

SPC Guiding Case No. 276: Nuo [X] Co., Ltd. v. China National Intellectual Property Administration (Administrative Dispute over Invalidation of Invention Patent; Third Party: Dai [X]liang)

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Unofficial English translation prepared for reference only. The official Chinese text prevails.

Discussed and adopted by the Judicial Committee of the Supreme People's Court; issued on February 28, 2026.

Keywords

Administrative / invalidation of invention patent right / inventive step / reasonable expectation of success / closest prior art / technical teaching

Holding

1. Where, in the trial of a patent case in the chemical or biological field, the "three-step method" is used to determine whether the patent in issue possesses inventive step, whether a person of ordinary skill in the art has a reasonable expectation of success in respect of the relevant invention is a factor for judging whether there is a motive to improve or a technical teaching, rather than a factor for determining the closest prior art. Where a party seeks to negate the determination of the closest prior art on the ground that there is no reasonable expectation of success, the people's court shall not support that position.

2. In a patent case in the chemical or biological field, the determination of whether there is a reasonable expectation of success should be based on whether a person of ordinary skill in the art would consider that there is a "necessity to attempt," and does not require "certainty of success" or a "high probability of success." Where a person of ordinary skill in the art has a motive to attempt to proceed from the closest prior art and can reasonably expect to obtain the patented technical solution, it may be found that the patented technical solution lacks inventive step.

Basic Facts

Nuo [X] Co., Ltd. ("Nuo [X] Company") was the patentee of an invention patent (the "Patent in Issue") entitled "Pharmaceutical Composition Containing Valsartan and an NEP Inhibitor," with an application date of January 16, 2003, a priority date of January 17, 2002, and a grant publication date of April 8, 2015. Claim 1 of the Patent in Issue defined a pharmaceutical composition containing valsartan and sacubitril, and Claim 2 defined a pharmaceutical kit of that pharmaceutical composition. The specification of the Patent in Issue stated that the pharmaceutical composition could be used to treat or prevent diseases such as hypertension, heart failure, and myocardial infarction.

On April 5, 2017, Dai [X]liang filed a request for invalidation against the Patent in Issue with the former Patent Reexamination Board of the State Intellectual Property Office, and submitted 19 pieces of evidence in the invalidation proceeding. Among them, Annex 13 was a copy of a European patent application publication dated February 4, 1992, together with a partial Chinese translation, which disclosed a composition of an NEP inhibitor and an angiotensin II receptor antagonist for treating hypertension and congestive heart failure; Annex 12 was a copy of a United States patent publication dated June 8, 1993, together with a partial Chinese translation, which disclosed that sacubitril and pharmaceutically acceptable salts thereof are NEP inhibitors that can be used to treat hypertension; Annex 14 was the article "Research on the New Antihypertensive Drug — the Angiotensin II Receptor Blocker Valsartan," published in the Chinese Journal of New Drugs (1999, Vol. 8, No. 9), which disclosed that valsartan is an angiotensin II antagonist whose blood-pressure-lowering effect is no less than that of various existing antihypertensive drugs and which has

few adverse reactions; and Annex 15 was the article "A New Angiotensin II Receptor Antagonist Drug: Valsartan," published in the Medical Herald (March 2001, Vol. 20, No. 3), which disclosed that valsartan is an angiotensin II antagonist that plays a key role in regulating systemic blood pressure and maintaining electrolyte and fluid balance, and has the advantages of being safe, long-acting, convenient to take, with mild adverse reactions and low price.

On December 27, 2017, the State Intellectual Property Office rendered a decision (the "Decision in Issue"), holding that Claims 1 and 2 of the Patent in Issue lacked inventive step in view of the combination of Annex 13 with Annexes 12, 14, and 15, and accordingly declared the entire patent right in issue invalid. Nuo [X] Company was dissatisfied after the judgment and brought a lawsuit in the Beijing Intellectual Property Court, requesting that the Decision in Issue be revoked and that the State Intellectual Property Office be ordered to render a new decision.

