

# Preliminary injunctions in pharmaceutical patent cases in Japan

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Five cases in which preliminary injunctions were granted are examined by Takanori Abe of Abe & Partners.

Recently, preliminary injunctions were filed and granted successively in pharmaceutical patent cases against generics in Japan. Below are overviews of five cases.

## 1. Toray v Sawai & Fuso (REMITCH® (Generic name: Nalfurafine Hydrochloride))

Toray is approved for the manufacture and sale of the oral pruritus improving agent 'REMITCH®' ('REMITCH® CAPSULES 2.5µg' and 'REMITCH® OD TABLETS 2.5µg': 'the product'). Based on its use patent (JP3531170, registration of extension: Application 2017-700154 and Application 2017-700310), the IP High Court issued a preliminary injunction order against Sawai and Fuso on October

7, 2022, for the manufacture and sale of the generics of the product, 'NALFURAFINE HYDROCHLORIDE OD Tablets [SAWAI]' and 'Nalfurafine Hydrochloride OD Tablets 2.5µg [FUSO]'. Toray had filed a petition for a preliminary injunction in 2022. The month and the date are unknown.

This case appears to concern the scope of the extended patent right relating to the use patent, which was not necessarily clear in the Grand Panel of the IP High Court's (Oxaliplatin case) judgment of January 20, 2017.

## **2. Asahi Kasei Pharma v Sawai (Teribone® (Generic name: Teriparatide Acetate))**

Asahi Kasei Pharma is the owner of a process patent (JP6025881) relating to 'Teribone® Injection 56.5µg' ('the product'). Based on the patent, the Osaka District Court issued a preliminary injunction order against Sawai on September 4, 2023, for the manufacture and sale of the generic of the product, 'TERIPARATIDE for Subcutaneous Injection 56.5µg [SAWAI]'. Asahi Kasei Pharma had filed a petition for a preliminary injunction on October 7, 2022.

This case concerns a process patent, which is generally considered challenging to prove infringement against.

## **3. BMS v Sawai (Sprycel® (Generic name: Dasatinib Hydrate))**

Bristol-Myers Squibb K.K. is approved for the manufacture and sale of 'Sprycel® Tablets 20 mg/50 mg'. Based on BMS's substance patent (JP3989175), the Tokyo District Court issued a preliminary injunction order against Sawai on November 28, 2023, for the manufacture and sale of the generics of the product, 'DASATINIB Tablets 20 mg/50 mg [SAWAI]'. BMS had filed a petition for a preliminary injunction on July 18, 2023.

There is a criticism of this case concerning the assertion that patent linkage did not work. That is, as the registration of an extension of the substance patent for Sprycel® Tablets 20mg/50mg was granted on the basis of an additional approval for 'chronic myeloid leukemia (excluding imatinib-resistant chronic myeloid leukemia)' as 'effectiveness and efficacy', the addition of 'chronic myeloid leukemia' to Sawai's 'effectiveness and efficacy' should not have been approved due to patent linkage. However, the Ministry of Health, Labour and Welfare (MHLW) may not have applied patent linkage, focusing on the difference between the active ingredient of Bristol-Myers Squibb K.K.'s Sprycel® Tablets and that of Sawai's generic in terms of hydrate and anhydrate.

## **4. MSD v Sawai, Medisa Shinyaku (JANUVIA® (Generic name: Sitagliptin Phosphate Hydrate))**

Merck Sharp & Dohme LLC (MSD) is the owner of a substance patent (JP3762407) and MSD K.K. is approved for the manufacture and sale of 'JANUVIA® Tablets'. Relating to the patent, MSD filed a patent infringement lawsuit and a petition for a preliminary injunction to the Tokyo District Court against Sawai and Medisa Shinyaku on October 6, 2023, for the manufacture and sale of 'SITAGLIPTIN tablets [SAWAI]', a generic of 'JANUVIA® Tablets'.

In this case as well, there is a criticism that patent linkage did not work. That is, as the registration of an extension of the substance patent for JANUVIA® Tablets was granted, Medisa's manufacture and sale of the generic should not have been approved due to patent linkage. However, the MHLW may not have applied patent linkage, focusing on the difference between the active ingredient of MSD K.K.'s JANUVIA® Tablets and that of Medisa's generic in terms of hydrate and anhydrate. It shares the same problem as Sprycel ® (Generic name: Dasatinib Hydrate), and therefore whether a preliminary injunction order will be issued will be worth watching closely.

Medisa postponed the December 2023 NHI price listing.

#### **5. Nobelpharma v Sawai (NOBELZIN® (Generic name: Zinc Acetate Hydrate))**

Nobelpharma is the owner of process patents (JP6716464 and JP6768984) and is approved for the manufacture and sale of 'NOBELZIN® Tablets'. On the grounds of infringement of these patents, it filed a petition for a preliminary injunction to the Tokyo District Court against Sawai on October 30, 2023, seeking an injunction against the manufacture and sale of 'ZINC ACETATE Tablets [SAWAI]', a generic of 'NOBELZIN® Tablets'.

This case concerns a process patent, which is generally considered challenging to prove infringement against.