

JAPAN


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Later submitted experimental data and inventive step

In the examination of inventive step, unexpected advantageous effect is an important factor. If the application is rejected based on lack of unexpected advantageous effect, is it possible to allege unexpected advantageous effect by submitting experimental data after the filing of the application? In other words, can the court take into account new evidence which is submitted after the application?

In Europe, it is possible to rely on new effects submitted subsequently during the proceedings by the applicant, provided that the skilled person would recognise these effects as implied by or related to the technical problem initially suggested in the originally filed application. In the United States, an applicant can allege unexpected advantageous effect which is not described or even implied in a specification by submitting new data subsequently.

In Japan, new evidence submitted after the filing of the application can be analysed under specific conditions. However courts and the JPO have not taken into account later submitted experimental data as much as Europe and the US. In this case, the IP High Court took into account later submitted experimental data under less strict conditions than before.

In this case, P&G filed a PCT application regarding sunscreen compositions. The JPO rejected the application due to lack of inventive step. Thereafter, P&G appealed to the Trial Board of JPO; however the request was dismissed. Thus, P&G appealed to the IP High Court.

P&G submitted the experimental data (Reference data 1) shown in table 1 and 2 during the JPO appeal procedure.

The invention as filed is a composition of example 1, which selects b1 as UVB sunscreen. b1 is a typical UVB sunscreen. The cited invention discloses

Reference data 1

Table 1

Example 1	b1+A+stabilizing agent
Comparative example 1	A+ stabilizing agent
Comparative example 2	b2+A+ stabilizing agent
Comparative example 3	b3+A+ stabilizing agent
Comparative example 4	b4+A+ stabilizing agent

*b1 to b4 are one of UVB sunscreens

*A is UVA sunscreen

sunscreen composition which uses UVB sunscreen, a general concept of b1. According to the reference data 1, example 1 provides superior effects regarding both SPF and PPD in comparison with comparative example 1 which does not use UVB sunscreen, and comparative examples 2 to 4 which use b2 to b4 as UVB sunscreen. Furthermore, example 1 provides superior photostability because it keeps high SPF and PPD even after UV irradiation. Therefore, P&G alleged by submitting the reference data 1 that the claimed invention which selected b1 as UVB sunscreen had an inventive step as compared with the cited invention which used UVB sunscreen. However, the JPO rejected taking into account the experimental data and denied unexpected advantageous effect.

According to JPO Examination Guidelines, the effects claimed or proved in written opinions etc, such as experimental results, are analysed when the specifications provide effects more advantageous to the claimed inventions than the cited inventions or when the person skilled in the art is able to presume effects more advantageous to the claimed inventions than the cited inventions from the descriptions of the specifications or drawings, although the advantageous effects are not explicitly described. In the specification of the claimed invention, there is only qualitative description regarding effects of the claimed invention, and there are no numerical data. Therefore, the JPO did not take into account the experimental data because the specifications did not provide any effects of using b1.

In contrast, in a judgment of July 15 2010, the IP High Court took into account the later submitted experimental data.

The reason it is not allowed to take into account later submitted experimental data in the examination of inventive step is that it is against the purpose of

Table 2

		SPF	PPD
Example 1	Before UV irradiation	59.4	16.0
	After UV irradiation	57.6	13.7
Comparative example 1	Before UV irradiation	7.0	9.0
	After UV irradiation	5.6	7.8
Comparative example 2	Before UV irradiation	9.5	8.6
	After UV irradiation	6.3	6.6
Comparative example 3	Before UV irradiation	6.8	7.8
	After UV irradiation	5.9	7.3
Comparative example 4	Before UV irradiation	15.7	14.1
	After UV irradiation	10.6	10.0

the first-to-file system and becomes unfair to third parties. Therefore, the court can take into account later submitted experimental data when a person skilled in the art is able to recognise or presume the effects of the invention from the description of the original application as long as the effects do not exceed the description, leaving aside when there are no descriptions regarding the effects in the specification of the original application. Whether it is allowed or not should be judged from the viewpoint of fairness.

In the specification, there are descriptions as “the claimed compositions provide excellent stability (especially photostability), efficiency, and UV protection efficacy (including both UVA and UVB protection)” and “Preferred UVB sunscreen active is b1”. In light of these descriptions, a person skilled in the art will recognise that the invention which selects b1 as UVB sunscreen provides improved UV protection efficacy etc. Therefore, the experimental data can be taken into account because no unfairness is incurred by taking into account the experimental data.

The defendant argued that the skilled person cannot presume how much SPF and PPD the invention provides because the specification of the original application has mere general description regarding the effects of the invention.

The IP High Court rejected this argument: according to the defendant’s allegation, when the effects are described qualitatively in the original specification or when numerical data is not described in the original specification, later submitted experimental data cannot be taken into account because the skilled person cannot presume the effects. This conclusion is not fair because at the time of the filing an applicant cannot know with what cited invention the invention will be compared in the future, it imposes an exces-

sive burden on the applicant and leads to loss of opportunity of objective verification based on the experimental results.

This judgment is rendered by Judge Imura, the current chief judge of the IP High Court. It promotes international harmonisation by putting Japanese practice which rarely accepted the later submitted experimental results closer to Western practice. Former precedents tended to reject later submitted new evidence when the effect is described qualitatively and generally as in the present invention. In contrast, this judgment opened the door for the new evidence to be accepted even when the applicant did not describe concrete numerical values and the description was qualitative such as “the invention provides superior effects”. Though not completely, the problem that a patent granted in Western countries would be rejected in Japan is solved to a certain degree. Therefore, it makes it easier for Western companies to pursue global IP strategy than before.

However, former judge Shiotsuki of the IP High Court says although the court is inclined to adopt experimental data if the related descriptions exist by connecting the experimental data with related descriptions in the specification, it is difficult to treat the case where no related descriptions exist. Thus, it is unclear whether the gist of this judgment will be followed by other courts in the future. Consequently, it will be safer for a patent holder to describe numerical data in a specification as much as possible. However, if the case goes to the IP High Court, it will be useful to cite this judgment and even in the examination and appeal stage in JPO it will be desirable to submit experimental data and cite this judgment.

In contrast, now third parties cannot easily assess other companies' patents as lacking inventive step when they conduct a patent search.