

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

Otsuka Pharmaceutical Co., Ltd., et al.,

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Plaintiff,

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v.

Case No. 15-cv-0852-GJH

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Sylvia Mathews Burwell, et al.,

*

Defendants.

* * * * *

MOTION FOR STAY OF PROCEEDINGS AND MEMORANDUM IN SUPPORT

Plaintiffs, Otsuka Pharmaceutical Co., Ltd., Otsuka Pharmaceutical Development & Commercialization, Inc., and Otsuka America Pharmaceutical, Inc. (collectively, “Otsuka”), hereby respectfully move for a stay of all proceedings herein pending the filing of an amended complaint and a motion for temporary and/or preliminary injunctive relief. In support of this motion, Otsuka says as follows:

1. Count one of Otsuka’s complaint in this case challenged the lawfulness of FDA’s drug approval decision, a final agency action in which, Otsuka asserted, FDA unlawfully approved Otsuka’s brand drug aripiprazole (marketed as Abilify®) for the treatment of Tourette’s Disorder in the general population when the drug had only been shown to be safe and effective in pediatric patients. Count two sought a declaratory judgment, requesting that the Court declare that, assuming but not conceding the validity of that broadened approval, FDA was precluded as a matter of law from approving generic versions of Abilify on April 20. A hearing on Otsuka’s motion for summary judgment is scheduled for April 14, 2015, at 10:00 AM.

2. On the afternoon of April 10, 2015, Otsuka’s undersigned counsel received from counsel for FDA a letter from FDA to Otsuka. In that letter, FDA reversed itself again and has now determined that “the approval of Abilify for Tourette’s Disorder is only for pediatric patients.”

FDA's April 10 action moots the claims in the complaint pending before the Court. While the present claims are moot, Otsuka respectfully urges the Court to stay this action, including the filing of the Administrative Record on April 13, the filing of Otsuka's Reply Memorandum on April 13, and the hearing on April 14, rather to dismiss the case.

3. A fundamental underlying issue – FDA's authority to approve generic versions of Abilify given FDA's orphan drug approval of the pediatric indication for the treatment of Tourette's Disorder, authority which Otsuka vigorously challenges – is unresolved and will fully ripen very shortly on or before April 20, when FDA is expected to grant, absent judicial intervention, approval of one or more generic versions of Abilify.

4. The issues involved in the case that Otsuka will bring by way of an amended complaint and motion for emergency injunctive relief will be back before the Court very soon. Those issues are so closely related to the issues in the present case that it is in the interest of judicial economy and the efficient handling of complex litigation for this case to remain "open" and for this Court to retain jurisdiction.

5. The Court has "broad discretion" to stay proceedings. *Clinton v. Jones*, 520 U.S. 681, 706 (1997). "A court may issue a stay pending resolution of an . . . administrative proceeding[] in the interest of efficiency and fairness." *N.C. Health & Human Servs. v. Shalala*, No. 5:98-cv-16, 1998 U.S. Dist. LEXIS 16370, *5 (E.D.N.C. Aug. 4, 1998). The moving party must show "clear and convincing circumstances outweighing potential harm to the party against whom it is operative." *Id.* Courts generally consider three factors when ruling on a motion to stay: "(1) the interests of judicial economy; (2) hardship and equity to the moving party if the action is not stayed; and (3) potential prejudice to the non-moving party." *Rodman v. Md. Dep't of Human Res.*, No. 12-cv-3218-JKB, 2013 U.S. Dist. LEXIS 74347, *4-5 (D. Md. May 28, 2013) (internal

quotation marks omitted); *see also Crown Cent. Petroleum Corp. v. Dep't of Energy*, 102 F.R.D. 95, 98-99 (D. Md. 1984). Those factors strongly weigh in favor of a stay here.

6. Otsuka is extremely concerned that FDA will manipulate the timing of its approval of generic versions of Abilify to compromise Otsuka's ability to obtain meaningful judicial review *before* generic approval is an accomplished fact and the "trucks roll" and distribution is underway. FDA's conduct in the present case, switching from a pediatric approval to approval in the population in general and then today switching back yet again to pediatric only, does not inspire confidence in this regard. FDA's conduct of seeking to insulate its generic drug approval decisions from meaningful judicial review has been criticized. *See AstraZeneca Pharms., LP v. FDA*, No. 12-472, 2012 U.S. Dist. LEXIS 54863, *10-11 (D.D.C. Mar. 28, 2012).

7. It is in the interests of judicial economy to keep this case before this Court open as Otsuka will file by Wednesday, April 15, 2015, an amended complaint, a motion for temporary or preliminary injunctive relief, and a proposed schedule to allow for a hearing before, not after, FDA grants the expected generic approvals on April 20.

8. Staying this case presents no harm to the non-moving parties.

9. Given the time constraints, counsel was unable to consult with counsel for the intervenor-defendants. Counsel consulted with counsel for FDA and does not represent the government's position on this motion.

For the reasons stated, Otsuka moves the Court for a stay of all proceedings herein with the right to seek to reopen the proceedings upon the filing, within a reasonable time appropriate, of amended or supplemental pleadings. A proposed Order is attached.

Respectfully submitted,

Dated: April 10, 2015

/s/ Ralph S. Tyler

Ralph S. Tyler (Bar No. 01747)
rtyler@venable.com
Maggie T. Grace (Bar No. 29905)
mtgrace@venable.com
VENABLE LLP
750 East Pratt Street, Suite 900
Baltimore, Maryland 21202
(410) 244-7400
Fax: (410) 244-7742

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 10th day of April, 2015, a copy of the foregoing MOTION FOR STAY OF PROCEEDINGS AND MEMORANDUM IN SUPPORT is available for viewing from the Court's ECF system. Notice of this filing will be sent to all counsel of record via the Court's ECF system.

/s/ Ralph S. Tyler
Ralph S. Tyler

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ORDER STAYING PROCEEDINGS

Pending before the Court is plaintiffs' motion to stay all proceedings herein, rather to dismiss, in light of FDA's decision on April 10, 2015, that "the approval of Abilify for Tourette's Disorder is only for the pediatric population." Having reviewed the motion and any opposition thereto and good cause for the requested relief having been shown, plaintiffs' motion for stay is hereby GRANTED and all scheduled proceedings herein, including the filing of the supplement to the administrative record, plaintiffs' reply memorandum, and the motions hearing scheduled for April 14, 2015, are hereby STAYED. This stay will be lifted upon the filing within a reasonable time of amended or supplemental pleadings by plaintiffs or other parties.

SO ORDERED this ____ day of April 2015.

United States District Judge