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New ANDA Cases Filed

Prolensa® (bromfenac ophthalmic solution (0.07%)) – NDA No. 203168

Senju Pharmaceutical Co., Ltd., Bausch & Lomb Incorporated, and Bausch & Lomb Pharma Holdings Corp. v. Aurobindo Pharma USA Inc. and Aurobindo Pharma Limited,
U.S.D.C. D.N.J., Case No. 3:19-cv-13348.

Senju/Bausch & Lomb, in a complaint filed on June 3, 2019, seeks to block approval of Aurobindo's ANDA products (bromfenac ophthalmic solution (0.07%)) prior to the expiration of U.S. Patent No. 8,129,431; 8,669,290; 8,754,131; 8,871,813; 8,927,606; 9,144,609; 9,517,220; 9,561,277 and 10,085,958 - Orange Book listed patents for Prolensa®, a nonsteroidal anti-inflammatory drug indicated for the treatment of postoperative inflammation and reduction of ocular pain in patients who have undergone cataract surgery.

Afinitor® (everolimus tablets) – NDA No. 022334

Novartis Pharmaceuticals Corporation and Novartis AG v. Mylan Pharmaceuticals, inc., U.S.D.C. D. Del., Case No. 1:19-cv-01042. Novartis,

in a complaint filed on June 5, 2019, seeks to block approval of Mylan's ANDA products (2.5, 5, 7.5 and 10 mg everolimus tablets) prior to the expiration of U.S. Patent Nos. 5,665,772; 8,778,962 and 8,436,010 – Orange Book listed patents for Afinitor®, a kinase inhibitor indicated for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer in combination with exemestane after failure of treatment with letrozole or anastrozole; adults with progressive neuroendocrine tumors of pancreatic origin (PNET) and adults with progressive, well-differentiated, non-functional neuroendocrine tumors (NET) of gastrointestinal (GI) or lung origin that are unresectable, locally advanced or metastatic; adults with advanced renal cell carcinoma (RCC) after failure of treatment with sunitinib or sorafenib and adults with renal angiomyolipoma and tuberous sclerosis complex (TSC), not requiring immediate surgery.

Epaned® (enalapril maleate oral solution) – NDA No. 208686

Silvergate Pharmaceuticals, Inc. v. Bionpharma Inc., U.S.D.C. D. Del., Case No. 1:19-cv-01067. Silvergate, in a second complaint filed on June 7, 2019, seeks to block approval of Bionpharma's ANDA Product (enalapril maleate oral solution) prior to expiration of U.S. Patent No. 10,154,987 – an Orange Book listed patent for Epaned®, an angiotensin-converting enzyme inhibitor indicated for the treatment of hypertension in adults and children older than one month, to lower blood pressure; the treatment of symptomatic heart failure, and the treatment of

asymptomatic left ventricular dysfunction.

Silvergate, in *Silvergate*

Pharmaceuticals, Inc. v. Bionpharma Inc., U.S.D.C. D. Del., Case No. 1:18-cv-01962, previously asserted U.S. Patent Nos. 9,669,008; 9,808,442 and 10,039,745 against Bionpharma.

By Lynn M. Terrebonne

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