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Abbott, Eli Lilly sues Watson Pharma for patent infringement on dyslipidemia drug and SERM respectively

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Watson Pharmaceuticals, Inc has confirmed that its subsidiary, Watson Laboratories, Inc, filed Abbreviated New Drug Applications (ANDAs) for two products – a generic version of Abbott's dyslipidemia drug Simcor and Eli Lilly's oral selective estrogen receptor modulator (SERM), Evista, with the US Food and Drug Administration (FDA).

With this, the company has entered into Para IV patent infringement suits with both Abbott Laboratories and Eli Lilly. Watson has filed ANDA seeking approval to market its 1000 mg/20 mg form of niacin extended-release/simvastatin tablets, which is the generic version of Abbott's 1000 mg/20 mg form of Simcor.

Simcor is indicated for people who have unhealthy cholesterol levels when treatment with simvastatin alone or niacin extended-release alone is not enough, and when a diet low in saturated fat and cholesterol and other non-drug measures alone have not been successful.

Abbott Laboratories and Abbott Respiratory, LLC filed suit against Watson on May 4, 2010 in the United States District Court for the District of Delaware seeking to prevent Watson from commercializing its product prior to the expiration of US Patent Nos. 6,080,428; 6,129,930; 6,406,715; 6,469,035; 6,676,967; 6,746,691; 6,818,229; and 7,011,848.

Abbott's suit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final US FDA approval of Watson's ANDA for up to 30 months or until final resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivity.

For the twelve months ending December 31, 2009, Simcor had total US sales of approximately US$ 88 million according to IMS Health data.

Evista, a raloxifene hydrochloride tablet for which the company has engaged in dispute with Eli Lilly is indicated for the treatment and prevention of osteoporosis in postmenopausal women, for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis, and for the reduction in the risk of invasive breast cancer in postmenopausal women at high risk of invasive breast cancer.

Eli Lilly and Company filed suit against Watson on May 3, 2010 in the United States District Court for the Southern District of Indiana seeking to prevent

Watson from commercializing its product prior to the expiration of US Patent Nos. 6,458,811, 6,797,719 and 6,894,064. Lilly's suit was filed under the provisions of the Hatch-Waxman Act, resulting in a stay of final FDA approval of Watson's ANDA for up to 30 months or until final resolution of the matter before the court, whichever occurs sooner, subject to any other exclusivities.

For the twelve months ending March 31, 2010, Evista had total US sales of approximately US $690 million according to IMS Health data.