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Insights into the evolution of Chinese second medical use patent claims

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Minnan (Miranda) Xie of Wanhuida Intellectual Property analyses how China's patent authorities and courts assess second medical use inventions, with key CNIPA decisions clarifying the treatment of dosage regimens and patient subgroups in novelty determinations

In most jurisdictions, China included, where a substance or composition is already known for one medical use, it may still be patentable for a second (or subsequent) medical use, provided that such use is novel and inventive. In China, second medical use claims are typically drafted in the form of Swiss-type claims.

With regard to subsequent inventions in the field of second medical use, inventions related to dosage regimens that do not influence the drug's preparation properties have been deemed to lack novelty in China, as established by the Supreme Court in its 2012 decision Zhi Xing Zi No. 75.

The Supreme Court ruled that a dosing regimen defined by time intervals constituted a methodological feature related to drug administration during treatment. Without altering the drug's preparation method/properties or imposing limitations on the manufacturing process, it could not confer novelty to the claimed pharmaceutical use and thus was not patentable. To date, the practice remains unchanged.

With respect to the novelty assessment of second medical use claims directed towards the treatment of a purposively selected patient subgroup with a known medicament, the CNIPA provides clearer guidance through its recent updates.

The CNIPA's recent practice on the novelty assessment of subgroup limitations

Inventions related to disease subtypes are patentable in China. However, for patient subgroup limitations – for instance, those defined by specific genotypes or physiological parameters – whether such definitions distinguish from the prior art in terms of disease subtyping and staging and thereby introduce a limitation that confers novelty is sometimes debatable.

In recent years, with advancements in precision medicine, the CNIPA has grown more applicant-friendly, as illustrated in the following decisions.

CNIPA decision No. 278419

In Re-examination Decision No. 278419 issued in 2021, the CNIPA overturned a refusal decision asserting that Claim 1, which distinguished the patient population via ROS1 mutation status in non-small cell lung cancer (NSCLC), could not incorporate this feature into the characterisation of the pharmaceutical use. It therefore failed to distinguish the application from prior art Document 1, which disclosed the use of the same compound for preparing a medicament to treat NSCLC.

In this decision, the panel held that to determine whether the protected pharmaceutical use "SLC34A2-ROS1, CD74-ROS1 or FIG-ROS1 fusion-positive NSCLC" in Claim 1 could be distinguished from the pharmaceutical use "NSCLC" and "KIF5B-RET fusion-positive NSCLC" disclosed in prior art, it was necessary to:

Assess whether the newly defined disease or indication could be clearly recognised and understood by a person skilled in the art; and

Determine whether the newly defined disease or indication was substantially different.

After reviewing technical literature in the NSCLC field, the panel concluded the following:

The technical literature indicated that ROS1-positive NSCLC as an indication was not equivalent to NSCLC in a broad sense. The panel found ROS1 fusion-positive NSCLC to be a known genetic subtype indication within the field, representing a subordinate concept of NSCLC.
Since ROS1 rearrangements showed no overlap with other known lung cancer driver genes, a person skilled in the art could reasonably expect to effectively distinguish the ROS1 fusion-positive NSCLC claimed in the application from the KIF5B-RET fusion-positive NSCLC disclosed in Document 1, with no overlap typically expected.

The panel ultimately determined that Claim 1 possessed novelty over Document 1 and reversed the refusal decision.

CNIPA decision No. 568709

In April 2025, the CNIPA released the Top Ten Patent Re-examination and Invalidation Cases of 2024, of which Case No. 2 pertains to the patentability assessment of second medical use inventions based on patient subgroups.

The subject case, CNIPA Invalidation Decision No. 568709, concerns a patent titled “Use of degarelix in the manufacture of a medicament for treating metastatic prostate cancer”. The patent in question protected the use of degarelix in the manufacture of a medicament for treating metastatic prostate cancer in a subject, wherein the treatment comprised administering an initial dose of 160–320 mg of degarelix, followed by a maintenance dose of 60–160 mg administered once every 20–36 days, and wherein the subject had a pre-treatment baseline serum alkaline phosphatase (S-ALP) level above about 150 international units per litre.

The validity of the aforesaid patent was challenged on grounds including novelty and inventive step. Although this patent was finally invalidated for not possessing inventive step, this case is particularly impactful in the assessment on limitation of subgroup, which the CNIPA explained in detail in a commentary article published thereafter.

In that article, the CNIPA opined that the claims characterised the patient population using the specific physiological parameter of the S-ALP level, thereby refining the protected medical use. Consequently, it was determined that this physiological parameter substantially influenced the scope of protection of the invention, and its limiting effect should be considered in the assessment of novelty and inventive step.

The CNIPA elucidated that where diseases can be classified into subtypes or stages based on one or multiple dimensions in the medical field, different disease classifications vary significantly.

This circumstance has given rise to a debate in examination practice regarding whether clinical recognition of a new subtype/stage is a requisite for establishing novelty of an invention.

In assessing the patentability of medical use inventions drafted as Swiss-type claims, the CNIPA underlined that if the aforesaid medical use is refined by characterising the patient population using specific physiological parameters, assessment should be made based on the disease’s pathogenesis, clinical manifestations, and therapeutic effects, to determine whether a person skilled in the art could confirm that the physiological parameter has practical clinical value for guiding administration.

In principle, the affirmative presence of clinical value for offering guidance to administration would lead to the recognition that the physiological parameter substantially influences the scope of protection of the invention. The methodology heralds an embrace of medical use inventions based on subgroup defined by physiological parameters/biomarkers, which is very welcome for applicants.

Final comments on patenting second medical use inventions in China

Applicants seeking to patent second medical use inventions in China should tread carefully in their subsequent limitations of claims. At present, dosage regimen limitations alone will not be deemed as distinguishing features from prior art, unless such limitations could affect the drug manufacture process.

For subgroup limitations, the CNIPA’s recent practice indicates a trend towards more readily accepting them as limitations defining a specific indication, even in the absence of explicitly established clinical subtyping or staging criteria. However, applicants are still advised to exercise caution and ensure that such limitations are not perceived as a ‘patchwork’ or part of an unreasonable ‘patent evergreening’.