July 2026

JAPAN NEEDS TO MAINTAIN THE INTEGRITY OF ITS PTE FRAMEWORK

Japan's patent term extension (PTE) framework for pharmaceuticals is designed to restore a portion of the patent life lost during the lengthy, resource-intensive clinical trial and regulatory approval process. While patents last 20 years from filing, new medicines typically require more than a decade of development to demonstrate their safety, efficacy and quality. PTE therefore is a critical mechanism to help innovators to recover some of this lost time and sustain investment into high-risk research and development.

Japan's Intellectual Property High Court has established a "substantial identity"[1] standard that the Ministry of Health, Labour and Welfare (MHLW) should apply when assessing follow-on (*e.g.,* generic) drug approvals during an extended substance patent term. Under this standard, MHLW should not approve a follow-on product if the differences are merely "minor" or "formal" compared to the innovative, patented product. However, recent approvals of follow-on drugs during active PTE terms, supported in certain cases by lower court interpretations, raise concerns regarding whether this standard is being applied consistently in practice.[2]

These developments reflect not a lack of legal protection, but rather a potential misapplication of controlling IP High Court precedent.

Immediate Concerns with Generic Approvals During the PTE Period

Innovator companies bear significant scientific and financial risks in developing new medicines, and patent protection—together with related exclusivity periods—is intended to provide a limited opportunity to recoup those investments. After exclusivities expire, innovator products serve as reference products for follow-on applicants, creating a balanced system that has long served patients, innovators and the broader health care ecosystem.

Recent approvals of follow-on drugs during PTE terms raises concerns about whether this balance is being maintained. In several cases, approved follow-on products differ from the reference product in the form of active substance or composition but share the same active substance. Allowing market entry before the PTE expires effectively shortens the period of protection, depriving innovators of the full benefit of the extension and weakening incentives for continued investment in Japan—particularly at a time when the

[1] Debiopharm International S.A. v. Towa Pharmaceutical Co., Ltd., Case No. 2016 (Ne) 10046 (Jan. 20, 2017) ("Oxaliplatin Case").

[2] The issue is compounded by structural features of Japan's system. Unlike other jurisdictions, Japan does not have a formal patent linkage framework and does not require notification to patent holders when a follow-on applicant seeks marketing approval.

country is already experiencing renewed drug lag and loss (*i.e.*, a situation where patients in Japan may wait longer than patients in other countries to access new medicines or where medicines never reach Japan at all).

Judicial Interpretation of PTE Scope

Japanese courts have addressed the issues facing the MHLW, in that they have clarified that PTE granted to a substance patent is not limited to literal replication of the approved reference product. Instead, under the "substantially identical" standard articulated in the *Oxaliplatin* decision, PTE protection is enforceable against follow-on products that are substantially similar to the approved reference product on which the extension was based. In other words, an extended substance patent should cover a follow-on product if the differences between the products would not be regarded by a person skilled in the art as materially significant. This jurisprudence reflects an effort to preserve the integrity and equity of the PTE framework by extending protection to products that are not meaningfully different in substance from the approved drug.

Preserving the Integrity of the PTE Framework

Maintaining the integrity of Japan's innovation ecosystem, and ensuring patients have timely access to the medicines they need, requires that PTE protections be realized not only in law but also in practice. This depends on consistent application by the MHLW of established jurisprudence confirming that PTE should protect approved products for the full duration of the extension, including against substantially similar products. Without such alignment, the predictability and reliability of Japan's innovation incentives are undermined, with potential consequences for future pharmaceutical investment and development decisions.