

## *Grünenthal GmbH vs China National Intellectual Property Administration (CNIPA)*

(Intellectual Property Court of the Supreme People's Court of China (SPC), filed as (2019) SPC  
IP Admin. Final 12)

Prepared by the Intellectual Property Court of SPC

### **Summary**

In this case, the SPC specified a criterion for assessing the inventiveness of novel crystalline forms of compounds. Although the preparation of the novel crystal form has a certain degree of uncertainty, merely preparing and obtaining a novel crystalline form does not necessarily mean that the said crystalline form meets the requirement of inventiveness under the patent law

### **Facts of the case**

The case concerns an invention patent entitled Crystalline Forms of phenol hydrochloride which relates to a technical field of compound preparation. While Claim 1 identifies a novel Form A, Claim 3 identifies a process to the preparation of the crystalline form and processes for preparing tapentastat hydrochloride. The patentee is Grünenthal GmbH.

*Jiangsu Hengrui Medicine Co., Ltd.* submitted a request to declare the patent invalid. After re-examination, CNIPA issued its decision to invalidate all the claims in the patent based on prior art information submitted to it. The patentee, Grünenthal GmbH, appealed to the Beijing Intellectual Property Court, which, however, rejected all of its pleadings. The patentee then appealed to the Intellectual Property Court of the Supreme People's Court. The main grounds as asserted by Grünenthal GmbH in its appeal are as follows:

- (1) The technical problem and the technical effect of the patent claims as ascertained in CNIPA's decision and the original court judgment were both wrong. CNIPA's decision held that the technical problem actually solved by Claim 1 was to provide an alternative crystal of tapentadol hydrochloride having a different crystalline form, but the technical problem actually solved by this patent was to obtain a novel crystalline form of tapentadol hydrochloride with improved stability. The technical effect achieved by this patent has been clearly described in the specification, as tested by data in the embodiments.
- (2) The conclusion that the novel crystalline form in question does not have inventiveness in CNIPA's decision and the original court judgment were both wrong. From the perspective of those skilled in the art, a novel crystalline form itself shall be non-obvious *per se* and has inventiveness, no matter whether it brings about unexpected technical effect or not.

## **Legal Issues**

Under Chinese patent law, in determining inventiveness, a patent examiner first identifies the closest prior art, then identify the distinguishing features of the claimed invention and the technical problem that is solves, then assess if a person skilled in the art (presumed to possess common technical knowledge) could be motivated to apply the invention when confronted with the technical problem. The SPC held that, ascertaining the technical problem actually solved by Claim 1 shall be based on the technical effect of the distinguishing feature actually achieved in the patent. As for the subject case, one needs to assess whether the content disclosed in the patent specification is sufficient to show that the novel crystalline Form A has better stability than the known Crystalline Form B. For the pharmaceutical field in which experimental proof is to be sought after, the assertion by the patentee, Grünenthal GmbH, regarding the alleged effect thereof needs to be proved by credible experimental data. Yet the assertion by the patentee that the novel crystalline Form A has better stability than the known Crystalline Form B cannot be supported by the content disclosed in the patent specification. The technical problem actually solved by Claim 1 was to provide an alternative crystal of tapentadol hydrochloride having a different crystalline form, and therefore CNIPA's decision and the original court judgment were correct in terms of the ascertaining of technical problem actually solved by Claim 1.

It is known to those skilled in the art that most solid organic pharmaceuticals have a plurality of crystalline forms. Although the preparation of the novel crystal form has a certain degree of uncertainty, merely preparing and obtaining a novel crystalline form does not necessarily mean that the said crystalline form meets the requirement of inventiveness under the patent law. At the time of studying and preparing solid organic pharmaceuticals, a person skilled in the art would be motivated to screen for novel crystalline forms for the sake of obtaining crystalline forms that satisfy the demand of pharmaceutical production and uses, and screening for novel crystalline forms can be normally achieved by conventional technical means. The content disclosed in the prior art evidence also corroborated the common technical knowledge and provided clear technical instruction. Based on the prior art data, and with the help of conventional technical means, a person skilled in the art would be motivated to prepare and obtain the crystalline form claimed in the technical solution of Claim 1.

Considering the fact that the assertion that the novel crystalline form A has better stability than the known Crystalline Form B is not supported by the content disclosed in the patent specification, there is no way to identify that the novel crystalline form has an unexpected technical effect over the original crystalline form. In addition, the prior art anticipates Claim 3. In view of the above, the relevant grounds asserted by Grünenthal GmbH regarding the inventiveness of Claim 1 and Claim 3 in its appeal are rejected in their entirety by the court.

## **Points of Significance**

1. The court specified that merely preparing and obtaining a novel crystalline forum does not necessarily mean that the said crystalline form meets the requirement of inventiveness under the patent law. The patent application has to demonstrate clearly and sufficiently the unexpected technical effects of the claimed invention in the specification

2. Considering the unique nature of the pharmaceutical field in which experimental proof is to be sought after, the decision emphasized on the importance of providing sufficient evidence proving the unexpected results at the time of filing.

**Key Words**

Inventiveness; technical problem; technical effect; unexpected effect; crystalline forms; polymorphs

PDF version of the full text of the judgment in Chinese is available upon request.