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Chengdu Sino-strong v CNIPA: shifting criteria for inventiveness assessments of polymorph patents?

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On April 30 2025, the Beijing Intellectual Property Court (BIPC) released its annual report on exemplary intellectual property cases of 2024, among which there is a noteworthy case concerning the validity of a polymorph patent related to rocuronium bromide. The BIPC, in revoking an invalidation decision made by the CNIPA, seems to develop a nascent assessment approach over the inventive step of a polymorph patent by underlining the successful marketing of the pharmaceutical crystal, marking a deviation from precedents.

Case brief

The patent at issue, ZL201911372921.X (the '921 Patent), relates to a crystal form of rocuronium bromide; namely, Form A. With an application date of December 27 2019, the '921 Patent is owned by Chengdu Sino-strong Pharmaceutical Co. Ltd.

The '921 Patent discloses that Form A has chemical stability markedly superior to that of the prior art. Rocuronium bromide is known, in the prior art, as an unstable compound that is supposed to be stored at a temperature below -15°C, according to the European Pharmacopoeia, or below -20°C, according to the US Pharmacopoeia. However, Form A of the '921 Patent can be stored in an open container at a temperature of 25°C for 30 days, with the level of impurities barely changed.

The invalidation proceeding was believed to be initiated by a 'straw man' (petitioner) acting in the interest of a rival drugmaker. The petitioner cited an amorphous form of rocuronium bromide as the closest prior art to attack the inventive step of the '921 Patent. The CNIPA recognised that Form A has better chemical stability than the prior art in the invalidation decision. However, the CNIPA reasoned that it is common knowledge that a person skilled in the art could anticipate that crystalline solids have better physical and chemical stability than amorphous solids, thus finding the technical effect of the '921 Patent not unexpected. Therefore, the CNIPA declared the '921 Patent invalid on August 17 2023.

Established practice

The CNIPA followed to the letter the established inventiveness assessment methodology over a polymorph patent, where inventiveness hinges on the presence of an "unexpected technical effect" or "non-obvious technical solutions".

In practice, a crystal patent, when subjected to patentability scrutiny, will most likely fail the test, if the assessment were to focus on whether it has achieved non-obvious technical solutions. That is because the crystal is often an optimised form, manufactured by employing a conventional preparation method and selected in a polymorph screening process.

In such circumstances, it is the prevailing assessment approach that the inventiveness of a crystal is underpinned by the presence of an unexpected technical effect. The rationale behind this is that once a pharmaceutical compound is disclosed, it is believed that a person skilled in the art would have the motivation to study the polymorphs of the compound to obtain an applicable crystal form, which would have an effect on the manufacturing, stability, safety, and efficacy of the drugs. Given that there are well-established methods to screen a polymorph, an unexpected technical effect is a prerequisite in ascertaining an inventive step of polymorph patents, which do not involve special structures or novel preparation methods.

Under current examination practice, the threshold for being recognised as an unexpected technical effect is quite high. For example, stability is one of the most underlined properties for a polymorph in drug R&D, but it would be very challenging to argue the stability of a polymorph is unexpected in China, as the examiners are prone to rebut such an assertion based on the common knowledge that crystallised solids tend to have higher stability than amorphous solids. Other properties such as non-hygroscopicity and a high melting point, as dictated by the lattice energy of the crystal, may be perceived as highly relevant to stability, rendering them an expected technical effect in the eyes of the examiners.

Court decision

The aforesaid assessment approach was first established by the Supreme People's Court of the People's Republic of China (SPC) in its ruling of Boehringer v CNIPA (2011), which has been followed by the CNIPA and the judiciary in their inventiveness assessments of polymorph patents for over a decade.

The BIPC tried a new approach, where the affirmation of an inventive step of a polymorph patent is grounded in the presence of a "better technical effect" rather than the predominant yet demanding "unexpected technical effect", by factoring in the marketing of drugs exploiting such patents.

The BIPC reached its conclusion based on the following reasoning steps.

Dichotomy between 'technical solution' and 'technical effect'

The predominant method for assessing inventive step in China is the 'three-step approach'; namely:

· Determining the closest prior art;
· Determining the distinguishing technical feature and the technical problem actually solved by the patent; and
· Determining whether the patent is obvious for a person skilled in the art.

In the context of polymorph patents, the court develops this methodology into a dichotomy between a "technical solution" (by following the aforesaid three-step approach) and a "technical effect", underlining the significance of technical effect in the assessment test. In a nutshell, the court finds that even if a polymorph patent is obvious in terms of the technical solution, it could still be inventive due to its technical effect.

