UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

HOSPIRA, INC.,

Plaintiff,

and

SANDOZ, INC.

Intervenor-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,

and

MYLAN INSTITUTIONAL LLC

and

PAR STERILE PRODUCTS INC.,

Intervenor-Defendants.

Civil Action No. 8:14-cv-02662-GJH

FEDERAL DEFENDANTS' BRIEF IN SUPPORT OF RECONSIDERATION AND MODIFICATION OF PARAGRAPHS 3 AND 4 OF THE TEMPORARY RESTRAINING ORDER

The federal defendants agree with Mylan Institutional LLC and Par Sterile Products Inc. that the forms of relief in paragraphs 3 and 4 of the temporary restraining order ("TRO") entered on August 19, 2014, (Dkt. #20) are not appropriate and should be modified to reflect orders issued in similar circumstances.[1] For example, this Court has previously ordered that a generic drug application's approval be suspended in *Glaxo Group Ltd. v. Leavitt*, No. 06-469 (order dated Feb. 23, 2006) (attached as Exhibit A). The *Glaxo* Court also ordered the generic company to cease distribution of the product and stop contracting with companies for distribution. In *Glaxo*, FDA temporarily suspended the drug's approval pursuant to that order. *See* Exhibit B. Notably, however, the *Glaxo* court did not order a mandatory recall of the generic drugs already on the market, nor did it retroactively declare that the FDA's approval of the drug be rescinded.

The purpose of injunctive relief is to prevent future harm. Paragraphs 3 and 4 of the TRO appear to be directed (at least in part) to products that have already been marketed. *See Rondeau v. Mosinee Paper* Corp., 422 U.S. 49, 61 (1975) ("the historic injunctive process was designed to deter, not to punish"); *see also United States v. Oregon Med. Soc'y*, 343 U.S. 326, 333 (function of injunctive relief is to forestall future violations). The relief ordered in paragraphs 3 and 4 goes well beyond the standard type of forward-looking temporary relief entered in *Glaxo*, and is not appropriately tailored to address the alleged harm.

Specifically, paragraph 3 of the TRO states that "FDA is ORDERED to recall any product sold or distributed under such an approval." But FDA cannot order recalls. *See* 21 C.F.R. § 7.40 ("Recall is a *voluntary* action that takes place because manufacturers and

[1] FDA has complied with paragraphs 1 and 2 of the Court's order and has issued letters to Mylan and Par, which are attached as Exhibits C and D. The federal defendants are limiting their arguments herein to paragraphs 3 and 4 of the TRO, but intend to oppose Plaintiff's motion for a preliminary injunction and respond to the merits of Plaintiff's arguments.

distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.") (emphasis added). If a company chooses not to comply with an FDA request to recall, FDA has no mechanism to enforce its request because it does not have statutory authority to order drug recalls.[2] Thus, as currently written, FDA cannot effectively implement paragraph 3 of the TRO.

At most, FDA can request a recall, but in circumstances that are not present here. *See* 21 C.F.R. §7.45 ("The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made: (1) That a product that has been distributed presents a risk of illness or injury or gross consumer deception. (2) That the firm has not initiated a recall of the product. (3) That an agency action is necessary to protect the public health and welfare."); *see also* 21 C.F.R. § 7.40. Hospira has neither alleged nor offered any evidence that such a standard has been met. Instead, Hospira alleges that the generic manufacturers will violate a patent, nothing more. There is neither legal authority nor any precedent for ordering a recall under these circumstances.

Moreover, the recall specified in this TRO, based upon a patent dispute between private parties, will negatively affect the perception of future recalls. As discussed above, FDA may only request a recall when the product that has been distributed presents a risk of illness or injury or gross consumer deception. As a result, consumers should believe that recalled products present a risk to health or are grossly deceptive. That is decidedly not the case here. When other future products are recalled, consumers may question whether the recall is related to a legitimate public health concern, or whether it is merely another patent dispute in which safety or efficacy is not at issue. The public interest weighs strongly against the injunction in paragraph 3 of the

[2] Because both Mylan and Par are parties to this lawsuit, this Court may separately order them to act. *See* Fed. R. Civ. P. 65(d)(2).

