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# Japan IP High Court Clarified Scope of Patent Term Extension and Awarded Highest Ever Damages in Landmark Nalfurafine Case

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On May 27, 2025, the Intellectual Property High Court of Japan ruled in favor of Toray Industries, Inc. in a landmark patent infringement lawsuit (Case No. 2021 (Ne) 10037) concerning the extended patent rights for the antipruritic agent “Remitch®” (nalfurafine). The court ordered two generic companies, Sawai Pharmaceutical Co., Ltd. and Fuso Pharmaceutical Industries, Ltd., to pay record damages (14.29 billion Yen (approximately US$ 100M) and 7.47 billion Yen (approximately US$50M), respectively) for infringing Toray’s extended patent rights. This award marks the highest ever awarded in a patent infringement case in Japan.

**Background:**

Toray held a medical use patent (Japanese Patent No. 3531170) for active ingredient “nalfurafine”. The patent term was extended for 5 years, until November 21, 2022, based on the marketing approval for Remitch® which contains “nalfurafine hydrochloride” (salt form).

In 2018, Sawai and Fuso launched generic versions of “nalfurafine hydrochloride” orally disintegrating tablets (OD tablets). Toray filed a lawsuit asserting infringement of its extended patent right (Case Nos. 2018 (Wa) 38504 and 2018 (Wa) 38508). However, the Tokyo District Court dismissed Toray’s claims on March 30, 2021, reasoning that the generic products contained “nalfurafine hydrochloride” (salt form), which differed from “nalfurafine” (construed to be only in free form) claimed in the patent.

Separately, Sawai filed invalidation requests with the JPO, arguing that Toray’s patent term extension (PTE) should not have been allowed based on the marketing approval for Remitch® — again, due to the distinction between “nalfurafine” and “nalfurafine hydrochloride.” The JPO agreed and invalidated the PTE.

However, on March 25, 2021 (5 days before the Tokyo District Court ruling above), the IP High Court reversed the JPO’s decision. The court held that a person ordinarily skilled in the art would understand that, once administered, nalfurafine hydrochloride dissociates and exerts its medicinal effects as nalfurafine. Thus, nalfurafine in both free form and salt form could be viewed as the active ingredient under the patent. This IP High Court’s interpretation significantly broadened the meaning of “nalfurafine” as used in the patent.

**The IP High Court's Infringement Decision:**

In its May 2025 decision, the IP High Court reversed the Tokyo District Court decision and found that Sawai and Fuso's generic products indeed infringed Toray's extended patent rights. Although the full decision has not yet been published (as of June 3, 2025), it is anticipated that the IP High Court again adopted the broader interpretation of "nalfurafine" to include "nalfurafine hydrochloride."

The crux of the dispute centered on the scope of the extended patent under Article 68-2 of the Japanese Patent Act. This provision limits the effect of an extended patent to the same product (and use, if specified) as the originator's approved product which was the basis for the patent term extension.

In 2017, the IP High Court Grand Panel issued its first major interpretation of this provision (Case No. 2016 (Ne) 10046; decision rendered January 20, 2017). The Grand Panel ruled that even if the accused product has partial differences from the approved originator's product as identified by "ingredients, quantity, dose and administration, indication" in the marketing approval which was the basis for the patent term extension, if those differences are slight or formal when seen overall, and the accused product is substantially the same as the approved originator's product, the effect of the extended patent would extend to the accused product. However, the exact meaning of "substantially the same" remained unclear.

Sawai and Fuso argued that their generic products differed from Remitch® due to differences in excipients, and thus were not "substantially the same." It is possible that they contended that unique use of excipient combinations (sometimes patented) rendered their products outside the scope of the extended patent. The IP High Court appears to have rejected this argument, finding that the generic products were still substantially the same as Remitch®, despite the excipient differences.

**Comments:**

Once the full decision is released, we will get to know the court's reasoning on how it assessed substantial similarity— especially in light of differing excipients — in more detail. Generic manufacturers frequently assert non-infringement based on excipient differences, sometimes bolstered by separate patents on excipient combinations. It would be particularly instructive if the court addressed these arguments, and established a threshold for when excipient differences become legally significant.

We expect that this decision will provide greater predictability in future PTE enforcement actions for originators and generic pharmaceutical in the Japanese market.

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