

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

AMNEAL'S RESPONSIVE POST-TRIAL BRIEF ON NON-INFRINGEMENT

Of Counsel:

Steven A. Maddox (*pro hac vice*)
Jeremy J. Edwards (*pro hac vice*)
Matthew C. Ruedy (*pro hac vice*)
Kaveh V. Saba (*pro hac vice*)
Maddox Edwards PLLC
1900 K Street N.W., Suite 725
Washington, D.C. 20006
(202) 830-0707
smaddox@meiplaw.com
jedwards@meiplaw.com
mruedy@meiplaw.com
ksaba@meiplaw.com

Frederick L. Cottrell, III (#2555)
Kelly E. Farnan (#4395)
Christine D. Haynes (#4697)
Richards, Layton & Finger, P.A.
920 North King Street
Wilmington, DE 19801
(302) 651-7700
cottrell@rlf.com
farnan@rlf.com
haynes@rlf.com

*Attorneys for Defendant-Counterclaim Plaintiff
Amneal Pharmaceuticals LLC*

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I. Procedural Note

Amneal submits this brief in the event that: (a) the Court adopts Hospira’s “long-term stability” construction of “no more than about 2% decrease” of dexmedetomidine (“dex”) for at least five months, over the intrinsic evidence of indefiniteness; *and* (b) the Court finds that “no more than about 2% decrease” under long-term conditions is not an inherent property of the claimed formulation in the sealed glass container, contrary to Hospira’s admission and all of the long-term stability data presented at trial. If the Court makes both of these rulings, then the question of infringement of the ’106 patent turns on whether Hospira’s Dr. Linhardt provided credible, or even admissible, expert evidence sufficient to meet Hospira’s burden—when considered against the unrebutted expert testimony of Amneal’s biostatistician Dr. Bloch that Dr. Linhardt’s statistical models lacked any statistical significance.

II. Introduction

Hospira relegates Dr. Linhardt’s trial evidence to the back of its brief for good reason. Dr. Linhardt arbitrarily selected two statistical models, and presented inaccurate and statistically meaningless results. He even admitted that he did not choose those models based on any scientific authority or literature. Instead, he chose them based on speculation and simplicity. In a *post hoc* effort to justify that choice, Hospira’s counsel provided him with unrelated articles from *The Journal of Water Research* and *The Journal of Hazardous Materials*. However, Dr. Linhardt was forced to admit that he did not know or use either of these journals—and that the articles did not concern dex or even pharmaceuticals in general.

Dr. Daniel Bloch, the only biostatistician in the case, provided *unrebutted* evidence that Dr. Linhardt’s results were statistically meaningless, and so failed to establish even a 50% likelihood that Amneal’s product met the “no more than about 2% decrease” limitation. Dr. Linhardt dared not attempt to rebut Dr. Bloch’s evidence of statistical insignificance. Nor did Dr. Linhardt offer a

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