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Assessing the inventiveness of pharmaceutical formulation patents in China

Xiaoping Wu, 11 November 2025, first published by MIP

On October 9 2025, the CNIPA issued Invalidation Decision No. 588549, declaring the invention patent titled ‘Tofacitinib oral sustained release dosage forms’ (the Patent) invalid in its entirety.

Tofacitinib is a JAK3 (Janus kinase 3) inhibitor, primarily used for the clinical treatment of patients with moderate to severe active rheumatoid arthritis, who are intolerant to or do not respond well to methotrexate. The Patent relates to a tofacitinib sustained-release tablet.

The invalidation petitioner challenged the validity of the Patent on multiple fronts, including:

Amendments exceeding the original scope of disclosure;
Insufficient disclosure in the specification;
Claims not being supported by the specification; and
Lack of inventive steps.

Background to the CNIPA’s decision

The CNIPA backed the invalidation based on the finding that all the claims lacked inventive steps.

Claim 1 of the Patent concerns a once-daily pharmaceutical dosage form, comprising:

A core containing 11 mg or 22 mg of tofacitinib, or an equivalent amount of tofacitinib in the form of a pharmaceutically acceptable salt thereof, and sorbitol accounting for 60–85% by weight of the dosage form; and A semi-permeable membrane coating that weighs about 5–10% of the aforesaid core prior to the coating process, consists essentially of cellulose acetate and hydroxypropyl cellulose in a weight ratio of 6:4, and has at least one delivery port with a diameter of 100–1,000 μm connecting the interior and exterior of the coating;

wherein the dosage form, as a sustained-release formulation, delivers the tofacitinib or a pharmaceutically acceptable salt thereof to a subject primarily by osmotic pressure, and the delivery system of the dosage form is an extrudable core system.

The invalidation decision identified Evidence 6 as the closest prior art – combined with Evidence 10, 4, 9, and common knowledge Evidence 7 – to assess the obviousness of the technical solution of Claim 1.

Evidence 6 relates to the development of a single-layer osmotic controlled-release tablet with an extrudable core system, wherein the tablet cores consisted of 15 mg of polymer, 75 mg of sertraline hydrochloride, 190.5 mg of sorbitol, 2.1 mg of sodium lauryl sulfate, 15 mg of Klucel EXF, and 3 mg of magnesium stearate, and were coated with 7:3 cellulose acetate:polyethylene glycol at 6–8 wt.%, with a 900-micron diameter hole drilled through the coating on the tablet surface.

A comparison of Claim 1 and Evidence 6 shows multiple distinguishing features involving the active ingredient, dosage strength, administration frequency, osmotic agent content, and coating composition. To address this, the invalidation decision combined the following technical literature to assess the obviousness of Claim 1, including:

Evidence 10 (disclosing the dosage strength of tofacitinib);

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Evidence 4 (disclosing modified-release oral dosage forms, dosage strength, administration frequency, and osmotic agent content for tofacitinib);
Evidence 7 (teaching relating to sustained-release formulations); and
Evidence 9 (teaching relating to composition of the coating).

The collegiate panel therefore concluded that a person skilled in the art would find it obvious to arrive at the technical solution of Claim 1, based on Evidence 6 and combining the teachings of Evidence 10, 4, 9, and common knowledge Evidence 7.

Comments

This decision offers a real-life example of the inventive step assessment in pharmaceutical formulation patents.

The invalidation decision used a combination of five pieces of literature to assess the inventive step of Claim 1, which is quite unusual in practice.

A primary reason cited in the invalidation decision for finding Claim 1 to be lacking inventive step over the combination of five documents was that the technical effects of Claim 1 could not be ascertained based on the description in the patent specification.

First of all, based on the objective of the invention stated in the specification (providing optimal pharmacokinetic properties for once-daily administration of tofacitinib) and the corresponding solution, the decision determined that an extrudable core system with a semi-permeable membrane must contain a polymer such as a water-swellable polymer or a viscosity-increasing polymer (thickening agent), otherwise it would not possess the desired effect of providing specific pharmacokinetics.

The decision further reasoned that, based on the fact that the relevant technical solutions described in the specification all include a thickening agent, while Claim 1 does not limit the presence of a thickening agent (covering both scenarios of with and without a thickening agent), the actual technical problem solved by Claim 1 could not be grounded in the technical effects achieved by the specific solutions containing a thickening agent as described in the specification. Therefore, the technical problem actually solved by Claim 1 was to provide a specific extrudable core osmotic delivery device with a different active ingredient.

In the three-step inventiveness assessment, the finding of non-obviousness of an invention is premised on the technical problem actually solved by the invention. In the present case, wherein the true technical effect of the invention is the mere change of the active ingredient, the technical solution is deemed obvious. Here, the patentee did not submit any response to the invalidation petition nor participate in the oral hearing. Apart from the limited level of inventiveness of formulation patents per se, this lack of action could be ascribed to the difficulty of remedying the aforesaid defects.

As the granted claims do not involve a thickening agent, it would no longer be possible to further limit the claims by a thickening agent based on the content of the specification during an invalidation proceeding, as such an amendment would be deemed as going beyond the scope of the granted claims. This defect directly led to the inability to affirm the effects of the technical solution defined by the claims.

Patentees drafting pharmaceutical formulation patents should therefore take heed that necessary components should be included at the very least in dependent claims, rather than being deliberately omitted to obtain a broader scope of protection.