

Pfizer, Mylan settle litigation over Detrol LA generic

10 September 2012 | News | By BioSpectrum Bureau



Singapore: Pfizer has settled its litigation against Mylan and Mylan Pharmaceuticals relating to Pfizer's patents covering Detrol LA (tolterodine tartrate) extended-release capsules.

The patent litigation was in connection with Mylan Pharmaceuticals' abbreviated new drug application (ANDA) for Tolterodine Tartrate ER capsules, 2 mg and 4 mg, which is the generic version of Pfizer's Detrol LA, indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

According to the terms of the settlement agreement, Mylan may begin to sell the product on January 1, 2014, or earlier under certain limited circumstances, and no later than March 1, 2014, subject to final approval from the US Food and Drug Administration. Under the terms of the agreement, Mylan may launch the product as either an authorized generic or under its own ANDA. Pursuant to the agreement, the pending litigation will be dismissed.

Tolterodine Tartrate ER capsules, 2 mg and 4 mg, had US sales of approximately \$599 million for the 12 months ending June 30, 2012, according to IMS Health.