

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

VELOXIS PHARMACEUTICALS, INC.)

Plaintiff,)

-v.-)

UNITED STATES FOOD AND DRUG)
ADMINISTRATION, *et al.*)

Defendants.)

Civil Action No. 14-cv-2126 (RBW)

**PLAINTIFF’S MOTION TO CONSOLIDATE HEARING
ON MOTION FOR PRELIMINARY INJUNCTION WITH THE
MERITS AND TO ADOPT AN EXPEDITED BRIEFING SCHEDULE**

Pursuant to Rule 65(a)(2) of the Federal Rules of Civil Procedure, Plaintiff Veloxis Pharmaceuticals, Inc. (“Veloxis”) respectfully requests that the Court consolidate the hearing on Veloxis’s Motion for Preliminary Injunction with a hearing on the merits, treating Veloxis’s Motion for Preliminary Injunction as a motion for summary judgment. Veloxis is submitting herewith a proposed schedule that, if adopted, would result in this matter being fully briefed for disposition by the Court no later than February 12, 2015. Pursuant to Local Civil Rule 7(m), Veloxis has consulted with counsel for Defendants, who oppose this motion.

Rule 65(a)(2) provides that “[b]efore or after beginning the hearing on a motion for a preliminary injunction, the court may advance the trial on the merits and consolidate it with the hearing.” Courts in this District routinely consolidate a hearing on a motion for preliminary injunction with a hearing on the merits in cases, such as this, where the plaintiff seeks review of agency action under the Administrative Procedure Act (“APA”), 5 U.S.C. §§ 701 *et seq.* See, e.g., *Pharm. Research & Mfrs. of Am. v. HHS*, No. 13-1501, 2014 WL 2171089, at *4 (D.D.C.

May 23, 2014) (granting parties' joint motion to consolidate under Rule 65(a)(2)); *Teva Pharm. USA, Inc. v. Sebelius*, 638 F. Supp. 2d 42, 48 (D.D.C. 2009) (granting plaintiff's request to consolidate under Rule 65(a)(2)), *rev'd on other grounds*, 595 F.3d 1303 (D.C. Cir. 2010).

Consolidation under Rule 65(a)(2) is appropriate in this case for three reasons. *First*, consolidation will result in an expedited resolution of the case. *See Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395, 101 S. Ct. 1830, 1834 (1981) (stating that when "an expedited decision on the merits [is] appropriate, Rule 65 (a)(2) of the Federal Rules of Civil Procedure provides a means of securing one"). An expedited resolution of this case is necessary to mitigate the irreparable harm to Veloxis and resolve whether Veloxis's immunosuppressant drug Envarsus[®] XR, which FDA already has found to be safe and effective for its intended use, should be immediately available to kidney transplant patients, who are currently being denied access to this drug.

Second, consolidation is appropriate here because the issues presented are "purely a matter of law." *Teva Pharm.*, 638 F. Supp. 2d at 48. Often, as in this case, when a party "seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (footnote and citations omitted). When reviewing the administrative record, "the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did." *Depomed, Inc. v. HHS*, No. 12-1592, 2014 WL 4457225, at *7 (D.D.C. Sept. 5, 2014) (quoting *Stuttering Found. of Am. v. Springer*, 498 F. Supp. 2d 203, 207 (D.D.C. 2007)), *appeal dismissed*, No. 14-5271, 2014 WL 5838247 (D.C. Cir. Nov. 7, 2014).

Third, consolidation is appropriate because it will “preserve judicial resources and save the parties from wasteful duplication of effort.” *NOW v. Operation Rescue*, 747 F. Supp. 760, 768 (D.D.C. 1990), *aff’d in part & vacated in part on other grounds*, 37 F.3d 646 (D.C. Cir. 1994); *see also Tea Party Leadership Fund v. FEC*, No. 12-1707, 2012 WL 5382844, at *1 (D.D.C. Nov. 2, 2012) (observing that Rule 65(a)(2) “is designed to conserve judicial resources and avoid duplicative proceedings”). Because the issue presented in this case is purely a question of law, the parties will present manifestly the same arguments at the preliminary injunction hearing as they will at a hearing on the merits. Thus, it would be wasteful of this Court’s limited resources and the efforts of the parties to require repetitive briefing and multiple hearings to resolve the matter. Accordingly, this case presents the ideal circumstances for consolidation.

For the reasons set forth above, Veloxis respectfully requests that the Court treat Veloxis’s Motion for Preliminary Injunction as a motion for summary judgment, *see, e.g., Ark Initiative v. Tidwell*, 895 F. Supp. 2d 230, 237 (D.D.C. 2012) (consolidating hearings under Rule 65(a)(2) and treating plaintiff’s motion for preliminary injunction as a motion for summary judgment), *aff’d*, 749 F.3d 1071 (D.C. Cir. 2014); *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 192 (D.D.C. 2002) (same), *aff’d*, 354 F.3d 877 (D.C. Cir. 2004), and adopt the following briefing schedule:

- Defendants shall file a certified list of the contents of the administrative records for Envarsus XR and Astagraf XL by no later than December 23, 2014. On that same day, defendants shall provide counsel for Veloxis with copies of the administrative record for Envarsus XR and Astagraf XL.
- If necessary, Veloxis shall file a motion to supplement the administrative record by no later than January 5, 2015. Any opposition thereto, shall be filed by no later than January 9, 2015.

- Defendants shall file their opposition to Veloxis's motion for preliminary injunction and, if applicable, any dispositive cross-motion by no later than January 16, 2015.
- Veloxis shall file its reply in support of its motion for preliminary injunction and, if applicable, a consolidated opposition to defendants' cross-motion by no later than February 2, 2015.
- Defendants shall file their reply in support of any cross-motion by no later than February 9, 2015.
- The parties shall jointly prepare an appendix containing those portions of the administrative records for Envarsus XR and Astagraf XL that are cited or otherwise relied upon by the parties in their briefing. Veloxis will file this joint appendix by no later than February 12, 2015.

Veloxis respectfully requests that a hearing on the merits be held by the Court as soon its schedule permits following submission of the joint appendix.

Dated: December 17, 2014

Respectfully submitted,
/s/ Mitchell S. Ettinger

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CERTIFICATE OF SERVICE

I hereby certify that on this date, the foregoing was filed and served electronically using the CM/ECF system to:

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