

March 23, 2020

Name of listed company: Chugai Pharmaceutical Co., Ltd.
Code number: 4519 (1st Section of Tokyo Stock Exchange)
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Chugai Files Patent Infringement Lawsuit against Fresenius Kabi in the U.S.

[Chugai Pharmaceutical Co., Ltd.](#) announced today that Chugai, Roche and Genentech have filed a patent infringement lawsuit in the United States District Court for the District of Delaware as follows.

1. Date of Complaint

March 19, 2020 (local time)

2. Reasons for the Action

Fresenius Kabi USA, LLC, in concert with Fresenius Kabi Oncology Limited and Fresenius SE & Co. KGaA (collectively “Fresenius”), filed an Abbreviated New Drug Application (“ANDA”) for approval of a generic version of Alecensa[®] (generic name: alectinib, an ALK inhibitor, anti-cancer agent) to the U.S. Food and Drug Administration. Under the framework of the Drug Price Competition and Patent Term Restoration Act (known as Hatch-Waxman Act), Chugai, Roche and Genentech filed a patent infringement lawsuit against Fresenius alleging submission of ANDA infringed Chugai’s U.S. Patents (Nos. 9,126,931; 9,440,922; 9,365,514 and 10,350,214).

3. Defendants

(1) Name: Fresenius Kabi USA, LLC, etc.

(2) Address: Three Corporate Drive, Lake Zurich, Illinois 60047, USA, etc.

4. Prospects

No changes are expected to be made to Chugai’s financial prospects at this point.

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