

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

NOVEN PHARMACEUTICALS, INC.,	:	
	:	
Plaintiff,	:	
	:	
v.	:	C.A. No. 17-1777-LPS
	:	
MYLAN TECHNOLOGIES INC., MYLAN PHARMACEUTICALS INC., MYLAN INC. and MYLAN N.V.,	:	
	:	
Defendants.	:	

**MEMORANDUM ORDER GRANTING LIMITED INJUNCTION**

At Wilmington this **22nd** day of **August, 2018**, having considered Plaintiff Noven Pharmaceuticals, Inc.’s (“Plaintiff” or “Noven”) motion for an injunction pending appeal pursuant to Fed. R. Civ. P. 62(c) or, in the alternative, a 10-day injunction to allow Noven time to pursue an expedited motion before the Court of Appeals pursuant to Fed. R. App. P. 8 (D.I. 182; D.I. 183 at 1-2, 9), as well as Defendants Mylan Technologies Inc., Mylan Pharmaceuticals Inc., Mylan Inc. and Mylan N.V.’s (“Defendants” or “Mylan”) opposition thereto (D.I. 186), **IT IS HEREBY ORDERED** that:

1. Noven’s motion is **GRANTED** to the limited extent that it seeks to preliminarily enjoin launch of Mylan’s Generic Product<sup>1</sup> until **4:00 p.m., next Thursday, August 30, 2018, or when the Court of Appeals grants or denies injunctive relief, whichever happens first**, and is **DENIED** in all other respects.

2. **IT IS FURTHER ORDERED** that this injunction shall be **VACATED** should the Court determine that Noven has failed to comply with any of the conditions being imposed

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<sup>1</sup>Defined terms have the same meaning as given in the Court’s Memorandum Order of August 20, 2018. (D.I. 176)

(see below), including the posting of a bond in an amount the Court finds to be reasonable to protect Mylan's interests.

On August 20, 2018, the Court issued an Order ("Order") denying Noven's motion for a preliminary injunction and granting a limited temporary restraining order against Mylan's launch of its Generic Product; the Order is set to expire today, August 22, at 4:00 pm. (*See* D.I. 176 ¶ 1) The Court found that Noven failed to demonstrate "a reasonable likelihood of success on the merits," "a balance of hardships tipping in its favor," or "the injunction's favorable impact on the public interest." (*Id.*) Noven argues that, despite this Court's denial of injunctive relief, it should enjoin the launch of Mylan's Generic Product pending appeal, given the irreparable harm Noven will immediately suffer in the absence of relief, the lesser harm it contends Mylan will suffer from an injunction pending appeal, and the possibility of an appellate reversal of this Court's findings. Mylan opposes Noven's requested relief but, in the alternative, proposes conditions the Court should impose if it is inclined to grant Noven's request. (*See* D.I. 186)

As Mylan correctly points out, in the present circumstances it is Noven's burden to demonstrate: "(1) a strong showing that it is likely to succeed on the merits in its appeal; (2) that absent an injunction it will be irreparably harmed; (3) that an injunction will not substantially injure [Mylan]; and (4) that an injunction will not harm the interests of the public." (D.I. 186 at 2) (citing *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)) To the limited extent Noven has addressed this standard, it has largely failed to meet it. Noven has not made a strong showing that it is likely to succeed on appeal; its showing of irreparable harm remains as it was when the Court addressed it in the August 20 Order (sufficient, but not overwhelming); any further injunction threatens greater risk to Mylan; and every day of delay of entry into the market of Mylan's Generic Product disserves the public interest. Hence, the Court will not grant an injunction for the pendency of the appeal, nor any lengthy injunction.

However, in hopes of sparing the Court of Appeals for the Federal Circuit some of the difficulties that were imposed on this Court from having to proceed so expeditiously, and because Mylan has proposed reasonable conditions that will meaningfully (though not entirely) address the harms Mylan will suffer (*see* D.I. 186 at 13-14), the Court has decided that an additional, minimal period of enjoining Mylan is, on the whole, warranted. The Court will enjoin Mylan's launch of its Generic Product for eight (8) more days, which will have given Noven ten (10) days in total to have pursued its expedited appeal and to seek additional relief from the Federal Circuit.

Accordingly, the Court's grant of this additional, limited injunction is expressly conditioned on Noven's compliance with the following terms, all of which the Court deems reasonable and appropriate to preserve the status quo for (at most) the next eight days:

- (1) Noven shall move to expedite its appeal in the Federal Circuit, including any motion practice regarding an injunction pending resolution of the appeal;
- (2) Noven shall not commercially launch an authorized generic version of Minivelle or otherwise permit marketing of a generic or brand product at a lower tier of pricing;
- (3) Noven shall not take any steps to provoke a revocation of FDA's approval of ANDA No. 206685;
- (4) Noven shall not take any steps to discontinue the Minivelle brand product;
- (5) Noven shall, no later than *August 24, 2018*, post a bond in the amount of \$2,448,000.00.

  
HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT COURT