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Core Patent for Blockbuster Obesity/Diabetes Drug Semaglutide Upheld in Final Ruling

—Judicial Practices and Strategic Implications Japanese Companies Should Know —

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On December 31, 2025, China's Supreme People's Court issued a final judgment upholding the first-instance ruling of the Beijing Intellectual Property Court, which affirmed the validity of the patent for semaglutide (Patent Publication No.: CN200680006674.6, Filing Date: March 20, 2006). This final judgment overturns the earlier invalidation decision (Case No.: 4W112521, Decision Date: September 5, 2022) by the CNIPA, which had declared the patent "Entirely invalid." The Supreme People's Court's ruling not only finalizes the validity of this patent in China amidst numerous invalidation challenges fueled by the expanding obesity/diabetes treatment market but also exemplifies the Chinese government's clear stance in supporting healthcare innovation, regardless of whether the entity is foreign or domestic.

In an official statement, Maziar Mike Doustdar, President and CEO of Novo Nordisk, praised the outcome, stating, "This result is highly favorable for semaglutide and demonstrates the government's strong support for the protection of medical innovation," and that "this decision strengthens foreign companies' confidence in sustainable development in China, further promoting the development and introduction of innovative medicines to benefit patients."[1]

Semaglutide, a long-acting GLP-1 analog developed by Novo Nordisk, is the active ingredient in the obesity treatment drug Wegovy, the type 2 diabetes treatment Ozempic, and the oral formulation Rybelsus. In Q1-Q3 of 2025, semaglutide's sales in the Chinese market reached USD 2.24 billion, with global sales exceeding USD 25.4 billion [2]. While the full judgment text is not yet publicly available, this article provides a detailed analysis of the key points surrounding the invalidation trial & appeal, pharmaceutical patent term extension, the Chinese anti-obesity drug market landscape, and China's pharmaceutical IP system.

1. Key Issue in the Invalidation Trial and Appeal—Admissibility of Post-Filing Experimental Data

The central point of contention between the invalidation authority and the courts regarding this patent's validity was the admissibility of experimental data generated after the filing/priority date. The criteria for this determination offer crucial insights for overseas companies seeking to obtain and maintain pharmaceutical patents in China.

In 2022, aiming to remove barriers for the early launch of a generic drug as the first domestic company to challenge the patent, Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd. filed an invalidation request against this patent. CNIPA ruled at the time that the specification submitted by Novo Nordisk during patent application only disclosed screening methods, not specific compound experimental data. To prove unexpected effects demonstrating inventiveness, Novo Nordisk submitted experimental data during the invalidation evidence stage. However, the Re-examination and Invalidation Department held that the technical effects proven by the subsequently supplemented data could not be derived from the original application documents and declared the patent wholly invalid.

Conversely, the Beijing Intellectual Property Court expressed the view that such data could be "conditionally accepted." It stated that "*supplemental data can be adopted as a basis for examination provided it proves technical effects that can be directly derived or reasonably inferred from the original specification and does not introduce new technical subject matter.*" As the court of second instance, the Supreme People's Court has now consistently affirmed this approach through its final judgment. This can be seen as a "judicial practice favoring innovative pharmaceutical companies," indicating the courts' recognition of the industry practice involving long drug development cycles and post-hoc data supplementation, prioritizing substantive contributions over formal deficiencies.

It is noteworthy that such cases, where supplemental data not accepted at the administrative trial stage is later accepted by the courts during litigation, are by no means isolated. Shenzhen Salubris Pharmaceuticals Co., Ltd. previously successfully invalidated an AstraZeneca patent (Patent Publication No.: CN200610002509.5, Invalidation Decision No.: 33975). The patent owner, AstraZeneca, subsequently appealed through first and second instance. In that case, the new evidence supplemented by AstraZeneca was accepted for the first time precisely at the second instance. In its second-instance judgment document for that case, "Administrative Judgment No. 33 (2019) of the Supreme People's Court (Zhixing)"[3], the Supreme People's Court explicitly stated that the following points should be the focus of examination regarding the admissibility of supplemental experimental data: *1) The fact that the supplemental experimental data intends to directly prove must be explicitly recorded or implicitly disclosed in the original patent application documents (positive condition); 2) The applicant cannot use supplemental experimental data to remedy inherent deficiencies in the original patent application documents (negative condition)*. Furthermore, regarding a common defense argument concerning employment or other interest relationships between the provider of the supplemental data and the patent applicant/owner, the Supreme People's Court held that "in the field of pharmaceutical R&D, especially in new drug development processes, R&D entities are relatively concentrated, and the relative concentration of

the source of supplemental experimental data aligns with the norms and practices of R&D," and expressed the view that "this should not constitute an absolute reason for rejecting supplemental experimental data."

