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., Intervenors-Defendants.	C.A. 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 official capacity as SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, and	C.A. No. 1:14-cv-01850 (KBJ)

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

Defendants,

and

HIKMA PHARMACEUTICALS PLC and WEST-WARD PHARMACEUTICAL CORP.,

Intervenors-Defendants.

HIKMA'S OPPOSITION TO PLAINTIFFS' EMERGENCY MOTIONS FOR INJUNCTION PENDING APPEAL

Plaintiffs Takeda Pharmaceuticals U.S.A., Inc. and Elliott Associates, et al. (collectively "Takeda") filed separate motions seeking a *mandatory* injunction to suspend FDA's approval of Hikma's colchicine product pending an appeal, or at least five business days. Despite seeking such an extraordinary remedy, Takeda has failed to "demonstrate that it is 'clearly' entitled to the relief it seeks or 'extreme or very serious damage will result.'" *Mylan Labs., Inc. v. Leavitt*, 495 F. Supp. 2d 43, 46-47 (D.D.C. 2007). After all, Takeda's attempt to block generic competition has been rejected by five federal judges from three courts, including this Court. Takeda is not entitled to relief—"clearly" or otherwise.

Indeed, Takeda offers *no* genuine reason to second-guess this Court's ruling or FDA's approval of Hikma's product. The Federal Circuit already has affirmed that competition from Hikma is unlikely to encroach on any of Takeda's patent rights. And this Court, after receiving many briefs and holding two detailed hearings, has found no APA violation.

Incredibly, Takeda has neglected to notify the Court that it is actively preparing to launch its own generic version of Colcrys® to preempt, or otherwise disrupt, Hikma's launch.

See Ex. 1 (press release announcing Takeda's authorized-generic launch). Takeda cannot explain why it should be free to launch its own generic product while Hikma is enjoined, even temporarily, especially when Takeda has not even offered to post a bond. Takeda has had its day—indeed, days—in court. Transparently, Takeda is now simply trying to delay legitimate generic competition while launching its own generic product.

Although Takeda says it will lose market share from Hikma's non-infringing competition, it has failed to address the significant harm an injunction pending appeal—even a five-day injunction—would cause Hikma, particularly without any safeguards in the injunction designed to protect Hikma from harm. Last October, Hikma had already shipped its product to customers when the Delaware court required Hikma to notify customers that no product could be sold. Now that the Federal Circuit has allowed "both" Hikma and Takeda "to immediately offer colchicine products for prophylactic use," Hikma's customers can finally sell the product. Even a five-day injunction would materially harm Hikma's reputation and customer relationships. In light of its own imminent launch, Takeda is plainly trying to use the courts to obtain a competitive windfall—a five-day head start to offer an automatically-substitutable generic product before Hikma can reach the market, thus reversing the competitive advantage Hikma had by virtue of the FDA's approval of its product. Such an injunction would cause irreparable harm *to Hikma*.

Nor does Takeda make any attempt to show how its requested mandatory injunction would harm the public. As the American College of Rheumatology put it, "[e]ven with the availability of insurance and patient-assistance programs, [Takeda's monopoly pricing] has put colchicine prophylactic therapy out of reach for many of the millions of Americans who suffer

from gout." D.E. 66 Ex. 1 at 1. By contrast, Hikma's product launch will finally put colchicine therapy back in the reach of all who need the drug.

For these and other reasons discussed below, Takeda's request for an extraordinary mandatory injunction should be denied.

ARGUMENT

This Court "analyzes motions for a stay pending appeal under the same factors that it considers for motions for a preliminary injunction." *Mylan Labs.*, 495 F. Supp. 2d at 46 (citation omitted). Thus, the court may issue a stay or injunction pending appeal "only when the movant demonstrates": "(1) a substantial likelihood of success on the merits, (2) that it would suffer irreparable injury if the injunction is not granted, (3) that an injunction would not substantially injure other interested parties, and (4) that the public interest would be furthered by the injunction." *Id.* at 46 (quoting *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1066 (D.C. Cir. 1998)); *see also Va. Petroleum Jobbers Ass'n v. Fed. Power Comm'n*, 259 F.2d 921, 925 (D.C. Cir. 1958) (applying these factors to an injunction pending appeal). Even a request for a five-day injunction must meet all the prongs for injunctive relief.

Where, as here, the moving party "seeks a mandatory injunction, rather than to merely maintain the status quo," that party "must demonstrate . . . that it is 'clearly' entitled to the relief it seeks or 'extreme or very serious damage will result.'" *Mylan Labs.*, 495 F. Supp. 2d at 46–47.[1] Other circuit courts agree.[2] As explained further in our opposition to Takeda's motion for a

[1] *See also, e.g.*, *King v. Leavitt*, 475 F. Supp. 2d 67, 71 (D.D.C. 2007); *Farris v. Rice*, 453 F. Supp. 2d 76, 78 (D.D.C. 2006); *Adair v. England*, 217 F. Supp. 2d 1, 3 n. 6 (D.D.C. 2002); *Mylan Pharm., Inc. v. Shalala*, 81 F. Supp. 2d 30, 36 (D.D.C. 2000); C*olumbia Hosp. for Women Found., Inc. v. Bank of Tokyo-Mitsubishi Ltd.*, 15 F. Supp. 2d 1, 4 (D.D.C. 1997), *aff'd*, 159 F.3d 636 (D.C. Cir. 1998).

preliminary injunction (D.E. 16), Takeda has failed "clearly" to satisfy any of the requirements for an injunction pending appeal.

