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CNIPA guidance on interpreting Swiss-type claims

HU Honghui, April 28 2026, first published by MIP

In China, medical use of a substance is generally perceived as a method for diagnosing or treating diseases, which is unpatentable under the Patent Law. However, such inventions would be allowed when the claims are reformulated as use of a substance for manufacturing a medicament for an indication – commonly known as Swiss-type claims.

The reformulation would in effect make such claims a manufacturing method in form. This practice often gives rise to disputes over the interpretation of the protection scope of Swiss-type claims. An examination of three invalidation cases illustrates how the CNIPA approaches such issues in practice.

The dapagliflozin case

Dapagliflozin, which is marketed as Forxiga and developed by AstraZeneca, is an SGLT2 inhibitor approved for multiple indications in China, including improved glycaemic control in adult patients with type 2 diabetes. AstraZeneca holds a Chinese patent, CN200780024135.X, on a crystal form of dapagliflozin. Claim 1 of the patent claims a crystal form of dapagliflozin defined by an X-ray powder diffraction pattern. Claim 9 claims “use of the crystal structure of Claim 1 in the manufacture of a medicament for the treatment of diabetes in mammals”.

The petitioner, Sino Universal Pharma, requested to invalidate the patent in January 2025. The focal point of the dispute centred on the interpretation of the scope of claim 9; specifically, whether it encompasses a technical solution where the crystal structure of dapagliflozin is used to produce a medicament, wherein dapagliflozin exists in another form in the final product. In other words, the question boiled down to whether the claimed crystalline structure of dapagliflozin constitutes a raw material for manufacturing the medicament, or an active ingredient present in the medicament.

The CNIPA apparently adopted the latter perspective. The administration elucidated the general cognisance of Swiss-type claims in the decision: “The reason for allowing the protection of medical use of a substance in the form of Swiss-type claims is to safeguard, on one hand, the doctor’s free choice of various methods and conditions in the course of diagnosis and treatment, whilst, on the other hand, providing patent protection to the right holder discovering the medical use of that substance. Therefore, Swiss-type claims constitute a special form of claim drafting in the field of medicine. In essence, they represent a special provision installed to address the unpatentability of ‘methods of treating diseases’ under the law, and thus should not be interpreted in an extended or expansive manner to cover [a] scenario where the substance as defined in the claim is used as a raw material to produce any drug or as part of a combination therapy for treating diseases.”

The reasoning affirms the CNIPA’s view that Swiss-type claims essentially protect the therapeutic application of a substance rather than a typical preparation method of a drug.

Based on such understanding and considering the prosecution history and description of the patent, the CNIPA concluded that claim 9 should be interpreted as a technical solution of using the crystalline structure of dapagliflozin as the active ingredient for the manufacture of a produced medicament, excluding the solution of using the crystalline structure as a raw material for producing a medicament.

The everolimus case

Everolimus, which is an mTOR inhibitor developed and marketed as Afinitor by Novartis, has been approved in

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China for a number of cancer-related indications. Novartis has a Chinese patent, CN200680051365.0, protecting therapeutic use of everolimus for pancreatic neuroendocrine tumours (PNET). In 2021, CTTQ, the petitioner, attacked the validity of the patent on several grounds, including lack of sufficient disclosure.

In assessing sufficient disclosure, the CNIPA started with interpreting the claim scope of the patent. Claim 1 of the patent claims use of everolimus in the manufacture of a medicament for the treatment of PNET. Despite both parties agreeing that the use as defined in claim 1 should be construed as everolimus being used alone (i.e., as the sole active ingredient) for treating PNET, the CNIPA disagreed.

The CNIPA held that Swiss-type claims constitute a special provision under China's Patent Law, which was specifically introduced to address the unpatentability of methods of treating diseases. This regime aims to provide protection and institutional incentives for medical use innovations. Such claims are typically drafted as "use of compound X in the preparation of a medicament for treating disease Y". Compound X is generally regarded as an active ingredient of the medicament. However, whether it is the sole active ingredient should be determined based on the wording of the claim. Without explicitly defining Compound X as the 'sole active ingredient', the common understanding dictates that the claim should be interpreted as Compound X may be used as the sole active ingredient or in combination with other active ingredient(s) for the treatment.