TRO because it threatens to disrupt the consistent regulatory standards for recalls. FDA therefore respectfully requests modification of paragraph 3 and offers the court's order in *Glaxo* as an example of an order consistent with the agency's statutory authority.[4]

Paragraph 4, in which Plaintiff requested that Mylan's and Par's ANDA approvals be rescinded, *ab initio*, is also well outside the norms of relevant case law. FDA is not aware of any other circumstance in which a court has issued such an order, and Plaintiff has provided no support for such relief.[5] Rather, as noted, courts may and have directed FDA to suspend approvals *temporarily*, which is fully consistent with a *temporary* restraining order. See *Glaxo* TRO (Exhibit A); *see also* TRO in *Valeant Pharm. Int'l v. Leavitt*, No. 08-449 (C.D. Cal) (Exhibit F). Indeed, FDA can withdraw approval of a drug, but only after going through a statutory process affording a hearing. *See* 21 U.S.C. § 355(e). And such a withdrawal would not be *ab initio*: a remedy that raises legitimate concerns about the regulatory status of drugs that were lawfully approved when they were marketed.

Finally, Hospira has repeatedly complained—with much vigor and little justification—that FDA refused to give advance notice of its decision, and that the relief in paragraphs 3 and 4 is necessary because the ANDA holders were able to market their product before Hospira was able to obtain judicial review of FDA's decision. But FDA does not give advance notice, for good reason, of such decisions in these situations. *See, e.g., AstraZeneca Pharmaceuticals LP v. FDA*, No. 12-00388 (D.D.C. Mar. 26, 2012) (order denying motion for advance notice) (attached as Exhibit E). The Administrative Procedure Act only provides for judicial review of *final*

[4] The government also has some concerns about how the ordered recall will affect the perception of the generics' products. We note that there is the reasonable possibility that the market will assume that, because they have been recalled, the generics' products are unsafe. We leave it to the Defendant-Intervenors to describe that possible impact, and whether it may cause them harm.

[5] Further, Congress has assigned the task of approving and withdrawing drugs to FDA, not the courts. 21 U.S.C. § 355. It has provided a limited exception allowing courts to change the effective date of approval of an application if it is found to infringe a patent in 35 U.S.C. § 271(e)(4), which is inapplicable here.

agency action, 5 U.S.C. § 704, and such advance notice would prompt premature lawsuits challenging a decision before it is ripe. *See, e.g., Abbott Laboratories v. Gardner*, 387 U.S. 136, 148-49 (1967) (stating that the purpose of the ripeness doctrine is "to prevent the courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies, and also to protect the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties"). Further, statutes and relevant disclosure regulations prohibit FDA from disclosing in advance any not-yet-final intention to approve a competitor's application. *See* 18 U.S.C. § 1905; 21 C.F.R. § 20.61(c); 21 C.F.R. § 314.430. The Federal Rules of Civil Procedure provide ample means for challenging FDA's decisions within a short timeframe.[6] While the parties and this Court might prefer to avoid the timing exigencies involved with these cases, the inconvenience does not justify novel remedies that are unable to be implemented, as written, and far exceed the relief ordinarily granted in these situations.

For all of these reasons, FDA respectfully requests that the Court's temporary restraining order be modified in accordance with the attached Exhibit G.

Respectfully submitted,

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Deputy Assistant Attorney General

[6] Plaintiff Hospira has, as of this filing, failed to post a bond to cover the amount of potential losses to Defendant-Intervenors Mylan and Par as required by Fed. R. Civ. P. 65(c) in order to be granted a TRO. *See* Fed. R. Civ. P. 65(c) ("The court may issue a preliminary injunction or a temporary restraining order *only if the movant gives security* in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.") (emphasis added); *see, e.g.*, Ex. A (ordering Glaxo to post a surety bond in the amount of $3,000,000).

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CERTIFICATE OF SERVICE

I hereby certify that, on this 21st day of August 2014, Defendants' NOTICE OF APPEARANCE was served on the following individuals who are counsel for the Plaintiffs through ECF, as well as all other counsel of record within ECF:

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