

July 14, 2023

Name of listed company: Chugai Pharmaceutical Co., Ltd.
Code number: 4519 (Prime Market of Tokyo Stock Exchange)
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Chugai Files Patent Infringement Lawsuit against Biogen MA Inc. and Bio-Thera Solutions, Ltd. 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 Massachusetts as follows.

1. Date of Complaint

July 13, 2023 (local time)

2. Reasons for the Action

In response to Biogen MA Inc. (“Biogen”)’s filing of an abbreviated biologics license application (“aBLA”) to the U.S. Food and Drug Administration for approval of a biosimilar to Actemra[®] (generic name: tocilizumab), Chugai, Roche and Genentech filed a patent infringement lawsuit against Biogen together with its business partner Bio-Thera Solutions, Ltd., who developed biosimilar products subject to Biogen’s aBLA, seeking judgments including infringement of Chugai, Roche, and Genentech’s U.S patents under the framework of Biologics Price Competition and Innovation Act (“BPCIA”). Patents in suit include but not limited to patents related to methods of using tocilizumab in intravenous form, and methods of manufacturing tocilizumab.

3. Defendants

(1) Name: Biogen MA Inc.

Address: 225 Binney Street Cambridge, MA 02142 USA

(2) Name: Bio-Thera Solutions, Ltd.

Address: 11 Kai-Yuan Blvd, Huangpu District, Guangzhou, China

4. Prospects

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

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