IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WYETH PHARMACEUTICALS, Plaintiff, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	)	Civil Action No.

PLAINTIFF'S MOTION FOR A PRELIMINARY INJUNCTION OR, IN THE ALTERNATIVE, A TEMPORARY RESTRAINING ORDER

Pursuant to Rule 65 of the Federal Rules of Civil Procedure, Plaintiff Wyeth Pharmaceuticals, through undersigned counsel, hereby moves this Court to issue a preliminary injunction or, if no preliminary injunction hearing can be held on or before Friday, September 25, 2009, a temporary restraining order pending such a hearing requiring the U.S. Food and Drug Administration ("FDA" or the "Agency"), the U.S. Department of Health and Human Services, Kathleen Sebelius, in her official capacity as Secretary of Health and Human Services, and Margaret Hamburg, M.D., in her official capacity as Acting Commissioner of FDA (collectively "Defendants") to withdraw or suspend FDA's approval of the Abbreviated New Drug Applications (ANDAs) submitted by Orchid Healthcare, and approved on September 15, 2009, which sought to market generic formulations of piperacillin sodium-tazobactam sodium that are materially different than Wyeth's branded formulation of piperacillin sodium-tazobactam sodium, Zosyn® ("Zosyn").

Plaintiff further requests, pursuant to Local Rule 65.1(d), a preliminary injunction hearing within twenty days of the filing of this motion. As set forth more fully below, based upon the best information currently available to Wyeth, Wyeth believes that a hearing will be required on or before Friday, September 25, 2009 in order to avoid the imminent irreparable injury to patients and to Wyeth threatened by FDA's action. If a hearing cannot be held on or before Friday, September 25, 2009, Wyeth requests that the Court issue a temporary restraining order, pending the completion of briefing and a hearing on its request for a preliminary injunction.

The reasons supporting this motion are set forth below and are more fully explained in the accompanying Memorandum of Points and Authorities, and declarations and exhibits thereto, in support of this motion:

1. FDA's decision is arbitrary, capricious, and contrary to law, and there is a substantial likelihood that Wyeth will succeed on the merits of this action. Specifically, approval of Orchid's ANDAs violates the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), FDA's implementing regulations, and the Administrative Procedure Act in that:

a) FDA's action violates the same-ingredients requirement. The approved generic formulations do not contain the same inactive ingredients as Wyeth's formulation of Zosyn, as required under FDA's regulations. *See* 21 C.F.R. § 314.94(a)(9)(iii). Due to the risk of medication errors and patient harm that arise from these differences, the change in inactive ingredients raises questions of safety and/or efficacy that preclude the applicability of any exception

to this regulatory requirement, (*id.* at § 314.127(a)(8)(ii)(B)), or waiver of this regulatory requirement (*id*. at § 314.99).

b) FDA's action violates the same-labeling requirement. Despite the statutory requirement that the labeling for the approved generic formulations be substantially "the same" as the labeling for Wyeth's formulation of Zosyn, *see* 21 U.S.C. § 355(j)(2)(A)(v), the generic labeling includes drug incompatibility warnings with respect to Lactated Ringer's Solution not found in the labeling for Wyeth's formulation of Zosyn. Because these differences reflect the conditions under which the generic formulations may be safely and effectively used, and may give rise to medication errors and patient harm, they do not fall under any statutory or regulatory exception. *Id*.; *see also* 21 C.F.R. § 314.94(a)(8)(iv).

c) Given the medication errors and patient harm that may result from the concurrent marketing of Orchid's generic products alongside Wyeth's formulation of Zosyn, the Agency's failure to meaningfully consider alternatives such as risk management plans and/or strategies to communicate to physicians and patients the differences between Orchid's generic product and Wyeth's product was arbitrary, capricious, an abuse of discretion, and not in accordance with the law.

2. Absent a preliminary injunction or temporary restraining order, the public health will suffer because the approved generic versions of Zosyn cannot be safely administered in essentially the same way as the innovator drug. This situations creates a significant risk of medication errors and patient harm. In addition, Wyeth will suffer irreversible harm in the form of (i) loss of goodwill if less favorable clinical outcomes

and patient injury result from the improper administration of the generic drug product due to product confusion and medication error; (ii) loss of sales revenue and market share; and (iii) loss of business opportunities. This harm is also irreparable because monetary and other damages cannot be recouped from the Agency.

3. The issuance of an injunction will not substantially injure Defendants because, among other things, FDA has the statutory duty to ensure that the new innovator drugs it approves are safe and effective and that generics drugs can be safely administered in the same way as the innovator drug.

