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Be careful with post-filing experimental data

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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 IP Office (the “SIPO”) of China. People tend to think that the window is about to open to post-filing experimental data, just like it is to software and business method patents. Some applicants have prepared to submit responses with such data to overcome relevant objections. However, we would say the situation is NOT that optimistic.

1. What are the proposed revisions?

The practice of post-filing of experimental data is specific for chemical (including pharmaceutical and biological) inventions. This is because, unlike mechanical and electronic substances, chemical and biological materials are invisible by human eyes. Their structures and way of working have to be determined via experiments and for others to know such chemical and biological substances, results of the experiments need to be described.

The Chinese patent system is a first-to-file system, under which a patent is granted to one who is the FIRST to file the invention. The Chinese Patent Law requires a patent application to include sufficient disclosure of the invention to tell what the invention is and why it deserves patent protection. In particular, for a chemical invention, the disclosure should include: (1) what the chemical is (the “identification”), (2) how to obtain the chemical (the “preparation”), and (3) what usages or effects the chemical brings (the “usages/effects”). If all the three elements are sufficiently disclosed, the description of the invention may be recognized to satisfy the sufficient disclosure requirement as provided under Item 3, Article 26 of the Chinese Patent Law (CPL A26.3). If the chemical can bring unexpected effects over the prior art, the chemical invention may satisfy the inventive step requirement as provided under Item 3, Article 22 of the Chinese Patent Law (CPL A22.3).

The current attitudes of the SIPO toward post-filing experimental data are different if the data are to satisfy the sufficient disclosure requirement as opposed to the inventive step requirement. Post-filing data are not accepted if the data are to overcome insufficient disclosure of patent description, as expressly provided by the current Guidelines (see below). Post-filing data may be considered based on merits if the data are to show unexpected technical effects of the invention, on condition that such technical effects have already been recited in the original description.

The proposed revisions of the Guidelines with regard to post-filing experimental data refer only to the sufficient disclosure requirement.

Current provisions:

“To evaluate whether the patent description has sufficient disclosure, only the original description and claims shall be considered. Post-filing examples and experimental data are not considered.”

Proposed revisions:

“To evaluate whether the patent description has sufficient disclosure, only the original description and claims shall be considered. Examiners shall review experimental data supplemented after the filing date. The technical effect of such post-filing experimental data should be determinable by the skilled person in the art in view of the original disclosure.”

With regard to post-filing data for proving inventiveness, the 2001 Guidelines provided that *“supplemented examples may only for examiner’s reference in examining novelty, inventiveness and practicability”*. The said reference was removed in the 2006 version of Guidelines, and remains no change so far.

2. What may be changed?

Our reading of the proposed revisions is that, the admissibility of post-filing experimental data is not guaranteed, and shall be decided at the examiner’s discretion based on merits. Below we will analyze the admissibility of post-filing data from the three elements of chemical inventions in the light of a precedent judgment issued by the Supreme People’s Court (the “SPC”) of China, on the Lipitor case (*IP Adm 8 (2014)*). This case was believed to have triggered the above proposed revisions.

In the Lipitor case, the patent in dispute was invalidated by the Patent Re-examination Board (the “PRB”) for insufficient disclosure; the patentee supplemented experimental data and overturned the PRB invalidation decision in the second instance court proceedings. The PRB successfully petitioned the SPC to retry the case and had the patent finally declared invalid.

In its retrial decision, the SPC made a standpoint that: post-filing experimental data for satisfying the sufficient disclosure requirement should not be denied only because they are post-filed, but should be considered on the merits, namely, to evaluate whether a skilled person in the art, with the general knowledge and skills available before the patent filing or priority date and in view of the original disclosure of the patent description, can directly obtain or easily think of the conditions and protocol of the experiment. After a detailed analysis in terms of the identification and preparation of the chemical substance claimed by the patent, the SPC came to a conclusion that the post-filing experimental data submitted by the patentee cannot overcome the insufficient disclosure problem.

