

Paper No. \_\_\_\_  
Filed: July 12, 2018

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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MYLAN TECHNOLOGIES, INC.,  
Petitioner,  
v.

NOVEN PHARMACEUTICALS, INC.  
Patent Owner.

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Case IPR2018-00173  
Patent 9,724,310

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**PETITIONER MYLAN TECHNOLOGIES, INC.'S  
REQUEST FOR REHEARING PURSUANT TO 37 C.F.R. § 42.71**

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## **I. PRECISE RELIEF REQUESTED AND OVERVIEW**

Mylan Technologies, Inc. (“Mylan,” or “Petitioner”) respectfully asks the Board to reconsider its June 12, 2018 decision (Paper 9, “Decision”) not to institute a trial regarding claims 1-15 of the ’310 patent. 37 C.F.R. § 42.71(c)-(d).

Petitioner respectfully submits that the Decision was limited in its consideration of the contentions in the petition materials while overlooking various contentions, as well as the fact that any conceivable imprecision in Dr. Brain’s permeation values would be immaterial to the grounds of challenge. For example, at page 18, the Decision states “Petitioner contends that ‘results [in Mueller] show an estradiol flux achieved by Example 3 of 0.015 and 0.014 mg/cm<sup>2</sup>/day when measured at 32 and 48 hours, respectively.’” The Decision then rejects the asserted ground of challenge addressing only this limited contention. But this is neither the only contention advanced in the Petition materials, nor is it a contention representing the full scope of Petitioner’s argument and evidence. Dr. Brain identifies multiple examples, and testifies that, “from just these few examples, it is clear Mueller teaches multiple time points at which Example 3 achieves a flux of ‘about 0.0125 mg/cm<sup>2</sup>/day[.]’” EX1002, ¶ 160. The Decision only addresses a few of those examples, thereby overlooking additional contentions provided in the petition materials.

Moreover, at page 20, the Decision states “the x-axis and y-axis of [Mueller

Figure 3] are not perpendicular to each other” and “[t]he deficiencies of Figure 3 are readily observable to the naked eye and when superimposed onto a grid.” The Decision, however, overlooks the fact this is a minor copying artifact immaterial to the analysis provided by Dr. Brain—particularly the examples provided by Dr. Brain left unaddressed in the Decision. Petitioner respectfully submits this immateriality is readily observable to the naked eye and from any reasonable review of the Mueller priority document—an analysis Patent Owner avoids in its carefully worded argument. *See, e.g.*, 37 C.F.R. § 42.12(a)(2) & (a)(3).

The Decision denied institution of Ground 4 on the additional basis that the Board was uncertain whether Chien Figure 5 depicts test results from a monolithic patch or a multi-layer patch. The Decision overlooks Petitioner’s argument that Chien Fig. 5 discloses flux using a *monolithic patch*, rather than multi-layer embodiments clearly denoted elsewhere in Chien. *See, e.g.*, Pet. 55-57. A monolithic patch, by definition, does not have the upper or middle layer Patent Owner speculated could have been tested to provide the graph in Chien Fig. 5.

Patent Owner’s expert’s speculation that Chien’s Fig. 5 might refer to a multi-layer patch would have the POSA wear blinders and ignore the teachings set forth in black and white of a prior art reference. When referring to results of experiments with multi-layer patches instead of monolithic patches, Chien uses the words “Tri-Layer” System, (Figs. 12-17) “Middle Layer,” and “Upper Layer.”

EX1009; *see also id.*, 11:64-66 (multi-layer patches “have three layers in addition to the backing layer and the peelable release liner.”).

Petitioner respectfully asks the Board to grant rehearing and institute trial on claims 1-15 of the '310 patent. To the extent the Board believes there is a genuine issue of material fact as to the permeation values Dr. Brain identified or whether Chien Fig. 5 discloses flux experiments for a monolithic patch, these questions should be viewed in the light most favorable to the Petitioner and institution should be granted. 37 C.F.R. § 42.108(c).

## II. SUMMARY OF THE CASE

Ground 1 of the Petition explained that claims 1, 2, 8, and 10-15 of the '310 patent are anticipated by Mueller, including by achieving a flux within the range of from about 0.0125 to about 0.05 mg/cm<sup>2</sup>/day. The Petition explained that Dr. Brain calculated flux from Mueller Fig. 3 by taking the difference between drug-permeation values and dividing it by the amount of time passed between two time points, the same way Patent Owner's expert calculated flux during prosecution. Pet. 6-7, 9-10, 31-33. It relied on Dr. Brain's testimony to establish that Mueller Fig. 3 discloses achievement of an estradiol flux of 0.012 mg/cm<sup>2</sup>/day at 24 hours, 0.015 mg/cm<sup>2</sup>/day at 32 hours, and 0.014 mg/cm<sup>2</sup>/day at 48 hours. *Id.* It also relied on Dr. Brain's testimony that the average flux was 0.013 mg/cm<sup>2</sup>/day over the first 48 hours, 0.013 mg/cm<sup>2</sup>/day between 8 and 32 hours, and 0.014 mg/cm<sup>2</sup>/day

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