

USV Patents Method To Make Aricept Ingredient

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Monday, Mar 10, 2008 --- Indian generics drugmaker USV has reportedly received a U.S. patent related to the pharmaceutical ingredient used in the blockbuster Alzheimer's drug Aricept, reversing an earlier refusal.

Mumbai-based USV Ltd. filed a patent in 2004 for a process of deriving donepezil hydrochloride, the active ingredient in Aricept, from donepezil oxalate.

The patented process presents an alternative means of creating the donepezil base without violating the several patents held by Japanese drugmaker Eisai Co. Ltd that cover the production of donepezil hydrochloride.

Aricept is used to treat the symptoms of mild, moderate and severe Alzheimer's disease, helping to improve memory, attention, language and the ability to function.

U.S. Patent Number 7,186,842 lays groundwork for a generic version of the world's No. 1 Alzheimer's drug, which has been used to treat more than 3.8 billion people worldwide, according to the Aricept Web site.

"A method of treating senile dementia of Alzheimer's disease ... is also envisaged as part of this invention," the USV patent application said.

Aricept is co-marketed in the U.S. by Pfizer. USV's patent is a breakthrough as generics drugmakers look toward the expiration of the U.S. patent for Aricept in November 2010, the Hindu Business Line reported Friday.

The patent was initially refused on the grounds that the description of the invention as a "composition of matter" was too vague. USV appealed to the Board of Patent Appeals and Interferences, which overturned the initial decision and issued the patent, Hindu Business Line reported.

When the patent for Aricept expires, USV may have an advantage over the other generics drugmakers that will begin manufacturing a generic Aricept drug.

Mark Pohl, the patent attorney for USV, underscored the significance of the patent, noting that it covers a way of making Aricept's active ingredient at a much lower cost, thus allowing an eventual generic to be sold well below the price of would-be competitors.

He attributed his success in representing USV to the company's scientists who have continually been at the leading edge of a competitive industry.

"I don't want it to sound like false modesty, but really the success goes to the lab in India. While we have not lost a case in some six years, ultimately the trend has more to do with the quality of work being done at USV than any individual accomplishment. The better the client, the easier it is for the lawyer to win a case," said Pohl.

Representatives for USV and Eisai were not available for comment Monday.

USV was represented in the patent application by Mark Pohl of Pharmaceutical Patent Attorneys LLC.

Indicus Pharma LLC is USV's stateside affiliate, based in Raleigh, N.C.

The patent marks the second recent success for USV, which earlier this month secured a patent to process the active ingredient for GlaxoSmithKline's Requip drug, which had sales of more than \$500 million last year, Dow Jones reported.

The patent covered a process for making a version of ropinirole, paving the way for a new generic form of the drug used to treat Parkinson's disease and the condition termed Restless-Leg Syndrome.

The invention is covered by U.S. patent number 7,186,842.