

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

HOSPIRA, INC.

Plaintiff,

v.

SYLVIA MATHEWS BURWELL,
Secretary of Health and Human Services

MARGARET A. HAMBURG, M.D.,
Commissioner of Food and Drugs,

and

UNITED STATES FOOD AND DRUG
ADMINISTRATION,

Defendants,

MYLAN INSTITUTIONAL LLC

Intervenor-Defendant.

Civil Action No. 14-cv-02662 (GJH)

MOTION FOR LEAVE TO FILE BRIEF BY 5:00 p.m. ON AUGUST 20, 2014.

Intervenor-Defendant Mylan Institutional LLC moves for leave to file a brief opposing the extraordinary and unprecedented relief requested by Plaintiff and its partner, Intervenor Sandoz, Inc., by 5:00 p.m. on August 20, 2014.

Despite being granted its verbal motion to intervene at today's Temporary Restraining Order hearing, Sandoz this evening filed a brief making unrequested arguments to the Court to which Mylan has not had a chance to respond. This on the heels of more than 200 pages filed by Plaintiff this morning—without notice to Mylan and despite knowing that Mylan was an interested party to this action. Mylan discovered Hospira's action in time to file its papers to intervene and to appear at today's hearing. Mylan has *not* had a full opportunity to rebut Plaintiff's numerous factually incomplete statements and erroneous statements of law, omissions

that are fatal to Plaintiff's extraordinary and unprecedented relief. As just one example, Plaintiff failed to inform the Court that its purely financial harms preclude any injunctive relief. *See Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, No. 13-854, 572 U.S. __ (2104), 34 S. Ct. 1621 (Mem.), 2014 WL 1516642, 18 April 2014 [http://www.supremecourt.gov/opinions/13pdf/13a1003_5h26.pdf] (Roberts, Circuit Justice, Apr. 18, 2014) (holding that where a brand pharmaceutical company can recover damages against an accused generic infringer, there is no irreparable harm); *see also Sampson v. Murray*, 415 U.S. 61, 90 (1974) ("The key word in this consideration is irreparable. Mere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay, are not enough.") (internal quotation marks omitted). As one court has noted in denying a preliminary injunction seeking to force FDA to withdraw approval of several ANDAs, "economic loss qualifies only if it 'threatens the very existence of the movant's business.'" *Viropharma, Inc. v. Hamburg*, 898 F. Supp. 2d 1, 25 (D.D.C. 2012) (citation omitted). Even where a plaintiff has no recourse other than against a government agency because of sovereign immunity, a plaintiff must still show "severe economic impact," or "prospective injunctive relief would often cease to be an 'extraordinary remedy' in cases involving government defendants." *Id.* at 26 & n.31 (internal citations and quotations omitted). Here, of course, Hospira retains other remedies—including an action for patent infringement damages against any alleged infringers. As another example, Plaintiff seeks unprecedented relief against FDA which no Court has ever granted.

Finally, any order against Mylan would be a boon to other ANDA filers who did not have the opportunity to appear at today's hearing – presumably because Plaintiff failed to notify them as well and so are not subject to this Court's order. Plaintiff cites no authority to support the assertion that FDA has the power to issue a recall of a safe and effective product. Plaintiff's

over-reaching grab for extraordinary relief demands more fulsome briefing before this Court issues any order on the Plaintiff's motion. Accordingly, Mylan respectfully requests leave to file a brief opposing the extraordinary and unprecedented relief requested by Plaintiff and its partner, Intervenor Sandoz, Inc., by 5:00 pm on August 20, 2014.

Dated: August 19, 2014

Respectfully Submitted,

/s/ Shannon M. Bloodworth

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