Judgment

On June 26, 2019, the Beijing Intellectual Property Court rendered Administrative Judgment (2018) Jing 73 Xing Chu No. 6483, dismissing Nuo [X] Company's claims. After the judgment was pronounced, Nuo [X] Company was dissatisfied and appealed to the Supreme People's Court. On June 30, 2021, the Supreme People's Court rendered Administrative Judgment (2019) Zui Gao Fa Zhi Xing Zhong No. 235: the appeal was dismissed and the original judgment affirmed. Nuo [X] Company was dissatisfied and applied to the Supreme People's Court for retrial. On September 29, 2022, the Supreme People's Court rendered Administrative Ruling (2022) Zui Gao Fa Xing Shen No. 72, dismissing Nuo [X] Company's retrial application.

Reasoning

In this case, the Decision in Issue held that Claims 1 and 2 of the Patent in Issue lacked inventive step in view of the combination of Annex 13 with Annexes 12, 14, and 15, in substance using Annex 13 as the closest prior art. Nuo [X] Company argued that, because Annex 13 did not provide a reasonable expectation of success in obtaining the technical solution of the Patent in Issue, Annex 13 did not constitute a qualified closest prior art. That argument actually conflated two issues at different levels: first, whether Annex 13 could serve as the closest prior art for evaluating the inventive step of the Patent in Issue; and second, whether a person of ordinary skill in the art had, based on Annex 13, a reasonable expectation of success in obtaining the technical solution of the Patent in Issue, and its impact on the inventive-step determination of the Patent in Issue.

I. Whether Annex 13 could serve as the closest prior art for evaluating the inventive step of the Patent in Issue

The "three-step method" is an inventive-step determination method generally applied in patent examination practice. Its basic steps are: first, determine the prior art closest to the patented technical solution; second, identify the distinguishing technical features between the two, and determine, based on the function and effect of the distinguishing technical features in the patented technical solution, the technical problem that the patented technical solution objectively needs to solve; and third, determine whether there is a technical teaching — that is, examine whether the prior art as a whole contains a technical teaching to combine the closest prior art with the distinguishing technical features to obtain the patented technical solution, and whether that technical teaching would motivate a person of ordinary skill in the art, when facing the corresponding technical problem, to improve the closest prior art and obtain the patented technical solution; if such a technical teaching exists, the invention is considered to lack inventive step. Among these, determining the closest prior art is the first step of the "three-step method." In principle, the core consideration in determining the closest prior art is whether the prior art and the invention are directed to the same or similar technical problem and have the same or similar technical objective; on that basis, further consideration is needed as to whether the technical solution of the prior art and that of the invention are

sufficiently close. Whether a person of ordinary skill in the art has, based on the closest prior art, a reasonable expectation of success in obtaining the invention usually depends on whether there existed, before the application date or priority date, any cognitive limitation that would impede obtaining the invention; this is a factor to be considered when determining, after the closest prior art has been determined, whether there is a technical teaching, rather than an essential or preferred factor for determining the closest prior art. For the invention for which protection is sought, even where prior art directed to the same technical problem and technical objective and with a sufficiently close technical solution is determined as the closest prior art, a person of ordinary skill in the art may still, due to factors such as limitations in technical knowledge or research-and-development conditions before the application date or priority date, lack a reasonable expectation of success in obtaining the invention based on that closest prior art, and may therefore find it difficult to be motivated to combine that closest prior art with other prior art or common general knowledge to obtain the technical solution of the invention; however, this cannot be used to overturn the determination of the closest prior art. Of course, if the closest prior art is manifestly infeasible, and a person of ordinary skill in the art would not complete the invention based solely on such infeasible prior art, then such infeasible prior art is in principle not suitable to serve as the closest prior art.

In this case, Annex 13 was directed to the same or similar technical problem and had the same or similar technical objective as the technical solution of the Patent in Issue, and the technical solutions were sufficiently close; it could therefore serve as the closest prior art for evaluating the inventive step of the Patent in Issue. Nuo [X] Company argued, on grounds such as the complexity of the drug's mechanism of action and the existence of specific embodiments in which the technical effect could not be realized, that a person of ordinary skill in the art would not have a reasonable expectation of success in obtaining the technical solution of the Patent in Issue based on Annex 13, and further argued that Annex 13 did not constitute a qualified closest prior art; this was, in essence, an attempt to overturn the determination of the closest prior art on the ground of a lack of a reasonable expectation of success. As stated above, whether a person of ordinary skill in the art has a reasonable expectation of success in obtaining the invention based on the closest prior art is, in principle, not an essential or preferred factor for judging whether a certain piece of prior art is qualified to serve as the closest prior art, and is more appropriately considered in the third step of the "three-step method." Nuo [X] Company's assertion of negating Annex 13 as the closest prior art on the above grounds lacked a basis and should not be supported.

