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China IP Developments in Biotech/Pharma

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Since 2010, the Patent Review Board (PRB) has published the top 10 patent invalidation cases of the year in April of each year. The selection criteria are high social concern, significant impact on the related industry, or involve difficult legal issues and important examination criteria. In the next few newsletters we will highlight cases that cover topics we think are significant and relevant to the biotech/pharma industry.

Post Filing Data

Can post-filing data showing unexpected technical effect be used to overcome inventive step if the specification contains no data but asserts the unexpected technical effect?

In short, the answer is no, post-filing data cannot be used to overcome inventive step even if the idea was asserted if the original data was not in the application.

Novartis's Chinese patent (201110029600.7) claimed the combination of AT 1-antagonist valsartan and NEP inhibitor Sacubitril. The specification asserted that the combination of the two drugs had synergistic effect, yet provided no data. The PRB sided with petitioner Dai Jinliang (戴锦良) and argued that one of skill in the art could not predict that the combination would be synergistic without experimental data. In other words, applicants had not solved the technical problem of providing a pharmaceutical combination with synergistic effects. At most, applicants provided a pharmaceutical composition for treating hypertension. The patent was declared invalid.

In our experience, if the surprising data is in the application as filed but another piece of prior art is cited during prosecution, the applicant may do follow-up comparison studies with the newly discovered art as long as the original data for the applicant's invention was already disclosed in the application.

We will keep you updated for further development. Stay tuned for more important updates on IP law in China.

Please contact us with any questions: eip@eipgroup.asia.

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