IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TAKEDA PHARMACEUTICALS U.S.A., INC., Plaintiff, 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 No.1:14-cv-01668 (KBJ)
ELLIOTT ASSOCIATES, L.P., ELLIOTT INTERNATIONAL, L.P., and KNOLLWOOD INVESTMENTS, L.P., Plaintiffs, v. SYLVIA MATTHEWS BURWELL, in her	)	Civil Action No.1:14-cv-01850 (KBJ)

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.

MEMORANDUM OF POINTS AND AUTHORITIES
IN SUPPORT OF PLAINTIFF'S
EMERGENCY MOTION FOR INJUNCTION PENDING APPEAL

Plaintiff Takeda Pharmaceuticals, U.S.A., Inc. ("Takeda"), by its undersigned attorneys, respectfully moves for immediate entry of an injunction pending appeal pursuant to Fed. R. Civ. P. 62 (c). Specifically, Takeda seeks an order enjoining FDA's approval of Hikma's Mitigare product pending appeal, or at least for 5 business days in order to allow Takeda the opportunity to review the Court's reasoning and seek a stay from the D.C. Circuit after judgment is entered. As discussed in Takeda's Motion for a TRO or Preliminary Injunction, entry into the marketplace of a generic colchicine product would cause Takeda immediate and irreparable harm. D.E. 10. A brief stay is warranted to protect Takeda's rights as it seeks relief from the D.C. Circuit.

Argument

A court faced with a motion for injunction pending appeal should consider factors similar to those reviewed for other injunctions, "although courts often recast the likelihood of success factor as requiring only that the movant demonstrate a serious legal question on appeal where the balance of harms strongly favors a stay." *Al-Anazi v. Bush*, 370 F. Supp. 2d 188, 193 n.5 (D.D.C. 2005).[1]

The balance of hardships weighs decidedly in Takeda's favor on the present motion. Any harm to Defendants of a brief extension of the status quo is minimal. In contrast, the harm to Takeda absent entry of an immediate injunction pending appeal is severe. As explained more fully in Takeda's motion for a TRO or preliminary injunction (D.E. 10), Takeda would face immediate and irreparable harm should Hikma's colchicine product enter the marketplace. Hikma is poised to flood the market with its low-cost generic product at any moment. Almost immediately after Hikma launches its product, Takeda will suffer irreparable harm in the form of irreversible changes to the structure of the market, reputational harm, and unrecoverable financial losses. The injunction requested here would prevent this harm during the time it will Takeda to review the reasoning in the Court's forthcoming Memorandum Opinion and allow Takeda an opportunity to seek a stay from the D.C. Circuit.

[1] Although it is still an open question in the D.C. Circuit, there is support for the proposition that even a preliminary injunction should be issued where the balance of hardships tips decidedly in favor of the moving party and there are "serious legal questions going to the merits." *See, e.g., Akiachak Native Community, et al., v. Jewell*, 995 F.Supp.2d 7, 13-14 (D.D.C. 2014); *Arpaio v. Obama*, -- F. Supp 3d --, Civ. Action No. 14-01966, 2014 WL 7279915 (D.D.C. Dec. 23, 2014).

On the other hand, the extremely limited duration of the injunction will ensure that the Defendants will suffer virtually no hardship.

Takeda also believes that it is likely to prevail on the merits of its claims before the D.C. Circuit. As set forth in its motion for TRO or preliminary injunction, FDA's approval of Mitigare violates the FDCA and runs afoul of well-established FDA precedent.

Accordingly, Takeda respectfully requests that the Court immediately enter an order enjoining FDA's approval of Mitigare pending appeal, or at least for 5 business days to permit Takeda the opportunity to review this Court's forthcoming Opinion, notice an appeal of the final judgment, and seek a stay of the status quo from the D.C. Circuit.

CONCLUSION

For all the foregoing reasons, Takeda's emergency motion for injunction pending appeal should be granted.

Date: January 9, 2015

Respectfully submitted,

/s/ Susan M. Cook
HOGAN LOVELLS US LLP
Catherine E. Stetson
Susan M. Cook
Jessica L. Ellsworth
555 Thirteenth Street, N.W.
Washington DC 20004-1109
Telephone: (202) 637-5600
Facsimile: (202) 637-5910
cate.stetson@hoganlovells.com
susan.cook@hoganlovells.com
jessica.ellsworth@hoganlovells.com

Attorneys for Plaintiff Takeda Pharmaceuticals U.S.A., Inc.

CERTIFICATE OF SERVICE

I, Kathryn Long, an attorney, hereby certify that on January 9, 2015, the foregoing notice was electronically filed with the Clerk of the Court and that, in the same manner, an electronic copy was served on all counsel of record who have entered and appeared in this case.

/s/ Kathryn Long
Kathryn Long