CNIPA clarifies examination rule over an inventiveness assessment step (2024)

Time：Apr 08
2024

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In China, the ‘three-step method’ is widely employed to assess the inventive step of claims. This method entails:

- Identifying the closest prior art;
- Identifying the distinguishing features and the technical problem actually solved by the invention; and
- Ascertaining whether the invention, as claimed, is obvious to a person skilled in the art.

Since non-obviousness of the invention is benchmarked against the closest prior art and the technical problem actually solved by the invention, should the technical problem be defined in an overly broad or narrow fashion – in particular, if it incorporates the distinguishing features of the invention or the guidance thereof – the assessment risks being subject to ‘hindsight bias’ and thus leads to a presumption of obviousness.

In practice, it is not rare for the examiners of the China National Intellectual Property Administration (CNIPA) to jump to an unpatentability conclusion based on an erroneous identification of the technical problem actually solved by the invention, as shown in the case study below.

Case brief

The patent at issue seeks to protect the use of a prodrug of aspirin in manufacturing a medicament, wherein the medicament can be administered transdermally at any part of the body in the form of a solution, an emulsion, or a spray, to achieve therapeutically effective plasma concentration for the treatment of aspirin-treatable conditions in humans or animals. The specification details in vitro and in vivo transdermal experiments and animal pharmacological experiments, demonstrating that the transdermal rate of the prodrug is hundreds of times faster than that of aspirin, and when administered transdermally, its antipyretic, analgesic, and anti-inflammatory effects are superior to oral aspirin.

The closest prior art, as introduced by Evidence 2 in an invalidity proceeding, discloses a specific prodrug of aspirin, acetylsalicylate N-diethylaminoethyl hydrochloride (AEAE), and tests its absorption via different administration routes.

In the test of transdermal administration, plasma concentrations were measured over time, when 5-gram AEAE ointment was applied to the abdomen of a rabbit. The result indicates that the AEAE ointment penetrates the skin barrier more easily than the diethylamine salicylate ointment, a known ointment for topical use.

The absorption for digestive administration was also tested in Evidence 2, with the corresponding plasma concentrations far higher than those of transdermal administration, and thus all subsequent pharmacological tests were conducted via digestive administration. Results from digestive administration showed that AEAE has a significant antipyretic effect, an almost identical analgesic property, but a very weak anti-inflammatory effect compared with aspirin.

In the invalidation decision, the CNIPA observed that the distinguishing features of claim 1 as compared to Evidence 2 are that claim 1 specifies the dosage form as a solution, a spray, or an emulsion, and that the medicament is used for the treatment of aspirin-treatable conditions in humans or animals, whereas Evidence 2 discloses a form of ointment yet fails to disclose the efficacy of such ointment.

The decision further concluded that the patent at issue fails to prove the advantages of “solution, spray, or emulsion form” that are specified in claim 1 over ointment form, and thus the technical problem actually solved by claim 1 is a mere alteration over the form of the medicament and the verification of its efficacy.

The CNIPA thus concluded that the patent at issue is devoid of inventiveness and shall be invalidated.

Analysis of the decision

The finding is obviously erroneous, as the invalidation decision failed to take into account the technical effects brought about by the distinguishing features, and the identified technical problem actually solved by the invention included implications for the distinguishing features. The invalidation decision found that it would be easy for a person skilled in the art to try other common dosage forms, such as a solution or an emulsion, so as to solve the problem of altering the form of the medicament and verifying the efficacy thereof. Therefore, based on the aforesaid finding, it would be easy to conclude that the technical solution of claim 1 was obvious.

In contrast, an objective reassessment of the technical effects achieved by the patent at issue relative to Evidence 2 would define the technical problem actually solved by claim 1 as, for instance, "providing a new medicament effectively treating aspirin-treatable conditions in humans or animals". In this sense, neither Evidence 2 nor any other evidence in the case provides technical teaching as to how to improve the efficacy of the ointment cited in Evidence 2, so it would be impossible to obtain the technical solution of the patent at issue.

In fact, in the absence of prior art reporting that aspirin-like medication could be administered transdermally to achieve the efficacy of oral administration, together with the fact that all the marketed medications for transdermal administration are administered via patches rather than through a solution or an emulsion, the conclusion on the obviousness of the technical solution of claim 1 over prior art has no legal or factual merits.

Revision of the patent examination guidelines

The hindsight bias deriving from the erroneous identification of the technical problem actually solved by the invention could be ascribed to the lack of explicit provisions regulating the examination practice in this regard.

In the newly revised Guidelines for Patent Examination (2023), the CNIPA cautions that "the redefined technical problem should match the technical effect that the distinguishing features could achieve in the invention. It should neither be identified as the distinguishing features per se, nor should it include guidance or implications on the distinguishing features."

In other words, the technical problem actually solved by the invention should be determined based on the technical effect that the distinguishing features could achieve in the invention, but the defined technical problem should not include the technical means proposed by the invention to solve that technical problem, nor should it include guidance on, or the implications of, such technical means.

The revised guidelines provide an example as follows: “The invention seeks to protect a consumer-grade electronic device that includes a biometric authentication unit for the purpose of user account authorisation. The authentication process of the said unit is based on a combination of a fingerprint and at least one of a palm print, an iris, a retina, or a facial feature. The specification records that authentication based on at least two features could make the user's account more secure. The closest prior art discloses a consumer-grade electronic device that performs identity authentication based solely on a fingerprint. The difference between them lies in the invention's authentication based on at least two biological features. According to the technical effect that the distinguishing features could achieve in the claimed invention, the technical problem actually solved by the invention can be identified as how to improve the security of a user account in consumer-grade electronic devices. The technical problem actually solved by the invention should not be identified as ‘how to add at least one biometric authentication feature such as a palm print’ or ‘how to improve the security of consumer-grade electronic devices by adding an authentication feature’ [emphasis added].”

Comments on the CNIPA’s revised guidelines

Although the new guidelines entered into force on January 20 2024, the aforesaid revisions are nothing new but the formalisation of the CNIPA’s unwritten examination practice.

As early as 2017, several senior examiners from the then Patent Reexamination Board (the predecessor of the CNIPA’s Patent Reexamination and Invalidation Department) explained in an essay that the re-identification of the technical problem actually solved by an invention should avoid hindsight bias. They cautioned that “the technical problem actually solved by the invention should neither include the technical ideas and means proposed by the invention to solve the problem, nor should it incorporate guidance on the introduction of such technical means, so as to avoid hindsight bias in the assessment of technical teaching".

The view is shared by the EPO in its Guidelines for Examination: “It is noted that the objective technical problem must be so formulated as not to contain pointers to the technical solution, since including part of a technical solution offered by an invention in the statement of the problem must, when the state of the art is assessed in terms of that problem, necessarily result in an ex post facto view being taken of inventive activity (see T 229/85).”

It is very welcome that the unwritten examination practice on determining the technical problem actually solved by an invention, which is pivotal to the patentability assessment, is incorporated in the CNIPA’s Guidelines for Patent Examination. It is expected to increase the predictability over the outcome of patentability assessment before the CNIPA.