4. Finally, it is in the public interest to issue an injunction because FDA's approval of Orchid's ANDA unnecessarily places the public health at risk. The differences between Zosyn and Orchid's generic product create a significant risk of confusion about whether the generic drug can be safely administered in the same way as Zosyn. Because these differences relate to drug-to-drug interactivity and conditions of administration, there is a substantial risk that the approved generic version will be used improperly, resulting in drug deactivation in critically ill patients.

5. As attested to in the accompanying Certificate of Counsel Pursuant to Local Rule 65.1(a), counsel for Plaintiff has informed counsel for Defendants of Plaintiff’s intention to seek a temporary restraining order in the alternative in this matter and the time of the making of this application, and has provided counsel for Defendants with copies of Plaintiff's Complaint for Declaratory, Injunctive, and Other Relief, this motion, and all supporting papers, including the accompanying proposed order.

6. Counsel for Plaintiff has complied with the requirements of Local Rule 7(m) by discussing this motion with counsel for Defendants. Counsel for Defendants do not consent to this motion.

7. Therefore, a preliminary injunction or, in the alternative, a temporary restraining order is appropriate and the Court should grant the requested relief.

8. The facts of this case make an expedited preliminary injunction hearing essential due to the imminent entry of the non-equivalent generic product into the marketplace and the health care system. Specifically:

a) The day after Orchid received FDA approval, Orchid's Managing Director stated in a press interview that Orchid expects to launch the product "straight away" with its marketing partner Apotex, Inc., a well-established company in the generic market with the resources to distribute the generic version to hospitals expeditiously and widely. *See* Declaration of Lewis L. Barrett III Declaration ("Barrett Declaration"), Exhibit A.

b) Wyeth has received reports that several major wholesalers, including Cardinal Health, are anticipating receiving shipments of generic Zosyn from Orchid within 7-10 days from last Thursday, September 17, 2009. Barrett Declaration, at ¶ 9. Other reports have indicated that shipments may begin within a month of FDA's approval, which occurred on September 15, 2009. *Id*.

c) Based upon its extensive experience with pharmaceutical distribution, Wyeth believes that, if wholesalers receive generic Zosyn on or about Thursday, September 24, 2009, hospitals could begin to receive generic Zosyn as soon as Friday, September 25, 2009. Barrett Declaration, at ¶ 12-13.

d) Some hospitals may require their Pharmacy & Therapeutic committees ("P&T committees") to meet before substituting generic Zosyn for the branded version in patient care, while others may not. Even in hospitals where P&T committee meetings are required, such meetings can take place as quickly as one day from the date on which a new product becomes available for use. Barrett Declaration, at ¶ 13.

e) Although Wyeth cannot know for certain when patients may first be exposed to the non-equivalent generic product, based on the best information currently available to it, Wyeth believes that generic Zosyn could be administered to patients as soon as Friday, September 25, 2009 and no later than the second week of October 2009. Barrett Declaration, at ¶ 14.

f) There is a serious and real risk that as soon as the approved generic formulation is substituted for reformulated Zosyn, the approved generic will be mistakenly used by nurses and physicians in situations that are improper, *i.e.*, where compatibility with Lactated Ringer's Solution is mistakenly believed to exist based on experience with Wyeth's formulation. Declaration of Manjari Joshi, M.D. Declaration, at ¶¶ 17-21; Declaration of J. Lyle Bootman, Ph.D., Sc.D., at ¶¶ 25-35. This could result in deactivation of the antibiotic and serious harm to gravely ill patients.

g) Given the risk of serious patient harm that could result if the generic product is mistakenly assumed to be interchangeable with the branded product, expedited action by this Court is necessary on or before Friday, September 25, 2009 to ensure the product does not enter the stream of commerce

or health care system until the Court has an opportunity to adjudicate Wyeth's claims that the FDA has acted unlawfully in approving a generic drug that presents such extraordinary risks to patient health and welfare.

9. Accordingly, Wyeth seeks a hearing on Plaintiff's motion on or before Friday, September 25, 2009, and a preliminary injunction requiring Defendants to withdraw or suspend its approval of Orchid's ANDAs approved on September 15, 2009, and withdraw or suspend Defendants approval of any ANDA seeking approval to market a generic version of Zosyn that does not contain the same inactive ingredients as Zosyn, is not compatible with LRS, and/or does not include the same labeling as Zosyn.

10. If a the motion for a preliminary injunction cannot be heard and adjudicated on or before Friday, September 25, 2009, Wyeth respectfully requests a temporary restraining order not to exceed the period allowed by Federal Rule of Civil Rule 65(b)(2), requiring Defendants to withdraw or suspend its approval of Orchid's ANDAs approved on September 15, 2009.

Dated: September 22, 2009

Respectfully submitted,

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