This outcome demonstrates the commitment of China's intellectual property courts in protecting domestic and foreign parties equally according to law, may bring some changes to the previous views of international innovative pharmaceutical companies on China's IP protection. It is expected that a globally competitive environment for scientific and technological innovation will continue to develop in China.

2. The Threshold for Pharmaceutical Patent Term Extension in China

In August 2024, Novo Nordisk submitted a patent term extension request for the same patent family to CNIPA.

As for PTE, Article 42(3) of the same law stipulates that "*To compensate for the time taken for the marketing approval review of a new drug, for an invention patent related to a new drug that has obtained marketing approval in China, the patent administration department under the State Council shall, upon the request of the patentee, compensate the term of the patent right. The extension period shall not exceed five years, and the total effective patent term after the new drug's marketing approval shall not exceed fourteen years.*" Semaglutide's first approval date in China was 2021 (first approval for injection for type 2 diabetes), which is after the new Patent Law took effect, making it a potential candidate for PTE. However, PTE is only granted for new drugs first marketed in China (i.e., first globally launched in China). Drugs already marketed overseas but not in China (classified as biological product Category 3.1 or chemical drug Category 5.1 under China's "Provisions for Drug Registration") are excluded. Therefore, PTE does not apply to the semaglutide patent.

PTEs are available for “New drugs” that have been approved in China; “New drugs” refers to innovative drugs and specified improved new drugs (Art. 42(3), The Provision for Drug Registration). “Innovative drugs” refers to new drugs that have not been marketed in China or abroad, which means Class 1 * new drugs, which are “new globally”. Drugs eligible for PTE are those covering an active pharmaceutical ingredient that are approved for marketing for the first time in China (“new API”) (Reg. 80）.

“Improved new drugs” will be eligible if the classes listed on the drug certificates issued by NMPA fall into one of the following categories (Gud. Part 5, Chapter 9, Section3.4）：

- Chemical drugs of class 2.1 that perform esterification or salification on known active ingredients
- Chemical drugs of class 2.4 (i.e. drugs containing known active ingredients for new indications)
- Preventive biological products of class 2.2 that are vaccines improved against bacterial or viral strains

- Therapeutic biological products of class 2.2 for new indications
- Traditional Chinese medicine of class 2.3 (i.e., traditional Chinese medicine with increased indications).

INELIGIBLE types of drugs

- 1) Drugs based on optical isomers of known active ingredients, or modified acid radicals, bases or metal elements of known salt active ingredients, or other non-covalent-bond-forming derivatives (such as complexes, chelates or inclusion compounds) (Class 2.1) ;
- 2) New dosage forms (including new drug delivery systems) containing active ingredients; new formulation processes, and new methods of administration(Class 2.2);
- 3) New combination formulations containing known active ingredients (Class 2.3);

Consequently, in the Pharmaceutical Patent Term Extension Examination Opinion Notice sent by CNIPA to Novo Nordisk in April 2025, the examiner concluded that "the drug involved in this case is a biological product manufactured overseas, already marketed overseas but not in China, and should be classified as 'Therapeutic Biological Product Category 3.1.' Therefore, it does not fall under the innovative new drugs or improved new drugs eligible for patent term extension as stipulated in Section 3.4, Chapter 9, Part V of the Patent Examination Guidelines." It was determined not to meet the requirements of Patent Law Article 42(3) and Implementing Regulations Article 80. This represents a significant constraint that many Japanese companies may also face when introducing globally-first-launched products into China, a point that should be considered early in China market entry patent strategy formulation.

