

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, LLC and )  
FOREST LABORATORIES HOLDINGS, LTD., )  
 )  
Plaintiffs, )  
 )  
v. ) C.A. No. 14-1119 (SLR) (SRF)  
 ) **CONSOLIDATED**  
SIGMAPHARM LABORATORIES, LLC, et al. )  
 )  
Defendants. )

**JOINT STIPULATION OF ENTRY AND [PROPOSED] ORDER OF ADVERSE  
JUDGMENT AND DISMISSAL OF COUNTERCLAIMS  
OF U.S. PATENT NOS. 7,741,358 AND 8,022,228**

This stipulation is made by and between Plaintiffs Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd. (hereinafter collectively referred to as “Forest” or “Plaintiffs”), and Defendants Hikma Pharmaceuticals, LLC, Hikma Pharmaceuticals, PLC, and West-Ward Pharmaceutical Corp., (hereinafter collectively referred to as “Hikma”).

WHEREAS, on February 2, 2015, Plaintiffs filed an Amended Complaint against Hikma for infringement of U.S. Patent Nos. 5,763,476; 7,741,358; and 8,022,228, captioned *Forest Laboratories, LLC, et al. v. Hikma Pharmaceuticals, LLC et al.*, C.A. No. 14-1266 (SLR), related to Hikma’s submission of Abbreviated New Drug Application No. 206117 (“ANDA 206117”) to the Food and Drug Administration seeking approval to market asenapine maleate sublingual tablets, 5 mg and 10 mg (“Hikma’s Proposed ANDA Products”);

WHEREAS, on February 3, 2015, C.A. No. 14-1266 (SLR) was consolidated with C.A. No. 14-1119 (SLR) (SRF) (“this Action”) for all purposes. (D.I. 21 of C.A. 14-1266 (SLR));

WHEREAS, on January 29, 2016, the Court issued its Claim Construction Opinion and Order (D.I. 133);

NOW THEREFORE, Plaintiffs and Hikma, by and through their respective undersigned counsel, and subject to the approval of the Court, stipulate and agree as follows:

1. Plaintiffs and Hikma stipulate that under the Court's current claim construction, judgment of non-infringement be entered as to U.S. Patent Nos. 7,741,358 ("the '358 Patent") and 8,022,228 ("the '228 Patent") under 35 U.S.C. § 271(e)(2) with respect to Hikma's Proposed ANDA Products as represented in the documents and samples produced to Forest as of January 29, 2016, for the following counts asserted by Forest in Civil Action No. 1:14-cv-01119-SLR against Hikma:

1. Count I: Infringement of the '358 Patent Under 35 U.S.C. § 271(e)(2). *See* Forest's Amended Complaint for Patent Infringement (D.I. 22, C.A. No. 14-1266-SLR) at ¶¶ 13-26.

2. Count II: Declaratory Judgment of Patent Infringement of the '358 Patent Under 35 U.S.C. §§ 271 (a), (b), and/or (c). *See id.* at ¶¶ 27-34.

3. Count III: Infringement of the '228 Patent Under 35 U.S.C. § 271(e)(2). *See id.* at ¶¶ 35-43.

4. Count IV: Declaratory Judgment of Patent Infringement of the '228 Patent Under 35 U.S.C. § 271 (a). *See id.* at ¶¶ 44-47.

2. The parties further stipulate and agree that Hikma will inform Forest in a reasonable amount of time, not to exceed 45 calendar days, but in no event less than 45 calendar days before any launch, of any material change to the solid state character of the asenapine maleate (i.e., the crystalline polymorph or amorphous form) used to manufacture Hikma's

Proposed ANDA Products that are the subject of ANDA 206117 (including any supplements or amendments), and Hikma will produce any documents and samples relevant to any such changes to the solid state character of the asenapine maleate in a reasonable amount of time, not to exceed 45 calendar days, but in no event less than 45 calendar days before any launch.

3. Entry of this stipulated judgment shall not preclude Forest from bringing suit against Hikma under 35 U.S.C. §§ 271(a)-(c) and (e) in the event that any such changes identified in the preceding paragraph to Hikma's Proposed ANDA Products materially alter the infringement analysis under the Court's current construction or in the event the Court's current claim construction is vacated or modified by the Court or on appeal. This Stipulation and Order shall in no way preclude or impair Plaintiffs' rights to appeal the Court's claim construction.

Each party is to bear its own costs and fees.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

SHAW KELLER LLP

*/s/ Maryellen Noreika*

*/s/ Jeffrey T. Castellano*

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PLC, and West-Ward Pharmaceutical Corp.*

March 24, 2016

SO ORDERED this \_\_\_\_\_ day of March 2016.

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Hon. Sue L. Robinson  
United States District Judge