



Qing Yang
Partner
Patent Attorney
China Sinda
qing.yang@chinasinda.com

Exploring applications for chemical patents and experimental data

Chemistry inventions in the majority of cases require experimental results for validation, only after which can they be confirmed. Here we will explore the importance of experimental data in applications for chemical patents.

Full disclosure

The third paragraph of article 26 of the Patent Law specifies that “the description shall provide a clear and complete description of the invention or utility model such that a person skilled in the art could realise the same”. Pursuant to the Patent Examination Guidelines, the phrase “such that a person skilled in the art could realise the same” means that such a person skilled in the art could, based on the information contained in the description, realise the technical solution of the invention or utility model, resolve its technical issues and produce the anticipated technical effect.

A problem often seen in applications for chemical patents is a lack in the description of qualitative or quantitative experimental data for realising the purpose and/or achieving the anticipated effect. Consequently, a complete description of the invention is not established, resulting in insufficient disclosure.

The requirement of full disclosure can only be satisfied if the description contains experimental data on the effect of the specific compound, although there has been a trend in judicial cases in recent years of lowering the threshold on this requirement.

Cases that have drawn a great deal of attention include the Pfizer invalidation case (administrative judgment [2006] Gao Xing Zhong Zi No. 519 of the Beijing Higher People’s Court) and the Eli Lilly review case (administrative judgment [2013] Gao Xing Zhong Zi No. 963 of the Beijing Higher People’s Court).

The point in common in these two cases is the failure to expressly state in the description which specific compound the experimental data comes from.



Eli Lilly's patent application No. 200580005788.4 involves compounds of a general formula, with the description providing experimental data on "representative compounds" and "exemplified compounds". The review decision and judgment at first instance were overturned on appeal, finding that the compounds of the general formula in the patent application satisfied the basic requirements for full disclosure. However, it was also found that because there was no experimental data for specific example compounds, the application could not request protection for specific example compounds.

Claim support

The fourth paragraph of article 26 specifies that "the claims shall be based on the description and concisely delimit the scope of patent protection that is claimed". Pursuant to the Patent Examination Guidelines, the phrase "the claims shall be based on the description" means that the claims should be supported by the description.

Usually the claims are reasonable summaries of the specific examples in the description. If the technical solution summarised by a claim includes a solution that is not capable of implementation, or a solution inferred by the applicant, and its effect cannot be determined or evaluated in advance, then such a claim will be found to be unsupported by the description.

The Takeda Pharmaceutical Company invalidation case (administrative ruling [2012] Zhi Xing Zi No. 4 of the Supreme People's Court) involved invention patent No. 93100008.4. The Supreme People's Court found that the description for the patent did not provide sufficient experimental data to show that, in addition to PEG 6000, "oxyalkylene polymers with a melting point range of 20-90°C" or "PEG with a molecular weight of 1,000-10,000" can likewise realise the objectives of the invention, resulting in the claims being unsupported by the description.

Determining inventiveness

Pursuant to the third paragraph of article 22 of the Patent Law, "the term 'inventive' means that, in comparison with prior art, the invention has prominent substantive features and represents distinctive progress, or that the utility model has substantive features and represents progress". In patent practice, inventiveness requires the invention to be non-obvious and with a beneficial effect, or merely to produce an unexpected technical effect. Such effect needs to be recorded in the description for it to serve as a basis for determining inventiveness. Supplementary



experimental data that substantiate an unexpected technical effect can be used to argue for inventiveness, provided that the technical effect is expressly recorded in the description.

The Xiangbei Welman invalidation case ([2011] Xing Ti Zi No. 9 of the Supreme People's Court) involved invention patent No. ZL97108942.6, a patent that requests protection for a compound preparation. The patent holder claimed that the compound preparation was safe, effective and stable, but failed to record this in the description. The Supreme People's Court found that, in general, technical solutions and technical effects that an applicant fails to disclose in the description may not serve as the basis for determining whether an application satisfies the statutory criteria for a patent to be granted, otherwise this would clash with the first-to-file principle in patent regulations and run counter to the essential attribute of a patent, i.e. exchanging disclosure for protection.

Mutual connection

A lack of the necessary experimental data will on the one hand result in insufficient disclosure of the technical solution in the description for which the claims request protection, and on the other hand the claim will be unsupported by the description. If the use and/or technical effect can be anticipated from prior art, the invention will generally lack inventiveness, despite the requirement of full disclosure being satisfied.

In patent practice, with respect to the issues of full disclosure and support, supplementary experimental data will generally not be taken into consideration. However, one should be mindful that the most recent criteria for the examination of full disclosure have changed, in that supplementary experimental data provided as evidence in support of the facts are acceptable. In the chemistry field, experimental data are of utmost importance for the determination of full disclosure, support and inventiveness.

It can be anticipated that, with the lowering of the threshold for the criteria for the examination of full disclosure, the threshold for the criteria for the examinations of support and inventiveness will be correspondingly raised, thereby achieving a new balance.

Beijing Office (Head Office)
11/F, Block B, Focus Place, 19 Financial Street
Beijing 100033, China
Tel.: +86 10 6657 6688
Fax: +86 10 6657 8088
E-mail: sinda@chinasinda.com
www.chinasinda.com



CHINA SINDA
— Intellectual Property —
中原信达知识产权代理有限公司