Nevertheless, the court cautions that this is not a panacea applicable to the assessment of all patents: "It is undeniable that this standard utilised in [the assessment of a] polymorph patent is not the same as the method usually employed in inventive step assessment. Normally, the technical effect is not a decisive factor in the assessment of inventive step […]

"However, the technical effect can be decisive in the assessment of inventive step of a polymorph patent. That is, if a crystal form achieves a better technical effect than the prior art, it could be recognised as inventive, even if the acquisition of this crystal form is obvious […] Even if the crystal form can be prepared by a conventional method, the trial-and-error process leading to its final acquisition and the uncertainty surrounding the viability of acquiring a crystal form aligning with the requirements of the pharmaceutical industry [in this process] demand considerable economic investment. Considering the development of a crystal form is usually aimed at resolving the applicational problems in the pharmaceutical industry, it would be conducive to providing protection for the economic investment in polymorph research so as to ensure [the patentee] obtains an anticipated economic reward, which in turn would fuel the development of drugs and the pharmaceutical industry and serve the public interest."

In sum, the BIPC holds that the technical effect of a polymorph patent alone can make the patent inventive, considering the investment and contribution of a polymorph research. This could prove a boon to the patentee, as long as clarity could be provided as to what technical effect a polymorph should achieve to meet the inventive step requirement.

Unexpected technical effect

Is an unexpected technical effect a must? The BIPC's answer is yes, and no.

In commenting on the technical effect of the '921 Patent, the court opines that: "The fact that the crystal form of rocuronium bromide is prepared by a conventional method in the '921 patent does not necessarily mean that it does not possess inventive step. Rather, whether this crystal form achieves unexpected effect still needs to be assessed. In other words, the crystal form possesses inventive step, as long as it achieves a better technical effect than the compound, salt form, or crystal form in the prior art, regardless of whether the acquisition of this crystal form is obvious."

The court made the only reference to “unexpected technical effect” here and defined that it should be equivalent to the mere “[achievement] of a better technical effect” over the prior art.

After recognising that Form A achieves better stability than the prior art, the court rules Form A of the ‘921 Patent achieves a better technical effect than the rocuronium bromide solid of Example 3 of Evidence 3, thus finding Claim 1 of the ‘921 Patent possesses inventive step.

It seems that from the BIPC’s perspective, the term “unexpected” has shifted from being the focus of this case, so the court did not feel the need to comment on whether a technical effect of stability is unexpected.

Role of marketing

The court decision does not touch on this subject per se. However, in the case analysis the BIPC published alongside the exemplary cases, the court elucidated its rationale as follows: “The decision of this case proposed a rule of determining whether a crystal form achieves a technical effect that makes it inventive over the prior art, which includes considering whether the technical effect disclosed in the patent description is relevant to the druggability [the suitability of a compound for pharmaceutical development and use]. Such technical effect should not be a generalised physiochemical property but a specific property such as purity, melting point, and hygroscopicity. If the disclosed technical effect is highly relevant to druggability, and the marketed drug uses the crystal form, it should be recognised that it achieves a beneficial technical effect. Consequently, the polymorph patent would possess inventive step and should be protected according to the Patent Law” (emphasis added).

In this sense, the court explicitly factored into its reasoning the fact that Form A is a marketed form of rocuronium bromide. On this basis, the patentee should prove that the polymorph has some favourable (if not necessarily unexpected) physiochemical properties, which contributed to the successful marketing of the crystal drug. In other words, by considering the fact of marketing, the standard employed in the inventiveness assessment for a polymorph patent is significantly lower compared with that of the traditional assessment approach, thus leading to an affirmative patentability finding diverging from the CNIPA decision.

The BIPC issued the first-instance ruling on October 29 2024, revoking the CNIPA invalidation decision. As no appeals were filed, the BIPC decision has come into force.

Final thoughts on the implications of the BIPC ruling

The decision is interesting. It introduces an innovative assessment approach over the inventive step of a polymorph patent, marking a notable departure from the precedents. The BIPC’s accentuation of the favourable properties of a crystal form and its contribution to druggability is inspiring to patentees investing heavily in the screening and R&D process and looking to patent and commercialise their findings.

However, as the case did not reach the Intellectual Property Court of the Supreme People’s Court and the SPC has not yet commented on the BIPC decision in public, it remains to be seen whether the decision is an outlier or a prelude to a lasting shift of criteria for inventiveness assessments of polymorph patents in China.