CNIPA guidance on the support of pharmaceutical use patent claims (2023)

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Article 26.4 of China's Patent Law prescribes that "claims shall be supported by the specification and shall define the extent of the patent protection sought for in a clear and concise manner". This rule is strictly enforced by the China National Intellectual Property Administration (CNIPA) in practice. In assessing whether claims can be supported by the specification, the claims need to define a scope of protection that corresponds to the contribution of the invented technology.

In a recent invalidation decision, #560109, issued by the CNIPA, the patent claims were declared entirely invalid for being devoid of support of the specification.

The patent

The patent in question involves the pharmaceutical use of nilotinib. The granted patent comprises only one claim, reciting the use of nilotinib in the preparation of a drug for treating chronic myeloid leukemia (CML), wherein nilotinib and a pharmaceutically acceptable carrier are dispersed in apple sauce.

The grounds for invalidation

The petitioner contended that – based on the specification of the patent and evidence 31, 32, and 29 – it is evident that the patent in question does not demonstrate whether the dispersion of nilotinib and apple sauce in other dosages and ratios, apart from those stated in the patent, would still achieve bioequivalence in the context of a complete capsule.

Given that claim 1 of the patent in question does not provide any specific limitations regarding the dosage and ratio of nilotinib and apple sauce, it would be impossible to anticipate that all the technical solutions covered by claim 1 could achieve the desired technical effect of bioequivalence. Therefore, claim 1 cannot be supported by the specification.

The defence raised by the patentee

The patentee argued that taking nilotinib dispersed in a teaspoon of apple sauce would be bioequivalent to consuming nilotinib in the form of a complete capsule. The embodiments provided demonstrated through comparison that the nilotinib capsules and the contents of the capsules dispersed in apple sauce are identical. The petitioner was merely speculating that the dosage and ratio of nilotinib might impact bioequivalence, without furnishing any concrete evidence.

The decision

The CNIPA's collegiate panel held that nilotinib, as an existing medication, is known for its therapeutic effect in treating CML, which is part of the prior art. The contribution of the patent in question relative to prior art lies in the discovery of bioequivalence between consuming 400mg of nilotinib dispersed in a teaspoon of apple sauce and consuming nilotinib capsules.

However, based on Example 2 provided in the specification, it is evident that the technique employed to achieve bioequivalence between dispersing the contents of nilotinib capsules in apple sauce and the nilotinib capsules is by dispersing the contents of two 200mg nilotinib capsules into one teaspoon of apple sauce, as compared to a 400mg nilotinib capsule.

Claim 1 does not specify:

The dosage of nilotinib;
The type of dosage form containing nilotinib for dispersion; or
The volume of apple sauce for dispersion.

Whether all the technical solutions covered by claim 1 can achieve bioequivalence would be unknown to those skilled in the art, as the exact in vivo absorption of nilotinib when dispersed in apple sauce is unpredictable.

Moreover, whether two formulations achieve bioequivalence is measured by comparing their bioavailability. The fact that two formulations are bioequivalent at specific dosages and forms does not necessarily give rise to the presumption that bioequivalence could be achieved across any random conventional dosages and forms. Evidence 29 and 35 attests various factors affecting bioavailability, dosage form included.

It is evident that the dosage and absorption of nilotinib is closely linked, yet there is no known pattern governing their correlation. The in vivo absorption could vary markedly when the same dosage is administered at a different frequency. Furthermore, the in vivo bio-absorption mechanism of nilotinib is highly complicated. Therefore, persons skilled in the art would be unable to predict bioequivalence between the in vivo absorption of a specific dosage of nilotinib dispersed in a certain amount of apple sauce, as described in Example 2, and the absorption of other dosages of nilotinib dispersed in varying amounts of apple sauce, so as to avoid the impact of known food effects on the absorption.

This unpredictability is compounded by the unspecified amount as denoted by "a teaspoon of" apple sauce in the specification. Moreover, prior to the filing date, the known food effect on nilotinib's bioavailability was sufficiently significant to warrant the prohibition of its concurrent consumption with food.

Given the crucial role of food effects on nilotinib absorption, persons skilled in the art could not anticipate how the food effect would manifest when nilotinib is dispersed in an amount other than a teaspoon of apple sauce, and whether it would still achieve bioequivalence, not to mention when the variable of dosage is added.

Since claim 1 failed to define specific technical means (such as the dosage of nilotinib and the volume of apple sauce for dispersion) in achieving the technical effect of bioequivalence, the technical effect achieved by the specific technical solution of Example 2, as provided in the patent in question, cannot support all the technical solutions covered by claim 1. Claim 1, including technical solutions that cannot achieve the stated technical effect of bioequivalence, is not supported by the specification and does not comply with Article 26.4 of the Patent Law.

Key takeaways

This case could serve as a point of reference in the design of embodiments and the generalisation of claims in patent drafting.

The technical solutions for which a claim seeks protection should be obtained or generalised by those skilled in the art from the contents sufficiently disclosed in the specification, without going beyond the scope of the specification.

In assessing the reasonableness of the scope of generalisation, persons skilled in the art need to take into account the technical problem the invention seeks to solve, in combination with the technical effects already established by the specification and the prior art. During the patent drafting process, the patentee needs to focus on those technical features that are highly unpredictable yet are essential for achieving the inventive technical effect, as these features often determine the extent to which they can be generalised.

In drafting the specification, patentees are strongly advised to provide ample embodiments demonstrating the impact of the technical features on the desired technical effects, to establish reasonable boundaries for those features.

In the meantime, in drafting the claims, patentees need to properly limit and generalise those technical features by taking into consideration the status quo of the prior art and the experimental evidence provided in the specification, to avoid the inclusion of solutions that cannot solve the inventive technical problem or whose effects are difficult to assess in advance. Only in this way can the claims accurately reflect the invention's scope and are sufficiently supported by the specification.