

April 18, 2018

Sumitomo Dainippon Pharma Co., Ltd.

Sumitomo Dainippon Pharma Announces U.S. Appellate Court Decision on Substance Patent Infringement Lawsuit Regarding LATUDA®

Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura) announced today that the U.S. Court of Appeals for the Federal Circuit issued a decision related to U.S. Patent No. 5,532,372 (“the Substance Patent”) for LATUDA® (lurasidone HCl) on April 16, 2018 (U.S. Eastern time) in the patent infringement lawsuits Sumitomo Dainippon Pharma and Sunovion Pharmaceuticals Inc. filed in the U.S. District Court for the District of New Jersey in 2015 against the Defendants*.

The District Court of New Jersey entered Judgments and Orders of Permanent Injunction against the Defendants holding that (1) their submissions of abbreviated new drug applications (“ANDAs”) constitute infringement of the Substance Patent under the District Court’s claim construction and (2) the asserted claim of the Substance Patent is valid and enforceable. The Defendants appealed the claim construction for the Substance Patent of the District Court of New Jersey to the Federal Circuit.

The Federal Circuit affirmed the claim construction of the District Court of New Jersey. As a result, the Substance Patent remains infringed, valid, and enforceable against the Defendants and other generic manufacturers.

This appeal concerns a different lawsuit than the patent infringement lawsuits Sumitomo Dainippon Pharma and Sunovion jointly filed in 2018 against multiple generic manufacturers regarding their submissions of ANDAs seeking to commercialize generic copies of LATUDA®. Those lawsuits allege infringement of U.S. Patent No. 9,815,827 and were announced in Sumitomo Dainippon Pharma’s press releases dated February 14 and February 24, 2018.

Sumitomo Dainippon Pharma has granted Sunovion an exclusive license in the U.S. under the Substance Patent, and Sunovion has been marketing lurasidone HCl tablets in the U.S. under the brand name LATUDA® since its launch in February 2011.

Sumitomo Dainippon Pharma and Sunovion continue to believe that our patent position for LATUDA® is very strong, and we will continue to vigorously protect the patent rights for LATUDA®.

The decision will not materially affect Sumitomo Dainippon Pharma’s consolidated financial

forecasts of the fiscal year ending March 31, 2019, which is being considered by us, and will be announced on May 11, 2018.

* The defendants are following generic manufacturers:

- Emcure (Emcure Pharmaceuticals Ltd. and Emcure Pharmaceuticals USA, Inc.)
- InvaGen (InvaGen Pharmaceuticals, Inc.)
- Teva (Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd.)

Disclaimer Regarding Forward-looking Statements

The statements made in this press release are forward-looking statements based on management's assumptions and beliefs in light of information available up to the day of announcement, and involve both known and unknown risks and uncertainties. Any forward-looking statements including financial results may differ materially from those presented in this document, being dependent on a number of factors.

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