

Crestor[®] Patent Upheld by US Court of Appeals for the Federal Circuit

Osaka, Japan, December 17, 2012 - Shionogi & Co., Ltd. (Head Office: Osaka; President: Isao Teshirogi; hereafter "Shionogi") announced that US Court of Appeals for the Federal Circuit (CAFC) has found on December 14, 2012 that the substance patent protecting Crestor[®] (generic name: rosuvastatin calcium; Patent number: RE37,314; hereafter "314 patent"), which was out-licensed to AstraZeneca (Head Office: London, United Kingdom), is valid and enforceable. This ruling affirmed the decision in June, 2010 upholding the 314 patent's validity and enforceability by the District Court for the District of Delaware.

As the result of this decision, the Food and Drug Administration is prohibited from approving the Abbreviated New Drug Applications (hereafter "ANDAs") of the 8 generic defendants (Apotex, Aurobindo, Cobalt, Mylan, Par, Sandoz, Sun and Teva) until July 8, 2016, (which includes the pediatric exclusivity).

Shionogi will continue to vigorously defend its intellectual property in the future.

About the Trial

Beginning in 2007, 8 generic drug manufacturers filed ANDAs along with Paragraph IV certifications of non-infringement, invalidity, or unenforceability with respect to the Crestor[®] patents. Shionogi, the owner of the 314 patent, and AstraZeneca filed patent infringement suits in the District Court for the District of Delaware against 8 manufacturers who had challenged the 314 patent. In 30 June, 2010, Judge Joseph Farnan, Jr. has found that the 314 patent is valid and enforceable.

About Crestor[®]

Crestor[®] works to lower cholesterol levels by inhibiting selectively and competitively the enzyme HMG-CoA reductase, which plays a central role in the production of cholesterol in the liver. Crestor[®] has been approved in over 100 countries and more than 19 million patients have been prescribed Crestor[®] worldwide. In Japan, AstraZeneca and Shionogi have been jointly marketing Crestor[®] since April, 2005.

Forward-looking Statements

This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials and entry of competitive products.



The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.

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