IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

HOSPIRA'S OPENING POST-TRIAL BRIEF ON INFRINGEMENT

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I. INTRODUCTION

Hospira asserts four patents covering its inventive ready-to-use dexmedetomidine formulation. (D.I. 95, Ex. A ¶¶ 9-11; JTX 1-4.) Amneal seeks FDA approval to market a copycat version of Hospira's embodiment of the patents, Precedex Premix. (D.I. 95, Ex. A ¶ 18; Tr. 5:6-9; PTX-63.51-52.) At the parties' August 21-24, 2017, trial, Hospira asserted the following claims (Tr. 3:15-21, 249:4-8):

- Claims 3 and 4 of U.S. Patent No. 8,242,158 ("the '158 patent");
- Claim 4 of U.S. Patent No. 8,338,470 ("the '470 patent");
- Claim 5 of U.S. Patent No. 8,455,527; and
- Claim 6 of U.S. Patent No. 8,648,106 ("the '106 patent").

With two exceptions, Amneal admits that it infringes all claim limitations. (*See* D.I. 95, Ex. A ¶¶ 21-27; Tr. 3:22-4:8, 271:5-272:7.) The two limitations in dispute are: (1) whether the Amneal products are disposed within a "sealed glass container," as required by each asserted claim;[1] and (2) whether the Amneal products "when stored in the glass container for at least five months exhibit[] no more than about 2% decrease in the concentration of dexmedetomidine" (hereinafter, "the 2% limitation"), as recited in the '106 patent.

At trial, Hospira proved by a preponderance of the evidence that Amneal infringes both limitations.

II. PERSON OF ORDINARY SKILL IN THE ART

Contrary to Amneal's proffer of a non-POSA statistician, infringement is determined from the perspective of a person of ordinary skill in the art ("POSA"). *E.g.*, *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 (Fed. Cir. 2008) (finding patent law expert "not qualified to testify as an expert witness on the issues of infringement or validity" because

[1] Amneal has stipulated that it infringes Claim 5 of the '527 patent, but the dispute remains with respect to the other asserted claims. (D.I. 95, Ex. A ¶¶ 26-27, Ex. B ¶ 44.)

"[t]hese issues are analyzed in great part from the perspective of a person of ordinary skill in the art"). Hospira's infringement expert, Dr. Linhardt, explained that a POSA has an advanced degree in science, chemistry, pharmacology or pharmaceutical development. (Tr. 268:6-20.) Dr. Linhardt based his definition on his experience, explaining that he has trained numerous POSAs over the course of his 35-year career who have gone on to play key roles in the pharmaceutical industry. (Tr. 268:21-269:10, 246:15-247:3; *see also* JTX-52.2, 52.47-64.)[2]

III. AMNEAL INFRINGES EACH ASSERTED CLAIM

Amneal's ANDA No. 207551 seeks FDA approval to market generic versions of Precedex Premix in 50 mL and 100 mL glass vials ("the Amneal Products"). (D.I. 95, Ex. A ¶ 18.) Both the 50 mL and 100 mL Amneal Products infringe each asserted claim.

In a Hatch-Waxman case, it is an act of infringement to submit an ANDA seeking approval to market a drug product covered by a patent. 35 U.S.C. § 271(e)(2). A patentee must prove infringement by a preponderance of the evidence. *E.g.*, *Eli Lilly & Co. v. Teva Parenteral Med., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017). Specifically, a patentee must prove that infringement is more likely than not. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 449 F. App'x 923, 928 (Fed. Cir. 2011).

A. The Amneal Products Are Disposed Within A "Sealed Glass Container"

The first limitation to which Amneal would not stipulate for purposes of infringement is that its products meet the "sealed glass container" limitation found in every asserted claim. Put

[2] Amneal's validity expert, Dr. Yaman, did not opine on infringement issues and never saw Amneal's ANDA submission. (Tr. 606:12-19.) Nonetheless, he and Hospira's Dr. Linhardt agree that a POSA holds an advanced degree in pharmaceutical sciences with knowledge of product formulation. (*See* Tr. 270:21-271:4 (Linhardt); 506:23-508:10 (Yaman).)

to its proofs at trial, Hospira proved that the Amneal Products are "disposed within a sealed glass container" under any proposed construction of the term.[3]

Amneal's ANDA documents prove that the Amneal Products are "sealed." ANDA Module 3.2.P.7 describes Amneal's container closure systems and how they are sealed, including information about packaging configuration and sizes, a comparison to Hospira's Precedex Premix packaging, and integrity testing. (PTX 64.5-13.) Unsurprisingly for a pharmaceutical seeking FDA approval, the Amneal Products are sealed and passed integrity testing. (Tr. 273:11-20 ("They show a stopper system that ensures the product remains sterile during storage.").) For example, its proposed 50 mL and 100 mL products passed the industry-standard dye ingress test—demonstrating that the container closure systems are "sealed." (PTX-65.2-3, 10-11; *see also* PTX-63.64 (describing container closure system for 50 mL and 100 mL products as designed to "achieve the target shelf-life and to ensure integrity and storage during shipping").)

The unrebutted testimony of Hospira's expert, Dr. Linhardt, also explained how the Amneal Products are disposed within sealed glass containers. (*See, e.g.*, Tr. 273:3-276:8.) After describing the primary closure system noted above, Dr. Linhardt showed that the products also

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[3] Hospira argued that the meaning of "sealed glass container" is a "glass container closed to maintain sterility by having a seal or other closure that passes closure integrity testing," and Amneal argued the meaning is "a container that is closed tightly to prevent unwanted materials entering or exiting the glass container." (Tr. 266:1-6, 584:14-19.) Although Amneal's meaning is inappropriately broad for a pharmaceutical composition, the Amneal Products nonetheless meet the limitation under either construction, as shown herein. (*See also* Tr. 277:17-21.)

After hearing the evidence, the Court proposed possible alternate constructions, including "a container that is closed tightly to maintain sterility." (Tr. 1176:2-21.) So long as this construction includes the limitation of "glass," Hospira agrees that this proposed meaning is supported by the record because a sealed container in this context maintains sterility. (*See, e.g.*, JTX-4.7 at 9:9-15; PTX-5.216; Tr. 36:13-37:1; 78:18-79:1 (Roychowdhury); Tr. 633:2-19 (Yaman).)

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