EXHIBITS A - F
REDACTED PUBLIC VERSION

EXHIBIT A

Parties' Statement of Undisputed Facts

Pursuant to Local Rule 16.3(c)(3), the parties submit this statement of undisputed facts that require no proof at trial.

I. PARTIES

1. Plaintiff Hospira is a Delaware corporation with its principal place of business at 275 North Field Drive, Lake Forest, Illinois 60045.

2. Defendant Amneal is a Delaware corporation with its principal place of business at 400 Crossing Boulevard, Third Floor, Bridgewater, New Jersey 08807.

II. JURISDICTION

3. Subject matter jurisdiction over this action is proper under 28 U.S.C. §§ 1331 and 1338(a). Subject matter jurisdiction over Amneal's counterclaims is proper under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 1 et seq.

4. No party contests venue or personal jurisdiction for the purposes of this litigation only.

III. PATENTS-IN-SUIT

5. U.S. Patent No. 8,242,158 ("the '158 patent"), entitled "Dexmedetomidine Premix Formulation," was issued by the United States Patent and Trademark Office ("PTO") on August 14, 2012. The '158 patent issued from U.S. Patent Application No. 13/343,672 ("the '672 application"), which was filed on January 4, 2012.

6. U.S. Patent No. 8,338,470 ("the '470 patent"), entitled "Dexmedetomidine Premix Formulation," was issued by the PTO on December 25, 2012. The '470 patent issued from U.S. Patent Application No. 13/541,524 ("the '524 application"), which was a continuation of the '672 application.

7. U.S. Patent No. 8,455,527 ("the '527 patent"), entitled "Methods of Treatment Using a Dexmedetomidine Premix Formulation," was issued by the PTO on June 4, 2013. The '527 patent issued from U.S. Patent Application No. 13/678,148 ("the '148 application"), which was a continuation of the '524 application.

8. U.S. Patent No. 8,648,106 ("the '106 patent"), entitled "Dexmedetomidine Premix Formulation," was issued by the PTO on February 11, 2014. The '106 patent issued from U.S. Patent Application No. 13/867,861 ("the '861 application"), which was a continuation of U.S. Patent Application No. 13/678,260 ("the '260 application"). The '260 application was a continuation of the '524 application.

9. The parties may collectively refer to the '158, '470, '527, and '106 patents as the "Patents-in-Suit" or the "Asserted Patents."

10. The inventors assigned their rights in the Patents-in-Suit to Hospira.

11. Hospira owns all rights, title, and interest to the Patents-in-Suit.

IV. HOSPIRA'S NEW DRUG APPLICATION

12. Hospira is the owner of New Drug Application ("NDA") No. 21-038 for dexmedetomidine hydrochloride injection, which Hospira sells in the United States under the trade name Precedex.

13. NDA No. 21-038 was approved by the Food and Drug Administration ("FDA") on December 17, 1999, for a 100 µg/mL dexmedetomidine hydrochloride formulation in a 2 mL glass vial.

14. On March 13, 2013, the FDA approved NDA supplement S-020 for 4 µg/mL ready-to-use formulations of dexmedetomidine hydrochloride injection in 50 mL and 100 mL glass bottles.

15. On November 14, 2014, the FDA approved NDA supplement S-024 for a 4 µg/mL ready-to-use formulation of dexmedetomidine hydrochloride injection in a 20 mL glass vial.

16. 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.

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

V. AMNEAL'S ABBREVIATED NEW DRUG APPLICATION

18. On June 8, 2014, Amneal submitted ANDA No. 207551 ("the Amneal ANDA") to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, importation, use, or sale of ready-to-use dexmedetomidine hydrochloride drug products in 50 mL and 100 mL glass vials ("the Amneal ANDA Products") prior to the expiry of the Patents-in-Suit.

19. Pursuant to 21 U.S.C. § 355(j)(2)(B), Amneal sent to Hospira a notice letter dated June 26, 2015, and received June 30, 2015, stating that it had submitted the Amneal ANDA with certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid and/or will not be infringed by Amneal.

20. On August 10, 2015, within 45 days of receipt of Amneal's notice letter, Hospira filed the present suit, alleging that Amneal's filing of its ANDA with a Paragraph IV Certification, as well as any future manufacture, use, sale, offer for sale, and/or importation of the Amneal ANDA Products, infringe the Patents-in-Suit.

21. Each Amneal ANDA Product contains dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 μg/mL.

22. Each Amneal ANDA Product contains sodium chloride at a concentration of about 0.9 weight percent.

23. The 50 mL Amneal ANDA Product is formulated as a total volume of 50 mL.

24. The 100 mL Amneal ANDA Product is formulated as a total volume of 100 mL.

25. The proposed Prescribing Information for the Amneal ANDA Products includes the indication of "sedation of non-intubated patients prior to and/or during surgical and other procedures."

26. The proposed Prescribing Information for the Amneal ANDA Products instructs users of the product, such as physicians or nurses, to provide sedation to a patient in need thereof by administering an effective amount of a ready-to-use liquid pharmaceutical composition for parenteral administration containing dexmedetomidine or a pharmaceutically acceptable salt thereof at a concentration of about 4 μg/mL disposed within a sealed glass container.

27. The proposed Prescribing Information for the Amneal ANDA Products instructs users of the product, such as physicians or nurses, to administer an Amneal ANDA Product by intravenous infusion.

VI. DEXMEDETOMIDINE

28. Dexmedetomidine is the active ingredient in Precedex and the Amneal ANDA Products.

29. Dexmedetomidine is an α_2-adrenoceptor agonist that is used for, among other things, sedation.

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