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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUMITOMO DAINIPPON PHARMA
CO., LTD. and SUNOVION
PHARMACEUTICALS INC.,

Plaintiffs,

v.

EMCURE PHARMACEUTICALS
LIMITED *et al.*,

Defendants.

Civil Action No. 15-280 (SRC) (CLW)
Civil Action No. 15-281 (SRC) (CLW)
Civil Action No. 15-6401 (SRC) (CLW)
(Consolidated)

(Filed Electronically)

**OPENING BRIEF IN SUPPORT
OF SUNOVION'S CLAIM CONSTRUCTION**

Exhibit 1052
Slayback v. Sumitomo
IPR2020-1053

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INTRODUCTION

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. and Sunovion Pharmaceuticals Inc. (collectively, “Sunovion”) filed this consolidated patent infringement action under the Hatch-Waxman Act against Defendants InvaGen Pharmaceuticals, Inc. (“InvaGen”), Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc. (collectively, “Emcure”), and Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, “Teva”) (InvaGen, Emcure, and Teva, together, “Defendants”), after each filed Abbreviated New Drug Applications (“ANDAs”) with the Food and Drug Administration (“FDA”) seeking approval to market generic versions of LATUDA[®], Sunovion’s highly successful medication for treating schizophrenia and bipolar depression. The active moiety in LATUDA[®] is a chemical compound known today as lurasidone. Sunovion submits this brief and the accompanying Declaration of Dr. Stephen G. Davies¹ in support of the proper construction of the sole patent claim at issue – Claim 14 of United States Patent No. 5,532,372 (“the ’372 patent”).²

This claim construction dispute concerns whether Claim 14 should be construed in accordance with its plain and ordinary meaning to encompass the

¹ “Davies Decl. ¶ ___” refers to citations to the accompanying June 15, 2016 Declaration of Dr. Stephen G. Davies.

² “Exh. ___” refers to exhibits attached to the accompanying June 15, 2016 Declaration of Preston K. Ratliff II. Exh. 1 is a true and correct copy of the ’372 patent.

chemical compound lurasidone, as Sunovion proposes, or should instead be limited and redefined to exclude lurasidone, as Defendants argue. Defendants' construction is improper and should be rejected.

After studying Claim 14, the '372 patent specification, and the '372 patent prosecution file history, each of the Defendants *admitted* that Claim 14 encompassed lurasidone in their respective Paragraph IV Notice Letters that provoked the filing of this action. For example, InvaGen did not contest its infringement of Claim 14.³ Similarly, Teva and Emcure did not contest infringement and *admitted* that Claim 14 covers lurasidone:

- “Claim 14 of the '372 patent is the narrowest claim that *covers lurasidone*” (Teva);⁴ and,
- “the compound of claim 14 of the '372 patent (*i.e., lurasidone*)” (Emcure).⁵

Despite their admissions that Claim 14 covers the active moiety lurasidone in their proposed generic products, Defendants now argue that this Court should adopt a

³ InvaGen did not contest its infringement of Claim 14 in its Notice Letter. (Exh. 2, InvaGen December 4, 2014 Paragraph IV Notice Letter, at 23-24.) InvaGen further confirmed its understanding that Claim 14 encompassed lurasidone when it did not submit a L. Pat. R. 3.6(e) Non-Infringement Contention. At the time that such contentions were due, InvaGen represented to Sunovion that “it ha[d] no Non-infringement contentions.” (Exh. 3, InvaGen L. Pat. R. 3.3, 3.4, and 3.6 Contentions at 4.) InvaGen also stated that the compound depicted in Claim 14 is “also known as lurasidone.” (*Id.* at 8-9.)

⁴ Exh. 4, Teva July 13, 2015 Paragraph IV Notice Letter at 11-12, 20 (emphasis added).

⁵ Exh. 5, Emcure December 3, 2014 Paragraph IV Notice Letter at 8-9, 17 (emphasis added).

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