Be careful with post-filing experimental data

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Please refer to this post as: Be careful with post-filing experimental data

A positive view is spreading on post-filing experimental data in China since the recent official post of the proposed revisions to the Guidelines for Patent Examination (the “Guidelines”) by the State Intellectual Property Office (SIPO) on the Chinese Patent Review Board (CPRB)’s website.

The proposed revisions refer to the current post-filing examples and experimental data as “post-filing experimental data” and state that “the proposed revisions to the Guidelines refer only to the admissibility of post-filing experimental data and not to the sufficiency of disclosure requirement.” They propose to allow post-filing experimental data to contribute to the sufficiency of disclosure if the three elements are sufficiently disclosed:

1. Identification
2. Preparation
3. Technical effect

They state that all three elements are to be considered, and that the technical effect is sufficient to prove that the post-filing experimental data contributed to the sufficiency of disclosure.

The proposed revisions state that “the admissibility of post-filing experimental data is not guaranteed, and that data is to be disclosed in the examination based on merits. Below we will analyze the admissibility of post-filing data that lack of three elements of identification in the light of a previous procedural judgment by the Supreme People’s Court (“SPC”) on the Lipitor case on 25 June 2013.

The SPC held in its retrial decision that post-filing experimental data submitted by the patentee cannot be admitted if in the original description, experiment and data were not sufficiently disclosed. The patentee repeated its preparation experiment to overcome insufficient disclosure of the preparation itself.

In analyzing the preparation of the claimed product, the SPC carefully compared the protocol used in the test report with the protocols described in the description. In the Lipitor case, the patent claimed a crystalline form I atorvastatin containing 1 to 8 mol of water, preferably 3 mol of water. In the patent description, two protocols were described to prepare this product but the prepared product was not further determined as to its water content. In SUMMARY OF THE INVENTION the water content was generally recited. In response to the challenge of insufficient disclosure, the patentee submitted a third-party test report, to repeat the protocols in the description and show that the final product did contain 3 mol of water.

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Our reading of the proposed revisions is that, the admissibility of post-filing experimental data is not guaranteed, and that data is to be disclosed in the examination based on merits. Below we will analyze the admissibility of post-filing data that lack of three elements of identification in the light of a previous procedural judgment by the Supreme People’s Court (“SPC”) on the Lipitor case on 25 June 2013.

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