China’s SPC offers guidance on identifying technical problems actually solved in inventiveness assessments

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The non-obviousness of a claimed invention to persons skilled in the art hinges on whether the prior art provides motivation for applying the distinguishing features of the invention to the closest prior art so as to solve the actual technical problem to be solved. If the technical problems actually solved by the invention are over-generalised, it will fail to identify the accurate improvement of the invention relative to the prior art, thus leading to an erroneous conclusion of obviousness.

The Intellectual Property Court of the Supreme People’s Court (SPC) of China offers valuable insight in this regard in a court decision rendered on November 30 2023.

Facts

The case relates to the invention patent application No. 201410707259.X for ‘VEGF (vascular endothelial growth factor) Antagonist Formulations Suitable for Intravitreal Administration’ (the Application). The Application was rejected by the China National Intellectual Property Administration (CNIPA) during a re-examination procedure, on the ground that the Application is devoid of an inventive step. The applicant challenged the decision before the Beijing Intellectual Property Court, but to no avail. An appeal was filed before the SPC, which revoked the CNIPA’s and the first-instance court’s decision.

CNIPA decision

The CNIPA based its decision on the below findings.

The differences between Claim 1 of the Application and Reference Document 1 are as follows:

1. The components of the ophthalmic formulation of the Application contain a specific amount of excipients such as sodium phosphate, without the presence of histidine or trehalose. In addition, the content of VEGF antagonists and polysorbide 20 is different from that in Reference Document 1, with a pH value ranging between 6.2 and 6.4.

2. The Application defines the VEGF antagonist as a dimer composed of two fusion proteins of SEQ ID No. 4, where at least 90% by weight of the VEGF antagonist is not present in an aggregate.

Based on the aforesaid distinguishing features and their effects in this application, the CNIPA ascertained the technical

problem actually solved in the Application as “providing a new ophthalmic formulation”.

Regarding distinguishing feature (1), the CNIPA found that persons skilled in the art could achieve better stability of the formulation through adjustment and optimisation as taught in Reference Document 1.

Regarding distinguishing feature (2), the CNIPA opined that Reference Document 2 discloses a VEGF capturing agent that could bind and inhibit VEGF activity. Based on the teaching of Reference Document 2, it would be easy to apply the ophthalmic formulation as described in Reference Document 2 to the technical solution of Reference Document 1, thereby obtaining the technical solution of the Application, with foreseeable technical effect. The feature of “at least 90% by weight of the VEGF antagonist is not present in an aggregate” as dictated in the Application is a conventional choice, and there is no evidence in the specification of this application to demonstrate any unexpected technical effects that this choice may bring to the Application.

Therefore, the CNIPA concluded that Claim 1 of this application is obvious to those skilled in the art. The findings were echoed by the Beijing Intellectual Property Court in the first-instance proceeding.

SPC decision

The SPC apparently disagreed.

The apex court found that the invention as cited in Reference Document 1 aims to provide a new drug delivery scheme for the treatment of intraocular neovascular diseases, without directly addressing the issue of how to produce stable, safe, and effective formulations from therapeutic compounds. Moreover, the VEGF antagonists in the Application are proteins different from those in Reference Document 1. The technical effects of embodiments 3 and 4 in this application could demonstrate the stability of the VEGF-specific fusion protein antagonist suitable for ophthalmic and intravitreal application as provided in this application.

Based on the technical effects determined by the distinguishing features in this application, the SPC identified the actual technical problem to be solved by the Application as “providing a stable ophthalmic liquid formulation containing high concentrations of different protein antagonists”.

As regards technical motivation, the SPC ascertained that the technical problem to be solved in the art lay in making stable, safe, and effective formulations out of the drugs at issue. In view of the technical teaching in Reference Document 1, persons skilled in the art have the motivation to use VEGF antagonists different from those cited in Reference Document 1 to produce formulations featuring similar concentrations.

However, it is also known knowledge in the art that polypeptide and protein drugs are very unstable and prone to spoilage. It is therefore a major technical challenge in the art to produce out of these drugs stable, safe, and effective formulations, not to mention to produce such formulations in high concentration. In particular, Reference Document 1 disclosed numerous VEGF antagonists, without giving any preference to VEGF trapping agents, making it harder to produce stable, safe, and effective high-concentration formulations. The SPC therefore concluded that Reference Document 1 does not provide any teaching or technical motivation as to how to prepare stable high-concentration protein formulations.

The SPC was of the opinion that Reference Document 1 does not provide any teaching or technical motivation in selecting from numerous excipients and in combining those selected to prepare stable formulations. Persons skilled in the art have long realised that the type and concentration level of buffering agents may affect the stability of proteins. The complex influencing mechanism of various excipients over the stability of proteins makes it hard for persons skilled in the art to determine the excipient combination that would stabilise the protein of this application through conventional or orthogonal experiments.

Similarly, the SPC held that Reference Document 2 does not touch the issue of producing stable high-concentration liquid formulations. Those skilled in the art would be unlikely to conceive that this VEGF antagonist may also be suitable for the same application method. It is also difficult to confirm through conventional experiments that the differences in VEGF antagonists in this application will have no bearing on the expectations of those skilled in the art over their intraocular efficacy or stability.

The SPC thus found that Claim 1, which is not obvious to those skilled in the art, possesses an inventive step.

Comment

Basically, a non-obviousness assessment is to assess whether the invention is obvious to those skilled in the art by taking into account the closest prior art reference and the technical problem actually solved by the invention. To cut the mustard, it requires the presence of technical motivation over the prior art in its entirety. That is, the prior art needs to provide a teaching to apply the above distinguishing features to the closest prior art to solve its existing technical problems (i.e., the technical problems actually solved by the invention). Such teaching will motivate persons skilled in the art to improve the closest prior art and obtain the invention at issue when facing the technical problems.

The technical problems actually solved is de facto the technical contribution of the invention over the prior art and the disclosure made by the present invention. The technical effect used to determine the technical problem actually solved should be straightforward and specific relative to the prior art. Over-generalisation of the technical problem actually solved would risk blurring the boundary between the invention and the prior art, improperly including the prior art that solves different problems and leading to an erroneous conclusion that the prior art provides the relevant technical motivation.

In this case, the SPC found the technical problem actually solved by the invention as ascertained by the CNIPA to be over-generalised, which failed to reflect the distinguishing features and rendered the obviousness assessment moot. By correcting the erroneous identification, the SPC boiled down the technical problem actually solved to “providing a stable ophthalmic liquid formation containing high concentrations of different protein antagonists”, which pinpointed the specific effects of the invention that differ from the prior art and provided a proper benchmark for the ensuing assessment of technical motivation.