

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

WARNER CHILCOTT COMPANY, LLC and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

C.A. No.1: 08-cv-0627-LPS
C.A. No. 1:11-cv-00081-LPS

WARNER CHILCOTT COMPANY, LLC and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

C.A. No. 09-143-LPS
(consolidated with C.A. No. 08-627-LPS)

WARNER CHILCOTT COMPANY, LLC and
HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS, INC.,

Defendant.

C.A. No. 10-285-LPS
(consolidated with C.A. No. 08-627-LPS)

THE PROCTER & GAMBLE COMPANY
and HOFFMANN-LA ROCHE INC.,

Plaintiffs,

v.

SUN PHARMA GLOBAL FZE,

Defendant.

C.A. No. 09-61-LPS
(consolidated with C.A. No. 08-627-LPS)

PUBLIC VERSION

**DEFENDANTS APOTEX, INC. AND APOTEX CORP.'S MOTION FOR SUMMARY
JUDGMENT OF NON-INFRINGEMENT OF U.S. PATENT NO. 6,165,513**

OF COUNSEL:

Steven E. Feldman
Louise T. Walsh
Philip D. Segrest, Jr.
Sherry L. Rollo
HUSCH BLACKWELL, LLP
120 South Riverside Plaza, Suite 2200
Chicago, Illinois 60606
Tel: (312) 655-1500

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1055465 / 37145
PUBLIC VERSION
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Richard L. Horwitz (#2246)
David E. Moore (#3983)
POTTER ANDERSON & CORROON LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

*Attorneys for Defendants
Apotex, Inc. and Apotex Corp.*

Defendants Apotex Corp. and Apotex, Inc. (collectively "Apotex"), by counsel, respectfully move for summary judgment, pursuant to Fed. R. Civ. P 56, of noninfringement of U.S. Patent No. 6,165,513 (the "'513 patent").

As grounds for this motion, Apotex states as follows:

1. This is a patent infringement action filed pursuant to 35 U.S.C. § 271(e) in response to Apotex's filing of an Abbreviated New Drug Application with the FDA seeking approval to market generic versions of the prescription drug Actonel® (risedronate sodium) in formulations including tablets containing 150 mg of the salt. The patent asserted by Plaintiffs Warner Chilcott Company, LLC and Hoffmann-La Roche Inc., include U.S. Patent No. 7,192,938 and U.S. Patent No. 7,718,634. *See* First Amended Complaint (D.I. 42) filed in Civil Action No. 09-143-LPS.

2. Apotex's Answer to the First Amended Complaint included a counterclaim for a civil action to obtain patent certainty in the form of a declaratory judgment action seeking a determination that Apotex does not infringe the '513 patent. *See* 21 U.S.C. § 355(j)(5)(C) and Apotex Inc.'s And Apotex Corp.'s Answer, Defenses, and Counterclaims To First Amended Complaint (D.I. 44) filed in Civil Action No. 09-143-LPS. This motion concerns only the '513 patent

3. All discovery, with the exception of the completion of one expert deposition, has been completed. A proposed Final Pretrial Order is due June 18, 2012. A Final Pretrial Conference is scheduled for July 2, 2012 to be followed by a one-week bench trial commencing on July 23, 2012. *See* Amended Consolidated Rule 16 Scheduling Order (D.I. 125).

4. In the joint claim construction statement filed in this action the parties have agreed that the '513 patent claims at issue are limited to an oval-shaped tablet. It is a matter of

undisputed fact that Apotex's proposed tablets are REDACTED. Plaintiffs have undertaken to extend to Apotex a covenant not to sue on the '513 patent. However, in this Hatch-Waxman litigation, a covenant not to sue does not remove all barriers of entry by Apotex's round-shaped tablets in the absence of a judgment of non-infringement of the '513 patent. Nor does such a covenant divest the Court of subject matter jurisdiction or render the issue of infringement or noninfringement of the '513 patent moot. There is sufficient injury-in-fact for constitutional purposes, traceable to the patentee, that can only be remedied by entry of a judgment of non-infringement.

5. In light of the undisputed facts and the pleadings filed in this action and in Civil Action No. 09-143, Apotex's proposed REDACTED does not infringe the claims of the '513 patent.

