-7700
cottrell@rlf.com
molina@rlf.com

*Attorneys for Plaintiffs
Meda Pharmaceuticals Inc. and Cipla Ltd.*

Dated: February 21, 2017

TABLE OF CONTENTS

INTRODUCTION 1

ARGUMENT..... 3

I. THE PATENTS-IN-SUIT ARE VALID, AND EIGHT OBJECTIVE INDICIA ARE AN ADDITIONAL AND INDEPENDENT BASIS CONFIRMING VALIDITY. 4

 A. UNEXPECTED RESULTS: A POSA in 2002 would not have expected Dymista[®]'s clinical benefits and successful formulation. 5

 1. Dymista[®]'s increased efficacy, accelerated onset, and reduced side effects were not expected in 2002. 5

 2. Dymista[®]'s benefits are differences in “kind.” 8

 3. A POSA would not have expected that a single formulation like Dymista[®] could be made suitable for nasal administration. 10

 B. FAILURE OF OTHERS: At least three sophisticated pharmaceutical companies failed to develop an antihistamine/steroid fixed-dose formulation..... 11

 C. ACQUIESCENCE: Meda took a license from Cipla for the Patents-in-Suit to market Dymista[®]. 15

 D. SKEPTICISM: Both Meda and FDA doubted whether a fixed-dose antihistamine/steroid combination would work..... 15

 1. Clinical skepticism, prior to and well after the invention date, confirms that a POSA would not have anticipated success. 16

 2. Industry participants were skeptical that an antihistamine/steroid combination could be formulated 18

 E. UNMET NEED: Dymista[®] satisfied a long-felt but previously unmet need for better, faster, and safer treatment of AR..... 19

 F. COMMERCIAL SUCCESS: Apotex has failed to overcome evidence of Dymista[®]'s commercial success..... 19

 G. COPYING: Duonase (the version of Dymista[®] in India) was immediately and widely copied by multiple pharmaceutical companies. 21

 H. PRAISE: Dymista[®] has been received by the medical community as best treatment for AR available. 22

II. THERE WERE NO “BLOCKING PATENTS” TO NEGATE ANY OBJECTIVE INDICIA OF NONOBVIOUSNESS..... 23

A. Cipla did not own any of the alleged “blocking patents.” 23

B. Cipla, Cramer, Segal, and Meda were not blocked or dissuaded by the alleged “blocking patents.” 24

C. Hettche and Phillipps were not blocking patents because they expired before Dymista[®]’s launch. 24

D. Hettche recites a closed *Markush* group of active ingredients that *cannot* cover a product that includes fluticasone..... 25

TABLE OF AUTHORITIES

Cases

Allergan, Inc. v. Sandoz Inc.
726 F.3d 1286 (Fed. Cir. 2013).....1, 16, 17

Allergan, Inc. v. Sandoz Inc.,
796 F.3d 1293 Fed. Cir. 2015).....9, 10

Apple Inc. v. Samsung Elecs. Co.,
839 F.3d 1034 (Fed. Cir. 2016).....3, 4

AstraZeneca LP v. Breath Ltd,
88 F. Supp. 3d 326 (D.N.J. 2015).....12

Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.,
320 F.3d 1339 (Fed. Cir. 2004).....12

Galderma Labs., L.P. v. Tolmar, Inc.,
737 F.3d 731 (Fed. Cir. 2013).....9, 17, 18, 21

Hybritech Inc. v. Monoclonal Antibodies, Inc.,
802 F.2d 1367 (Fed. Cir. 1986).....14

In re Brimonidine Patent Litig.,
643 F.3d 1366 (Fed. Cir. 2011).....1, 18

In re Geiger,
815 F.2d 686 (Fed. Cir. 1987).....7

In re GPAC Inc.,
57 F.3d 1573 (Fed. Cir. 1995).....15

Kinetic Concepts, Inc. v. Smith & Nephew, Inc.,
688 F.3d 1342 (Fed. Cir. 2012).....4

Knoll Pharm. Co. v. Teva Pharm. USA, Inc.,
367 F.3d 1381 (Fed. Cir. 2004).....14

Leo Pharm. Prods. Ltd. v. Rea,
726 F.3d 1346 (Fed. Cir. 2013).....1, 3, 4, 18

Multilayer Stretching Cling Film Holdings, Inc. v. Berry Plastics Corp.,
831 F.3d 1350 (Fed. Cir. 2016).....25

Otsuka Pharm. Co., Ltd. v. Sandoz, Inc.,

678 F.3d 1280 (Fed. Cir. 2012).....24

Procter & Gamble Co. v. Teva Pharm. USA, Inc.,
566 F.3d 989 (Fed. Cir. 2009).....5

Richardson-Vicks, Inc. v. Upjohn Co.,
122 F.3d 1476 (Fed. Cir. 1997).....1, 16, 17

Shire Development, LLC v. Watson Pharms., Inc.,
--- F.3d ---, 2017 WL 541013 (Fed. Cir. February 10, 2017).....25

TriMed, Inc. v. Stryker Corp.,
608 F.3d 1333 (Fed. Cir. 2010).....11

Unigene Labs. Inc. v. Apotex Inc.,
2009 WL 2762706 (S.D.N.Y. Aug. 31, 2009).....11

Unigene Labs., Inc. v. Apotex, Inc.,
2010 WL 2730471 (S.D.N.Y. July 7, 2010).....11

Unigene Labs., Inc. v. Apotex Inc.,
655 F.3d 1352 (Fed. Cir. 2011).....11

ViiV Healthcare UK Ltd. v. Lupin Ltd.,
6 F. Supp. 3d 461 (D. Del. 2013), *aff'd*, 594 F. App'x 686 (Fed. Cir. 2015).....20, 23, 25

WBIP, LLC v. Kohler Co.,
829 F.3d 1317 (Fed. Cir. 2016).....15, 19

Windsurfing Int'l, Inc. v. AMF, Inc.,
782 F.2d 995 (Fed. Cir. 1986).....22

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.