IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

TAKEDA PHARMACEUTICALS U.S.A., INC.

Plaintiff,

and

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

Consolidated 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.

Case Nos. 1:14-cv-01668-(KBJ)
1:14-cv-01850-(KBJ)

RESPONSE IN OPPOSITION TO INJUNCTIVE RELIEF PENDING APPEAL

Plaintiff Takeda Pharmaceuticals U.S.A., Inc. ("Takeda") and Plaintiffs Elliott Associates, L.P., Elliott International, L.P., and Knollwood Investments, L.P. (collectively,

"Elliott") have both filed motions requesting that this Court enter an injunction pending the appeal of this Court's Order dated January 9, 2015. (Docs. #69 and 70). The Government submits this Response in opposition to Takeda and Elliott's requests for injunctive relief.

The pending motions fail to discuss the grounds upon which the injunctive relief Takeda and Elliott seek should be granted, however, review of the relevant factors demonstrates that an injunction is not appropriate in these circumstances. Federal Rule of Civil Procedure 62 states that "[w]hile an appeal is pending from an interlocutory order or final judgment that grants, dissolves, or denies an injunction, the court may suspend, modify, restore, or grant an injunction on terms for bond or other terms that secure the opposing party's rights." Fed. R. Civ. P. 62(c). Whether to grant a stay pending appeal is:

> a discretionary matter to be informed by a flexible application of the well-established, four-factor balancing test employed to consider preliminary injunctive relieve and other stays pending appeal in this circuit – (1) whether there is a substantial likelihood that the movant will succeed on the merits of the claims/appeal; (2) whether the movant will suffer irreparable injury if an injunction/stay does not issue; (3) whether others will suffer harm if an injunction/stay is granted; and (4) whether the public interest will be furthered by an injunction/stay.

Thorpe v. District of Columbia, No. 10-2250 ESH, 2014 WL 3883417, *2 (D.D.C. Aug. 8, 2014) (*quoting In re Lorazepam & Clorazepate Antitrust Litig.*, 208 F.R.D. 1, 3 (D.D.C. 2002)).

The merits of the arguments raised by Takeda and Elliott have been briefed extensively before this Court, and while the parties do not yet have a copy of the Court's Opinion, the Order issued on January 9, 2015, demonstrates that the Court did not find the merits arguments raised by Takeda and Elliott to be convincing. Takeda and Elliott are likely to maintain their same legal arguments upon appeal, and "a party offering a 'regurgitation of rejected arguments,' cannot establish a likelihood of success on the merits[,]" *Akiachak Native Community v. Jewell*, 995 F. Supp. 2d 7 (D.D.C. 2014)) (*quoting Shays v. Federal Election Com'n*, 340 F. Supp. 2d 39

(D.D.C. 2004)), much less a "substantial" likelihood of prevailing on appeal. Even if the Court were to find that Takeda and Elliott had raised "'serious legal questions going to the merits, so serious, substantial, difficult as to make them a fair ground of litigation[,]'" *Akiachak Native Community*, 995 F. Supp. 2d at 13-14 (*quoting Population Inst. v. McPherson*, 797 F.2d 1062, 1078 (D.C. Cir. 1986)), that finding alone would not warrant granting the extraordinary injunctive relief sought, especially as the other relevant factors do not support the entry of an injunction.

The second factor requires that the Court consider any harm Takeda and Elliott will face if the request for injunctive relief is not granted. The only harm referenced in the pending motions is the financial loss that may be suffered. In this circuit, mere economic loss—even irrecoverable economic loss—does not constitute irreparable harm unless the financial injury is so great as to threaten the continued existence of the movant's business:

> To satisfy the standard of irreparable injury to justify a preliminary injunction, the movants' loss must be "more than simply irretrievable." *Mylan Labs., Inc. v. Thompson*, 139 F. Supp. 2d 1, 27 (D.D.C. 2001); *see also Wisc. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). Instead, the injury must be such that it "cause[s] extreme hardship to the business, or even threaten[s] destruction of the business." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1025 (D.D.C. 1981); *see also, Sandoz, Inc. v. FDA*, 439 F. Supp. 2d 26 (D.D.C. 2006) (noting that "[t]o successfully shoehorn potential economic loss into the irreparable harm requirement, a plaintiff must establish that the economic harm is so severe as to 'cause extreme hardship to the business' or threaten its very existence.").

Mylan Labs., Inc. v. Leavitt, 484 F. Supp. 2d 109, 123 (D.D.C. 2007). As discussed at length in the Government's response to Takeda's motion seeking the entry of a preliminary injunction (Doc. #15), Takeda is part of a large, global corporation, and its financials must be viewed as such. Colcrys revenues account for a mere 3% of Takeda's worldwide revenue, and any losses it may suffer cannot satisfy this standard. As a result, this factor does not weigh in favor of Takeda.

Similarly, any economic harm that might befall Elliott is also insufficient to cause this factor to weigh in favor of injunctive relief. The Elliott plaintiffs describe themselves in their complaint as "investment vehicles that provide income to their partners based on their strategic investments" and assert that they are entitled to royalties from the sale of Colcrys. Elliott's claims are merely financial, as they anticipate that they will lose the value of their investment royalties. Mere financial harm is insufficient in this Circuit to warrant the entry of injunctive relief. *See, e.g. Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). This factor does not weigh in favor of the entry of injunctive relief.

The third factor considers what harm an injunction would cause to others, and ultimately weighs against the entry of an injunction. Here, due to the injunction entered in the patent litigation, Hikma and West-Ward have thus far been unable to market their colchicine product despite the fact that it was approved by FDA on September 26, 2014. Entering an injunction in this case would certainly cause Hikma and West-Ward great economic harm, and it is likely that the harm they would face if an injunction is entered would match, if it did not exceed, the economic harm Takeda and Elliott may experience. *See Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (finding in a case with similar circumstances that the harm faced by the parties "results roughly in a draw").

Finally, the Court must consider the public interest, and whether it would be furthered by the entry of an injunction. The public has an interest in competition from generic drug providers, and is harmed every day that consumers are unable to purchase an approved, low-cost, alternative colchicine product. The public interest is "inextricably linked" to Congress's purpose in enacting the Hatch-Waxman Amendments, which includes providing consumers with faster

access to generic drugs. *Id.* The public interest weighs against entering the injunction sought by Takeda and Elliott.

In sum, the balance of these factors demonstrates that the extraordinary injunctive relief Takeda and Elliott seek should not be entered. While a request for a temporary five-day injunction may not seem unreasonable upon first blush, there is no valid basis for entering *any* injunctive relief pending appeal unless Takeda and Elliott can satisfy the stringent standards of Rule 62(c). Because it is clear that neither of them can make the requisite showings, their motions for an injunction pending appeal must be denied.

Dated: January 11, 2015

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Respectfully submitted,

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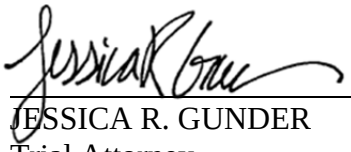

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CERTIFICATE OF SERVICE

I certify that on January 11, 2015, I caused a true and correct copy of the above-entitled Response in Opposition to Injunctive Relief Pending Appeal to be served via the Court's Electronic Case Filing system to all counsel of record.

s/ JESSICA R. GUNDER_____
JESSICA R. GUNDER