

Cephalon files patent lawsuit against Teva for armodafinil tabs

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Frazer, Pennsylvania

Cephalon, Inc has filed a lawsuit in US District Court in Delaware against Teva Pharmaceuticals USA, Inc for infringement of US Patent Nos. 7,132,570 (the "'570 Patent"), 7,297,346 (the "'346 Patent") and RE37,516 (the "'516 Patent") for the Cephalon product Nuvigil (armodafinil) Tablets [C-IV]. Cephalon has a three-year period of marketing exclusivity for Nuvigil that extends until June 15, 2010. In addition, including the six-month paediatric extension, the '516 Patent, the '346 Patent, and the '570 Patent expire on April 6, 2015, May 29, 2024, and June 18, 2024, respectively. Teva did not challenge Orange Book-listed US Patent No. 4,927,855 (the "'855 Patent"), which provides additional protection until October 22, 2010, the expiration date of the '855 Patent.

The lawsuit is based upon an Abbreviated New Drug Application (ANDA) filed by Teva seeking FDA approval for a generic equivalent of armodafinil to be sold in the United States. Teva alleges that the above Nuvigil patents are invalid, unenforceable and/or will not be infringed by Teva's manufacture, use or sale of the product described in its ANDA.

"We believe that our Nuvigil patents, approved by the US Patent & Trademark Office, are valid, enforceable and are infringed by the proposed Teva ANDA product," said Jerry Pappert, executive vice president and General Counsel. "Our patent position for this product is strong and we intend to vigorously defend our intellectual property."

The filing of this lawsuit is provided for by the Hatch-Waxman Act, a federal statute governing certain aspects of generic drug approvals. Under that statute, the filing of the lawsuit stays any FDA approval of the Teva ANDA until the earlier of entry of a district court judgment finding the patents invalid or not infringed or 30 months from the company's October 2009 receipt of a Paragraph IV certification letter from Teva.

Founded in 1987, Cephalon is an international biopharmaceutical company dedicated to the discovery, development and commercialization of many unique products in four core therapeutic areas: central nervous system, inflammatory diseases, pain and oncology.