IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HOSPIRA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	Civil Action No. 15-697-RGA
AMNEAL PHARMACEUTICALS LLC,	)	
	)	**PUBLIC VERSION:**
Defendant.	)	**Filed August 14, 2017**
	)	

PROPOSED JOINT PRE-TRIAL ORDER

TABLE OF CONTENTS

Index of terms

Term / abbreviation	**Meaning**
RTU	Ready-to-use
mL	milliliter
µg/mL	Microgram (10^{-6} gram) per milliliter
NMT	No more than
NDA	New Drug Application
ANDA	Abbreviated New Drug Application
FDA	Food and Drug Administration
Precedex Concentrate	Hospira's 100 µg/mL dexmedetomidine in 2 mL vial product approved by FDA in 1999.
Precedex Premix or RTU Precedex	4 µg/mL dexmedetomidine product sold by Hospira in 20 mL, 50 mL, and 100 mL vials since 2013.

I. INTRODUCTION

1. Pursuant to the Court's Scheduling Order (D.I. 13 ¶ 14) and Oral Order (D.I. 94), Plaintiff Hospira, Inc. ("Hospira") and Defendant Amneal Pharmaceuticals LLC ("Amneal") submit this Proposed Joint Pre-Trial Order.

2. This Order shall control the subsequent course of the action, unless modified by the Court to prevent manifest injustice.

A. Nature of the Action

3. This is a civil action for patent infringement under the patent laws (Title 35 of the United States Code) and the Hatch-Waxman Act pertaining to generic pharmaceuticals. *See* 35 U.S.C. § 101 *et seq.*; 21 U.S.C. § 355.

4. The action arises from Amneal's submission of Abbreviated New Drug Application ("ANDA") No. 207551 to the United States Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, importation, use or sale of 4 µg/mL dexmedetomidine drug products in 50 mL and 100 mL glass vials ("Amneal ANDA Products") prior to the expiration of Hospira's U.S. Patent Nos. 8,242,158 ("the '158 patent"); 8,338,470 ("the '470 patent"); 8,455,527 ("the '527 patent"); and 8,648,106 ("the '106 patent") (collectively, the "Patents-in-Suit").

5. The four Patents-in-Suit share a common specification and are part of the same patent family. The application leading to the '158 patent was the first application in the family to be filed, and was filed on January 4, 2012. The inventors listed on each Patent-in-Suit are Priyanka Roychowdhury and Robert A. Cedergren. Neither named inventor is currently employed by Hospira.

6. Hospira markets its dexmedetomidine products under the trade name Precedex™. Since 1999, Hospira has sold 100 µg/mL dexmedetomidine, which is diluted to 4 µg/mL prior to

administration to a patient, in 2 mL glass containers. Since 2013, Hospira has also sold 4 µg/mL dexmedetomidine in 20 mL, 50 mL, and 100 mL glass containers. In this litigation, the parties refer to the 100 µg/mL Precedex product as Precedex Concentrate and to the 4 µg/mL Precedex products as Precedex Premix or RTU Precedex.

7. Dexmedetomidine is used as a sedative. Precedex is indicated for (1) sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting, and (2) sedation of non-intubated patients prior to and/or during surgical and other procedures.

8. Under 21 U.S.C. § 355(b)(1), Hospira listed the Patents-in-Suit in FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") as covering Precedex Premix.

9. By letter dated June 26, 2015, and received June 30, 2015, Amneal informed Hospira that it filed its ANDA with the FDA seeking approval to market its ANDA Products prior to the expiry of the Patents-in-Suit. The letter notified Hospira that the ANDA contained a certification under 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certification") that the Patents-in-Suit were invalid and/or would not be infringed by Amneal.

10. On August 10, 2015, within 45 days of receiving Amneal's letter, Hospira filed suit against Amneal for infringement of the Patents-in-Suit by virtue of Amneal's filing of its ANDA with a Paragraph IV Certification. (D.I. 1.) Hospira requested, among other things, an Order that the effective date of any approval of the Amneal ANDA be no earlier than the expiration of the Patents-in-Suit (including extensions), and an injunction enjoining Amneal from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation into

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