2.1 The Identification

Formula of a compound, cell parameters or XRPD spectrum of a crystal form, water content of a hydrate, and so on, are usually used to identify a chemical product. Two questions relating to sufficient disclosure of the identification are (1) what identifiable features must be sufficiently disclosed? (2) whether the identification should be disclosed together with the preparation, to show that the prepared product indeed has the identifiable features? We saw many cases describing preparation in EXAMPLEs but identification elsewhere in the description. The SPC addressed these issues in the Lipitor case.

The Lipitor case concerns 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.

The SPC held in *IP Adm 8 (2014)* that, in the claim set, the water content was limited as one structural feature of the product, accordingly *identification of the feature should be essential to the original description; no matter whether the post-filing experiment was able to prove that the final product of the experiment did contain the defined water content, the fact was not changed that the identification of the water content was missing in the original description, and thus the patent was declared invalid for insufficient disclosure.*

The SPC concluded the water content to be an identifiable feature of the claimed substance because it was an essential feature defined by the patent and hence such feature should be sufficiently disclosed. The SPC obviously did not believe the recitation of water content in the SUMMARY OF THE INVENTION in the original disclosure qualified a sufficient disclosure. The SPC required that the determination of water content should be described in the EXAMPLE of the description.

In light of the Lipitor case, essential features limited by patent claims are recognized as features to identify the patented chemical product and must be disclosed along with the preparation of the product, in order to meet the sufficient disclosure requirement. Post-filing experimental data are not admissible to overcome an identification defect.

2.2 The Preparation

In analyzing the preparation of the claimed product, the SPC carefully compared the protocol used in the test report post-filed by the patentee with the protocol described in the description, and identified that the test report included more than the described protocol. The SPC came to a conclusion that, *because the identification of water content was missing in the preparation, the skilled person would be unable to prepare under control the claimed compound according to the disclosure of the description; even if the post-filing experiment could prove that the claimed compound could be prepared, it could not change the fact that the patent violated CPL A26.3 (the sufficient disclosure requirement).*

Although the SPC's conclusion was negative, the Lipitor case shows a positive view that, the SPC appeared to be ready to accept post-filing experimental data if (1) the repeated preparation protocol is consistent with the protocol described in the original description; and (2) the identification disclosure has no problem and the repeated preparation experiment is to overcome insufficient disclosure of the preparation itself.

2.3 The Usages/Effects

The SPC did not address this element in the Lipitor case. Insufficient disclosure of the usages/effects of a chemical substance may cause invalidation of the patent for insufficient disclosure and lack of inventiveness. Post-filing experimental data to show usages/effects could be admitted in very limited circumstances, only when a patent has satisfied the sufficient disclosure requirement.

In an invention that only claims one use/effect of the claimed chemical, in no way that post-filing data could be admitted if in the original description, experiment and data were not sufficiently disclosed. The patent would be invalidated for insufficient disclosure regardless of whether it is inventive or not.

In an invention that claims multiple usages/effects, if in the original description, sufficient disclosure has been included in respect of one of the usages/effects, it is acceptable that the other usages/effects could be merely recited with no experiment data in the original description, and post-filing experimental data to support inventive steps could be admitted.

Accordingly, the practice with respect to sufficient disclosure requirement may still be the same as before: experimental data for effects required by sufficient disclosure are not acceptable to be post-filed.

Conclusion

The proposed revisions do not bring substantial change to the practice of the acceptability of post-filing experimental data. Careful review and assessment are needed before filing supplemental data.

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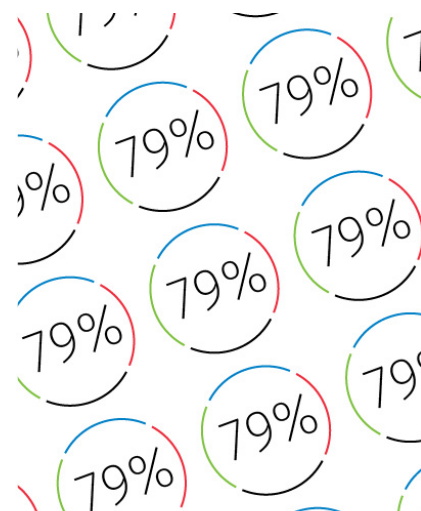
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