

November 27, 2020

Name of listed company: Chugai Pharmaceutical Co., Ltd.  
Code number: 4519 (1<sup>st</sup> Section of Tokyo Stock Exchange)  
Head office: 1-1, Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo  
Chairman & CEO: Tatsuro Kosaka  
Inquiries to: Masahiko Uchida  
Head of Corporate Communications Dept.  
Tel: +81-(0)3-3273-0554

## **Chugai Files Patent Infringement Lawsuit concerning Ediol Capsules**

[Chugai Pharmaceutical Co., Ltd.](#) announced today that it has filed a patent infringement lawsuit with the Tokyo District Court, based on the substance patent owned by Chugai, demanding the suspension of manufacturing, use of materials, and disposal of stock for the active pharmaceutical ingredient (API) of the generic drugs of an osteoporosis agent, active vitamin D<sub>3</sub> derivative Ediol® Capsule 0.5µg / 0.75µg (generic name: eldecacitol, hereafter, Ediol Capsule) against Nissan Chemical Corporation (hereafter, Nissan Chemical), also demanding damage compensation against Nissan Chemical, Sawai Pharmaceutical Co., Ltd. (hereafter, Sawai) and Nichi-Iko Pharmaceutical Co., Ltd (hereafter, Nichi-Iko). Concurrently, Chugai filed the petition for provisional disposition order against Nissan Chemical.

1. Date of Complaint  
November 27, 2020

2. Reasons for the Action

On February 17, 2020, Sawai and Nichi-Iko obtained approval from the Ministry of Health, Labour and Welfare for their generic drugs of Ediol Capsule, respectively. At this point, only Sawai and Nichi-Iko have launched the generic drug. Nissan Chemical has recently been focusing on the API business of eldecacitol for the generic drug of Ediol Capsule.

In response to this situation, Chugai filed a patent infringement lawsuit with the Tokyo District Court, based on the substance patent owned by Chugai, demanding the suspension of manufacturing and use of materials, and disposal of stock for the API of the generic drugs of Ediol Capsule against Nissan Chemical, also demanding damage compensation against Nissan Chemical, Sawai and Nichi-Iko. Concurrently, Chugai filed the petition for provisional disposition order against Nissan Chemical.

In this proceeding, Chugai alleges that Sawai and Nichi-Iko have outsourced the manufacturing of the API to Nissan Chemical and purchased and used the API from Nissan Chemical to manufacture and sell their generic drugs. Additionally, the API produced and used by Nissan Chemical in the manufacturing of the API infringes the substance patent (patent number 3429432) owned by Chugai.

3. Defendants

- (1) Name: Nissan Chemical Corporation  
Address: 5-1, Nihonbashi 2-Chome, Chuo-ku, Tokyo, Japan
- (2) Name: Sawai Pharmaceutical Co., Ltd.  
Address: 5-2-30, Miyahara, Yodogawa-ku, Osaka, Japan
- (3) Name: Nichi-Iko Pharmaceutical Co., Ltd.  
Address: 1-6-21 Sogawa, Toyama City, Toyama Prefecture, Japan

4. Prospects

No changes are expected to Chugai's financial prospects at this point.

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