

Meda has settled the U.S. Astelin® patent litigation with Apotex

Meda, through its wholly owned U.S. subsidiary, Meda Pharmaceuticals Inc., has entered into a settlement agreement with Apotex Inc. and Apotex Corp. (hereafter Apotex) that resolves the U.S. patent litigation between the companies regarding Apotex's proposed generic versions of Astelin[®] and Optivar[®].

Astelin[®] (azelastine hydrochloride nasal spray) is used for treatment of allergic and non-allergic rhinitis and Optivar[®] (azelastine hydrochloride ophthalmic solution) is used for treatment of allergic conjunctivitis. These products are protected in the U.S. by a patent that expires on 1 November 2010, with paediatric exclusivity extending until 1 May 2011.

The settlement agreement resolves patent infringement actions filed by Meda after Apotex's submission of ANDAs (Abbreviated New Drug Applications) to the U.S. FDA (Food & Drug Administration) for generic versions of Astelin[®] and Optivar[®] in 2006 and 2007, respectively. Under the settlement agreement, Apotex admits infringement of Meda's patent. Given the settlement agreement, the parties will jointly request that scheduled trials regarding Apotex's proposed generic version of Astelin[®] in May 2008 and proposed generic version of Optivar[®] in February 2009 be adjourned and the actions closed.

The settlement agreement allows Apotex to launch a generic version of Astelin[®], under a license from Meda, on 1 March 2010. In such case, Apotex will pay 32.5% of their net sales of this product to Meda until 1 February 2011. The agreement also allows Apotex to launch a generic version of Optivar[®], under license from Meda, on 1 December 2009, without further payments to Meda.

"This settlement agreement brings clarity to Meda's intellectual property rights on the U.S. patent for Astelin® and Optivar®," said Anders Lönner, CEO Meda.

In compliance with U.S. law, the settlement agreement will be submitted to the U.S. Federal Trade Commission and Department of Justice and is subject to their review.

This settlement agreement does not settle the two remaining patent infringement actions brought by Meda in the U.S. against Sun Pharmaceutical Industries Ltd. (hereafter Sun) regarding a proposed generic version of Optivar® and Cobalt Pharmaceuticals Inc. (hereafter Cobalt) regarding a proposed generic version of Astelin®. The trial with Sun is scheduled to start on 20 July 2009. The trial with Cobalt has not been scheduled.

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