IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, and IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	**MDL No. 19-2875 (RBK/KW)**
This Order Relates to all Cases	:	

SPECIAL MASTER ORDER NO. 13

March 31, 2021

THE BACKGROUND OF THIS ORDER IS AS FOLLOWS:

By Order dated April 29, 2019, Magistrate Judge Joel Schneider set the parameters for "core discovery" in this matter. Relevant to this Order, Judge Schneider directed that the "core discovery" applied only to API manufacturer and supplier defendants as well as finished product/dose manufacturer defendants, which he referred to collectively as the "responding defendants." (Doc. 303.) He also directed that "responding defendants shall only produce core discovery *concerning the facilities that manufactured the API used in Valsartan or the finished products at issue in the litigation*. (*Id.*; emphasis added.)

Defendant Mylan manufactured the API used in Valsartan at a facility known as Unit 8, and Mylan has produced documents falling within the "core discovery" order for Unit 8. During the course of discovery, Plaintiffs learned of an FDA

investigation of Mylan's Unit 7 that disclosed solvent contamination similar to that suspected to be the cause of the nitrosamine contamination of Valsartan. Although Unit 7 is outside the scope of "core discovery," Plaintiffs seek to require Mylan to produce the "[FDA] inspection reports and exhibits, Mylan's responses and exhibits, and any FDA correspondence and meeting minutes" pertaining to the discovery of the solvent contamination found at Unit 7.[1] Mylan objects, pointing out that Unit 7 is located about 200 hundred miles from Unit 8 and was not involved in the production of the API used in Valsartan. (Doc. 1065 at 17.) Mylan warns of the "slippery slope" of open-ended discovery that the "core discovery" order was intended to prevent.

There is good reason to be concerned about too broad a reach for discovery in a matter as substantial as this. Indeed, discovery to date has been massive. But discovery also has to be an iterative process, especially in a case as large as this one. And when facts are learned that suggest that the constraints of an order issued prior to discovery may be too tight, relief from those constraints is proper.

Plaintiffs point out that the FDA findings with respect to Unit 7 concern "o-xylene, the very solvent Mylan's root cause investigation attributed to introducing

[1] In a letter submitted on March 31, 2021, Plaintiffs submitted the FDA warning letter on Unit 7 and pointed out the warning letter's reference to March 20, 2020 response from Mylan to the FDA Form 483 and "subsequent correspondence." Plaintiffs' request encompasses these documents.

NDEA contamination into all of Mylan's valsartan API." (Doc. 1066 at 20; emphasis omitted.) Plaintiffs further assert that "the FDA's observations regarding inadequate solvent vendor evaluations specifically related to Vega Life Sciences, the very same vendor Mylan used to recover o-xylene for valsartan API at Unit 8." (*Id.*; emphasis omitted.) Finally, Plaintiffs point out that Mylan's written responses to the FDA "specifically referred the FDA to its corrective actions taken at Unit 8 arising from the valsartan API contamination." (*Id.*) Mylan counters by pointing out that the FDA investigation of a completely different manufacturing facility occurred "more than two years after Mylan (i) recalled its valsartan in the US market, and (ii) stopped using recovered solvent in the manufacture of its valsartan API." (Doc. 1065 at 17.)

Although certainly not limitless, discovery is deliberately designed in the United States to be broad. *See Hickman v. Taylor*, 329 U.S. 495, 507 (1947) (the "discovery rules are to be accorded a broad and liberal treatment"). And although Judge Schneider did restrict core discovery to facilities that manufactured API involved in the production of Valsartan, he could not have contemplated a scenario where the very solvent expected to have caused the contamination of Valsartan would be involved at another Mylan facility and involve the same vendor used at Unit 8. Finally, the additional discovery sought by Plaintiffs is precisely targeted and not burdensome. Plaintiffs seek production only of Mylan's March 20, 2020

reply to the FDA Form 483; the "subsequent correspondence" referenced in the FDA warning letter; the FDA inspection reports and exhibits; Mylan's responses and exhibits; and any related FDA correspondence and meeting minutes. In light of the patent relevance of this evidence and the minimal additional discovery being sought, Plaintiffs' request will be granted.[2]

NOW, THEREFORE, IT IS HEREBY ORDERED THAT within seven days from the date of this Order, Mylan shall produce to Plaintiffs its March 20, 2020 reply to the FDA Form 483; the "subsequent correspondence" referenced in the FDA warning letter; the FDA inspection reports and exhibits; Mylan's responses to that report and exhibits; and any related FDA correspondence and meeting minutes.

s/ Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

[2] Plaintiffs are cautioned that this ruling does not open the door to broad discovery beyond the limits of the "core discovery" order. Variances from that order will be allowed only upon a compelling showing of relevance and only to the extent that the additional discovery is narrowly focused and not burdensome. These requirements are met here.