As to the merits, Takeda cannot overcome the highly deferential standard of review for agency action based on scientific determinations within its expertise. *Baltimore Gas & Elect. Co. v. NRDC*, 462 U.S. 87, 103 (1983); *see also Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (explaining that rationale for deference is "particularly strong" when agency evaluates "scientific evidence within its technical expertise"). After due deliberation, FDA found Hikma's Mitigare™ product safe. And this Court has rejected all arguments to the contrary. "[B]ecause [this court] has previously considered the precise legal issue on appeal, the movant's showing of likelihood of success must be impressive." *Mylan Labs.*, 495 F. Supp. 2d at 47. Takeda has made no showing at all, much less an "impressive" one.

Nor has Takeda shown that its claimed injuries are "both certain and great." *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985). Because Takeda seeks to undermine—not preserve—the status quo, it faces an even higher burden: It must also show that "extreme or very serious damage will result." *Mylan Labs.*, 495 F. Supp. 2d at 46–47. Takeda points only to supposed lost profits, but it is "well settled that economic loss does not, in and of itself, constitute irreparable harm." *Wisconsin Gas Co.*, 758 F.2d at 674. Rather, "[r]ecoverable monetary loss may constitute irreparable harm only where the loss threatens the very existence of the movant's business." *Id.*; *see also United States v. W. Elec. Co.*, 777 F.2d 23, 29–30 (D.C. Cir. 1985) (holding that "the potential consequences outlined [by Western Electric] would not qualify as irreparable injury in the context of a stay application" because the company "does not allege that its destruction is imminent."). Takeda has made no such *argument*, much less a showing.

[2] *See Abdul Wali v. Coughlin*, 754 F.2d 1015, 1025 (2d Cir. 1985); *Stanley v. Univ. of S. California*, 13 F.3d 1313, 1319 (9th Cir. 1994); *Martinez v. Mathews*, 544 F.2d 1233, 1243 (5th Cir. 1976).

Nor has Takeda shown irreparable harm by pointing to purported safety concerns. After all, as a matter of law, issues of public safety are not irreparable harm *to Takeda*. *Cardinal Health, Inc. v. Holde*r, 846 F. Supp. 2d 203, 213 (D.D.C. 2012) ("This argument fails because it shows irreparable harm not to [Takeda], but to third parties."); *City of Moundridge v. Exxon Mobil Corp.*, 429 F. Supp. 2d 117, 129 (D.D.C. 2006) (holding that movants cannot "substitute proof of irreparable harm to the public for their own").

The balance of the equities also favors Hikma. Takeda fears loss of monopoly profits. But if Hikma's product were enjoined, Hikma would lose significant profits. Thus, even if lost profits constituted irreparable injury (they do not), it makes no sense to save Takeda from such injury when the very same injury threatens Hikma.

Indeed, the equities here tip heavily in favor of Hikma, as Takeda does not even offer to post a bond and has announced the launch of its own product. A mandatory injunction thus would give Takeda a head-start—reversing the situation when Hikma obtained FDA approval—and seriously injure Hikma, which spent years developing its generic colchicine product *solely* for a non-patented use. This is Hikma's biggest product launch. An injunction stopping that launch would cause tremendous disruption to Hikma's ongoing business operations, employees, shareholders, and customers. D.E. 16, Gavaris Decl. ¶¶ 17-29; D.E. 16, Todd Decl. ¶¶ 67-72.

The public interest also strongly cuts against injunctive relief. FDA has not only determined that Hikma's drug is safe, but patients are anxiously awaiting the *re*-launch of generic colchicine products. If the requested injunction issues, the public would lose access to a safe drug at a significantly reduced cost. "[A] strong public interest supports a broad choice of" drugs. *Cordis Corp. v. Boston Scientific Corp.*, 99 F. Appx. 928, 935 (Fed. Cir. 2004). Thus, "courts are generally reluctant to enjoin the sale of allegedly infringing medicines and medical devices

because of the public's interest in having access to medical treatment." *Boston Heart Diagnostics Corp. v. Health Diagnostics Lab., Inc.*, No. CIV. 13-13111-FDS, 2014 WL 2048436, at *2 (D. Mass. May 16, 2014); *see also Cordis Corp.*, 99 F. Appx. at 935 ("[F]or good reason, courts have refused to permanently enjoin activities that would injure the public health.").

According to the American College of Rheumatology ("ACR"), an organization Takeda itself has relied on to support its Delaware claims, Takeda's "five-year monopoly over colchicine, a drug *that has been used for centuries* to treat gout, has resulted in a *fiftyfold price increase* for the once affordable medication." D.E. 66 Ex. 1 at 1 (emphasis added). Worse still, "[e]ven with the availability of insurance and patient-assistance programs, the price surge has put colchicine prophylactic therapy out of reach for many of the millions of Americans who suffer from gout." *Id.* As ACR further explained, Takeda's substantial price hike for colchicine has caused patients to engage in risky behavior, such as "discounting their treatment or obtaining the drug from foreign countries." *Id.* at 10.

In sum, the public has a strong interest in "FDA … being able to discharge the duties entrusted to it by Congress free from judicial interference[.]" *AstraZeneca Pharm. LP v. FDA*, 850 F. Supp. 2d 230, 249 (D.D.C. 2012) (denying preliminary injunction motion). Courts have thus denied similar requests for injunctions and stays pending appeal. Order, *Mylan v. Leavitt*, No. 07–5156 (D.C. Cir. May 23, 2007) at 1 (quoted in *Mylan Labs.*, 495 F. Supp. 2d at 46 (D.D.C. 2007)). The same result is warranted here.

Takeda completely fails to establish any of the factors justifying an injunction pending appeal. The motion should be denied.

Dated: January 12, 2015

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I, Charles B. Klein, an attorney, hereby certify that on Monday, January 12, 2015, a true and correct copy of the foregoing memorandum and proposed order was served via the Court's CM/ECF system on all counsel of record.

/s/ Charles B. Klein
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