AstraZeneca AB (Sweden) vs China National Intellectual Property Administration (CNIPA):

(Intellectual Property Court of the Supreme People's Court of China (SPC), *(2019) SPC IP Admin. Final 33*)

Prepared by the Intellectual Property Court of SPC

Summary

In this case, the SPC established the standard for accepting supplementary experimental data by CNIPA in patent invalidation process.

Facts of the case

This case concerns an invention patent with patent number 200610002509.5 and named *Novel Crystalline Form and Non-crystalline Form of Triazolo [4, 5-D] Pyrimidine Compound*, and the patentee is *AstraZeneca AB. Shenzhen Salubris Pharmaceuticals Co., Ltd.* submitted a request to declare the patent to be invalidated, on the ground that claims 1-4 of the patent do not have inventiveness. To prove the inventiveness, *AstraZeneca AB* submitted rebuttal evidence. CNIPA held that the relevant rebuttal evidence cannot prove that the patent has an unexpected technical effect, and the patent does not have inventiveness. As a result, CNIPA issued its decision to invalidate claims 1-4 of the patent.

AstraZeneca AB was not satisfied and filed a lawsuit with Beijing Intellectual Property Court, which held that, firstly, the experimental data in the rebuttal evidence was completed after the filing date of the patent; secondly, only the Background section of the specification of the patent alleged that the claimed compound high potency for the claimed purpose and has *a "surprisingly high metabolic stability and bioavailability.*" The patent specification neither mentioned nor provided any experimental data about the technical effects, and persons skilled in the art can't confirm the alleged technical effect based on the specification. Thirdly, the rebuttal evidence is an experiment completed by an attester itself who has a relationship with *AstraZeneca AB*, and that the specific scenarios of experimental condition and experimental data cannot be corroborated by other evidence. Therefore, this case cannot rely on the technical effect described in the rebuttal evidence to determine the technical problem actually solved by the patent. *AstraZeneca AB* appealed to the SPC on the ground that the rebuttal evidence which serves as the supplementary experimental data shall be accepted.

Legal Issues

The SPC held that it is unavoidable that patent applicants do not incorporate certain specific experimental data into their original application documents due to the difference in perception of prior art, the difference in understanding of the inventive point of technical solution, and the inconsistency in the grasp of cognitive level of those skilled in the art. As far as inventiveness is concerned, the inventiveness of a pharmaceutical compound can be based on the structures or configurations of the compound *per se* or can be based on the pharmaceutical effects. The aforesaid

pharmaceutical effects can be pharmaceutical uses, i.e. indications, or can be efficacy of the pharmaceuticals, i.e. activity, toxicity, and stability of the pharmaceuticals as well as velocity of controlled release. Any non-obvious technical contribution to the aspects above can be used as a basis to determine the technical problem that is actually solved by the technical solution such that the technical solution would meet the standards of inventiveness for patent-granting. It is difficult for the applicant to precisely foresee the inventive point on the filing date or the priority date.

Even if the applicant could give a precise forecast of the inventive point, there would be possibly different facts and data required to prove the non-obvious technical contribution due to the different understanding of prior art and the different choices of the closest prior art in respect to the same technical problem. Taking sufficiency of disclosure as another example, because examiners and petitioners for invalidation may both have different understandings on patent application documents and may both have different choices of the closest prior art to that of the patent applicants, the former may therefore question whether the patent application meets the requirement of sufficiency of disclosure. Under the circumstances above, the patent applicants need to rely on supplementary experimental data submitted after the filing date or the priority date to prove that their patent applications are eligible for granting. Therefore, the supplementary experimental data submitted by the patent applicant after the filing date shall be examined.

Of course, allowing patent applicants to submit supplementary experimental data after filing date or priority date and examining them does not mean that such data must be accepted for sure. Considering the impact on priority claims over inventions and the need to ensure compliance to the rules on sufficiency of disclosure at the time of patent filling, there is a need to avoid these problems when accepting supplementary experimental data.

First, the original patent application documents shall clearly describe or implicitly disclose the to-be-confirmed fact that is intended to be directly proved by supplementary experimental data, and this is a positive requirement.

Second, the applicant cannot remedy the deficiencies inherently and naturally present in the original application by the supplementary experimental data. The supplementary experimental data shall be normally used when the to-be-confirmed fact is to serve as a supplementary proof for the legally required fact which needs to be eventually proved by the applicant. However, the supplementary experimental data shall not be independently used to prove for the contents that are not disclosed in the original application, or to overcome the deficiencies inherently present in the original application, such as insufficiency of disclosure.

In this case, the original patent application documents described a technical effect of a surprisingly high metabolic stability and bioavailability. But a person skilled in the art cannot confirm the compound of Claim 1 actually has the said effect merely based on the original patent application. The supplementary experimental data provided by *AstraZeneca AB* intended to prove that the to-be-confirmed fact is authentic, i.e. the

compound of Claim 1 does have a surprisingly high metabolic stability and bioavailability, so as to prove inventiveness in a further step. Therefore, the supplementary experimental data was not used to overcome the deficiencies inherently present in the original application and shall be accepted.

The court held that, in the field of pharmaceutical research and development, in particular for the R&D of a novel pharmaceutical, the subjects of R&D are relatively centralized. Therefore, the sources where the supplementary experimental data come from are also relatively centralized. The fact that the provider of the relevant supplementary experimental data and the patent applicant or the patentee has a relationship of interest such as employment or the like is in line with the convention or practice of R&D, and these facts shall not be the sole ground for not accepting supplementary experimental data.

In view of the above, the original judgment for not accepting the supplementary experimental data submitted by *AstraZeneca AB* was erroneous and has been corrected by the appellant court.

Points of Significance

Courts should accept supplementary data where the original patent application documents have clearly described or implicitly disclosed the to-be-confirmed fact that is intended to be directly proved by the supplementary experimental data, and where the data is not intended to remedy deficiencies present in the original patent application.

Key Words

Supplementary experimental data; disclosure