6. The grounds supporting Apotex's summary judgment motion of noninfringement of the '513 patent are discussed with particularity in the accompanying Defendants Apotex, Inc. and Apotex Corp's Brief In Support Of Motion For Summary Judgment Of Noninfringement Of U.S. Patent No. 6,165,513 filed concurrently herewith. In addition, Defendants respectfully submit an Appendix To Defendants Apotex, Inc. and Apotex Corp.'s Motion For Summary Judgment Of Noninfringement Of U.S. Patent No. 6,165,513 also filed concurrently herewith.

Apotex respectfully request that the Court enter an order granting summary judgment of noninfringement of the '513 patent.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

OF COUNSEL:

Steven E. Feldman
Louise T. Walsh
Philip D. Segrest, Jr.
Sherry L. Rollo
HUSCH BLACKWELL, LLP
120 South Riverside Plaza, Suite 2200
Chicago, Illinois 60606
Tel: (312) 655-1500

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By: /s/ Richard L. Horwitz
Richard L. Horwitz (#2246)
David E. Moore (#3983)
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com

Attorneys for Defendants
Apotex, Inc. and Apotex Corp.

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CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on April 23, 2012, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I further certify that on April 23, 2012, the attached document was Electronically Mailed to the following person(s):

Frederick L. Cottrell , III
Steven J. Fineman
Jaclyn C. Levy
Richards, Layton & Finger, PA
One Rodney Square
920 N. King Street
Wilmington, DE 19801
cottrell@rlf.com
fineman@rlf.com
levy@rlf.com
Attorneys for Plaintiffs

William F. Lee
Wyley Sayre Proctor
Vinita Ferrera
Richard Ewenstein
Bo Han
Allen Nunnally
Wilmer Cutler Pickering Hale & Dorr LLP
60 State Street
Boston, MA 02109
william.lee@wilmerhale.com
wyley.proctor@wilmerhale.com
vinita.ferrera@wilmerhale.com
richard.ewenstein@wilmerhale.com
bo.han@wilmerhale.com
allen.nunnally@wilmerhale.com
*Attorneys for Plaintiff Warner Chilcott
Company LLC*

David B. Bassett
Martin E. Gilmore
Wilmer Cutler Pickering Hale & Dorr LLP
399 Park Avenue
New York, NY 10022
david.bassett@wilmerhale.com
martin.gilmore@wilmerhale.com
*Attorneys for Plaintiff Warner Chilcott
Company LLC*

Joshua H. Harris
Mark E. Waddell
John M. Griem, Jr.
Loeb & Loeb LLP
345 Park Avenue
New York, NY 10154
jharris@loeb.com
mwaddell@loeb.com
jgriem@loeb.com
*Attorneys for Plaintiff Hoffmann-La Roche
Inc.*

Karen L. Pascale
Young, Conaway, Stargatt & Taylor LLP
Rodney Square
1000 North King Street
Wilmington, DE 19801
kpascale@ycst.com
*Attorneys for Defendant
Teva Pharmaceuticals USA Inc.*

James Galbraith
Maria Luisa Palmese
A. Antony Pfeffer
Peter L. Giunta
Kenyon & Kenyon LLP
One Broadway
New York, NY 10004
jgalbraith@kenyon.com
mpalmese@kenyon.com
apfeffer@kenyon.com
pgiunta@kenyon.com
*Attorneys for Defendant
Teva Pharmaceuticals USA Inc.*

Richard K. Herrmann
Mary Matterer
Morris James LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19899-2306
rherrmann@morrisjames.com
mmatterer@morrisjames.com
*Attorneys for Defendant
Mylan Pharmaceuticals Inc.*

Edgar H. Haug
Robert E. Colletti
Richard E. Parke
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, NY 10151
ehaug@flhlaw.com
rcolletti@flhlaw.com
rparke@flhlaw.com
*Attorneys for Defendant
Mylan Pharmaceuticals Inc.*

John C. Phillips , Jr.
Megan C. Haney
Phillips, Goldman & Spence, P.A.
1200 North Broom Street
Wilmington, DE 19806
jcp@pgslaw.com
mch@pgslaw.com
Attorneys for Defendant
Sun Pharma Global FZE

Eric C. Cohen
Jeremy C. Daniel
525 West Monroe Street
Chicago, IL 60661-3693
eric.cohen@kattenlaw.com
jeremy.daniel@kattenlaw.com
Attorneys for Defendant
Sun Pharma Global FZE

By: /s/ Richard L. Horwitz
Richard L. Horwitz
David E. Moore
POTTER ANDERSON & CORROON LLP
Tel: (302) 984-6000
rhowitz@potteranderson.com
dmoore@potteranderson.com

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