Based on the language of the claim, which did not specify everolimus as the sole active ingredient, and considering the disclosure in the patent specification, the CNIPA concluded that the claimed scope covered both the sole use of everolimus and its use in combination with other drugs.

The chidamide case

Chidamide, marketed as Epidaza, is the world's first subtype-selective histone deacetylase inhibitor, developed by Chipscreen. In China, it has been approved for a number of indications, including peripheral T-cell lymphoma. Chipscreen has a Chinese patent, CN201410136761.X, relating to medical use of chidamide. In December 2024, Nanjing CTTQ challenged the patent on the grounds of lack of novelty and inventiveness. The disputed claims concern the use of chidamide in the manufacture of a medicament for the treatment of cutaneous T-cell lymphoma (CTCL).

The petitioner attacked the novelty of the patent by citing prior art evidence concerning a Phase I clinical study report on chidamide, showing its partial remission in cancer patients, including one patient with CTCL. The patentee contended that the patent disclosed a Phase II clinical trial of chidamide for the treatment of CTCL, thereby demonstrating its therapeutic efficacy in a patient population, whereas the prior art merely showed effect in a single patient, indicating the claims possessed novelty.

The CNIPA affirmed that for Swiss-type claims, if the compound cannot effectively treat the defined indication, it would be moot to protect that medical use of the compound. Therefore, the use feature of the claims should be construed in so far as the compound is effective in treating the indication as defined. However, the assessment over indication treatment efficacy does not necessarily hinge on clinical trials, in light of alternatives such as cell- or animal-based experiments, as the CNIPA held. In other words, the use feature does not necessarily imply limitations of clinical effectiveness unless explicitly stated in the claims.

The CNIPA thus opined that as the claims of the patent did not define features such as size of the subject population in the clinical trial, they could not be interpreted as implicitly containing a "population" feature.

The CNIPA, in determining whether the prior art disclosed the claimed use of effectively treating CTCL, further held that a person skilled in the art could confirm that, in Phase I clinical trials, there was at least one case of a CTCL patient whose symptoms were alleviated after the administration of chidamide. The CNIPA therefore concluded that the prior art disclosed the claimed technical solution, rendering the claim not novel.

Practical takeaways

The aforesaid decisions corroborate the consistency in the CNIPA's stance; namely, the Swiss-type claim essentially protects the medical use of a substance.

However, in practice, the workaround in drafting a medical use invention claim creates a misalignment between the formality and substance of the claim, which is the underlying cause of disputes over the interpretation of the claimed scope and perception of the limiting effect of the claim features.

In the dapagliflozin case, the CNIPA clarified that a Swiss-type claim cannot be perceived as a claim for a typical manufacturing method. However, in assessing the novelty and inventiveness of a Swiss-type claim, the Patent Examination Guidelines provide that assessment focuses on whether the claim features have any limiting effect on the manufacturing process, which may explain the arguments made by the patentee in the dapagliflozin

case. The misalignment creates a dilemma that remains to be resolved within the existing legal framework.

The everolimus case clarifies the scope of a typical Swiss-type claim, specifically addressing whether the claim involves use of a substance alone or in combination. The chidamide case confirmed that Swiss-type claims implicitly define that the substance, as an active ingredient, should be effective in treating the indications, though the “effective treatment” does not seem to align with general cognisance, especially whether efficacy in one patient would suffice to render the treatment effective. To satisfy the requirement of sufficiency, animal or in vitro tests are allowed to establish the claimed use, which is based on the common expectation of a person of ordinary skill in the art (POSA) from those test results. In contrast, in novelty assessment, the “effective treatment” needs to be directly and unambiguously disclosed for the POSA, rather than being expected. In the chidamide case, the CNIPA seemed to confuse the parameters for the assessment of sufficiency and novelty.

In a nutshell, proper interpretation of a Swiss-type claim is pivotal as it could serve as a point of reference on claim drafting, assessment of patentability, and interpretation of the protection scope.