

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

MYLAN LABORATORIES, INC. <i>et al.</i> ,	:		
	:		
Plaintiffs,	:	Civil Action No.:	07-579 (RMU)
	:		
v.	:		
	:	Document. No.:	8
MICHAEL LEAVITT, <i>et al.</i> ,	:		
	:		
Defendants,	:		
	:		
and	:		
	:		
TEVA PHARMACEUTICALS USA, INC.	:		
	:		
Intervenor.	:		

**ORDER**

**GRANTING TEVA PHARMACEUTICALS USA INC.’S MOTION TO INTERVENE; DENYING TEVA  
PHARMACEUTICALS USA INC.’S MOTION TO AMEND THE SCHEDULING ORDER**

On March 26, 2007, the court enjoined the FDA from granting any abbreviated new drug applications (“ANDAs”) for amlodipine besylate from April 11, 2007 until April 13, 2007 at 5:00 pm to afford the parties the opportunity to brief the court on the pending application for a temporary restraining order (“TRO”) lodged by the plaintiff on March 26, 2007. This case concerns solely the plaintiff’s petition for a TRO, which seeks to enjoin the FDA from granting ANDA approvals. Mylan claims that it has a statutory right to a 180-day period of exclusive marketing and sale of the drug’s generic version.

Pending before the court is Teva Pharmaceuticals USA Inc.’s (“Teva”) motion to intervene and modify the court’s scheduling order. The parties in this action do not oppose Teva’s motion to intervene, but Mylan opposes Teva’s request for modification of the scheduling order. Because Teva has an interest in the present action, the court grants its motion to intervene

for the limited purpose of responding (the court presumes opposing) Mylan's application for a TRO. FED. R. CIV. P. 24(a).

Teva also asks the court to formulate a briefing schedule so that if the FDA denies final approval of its ANDA, Teva can file with dispatch its complaint and motion for summary judgment. Teva's Mot. to Intervene at 3. The court declines this invitation.

The sole dispute in this case concerns Mylan's attempt to block other generic drug approval. If the FDA, in its own procedures, does not grant other generic approval, Mylan's request for an injunction becomes moot. Should Teva wish to take legal action to enforce its alleged rights to FDA approval, it may do so. But Teva's claimed entitlement to FDA approval, and Mylan's claimed right to 180-day exclusivity, are legally distinct. As such, if the FDA denies ANDA approval, this case does not present Teva with an appropriate vehicle for asserting its claims.

For these reasons, it is this 29th day of March, 2007 hereby

**ORDERED** that Teva's motion to intervene is **GRANTED**, and it is

**FURTHER ORDERED** that Teva may file a responsive pleading to Mylan's application for a temporary restraining order by 9:00 am on April 12, 2007, and it is

**ORDERED** that Teva's request for the court to set a briefing schedule should the FDA deny its ANDA is **DENIED**.

**SO ORDERED.**

RICARDO M. URBINA  
United States District Judge