

Astellas Pharma Inc.: Files Lawsuit Against Sandoz For Patent Litigation In Canada

Tokyo, July 14, 2011 - Astellas Pharma Inc. (“Astellas”; headquarters: Tokyo; President and CEO: Yoshihiko Hatanaka) announced today that Astellas and its Canadian affiliate Astellas Pharma Canada, Inc. jointly filed a Notice of Application pursuant to the Patented Medicine (Notice of Compliance) Regulations in Canada against Sandoz Canada Inc. (“Sandoz”) in response to Sandoz’s abbreviated new drug submission (“ANDS”) for a generic version of Prograf® (generic name: tacrolimus hydrate). The application was filed in the Federal Court of Canada on July 13, 2011 requesting, among other things, an order prohibiting the Canadian Minister of Health from issuing marketing approval in respect of Sandoz’s ANDS before the expiration of Astellas’ patent for tacrolimus hydrate (Canadian Patent No.: 1,338,491).

Tacrolimus is an immunosuppressant discovered and developed by Astellas and is marketed as an immunosuppressant for organ transplantation under the brand name Prograf in *97 countries/areas. Additionally, a once-daily oral formulation of tacrolimus is available in *39 countries/areas worldwide, including Japan under the brand name Graceptor®, Europe under the brand name Advagraf® and Canada under the brand name ADVAGRAF®. In Canada, Astellas Pharma Canada, Inc. has been marketing Prograf since February 1996 and ADVAGRAF since April 2008.

Astellas is committed to defending its patent rights.

The impact from this lawsuit on Astellas’ financial forecast for the current fiscal year (from April 1, 2011 to March 31, 2012) will be immaterial.

*as of June 2011

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