CNIPA clarifies inventiveness assessment of pharmaceutical use claims

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CNIPA clarifies inventiveness assessment of pharmaceutical use claims

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On December 16 2025, the CNIPA issued Invalidation Decision No. 600371 (the Invalidation Decision), declaring Patent No. 201580081186.0 (the Patent at Issue) – titled 'Methods for treating or preventing migraine headache', owned by Amgen Inc. – invalid in its entirety.

The Patent at Issue is a medical use patent, the claims of which concern the use of a known drug to treat a known disease using a new dosage regimen or new administration mode. The Invalidation Decision offers guidance as to the parameters in assessing the inventiveness of pharmaceutical use claims, particularly how technical features such as dosage and formulation limit the scope of protection of such claims.

The invalidation decision

The petitioner challenged the validity of the Patent at Issue on multiple grounds, including:

Insufficient disclosure in the specification;
Ambiguous scope of protection for claims 1–25;
Lack of novelty for claims 1–11 and 14–19;
Lack of inventiveness for claims 1–25; and
Lack of support for claims 1–25 in the specification.

In response, the patentee amended the claims. Amended claim 1 reads as follows: "1. Use of an anti-CGRP receptor antibody in the manufacture of a medicament for preventing or reducing the occurrence of migraine in a patient in need thereof, wherein the medicament is formulated to be administered in a dosage of 70 mg to 140 mg per month, wherein the anti-CGRP receptor antibody comprises CDRH1 of the sequence of SEQ ID NO:14, CDRH2 of the sequence of SEQ ID NO:23. CDRH3 of the sequence of SEQ ID NO:34, CDRL1 of the sequence of SEQ ID NO:44, CDRL2 of the sequence of SEQ ID NO:55, and CDRL3 of the sequence of SEQ ID NO:65, wherein the anti-CGRP receptor antibody is a monoclonal IgG1 or monoclonal IgG2 antibody, and wherein the medicament is formulated to be administered subcutaneously."

The Invalidation Decision found that all claims should be invalidated for being devoid of inventiveness.

Regarding claim 1, the Invalidation Decision used Evidence 14 as the closest prior art, combined with Evidence 16 and common knowledge, to analyse its inventiveness.

The collegiate panel opined that Evidence 14 disclosed the use of an anti-CGRP receptor antibody having the structure defined in claim 1 for manufacturing a medicament for preventing or reducing the occurrence of migraine. The sole difference between claim 1 and the technical solution disclosed in Evidence 14 was that Evidence 14 did not specify that the prepared medicament formulation could be formulated for subcutaneous administration.

Given that subcutaneous formulations are conventional for antibody drugs and represent one of the routine formulation choices for a person skilled in the art, in combination with the technical teaching of Evidence 14 that antibodies can be prepared in parenteral composition forms for injectable use, and that of Evidence 16 that the anti-CGRP-1 monoclonal antibody AMG 334 can be administered via subcutaneous injection, a person skilled in the art would be motivated to formulate the anti-CGRP receptor antibody disclosed in Evidence 14 into a formulation that can be prepared for subcutaneous administration.

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Furthermore, the panel found that the Patent at Issue failed to demonstrate that the subcutaneous formulation achieved any unexpected technical effects in terms of therapeutic efficacy, as compared to other formulations. Therefore, the panel concluded that claim 1 lacked inventiveness.

Comments

Parsing the specification of the Patent at Issue could lead to the conclusion that the superiority of the invention over the prior art lies in its verified clinical therapeutic effect and safety of the anti-CGRP antibody AMG 334 in preventing or reducing the occurrence of migraine in patients in need, with an appropriate dosage range of “70 mg to 140 mg per month” as proposed in claim 1.

However, whether such dosage features limit the protection scope of the claim depends on the circumstances. The latest Patent Examination Guidelines stipulate: “For pharmaceutical use inventions involving chemical products, the novelty examination should consider the following aspects: [...] (iv) Whether the features related to use, such as administration subject, administration mode, route, dosage, and time interval, can limit the pharmaceutical preparation process. Distinguishing features reflected solely in the administration process cannot confer novelty to the use.”

In assessing the limiting effect of the aforesaid dosage range, the panel reasoned that “[s]ince claim 1 does not limit this to a single administration dose, and paragraph [0063] of the patent specification explicitly states that ‘For a dosing frequency period of one month, the monthly dose may be divided into four doses and administered on a weekly basis or divided into two doses and administered every two weeks. Any of the doses of the anti-CGRP receptor antibody or binding fragment described herein can be divided among two or more administrations,’ it would be impossible to determine whether ‘70 mg to 140 mg’ refers to the dose for a single administration. Therefore, the limitation ‘the medicament is formulated to be administered in a dosage of 70 mg to 140 mg per month’ in claim 1 is a limitation on the method of use of the drug, which is not necessarily associated with the pharmaceutical preparation method, and does not limit the drug specifications. Consequently, it does not limit the scope of protection of claim 1.”

The panel also assessed the limiting effect of the “subcutaneous administration” mode defined by claim 1. The panel held that “this expression indicates that the medicament can be formulated for subcutaneous administration, limiting the administration process of the drug. Although it does not clearly limit the medicament prepared in claim 1 to a form that can be used directly for subcutaneous administration, it implicitly limits the drug preparation process in the sense that the prepared medicament should be capable of being formulated into a form suitable for subcutaneous administration. For example, as far as the general understanding in the art is concerned, most oral formulations containing excipients such as pigments, preservatives, or fillers cannot typically be adapted for subcutaneous administration. Thus, in terms of the medicament formulation, it at least excludes formulations such as oral dosage forms that cannot be adapted for subcutaneous administration. Therefore, the limitation ‘the medicament is formulated to be administered subcutaneously’ in claim 1 does limit the scope of protection of the claim.”

Based on the above reasoning, the panel merely identified "the medicament is formulated to be administered subcutaneously" as the distinguishing feature, which logically leads to the determination of non-inventiveness of claim 1.

In a nutshell, claiming a pharmaceutical use of a known substance for a known indication characterised by a dosing regimen and/or administration feature could be tricky in China, as these features closely relate to methods of treating diseases, which is an unpatentable subject matter in China.

The key takeaway for patent applicants in drafting pharmaceutical use claims for such applications would be to ensure these features are directly related to the pharmaceutical preparation process. The Invalidation Decision could serve as a point of reference regarding whether such features limit the scope of protection of the claims.