

February 17, 2021

Name of listed company: Chugai Pharmaceutical Co., Ltd.
Code number: 4519 (1st Section of Tokyo Stock Exchange)
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Chugai Refiles Patent Infringement Lawsuit concerning Ediol Capsules

[Chugai Pharmaceutical Co., Ltd.](#) announced today that it has refiled a patent infringement lawsuit with the Tokyo District Court, based on the substance patent owned by Chugai, regarding the generic drugs of an osteoporosis agent, active vitamin D₃ derivative Ediol® Capsule 0.5µg / 0.75µg (generic name: eldecacitol, hereafter, Ediol Capsule) against Sawai Pharmaceutical Co., Ltd. (hereafter, Sawai), Nichi-Iko Pharmaceutical Co., Ltd. (hereafter, Nichi-Iko) and Nissan Chemical Corporation (hereafter, Nissan Chemical) as per below. The lawsuit was initially filed on November 27, 2020, but the proceeding was withdrawn for litigation strategic reasons on January 15, 2021.

1. Date of Complaint
February 17, 2021

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 production and use and disposal of the crystalline form, for which Chugai holds the patent, in association with the generic drug, and also demanding damage compensation against Sawai, Nichi-Iko and Nissan Chemical. Concurrently, Chugai filed the petition for provisional disposition order against the above three companies.

In this proceeding, Chugai recognizes that Sawai and Nichi-Iko have outsourced the manufacturing of the active pharmaceutical ingredient (API) to Nissan Chemical, purchased and used the API from Nissan Chemical to manufacture and sell their generic drugs, and at that time the above three companies have been producing and using the crystalline form for which Chugai holds the patent in order to manufacture and sell their generic drugs. Chugai alleges that said action infringes the substance patent (patent number 3429432) owned by Chugai.

3. Defendants

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

4. Prospects

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

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