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Glenmark confirms patent challenge for generic Finacea

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Glenmark confirms patent challenge for its generic version of FINACEA

Glenmark Pharmaceuticals, a manufacturer of generic formulation products and active pharmaceutical ingredients (API), has confirmed that it has filed an Abbreviated New Drug Application (ANDA) for Azelaic Acid, Gel 15 percent Topical, with the US Food and Drug Administration (FDA). Glenmark's ANDA product is a generic version of Finacea, which is indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea.

Intendis GmbH, Intraserv GmbH and Co, and Bayer Healthcare Pharmaceuticals had filed a suit against Glenmark Generics on March 14, 2013, in the United States District Court for the District of Delaware, seeking to prevent Glenmark from commercializing its ANDA product prior to the expiration of US patent number 6,534,070. This lawsuit was filed under the provisions of the Hatch-Waxman Act, which triggers a stay of final FDA approval of Glenmark's ANDA product for up to 30 months or until final resolution of the matter before the Court, whichever occurs sooner.

Based on available information, Glenmark believes it may be a "first applicant" to file an ANDA for the generic version of Finacea and may be entitled to 180 days of generic market exclusivity.

According to the IMS health data for the twelve months ending September 30, 2012, Finacea had total US sales of approximately $95 million.