IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC., Plaintiff, v. AMNEAL PHARMACEUTICALS LLC, Defendant.	)	Civil Action No. 15-697-RGA

HOSPIRA'S POST-TRIAL REPLY BRIEF ON INFRINGEMENT

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Amneal takes numerous contradictory positions regarding the 2% limitation. For obviousness, Amneal proffers a select few stability data points from Hospira's internal work and asserts that they prove by clear and convincing evidence that all dexmedetomidine compositions meet the 2% limitation. (D.I. 100 at 14-16.) Then, on indefiniteness, it takes a single stability data point from Example 6 of the patent and contends that it shows by clear and convincing evidence that the product discussed there does not meet the limitation. (*Id.* at 23-24.) Now, Amneal argues that its entire stability study—submitted to the FDA to establish the "stability characteristics" of its products (PTX 93.4)—is insufficient to establish infringement of the 2% limitation by a preponderance of the evidence. (D.I. 105 at 13.) This comes after Amneal earlier averred that its ANDA "sufficiently describes" its product for purposes of this case such that test samples would be merely "duplicative" of information in the ANDA. (JTX 83.13-14.)

Amneal's house-of-cards defense cannot stand. The 2% limitation, along with all of the limitations from the remainder of the asserted claims, are valid and infringed.

I. AMNEAL INFRINGES THE 2% LIMITATION

As described in Hospira's Opening Brief (D.I. 101 at 4-14), Amneal infringes the 2% limitation as a matter of both law and fact.[1]

A. Amneal Meets The 2% Limitation As A Matter Of Law.

Amneal cannot escape *Sunovion* here. In *Sunovion*, the Federal Circuit held that a claim to 'less than 0.25%' impurity was infringed by an ANDA specification providing for less than 0.6% of the impurity. *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1278

[1] The relevant claim language is "wherein the liquid pharmaceutical composition when stored in the glass container ***for at least five months exhibits no more than about 2% decrease in the concentration of dexmedetomidine***." (JTX 4.15.)

(Fed. Cir. 2013). Here, the claim to 'not more than about 2% decrease' is infringed by Amneal's ANDA specification of not more than 10% decrease. (D.I. 101 at 5-7.)

Amneal argues that *Sunovion* does not apply because its ANDA specification is for twenty-four months of storage whereas the claim is directed to five months of storage. (D.I. 105 at 3-4.) This is incorrect. First, its specification of no more than 10% loss after twenty-four months necessarily specifies no more than 10% loss after five months—there cannot be more loss at five months than is permitted over the product's entire shelf life because the amount of dexmedetomidine does not increase over time. (*See* Tr. 286:17-23; 447:1-7.) Second, the claim recites "at least five months" of storage, and so covers no more than about 2% loss after twenty-four months of storage. Third, Amneal's argument implies that a claim requiring no more than about 2% loss at twenty-four months would be infringed, but that a broader claim requiring only no more than about 2% loss after five months would not be infringed. This cannot be. *See, e.g.*, *Nikken USA, Inc. v. Robinsons-May, Inc.*, 51 F. App'x 874, 882 (Fed. Cir. 2002) (noting that infringement of narrower claim necessarily results in infringement of broader claim).

Amneal's reliance on the far-afield *Ferring* case is instructive. (D.I. 105 at 3-4.) That case is inapposite because the ANDA specification there was silent on certain claim limitations. *Ferring B.V. v. Watson Labs., Inc.*, 764 F.3d 1382, 1387 (Fed. Cir. 2014). Specifically, the claims recited a gradually-dissolving drug whose dissolution matched the drug's absorption rate in the body. *Id.* at 1384. They required that *less* than 40% of the drug dissolve after 15 minutes, *less* than 70% of the drug dissolve after 45 minutes, and *more* than 50% of the drug dissolve after 90 minutes (one claim had only the 45-minute requirement). *Id.* at 1385. By contrast, the ANDA provided only that *more* than 80% of the drug dissolve in 60 minutes. *Id.* at 1385-86.

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