IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC,	)	
Plaintiffs,	)	Civil Action No. 17-944-JFB-SRF
v.	)	**UNDER SEAL**
HOSPIRA, INC.,	)	
Defendant.	)	

MEMORANDUM ORDER

At Wilmington this **3rd** day of **August, 2018**, the court having considered the parties' letter submissions regarding defendant Hospira, Inc.'s ("Hospira") request for leave to file a motion for summary judgment of non-infringement in the above-captioned matter (D.I. 70; D.I. 72), IT IS HEREBY ORDERED THAT the request for leave to file a motion for summary judgment of non-infringement is DENIED for the reasons set forth below.

1. **Background.** On July 13, 2017, plaintiffs Par Pharmaceutical, Inc., Par Sterile Products, LLC, and Endo Par Innovation Company, LLC (collectively, "Par") filed a complaint for patent infringement under the Hatch-Waxman Act against Hospira. (D.I. 1) The action relates to Abbreviated New Drug Application ("ANDA") No. 208908, which was filed by Hospira with the U.S. Food and Drug Administration ("FDA") seeking approval to market generic versions of Par's Adrenalin® epinephrine injection, 1 mg/mL ("the ANDA product") prior to the expiration of the patents-in-suit. (D.I. 1 at ¶ 24)

2. Par's Adrenalin® product is a clear, colorless, sterile parenteral solution containing the active ingredient L-epinephrine, which is intended for intramuscular or subcutaneous administration, and is indicated for emergency treatment of allergic reactions, including anaphylaxis. (*Id.* at ¶ 13) Par is the holder of New Drug Application ("NDA") No. 204200 for Adrenalin® brand epinephrine injection 1 mg/mL. (*Id.* at ¶ 13) Par's Adrenalin® product is indicated for emergency treatment of allergic reactions, including anaphylaxis. (*Id.* at ¶ 13)

3. The complaint alleges infringement of U.S. Patent Nos. 9,119,876 ("the '876 patent") and 9,295,657 ("the '657 patent") (together, the "patents-in-suit"). (*Id.* at ¶ 1) The '876 patent, entitled "Epinephrine Formulations," was issued on September 1, 2015 to Par Pharmaceutical, Inc. as the assignee. (*Id.* at ¶ 9) The '876 patent claims are directed to compositions comprising epinephrine, a tonicity regulating agent, a pH raising agent, an antioxidant comprising sodium bisulfite and/or sodium metabisulfite, a pH lowering agent, and a transition metal complexing agent, in certain ranges. (*Id.* at ¶ 21) The '657 patent, which is also entitled "Epinephrine Formulations," was issued on March 29, 2016 to Par Pharmaceutical, Inc. as the assignee. (*Id.* at ¶ 11) The '657 patent covers methods of using the inventive formulations to treat Type 1 allergic reactions, including anaphylaxis, by administering the composition claimed in the '876 patent. (*Id.* at ¶ 22) Par owns and has exclusive rights to the patents-in-suit, including all rights to sue for infringement. (*Id.* at ¶¶ 9, 11)

4. The court held a Rule 16 scheduling conference on December 19, 2017. In the parties' joint proposed scheduling order, both parties took the position that case dispositive motions should not be permitted without prior authorization of the court because this ANDA

matter is scheduled for a bench trial. (D.I. 27 at ¶ 10) On June 12, 2018, the court entered an amended scheduling order postponing the *Markman* hearing date until March 27, 2019. (D.I. 69)

5. Analysis. Hospira's request for leave to file a motion for summary judgment of non-infringement is denied. The parties' dispute centers on whether or not the [redacted] contained in the ANDA product falls within the scope of the claimed "in the range of about 6 to 8 mg/mL of a tonicity regulating agent" in the patents-in-suit, either for purposes of literal infringement or under the doctrine of equivalents. (D.I. 70; D.I. 72; '876 patent, col. 28:5-6) In their joint claim construction chart filed on May 25, 2018, the parties agreed to construe "about" as having its "[p]lain and ordinary meaning, *i.e.*, approximately," which does not expressly limit the term to "less than 8.5 mg/mL" of a tonicity regulating agent. (D.I. 67, App'x A at 1) This agreed-upon construction controls. *See Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1311 (Fed. Cir. 2015).

6. Hospira argues that a summary judgment motion practice would streamline the case considering statements made by Par during the prosecution of two continuation-in-part child applications filed after the issuance of the parent patents-in-suit. (D.I. 70 at 1) According to Hospira, these subsequent applications allegedly limited the scope of the claimed concentration range because the inventor distinguished the inventions over WIPO Patent Publication No. WO 2014/127015 to Surakitbanharn ("Surakitbanharn") by observing that "all of the formulations disclosed in Surakitbanharn contain 8.5 mg/mL of sodium chloride, which is higher than the presently claimed concentration range." (D.I. 70, Ex. B at 5; Ex. C at 6) While these statements are relevant and may inform the scope of the claims of the patents-in-suit, the Federal Circuit has held that statements made during the prosecution of a subsequently-filed application in the same patent family are not binding and have no estoppel effect. *See Microsoft Corp. v. Multi-Tech*

Sys., Inc., 357 F.3d 1340, 1350 (Fed. Cir. 2004); *Georgia-Pacific Corp. v. U.S. Gypsum Co.*, 195 F.3d 1322, 1333 (Fed. Cir. 1999). Consequently, the present record does not reflect a binding disclaimer of claim scope.

7. Fact and expert discovery are necessary to determine whether the [redacted] in the ANDA product is "approximately" 8 mg/mL. The record reflects that Hospira allows for [redacted] (D.I. 72, Ex. 1; Ex. 2 at Ex. A) Par should also be given the opportunity to develop a full factual record regarding whether [redacted] used in Hospira's ANDA product is equivalent to the claimed tonicity regulating agent.

8. Conclusion. In view of the foregoing analysis, Hospira's request for leave to file a motion for summary judgment of non-infringement is denied.

9. Given that the court has relied upon material that technically remains under seal, the court is releasing this Memorandum Order under seal, pending review by the parties. In the unlikely event that the parties believe that certain material in this Memorandum Order should be redacted, the parties should jointly submit a proposed redacted version by no later than **August 10, 2018**. The court will subsequently issue a publicly available version of its Memorandum Order.

10. This Memorandum Order is filed pursuant to 28 U.S.C. § 636(b)(1)(A), Fed. R. Civ. P. 72(a), and D. Del. LR 72.1(a)(2). The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Memorandum Order. Fed. R. Civ. P. 72(a). The objections and responses to the objections are limited to ten (10) pages each.

11. The parties are directed to the court's Standing Order For Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the court's website, www.ded.uscourts.gov.

Sherry R. Fallon
United States Magistrate Judge