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CNIPA sides with generic drug maker in dispute over mirogabalin besylate tablets

Yue Guan, 29 January 2026, first published by MIP

Yue Guan of Wanhuida Intellectual Property explains how the CNIPA's rulings on mirogabalin besylate tablets highlight the importance of formulation patent drafting and claim amendments in China's drug patent landscape

On December 3 2025, the CNIPA published three administrative rulings: (2025) Guo Zhi Yao Cai No. 10, 11, and 12. The decisions confirmed that the three dosage forms of the generic mirogabalin besylate tablets, for which Chengdu Easton Biopharmaceuticals Co., Ltd. (Chengdu Easton) applied for regulatory approval, do not infringe upon the formulation patent (Chinese patent ZL201480001374.3, titled 'solid composition of amino carboxylate salt') owned by the innovator drug maker, Daiichi Sankyo Co., Ltd.

The rulings will be appealable until the expiry of the six-month statutory window, counting from the date of receipt of the decisions.

Mirogabalin besylate tablet is a third-generation calcium channel modulator drug developed by Daiichi Sankyo and marketed under the trade name Tarlige. The drug was approved in China in June 2024 for the treatment of diabetic peripheral neuropathic pain in adults, making it the country's first imported innovator drug approved for this indication.

The Phase III clinical study of Tarlige demonstrated that pain scores improved significantly within just two days of administration, with sustained efficacy lasting over 52 weeks. Through price negotiations, it was later included in China's National Reimbursement Drug List, the catalogue of medications covered under the country's public health insurance system, and has been recommended in authoritative diagnosis and treatment guidelines. The global cumulative sales of the drug were approximately $1 billion from 2019 to 2023.

Under China's drug patent linkage regime, an innovator drug maker needs to register with China's Marketed Drug Patent Information Registration Platform the patent information on active ingredients, pharmaceutical composition, and pharmaceutical uses, and a chemical generic drug applicant is obligated to make a statement based on the status of the patent.

Daiichi Sankyo has registered four patents, including one compound patent expiring in September 2028 and three formulation patents expiring successively in April 2034, March 2036, and December 2040. Chengdu Easton filed a Category 3 declaration regarding the compound patent, avowing not to market its generic version before the patent expires. For the three formulation patents, it filed Category 4.2 declarations, asserting that the generics do not fall within the protection scopes of these patents. The patent involved in the aforesaid ruling is one of the three formulation patents.

CNIPA reasoning

The CNIPA's ruling does not divulge many details, except a synopsis of its reasoning.

Claim construction

The CNIPA cautions that where it is impossible to clearly construe the terminology or technical features based solely on the description of patent claims, it is necessary to refer to internal evidence such as the patent specifications, as well as external evidence such as textbooks and technical manuals. In principle, the interpretation of the aforesaid terms shall not deviate from the purpose of the invention as perceived by a person

skilled in the art based on the context and content of the specifications.

Doctrine of equivalents and burden of proof

The CNIPA concludes that it would be untenable to argue patent infringement under the doctrine of equivalents if the technical solution of the generic drug differs from the patent claims in at least one technical feature, provided that the patentee fails to provide sufficient evidence to demonstrate that this differing feature, which would have been obvious to a person skilled in the art, constitutes an 'equivalent' of performing substantially the same function, in substantially the same manner, to achieve substantially the same result.

Estoppel

'Estoppel' is a legal term meaning that a second argument is barred if it is inconsistent with a first argument. In a patent prosecution process, it is not unusual that the patentee amends the claims in response to the office actions issued by the examiner, to facilitate the grant of the patent.

The CNIPA underscores that where a disputed technical feature was incorporated into the granted claims through an amendment made by the patentee during prosecution, yet the patentee contends that a specific technical solution falling between the scope of the original claims and the amended claims had not been disclaimed, the patentee shall bear the burden of proof or make a reasonable explanation to support this contention. In other words, the estoppel principle bars the patentee from admitting the removal of a technical solution from the patent claims in the patent prosecution process and later contradicting that admission in the patent dispute administrative adjudication proceeding.

Comments

The case is very intriguing. Although the formulation details of the generic drug filed by Chengdu Easton are not publicly available, a search of the CNIPA's database revealed the claim amendment to the patent at issue (as shown below), with the newly added features in bold.

Original claim 1	Published claim 1 (granted after amendment)
A pharmaceutical composition comprising: [(1R,5S,6S)-6-(aminomethyl)-3-ethylbicyclo[3.2.0]hept-3-en-6-yl]acetic acid monobenzenesulfonate of formula (I),	A pharmaceutical composition comprising: [(1R,5S,6S)-6-(aminomethyl)-3-ethylbicyclo[3.2.0]hept-3-en-6-yl]acetic acid monobenzenesulfonate of formula (I),
(i) one or two or more components selected from the group consisting of D-mannitol, lactose, corn starch, and crystalline cellulose; and	and (i) D-mannitol **having an average particle size of 100μm or less**,
(ii) any one or both of carmellose calcium and sodium carboxymethyl starch.	and (ii) calcium carboxymethylcellulose,
	and further comprising **magnesium stearate or sodium stearyl fumarate, wherein the pharmaceutical composition is a tablet prepared by a direct extrusion process**.

The granted claim 1 defines the excipients and particle sizes and incorporates the preparation method, thus markedly narrowing the scope of protection of the patent at issue.

Based on the amendment and the CNIPA's reasoning, the following deduction could be made:

The technical solution of Chengdu Easton's generic drug is not identical to that protected by the patent claims;
The claim of Daiichi Sankyo's patent at issue was amended during the prosecution process to incorporate new technical features; and
The technical solution of the generic drug does not contain the said incorporated technical features, but the chances are high that such solution could have fallen within the original, yet much broader, scope of the patent claims.

A focal point of the case is whether the protection scope excluded in a claim amendment can be reclaimed in a patent infringement case. The CNIPA does not rule out the possibility, but the burden of proof lies with the patentee to justify why the excluded technical solutions should not be deemed to have been disclaimed. In exchange for the quick grant of the patent at issue, the narrow protection scope proposed by the patentee during amendment could be self-defeating in hindsight.

This case underscores the pivotal role that the drafting strategy of formulation patents plays in withstanding a patentability challenge brought by invalidity petitioners and in maximising its enforceability in future assertion actions. The baseline is to ensure the granted patents could effectively hedge against potential generic competitors and extend the drug's market exclusivity.

It is worth noting that, in view of the often high threshold for the patentability of formulation inventions, it would be more advisable for patentees to proactively build claims around core technical features by including a range of potentially equivalent variations and providing comprehensive experimental data demonstrating the effects of these variations. This approach helps to lay a solid foundation to support arguments for a broader scope of protection during prosecution and future enforcement proceedings.