IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	Civil Action No. 3:14-cv-07869(MAS)(LHG) Civil Action No. 3:14-cv-08082(MAS)(LHG) Civil Action No. 3:15-cv-02631(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACCORD HEALTHCARE, INC., Defendant.	Civil Action No. 3:14-cv-08079(MAS)(LHG) Civil Action No. 3:15-cv-02520(MAS)(LGH)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BPI LABS, LLC AND BELCHER PHARMACEUTICALS, LLC, Defendants.	Civil Action No. 3:14-cv-08081(MAS)(LHG) Civil Action No. 3:15-cv-02521(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. APOTEX CORP. AND APOTEX, INC., Defendants.	Civil Action No. 3:15-cv-00287(MAS)(LHG) Civil Action No. 3:15-cv-01835(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. 3:15-cv-00289(MAS)(LHG) Civil Action No. 3:15-cv-01836(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. MYLAN LABORATORIES LTD., Defendant.	Civil Action No. 3:15-cv-00290(MAS)(LHG) Civil Action No. 3:15-cv-03392(MAS)(LHG)

SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. ACTAVIS LLC, Defendant.	Civil Action No. 3:15-cv-00776(MAS)(LHG) Civil Action No. 3:15-cv-03107(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. 3:15-cv-02522(MAS)(LHG)
SANOFI-AVENTIS U.S. LLC, AVENTIS PHARMA S.A. and SANOFI Plaintiffs, v. GLENMARK PHARMACEUTICALS, INC., USA and GLENMARK PHARMACEUTICALS LTD., Defendants.	Civil Action No. 15-cv-02523(MAS)(LHG)

JOINT CLAIM CONSTRUCTION AND PREHEARING STATEMENT

Pursuant to Local Patent Rule 4.3 of the United States District Court for the District of New Jersey and the Court's Pretrial Scheduling Order entered June 12, 2015 (C.A. No. 14-7869, ECF No. 23), plaintiffs Sanofi-Aventis U.S. LLC, Aventis Pharma S.A., and

Sanofi ("Plaintiffs") and defendants Fresenius Kabi USA, LLC ("Fresenius"); Accord Healthcare, Inc. ("Accord"); BPI Labs, LLC and Belcher Pharmaceuticals, LLC (collectively, "BPI-Belcher"); Apotex Corp. and Apotex Inc. (collectively, "Apotex"); Breckenridge Pharmaceutical, Inc. ("Breckenridge"); Mylan Laboratories Limited ("Mylan"); Actavis LLC ("Actavis"); Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively, "DRL"); and Glenmark Pharmaceuticals Inc., USA (formerly known as Glenmark Generics Inc., USA) and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark") (all collectively, "Defendants") hereby provide their Joint Claim Construction and Prehearing Statement concerning U.S. Patent Nos. 5,847,170 ("the '170 patent"), 7,241,907 ("the '907 patent"), and 8,927,592 ("the '592 patent") (collectively "Patents-In-Suit").

I. BACKGROUND

This is a Hatch-Waxman Act patent action. Plaintiffs assert, among other things, that Defendants infringed the Patents-In-Suit by filing a New Drug Application ("NDA") and/or an Abbreviated New Drug Application ("ANDA") pursuant to 21 U.S.C. §§ 355(b)(2) and/or (j) (§ 505(b)(2) or § 505(j) of the Federal Food, Drug and Cosmetic Act) with the U.S. Food and Drug Administration seeking approval to market proposed drug products, which are as follows:

a. For Fresenius: Cabazitaxel Injection, 60 mg/3 mL solution ("Fresenius's NDA Product") and Cabazitaxel Injection, 60 mg/1.5 mL solution ("Fresenius's ANDA Product");

b. For Accord: Cabazitaxel Injection, 60 mg/1.5 mL ("Accord's ANDA Product") and Cabazitaxel Injection, 20 mg/mL, 3mL ("Accord's NDA Product");

c. For BPI-Belcher: Cabazitaxel, 60 mg/1.5 mL solution for intravenous infusion ("BPI-Belcher's ANDA Product");

d. For Apotex: Cabazitaxel Injection, 60 mg/1.5 mL ("Apotex's ANDA Product");

e. For Breckenridge: Cabazitaxel Solution, IV, 60 mg/1.5 mL ("Breckenridge's ANDA Product");

f. For Mylan: Cabazitaxel Injection [60 mg/1.5 mL] [40 mg/mL] ("Mylan's ANDA Product");

g. For Actavis: Cabazitaxel Injection, 10 mg/mL (40 mg/4 mL, 60 mg/6 mL) ("Actavis's NDA Product");

h. For DRL: Cabazitaxel Solution for Infusion, 60 mg/1.5 mL ("DRL's ANDA Product"); and

i. For Glenmark: Cabazitaxel for Injection, 60 mg/1.5 mL (40 mg/mL) ("Glenmark's ANDA Product") (collectively "Defendants' Cabazitaxel Products").

Plaintiffs also assert that Defendants will infringe the Patents-In-Suit if Defendants commercially make, use, offer to sell, or sell Defendants' Cabazitaxel Products, or import Defendants' Cabazitaxel Products into the United States, or induce or contribute to any such conduct. Defendants allege that they do not and will not infringe the Patents-In-Suit and that the Patents-In-Suit are invalid.

II. CONSTRUCTION OF TERMS

A. Construction of Terms on Which the Parties Agree

In accordance with Local Patent Rule 4.3(a), Plaintiffs and Defendants (collectively the "Parties") have agreed to the construction of the following terms.

With respect to claims 7 and 9 of the '592 patent, the Parties agree that "AUC of about 991 ng·h/mL (CV 34%)" and "plasma clearance of 48.5 L/h (CV 39%)" do not need to be construed. The Parties do not thereby propose a construction for either of those terms.

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