3. Semaglutide Patent Secured, Anti-Obesity Drug Market Ushers in an Era of "Fierce Competition"

This patent invalidation litigation lasted nearly five years, with Novo Nordisk's victory coming extremely close to the patent expiry date. According to pharmaceutical data service provider BCPM, there are currently 10 domestic semaglutide biosimilar applications under regulatory review in China, submitted by Zhengda Tianqing, CSPC Pharmaceutical Group, Fosun-Wanbang, Better Pharmaceutical, Huisheng Biotech, Zhongmei Huadong, United Laboratories, Jiuyuan Gene, Livzon Pharmaceutical Group, and Qilu Pharmaceutical. In a November 2025 financial analysis report, leading Chinese securities firm Haitong Securities pointed out that by the end of 2026, around five semaglutide biosimilars in the Chinese market are expected to engage in competition with the originator drug. This is anticipated to impact Novo Nordisk's market share and pricing in China, while also posing significant challenges to other companies' similar marketed products, such as mazdutide and tirzepatide.

In addition to the impending patent expiry and numerous semaglutide biosimilars preparing for launch, the new version of the "China National Reimbursement Drug List" (NRDL), effective January 1, 2026, will also have a substantial impact. The new list includes efpeglenatide α injection and tirzepatide injection (both for glycemic control in adults with type 2 diabetes) [4]. Post-NRDL

inclusion, drug prices will drop, and patients can receive reimbursement for a certain percentage (e.g., 70%-80%) based on local insurance policies, significantly reducing out-of-pocket costs. This will allow more patients to access the drugs at lower prices in hospitals or designated pharmacies. Furthermore, the significant price reduction for weight-loss drugs in January of this year may also be related to strategic considerations such as preemptively occupying the existing market and fostering patient adherence.

In early November 2025, the transaction price for Eli Lilly's tirzepatide injection (specification: 2.4ml: 10mg) on a major Chinese e-commerce platform was approximately $162 per pen. By early January this year, the price had dropped to around $82 per pen, a discount of nearly 50%. Based on a 2.5mg single dose, the user's weekly cost was reduced to approximately $21. Driven by high consumer purchasing sentiment, higher-dose versions of tirzepatide injection—20mg (~$124), 30mg (~$177), and 40mg (~$220)—were shown as out of stock. Although its NRDL reimbursement price has not been announced and weight-loss indications are not covered, the weight-loss market represents a significant out-of-pocket market that cannot be ignored for GLP-1 (Glucagon-like peptide-1) and dual-targeting agents. The platform's uniform price cuts across all indications before NRDL implementation aim to capture market share early and directly stimulate growth in the self-pay weight-loss market.

Under pressure from domestic generic/biosimilar competition, Novo Nordisk has also proactively lowered its price anchor. Through a strategy of "trading price for volume" in intense competition, it seeks to build a market defense system in advance. Coupled with subsidies from multiple e-commerce platforms, Novo Nordisk's semaglutide products have seen notable price declines. The lowest transaction price for the lowest-dose glycemic control version, "Novotai" semaglutide injection (1.34mg/ml × 1.5ml), has fallen to approximately $45 per pen. The lowest price for the weight-loss version, "Novoin" semaglutide injection (1ml:1.34mg × 1.5ml), has also dropped to around $53 per pen, a significant decrease from the previous mainstream market price of approximately $97 per pen.

4. Semaglutide’s Extra Year of Exclusivity: How Data Protection Delayed Generic Entry

Semaglutide’s core compound patent in China expired on March 20, 2026. Yet more than a month later, no generic or biosimilar version has been approved – despite at least ten domestic applicants ready to launch.

The reason lies not in patent law, but in drug test data protection. Novo Nordisk obtained marketing approval for semaglutide in April 2021. Critically, it designated its Swiss subsidiary (Novo Nordisk Pharma AG), not its Danish parent, as the marketing authorisation holder (MAH). This seemingly minor move has included semaglutide in the protection scope of Article 11.11 (2) of the China-Switzerland Free Trade Agreement (FTA) [5], which mandates at least six years of data exclusivity for Swiss-origin drugs, running until April 2027.

As a result, Chinese generic manufacturers cannot rely on Novo Nordisk’s clinical trial data for their abbreviated applications. Their submissions have been effectively suspended. For competitors, the only alternatives are to wait until April 2027 or conduct full-scale clinical trials, which is a

prohibitively costly and time-consuming path. China's drug data protection regime has expanded through bilateral FTAs, for now, Novo Nordisk enjoys an extra year of de facto market monopoly.

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