FROM THE BOARD:
Japan at a crossroads: pharmaceutical patents and generic entry

Osamu Yamamoto of YUASA AND HARA examines the structural vulnerabilities in Japan's patent term extension and patent linkage systems highlighted by the Intellectual Property High Court's decision in the "Remitch®" case.

Osamu Yamamoto

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On May 27, 2025, the Intellectual Property High Court of Japan (IPHC) rendered its decision in the "Remitch®" patent infringement litigation (2021 (Ne) 10037), sending shockwaves through Japan's pharmaceutical industry. The IPHC held that the sale of generic products by Sawai Pharmaceutical Co., Ltd. and Fuso Pharmaceutical Industries, Ltd. infringed Toray Industries, Inc.'s extended-use patent relating to Nalfurafine Hydrochloride and ordered damages totaling approximately JPY 21.7 billion. The judgment is widely viewed as one of the largest patent damage awards ever rendered in Japan. Given that the Tokyo District Court, in the first instance, dismissed the claim for non-infringement, the impact of this reversal is expected to be far-reaching for future pharmaceutical patent practice.

The decision is particularly significant because it relates not only to the interpretation of the "active ingredient" in a claim of a pharmaceutical invention but also to the scope of protection of a patent after patent term extension (PTE) is granted. The reversal has raised serious concerns regarding the predictability of infringement risks for generic pharmaceutical companies. More than a dispute between private parties, the case represents a critical milestone that calls into question the robustness of Japan's patent linkage system.

Claim interpretation "active ingredient"

The claims of the use patent at issue (JP No. 3531170) identified "Nalfurafine free base" as the active ingredient of the antipruritic agent. In contrast, both the originator and the generics used the hydrochloride salt as their active ingredient. The central legal question was whether a use patent specifying the "free base" could extend to generic products formulated with "Nalfurafine Hydrochloride." Notably, it may not have been intentional, but, from a formal standpoint, references to the hydrochloride salt were removed from the claims by an amendment during prosecution.

The Tokyo District Court adopted a strict, literal interpretation of the claim, ruling that "active ingredient" refers to the active pharmaceutical ingredient as formulated in the drug. It therefore held that the active ingredient in the defendants' products was "Nalfurafine Hydrochloride," not the free base, and found no infringement. The Court also rejected the doctrine of equivalents, reasoning that the difference concerned an essential element of the invention.

In contrast, the IPHC adopted a purposive construction, considering the descriptions in the patent specification, common general technical knowledge in the pharmaceutical field, and an understanding of pharmacological actions. The IPHC interpreted "active ingredient" to mean the chemical substance that is released in the body to exert a pharmacological effect. It was therefore concluded that the patent should properly be understood as covering antipruritic agents in which "Nalfurafine," including its salt forms, functions as the pharmacologically active substance. In the pharmaceutical field, active ingredients are commonly administered in salt forms, while the pharmacologically active moiety is often regarded as the free base. On this basis, the Court held that the defendants' products fell within the technical scope of the patented invention.

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Scope of extended patent right

In Japan, when an originator company obtains a new approval for a new dosage or administration method using the same active ingredient and indication, it may apply for and receive a PTE based on that approval. In other words, multiple PTEs can be granted. Consequently, the scope of extended patent rights becomes a significant issue. In this case, the framework established by the Grand Panel decision of the IPHC in the 2017 "Oxaliplatin" case (2016 (Ne) 10046) was applied. In that landmark decision, the Grand Panel adopted the standard of "substantial identity" and explained that the purpose of the PTE system is to compensate patentees for the loss of effective patent term caused by the time required for regulatory approval. Accordingly, the effect of the extended patent right is limited to products that can be regarded as substantially identical to the approved pharmaceutical product. However, the precise contours of "substantial identity" leave room for interpretation on a case-by-case basis.

In this case, the IPHC focused on the fact that the "active ingredient" constituted the core element defining the technical scope of the use patent. Differences in excipients between the originator and generic products were deemed immaterial so long as they did not interfere with the pharmacological effect of Nalfurafine. Accordingly, the generics were held to be "substantially identical" to the approved drug.

Impact of JPY 21.7 billion in damages

The damages awarded—approximately JPY 14.2 billion against Sawai and JPY 7.5 billion against Fuso—underscore that the business risks associated with "launching at risk" have reached a level that could threaten the financial viability of generic manufacturers. For small and mid sized companies in particular, the barriers to market entry may rise significantly, potentially accelerating consolidation within the generic industry.

Expert committee on patent issues in the generic drug approval process

Unlike the US *Hatch–Waxman* system, Japan lacks a statutory mechanism that comprehensively coordinates pharmaceutical approval and patent dispute resolution prior to generic launch. Instead, it is based on Ministry of Health, Labour and Welfare (MHLW) notifications issued in 1994 and 2009. From the standpoint of ensuring a stable drug supply, the MHLW examines whether generic products conflict with patents covering originator drugs. However, this opaque and insufficient administrative practice can create a risk of patent disputes after approval.

Against this backdrop, the "Notification" was revised in October 2025, clarifying the regulatory positioning of biosimilars and the handling of patent information reporting forms. Yet the revision did not alter the system's fundamental structure; it is best understood as a refinement within the existing framework.

Furthermore, in November 2025, a pilot "Expert Committee System" was introduced under which expert opinions may be solicited during the generic drug approval process for complex patent issues. Under this framework, three committee members discuss patent issues and submit a written opinion to the MHLW within approximately 30 business days of receiving the relevant materials. The system is expected to serve as "preliminary traffic control" for patent disputes. However, unlike a court judgment, it does not render legally binding determinations on infringement, and therefore, its capacity to resolve disputes remains inherently limited within the current framework. Even so, its practical significance as a mechanism bridging the gap between administrative review and judicial proceedings should not be underestimated. The author is also involved as a candidate member of the expert committee system and has high expectations for the role it may play in practice.

Toward a reconstruction of the system

The case is now pending before the Supreme Court, and its outcome may have an enormous impact on future practice in the pharmaceutical field.

The case has exposed the structural vulnerabilities of Japan's patent linkage system, which relies on administrative notices. Moreover, the difficulty in determining the scope of extended patent rights affects generic companies' entry decisions. For Japanese IP stakeholders, this case should be viewed as an opportunity to reconfigure the system—including a fundamental review of the PTE system, which differs significantly from that in other jurisdictions—from a perspective of harmonizing intellectual property protection with access to medicines.

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RÉSUMÉ

Osamu Yamamoto is a patent attorney and a partner at YUASA AND HARA, Japan. He is the acting Chief of the Life Science & Chemistry Group of the Patent Division. He has about 25 years of experience in intellectual property, focusing on patents, including drafting patent applications, providing expert opinions, and defending or attacking patent rights. He has represented a variety of companies in the fields of biotechnology, pharmaceuticals, diagnostics, and foods and beverages etc. He often gives lectures on patents. Before specializing in IP, he gained 10 years of experience working in pharmaceutical and biotechnology research and development for a chemical company.

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