II. Whether a person of ordinary skill in the art had, based on Annex 13, a reasonable expectation of success in obtaining the technical solution of the Patent in Issue, and its impact on the inventive-step determination of the Patent in Issue

Given that the closest prior art had already disclosed the pharmaceutical functions of a combination of two classes of known compounds, the Patent in Issue was in substance the development of a specific composition with pharmaceutical effect. In this context, the "reasonable expectation of success" as to the pharmaceutical effect of the specific compound combination is an important factor for judging the existence of a "technical teaching." If a person of ordinary skill in the art had no reasonable expectation of success as to the pharmaceutical effect of the specific compound combination, yet the patent applicant nonetheless made an attempt and obtained a corresponding specific composition technical solution with pharmaceutical function, then that specific pharmaceutical composition technical solution can generally be found to possess inventive step. If a person of ordinary skill in the art had a reasonable expectation of success as to the pharmaceutical effect of the specific compound combination, then the specific pharmaceutical composition technical solution can be found to possess inventive step only where verifying the pharmaceutical effect of the specific composition required inventive labor or achieved an unexpected technical effect.

A reasonable expectation of success is an objective assessment and rational prediction by a person of ordinary skill in the art, based on his or her technical knowledge and the general experimental conditions in the field before the application date or priority date of the patent in issue, of the probability of success in

obtaining the patented technical solution from the prior art, and does not depend on the subjective intent of the patent applicant. A reasonable expectation of success requires only reaching the degree at which a person of ordinary skill in the art considers that there is a "necessity to attempt," and does not require "certainty of success" or a "high probability of success." Having a reasonable expectation of success generally does not presuppose that the anticipated attempt will necessarily or highly probably achieve the technical objective or solve the technical problem; it only requires that a person of ordinary skill in the art, after comprehensively considering factors such as the state of the prior art in the specific field, the characteristics of technical evolution, the mode and conditions of innovation, the average cost of innovation, and the overall success rate of innovation, would still not abandon the attempt.

Nuo [X] Company argued that a person of ordinary skill in the art would not have a reasonable expectation of success as to the technical solution of the Patent in Issue (i.e., using a combination of valsartan and sacubitril to treat hypertension), mainly on the following grounds: angiotensin II antagonists and NEP inhibitors exhibit opposite and complex physiological effects; Annex 13 acknowledged the unpredictability of the mechanisms of action of angiotensin II antagonists and NEP inhibitors and did not provide any conclusion; and the combination of angiotensin II antagonists and NEP inhibitors contains "bad points" in which the blood-pressure-lowering effect cannot be realized. The specific analysis in this regard is as follows: Annex 13, as the closest prior art, disclosed a technical solution in which a combination of an angiotensin II antagonist and an NEP inhibitor can treat hypertension, and stated technical information such as the relevant experimental methods, experimental conclusions, modes of administration, and therapeutic dosages, which provided a clear technical teaching for a person of ordinary skill in the art to select a specific angiotensin II antagonist and a specific NEP inhibitor to treat hypertension. Where Annex 13 had given clear guidance on the pharmaceutical function of the typed drug combination, and there were other options for the specific drug combination, even if the development of the specific drug combination with the relevant pharmaceutical function did not have "certainty of success," this was insufficient to prove that a person of ordinary skill in the art would abandon developing, based on Annex 13, a combination of a specific angiotensin II antagonist and a specific NEP inhibitor with a blood-pressure-lowering function. On this basis, considering that Annex 12 disclosed that sacubitril is an NEP inhibitor usable to treat hypertension, and Annexes 14 and 15 disclosed that valsartan is an angiotensin II antagonist with a blood-pressure-lowering effect, it could be found that a person of ordinary skill in the art had a motive to attempt to proceed from Annex 13 and could reasonably expect to obtain a pharmaceutical composition containing valsartan and sacubitril for treating hypertension; that is, a person of ordinary skill in the art had a reasonable expectation of success in obtaining the technical solution of the Patent in Issue from Annex 13, and the technical solution of the Patent in Issue lacked inventive step.

Relevant Legal Provisions

Article 22(3) of the Patent Law of the People's Republic of China (2020 Amendment) (the case applied Article 22(3) of the Patent Law of the People's Republic of China, 2000 Amendment).

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