

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

ELLIOTT ASSOCIATES, L.P.,
ELLIOTT INTERNATIONAL, L.P., and
KNOLLWOOD INVESTMENTS, L.P.,

Plaintiffs,

v.

SYLVIA MATHEWS BURWELL, in her
official capacity as SECRETARY, UNITED
STATES DEPARTMENT OF HEALTH AND
HUMAN SERVICES,

and

MARGARET HAMBURG, M.D., in her
official capacity as COMMISSIONER OF
FOOD AND DRUGS, FOOD AND DRUG
ADMINISTRATION,

Defendants,

and

HIKMA PHARMACEUTICALS PLC and
WEST-WARD PHARMACEUTICAL CORP.,

Intervenor-Defendants.

Civil Action Nos. 1:14-cv-1668 (KBJ)
1:14-cv-1850 (KBJ)

**PLAINTIFFS' MOTION FOR INJUNCTION PENDING APPEAL AND
JOINDER IN TAKEDA PHARMACEUTICALS USA, INC.'S MOTION FOR SAME**

Michael A. Sitzman, Cal. Bar No. 156667
(*admitted pro hac vice*)
GIBSON, DUNN & CRUTCHER LLP
555 Mission Street, Suite 3000
San Francisco, CA 94105
Telephone: 415-393-8200

Matthew D. McGill, D.C. Bar No. 481430
Lucas C. Townsend, D.C. Bar No. 1000024
Mithun Mansinghani, D.C. Bar No. 1010818
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, NW
Washington, DC 20036
Telephone: 202-955-8500

Dated: January 10, 2014

Counsel for Plaintiffs

Pursuant to Fed. R. Civ. P. 62 (c), Plaintiffs Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P. (collectively, “Plaintiffs”), by its undersigned attorneys, hereby move for entry of an injunction pending appeal and join in the motion made by plaintiff Takeda Pharmaceuticals USA, Inc. (“Takeda”) for the same relief in Civil Action No. 1:14-cv-1668 (KBJ). *See* D.E. 69.

Plaintiffs have received the Court’s Order dated January 9, 2015, denying its motion for summary judgment and dismissing Civil Action No. 1:14-cv-1850 (KBJ). D.E. 68. Plaintiffs are awaiting the Court’s Memorandum Opinion.¹ However, in view of the outcome, Plaintiffs intend to timely appeal the Court’s decision in this matter and ask the D.C. Court of Appeals to review this matter on an expedited basis. So as to preserve the status quo during the pendency of the appeal and to avoid the irreparable harm that will befall Plaintiffs and Takeda should Intervenor-Defendants Hikma Pharmaceuticals PLC and West-Ward Pharmaceutical Corp. (collectively, “Hikma”) launch its colchicine product Mitigare, Plaintiffs respectfully request that the Court enter an order enjoining Hikma from launching and/or staying FDA’s approval of Mitigare during the pendency of the appeal.

FDA’s approval of Mitigare without certifying to Takeda’s Colcris® patents permits Hikma to launch its colchicine product into the market at any moment. New drug entrants into the market have an immediate and precipitous effect upon the market share and pricing of the brand name drugs upon which they are based. Such competition from Mitigare would markedly decrease revenue from the sale of Colcris®, thereby directly harming the interests of Plaintiffs and Takeda. It has been reported that Mitigare is expected to capture 60 to 70 percent of the

¹ As the Court’s Memorandum Opinion is not yet available, Plaintiffs are unable to provide any detail about the grounds and/or issues for appeal. Accordingly, Plaintiffs reserve the right to file an additional brief after it has reviewed the Court’s Memorandum Opinion.

Colcrys® market within four weeks of Mitigare's launch, and 95 to 98 percent of the Colcrys® market within twelve months of Mitigare's launch. The lost market share for Colcrys® will be unrecoverable. In the absence of immediate injunctive relief, Plaintiffs and Takeda will suffer irreparable injury.

In the event that the Court denies such relief, Plaintiffs seek an interim order enjoining FDA's approval of Hikma's Mitigare product for 5 - 10 business days in order to allow Plaintiffs the opportunity to seek injunctive relief from the Court of Appeals.

Respectfully Submitted,

Dated: January 10, 2015

/s/ Michael A. Sitzman

MATTHEW D. MCGILL, D.C. Bar No. 481430

MMcGill@gibsondunn.com

LUCAS C. TOWNSEND, D.C. Bar No. 1000024

LTownsend@gibsondunn.com

MITHUN MANSINGHANI, D.C. Bar No. 1010818

MMansinghani@gibsondunn.com

GIBSON, DUNN & CRUTCHER LLP

1050 Connecticut Avenue, NW

Washington, DC 20036

Telephone: 202-955-8500

Facsimile: 202-467-0539

MICHAEL A. SITZMAN, Cal. Bar No. 156667

(*admitted pro hac vice*)

MSitzman@gibsondunn.com

GIBSON, DUNN & CRUTCHER LLP

555 Mission Street, Suite 3000

San Francisco, CA 94105

Telephone: 415-393-8200

Facsimile: 415-393-8306

CERTIFICATE OF SERVICE

I hereby certify that on this 13th day of December 2014, I caused a copy of the foregoing Plaintiffs' Motion For Injunction Pending Appeal And Joinder In Takeda Pharmaceuticals USA, Inc.'s Motion For Same, to be served upon all parties via this Court's Electronic Case Filing system.

/s/ Michael A. Sitzman

Matthew D. McGill, D.C. Bar No. 481430
GIBSON, DUNN & CRUTCHER LLP
1050 Connecticut Avenue, N.W.
Washington, DC 20036
Telephone: 202.955.8500
MMcGill@gibsondunn.com