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

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| HOSPIRA, INC.,<br><br>Plaintiff,<br><br>v.<br><br>AMNEAL PHARMACEUTICALS LLC,<br><br>Defendant. | Civil Action No. 15-697-RGA |

# AMNEAL'S REPLY POST-TRIAL BRIEF ON INVALIDITY

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## I. The Asserted Claims Are Invalid as Obvious.

Hospira's brief leads with the usual declamations against hindsight and for deference to the examiner. (*See* D.I. 106 at 1–11.) Amneal addresses these below, *infra* at 7–11. But first, Amneal addresses the specific obviousness issue on which the Court asked the parties to focus—that is, the inherency of the '106 patent's "no more than about 2% decrease" in the concentration of dexmedetomidine ("dex") at five months. (Tr. 1178:6–11.)

### A. Hospira Cannot Avoid Inherency of the Claimed 2% Limitation by Rewriting the Law and Trial Record.

Amneal showed that the trial record clearly and convincingly proves the factual issue of inherency, beginning with Hospira's own admission, and Dr. Yaman's testimony on the unrebutted and undisputed experimental evidence all showing less than about 2% decrease after at least five months. (D.I. 100 at 9–19.)

Unable to refute any of this dispositive evidence under existing law, Hospira tries to create new law. Hospira generally asserts that the experimental evidence and interrogatory response should be dismissed because they come from the inventors and the patent themselves. (D.I. 106 at 14–22.) Hospira's assertion contradicts the numerous Federal Circuit decisions cited by Amneal. These decisions confirm that evidence from the inventors' work reflected in the patents is not only relevant, but often *dispositive* proof of inherency. (D.I. 100 at 10–14 (citing *In re Kubin*, 561 F.3d 1351, 1357 (Fed. Cir. 2009); *In re Kao*, 639 F.3d 1057, 1070 (Fed. Cir. 2011); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1369 (Fed. Cir. 2012); *King Pharm., Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1275 (Fed. Cir. 2010)).) Moreover, the few legal authorities on inherency that Hospira does acknowledge—including the *Par v. TWi* decisions—unmistakably counter Hospira's argument about the relevance of the patentee's work here. (*See* D.I. 106 at 16 (citing *Par Pharm. v. TWi Pharm., Inc.*, 773 F.3d 1186, 1194–96 (Fed. Cir. 2014) and *Par Pharm., Inc. v. TWi Pharm., Inc.*, 120 F. Supp. 3d 468, 475 (D. Md. 2015), *aff'd*, 624 F. App'x 756 (Fed. Cir. 2015)).)

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