

Session 1 Patent prosecution practice in Japan Tips for obtaining a patent in Japan - Part II -

Enablement requirement in Japan

Japan Patent Attorneys Association International Activities Center

REQUIREMENTS

US: written description, enablement, best mode

JP: supporting, enablement, clarity

JP applications of these requirements are <u>a little</u> bit different from those in the US.

Especially, the enablement requirement in chemical inventions (i.e. bio-tech field)



In detailed description of a specification, a claimed invention should be described as one skilled in the art is able to practice the claimed invention (Article 36, Par. 4, No.1).

PRACTICE OF THE CLAIMED INVENTION

Usually, skilled artisan should understand how to practice the claimed invention based on a specification and knowledge in the art.

In chemical fields, we have an additional and specific point of view.

A chemical invention is based on a discovery of an effect of a chemical substance.

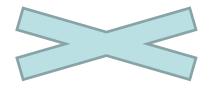
THE EFFECT OF THE CHEMICAL SUBSTANCE IS **UNPREDICTABLE**.

The effect of chemical invention should be described in a specification.

THE EFFECT OF THE ENTIRE CLAIMED RANGE SHOULD BE DESCRIBED IN THE ORIGINAL SPECIFICATION.



When an effect of an entire claimed range is described in a working example(s), an application fulfils the enablement requirement.



When one skilled in the art is not able to predict an effect of a clamed invention;

the clamed invention is <u>unable to practice</u> because skilled artisan needs **intense and undue practice** to attain the claimed invention (having the effect).



Enablement requirement TIPS 1

Against a notification of refusal based on the enablement requirement stating necessity of undue practice to obtain a target effect;

Explain that a skilled artisan is rationally able to conceive the effect of the whole range of the claimed invention based on the working example(s) in the original specification,

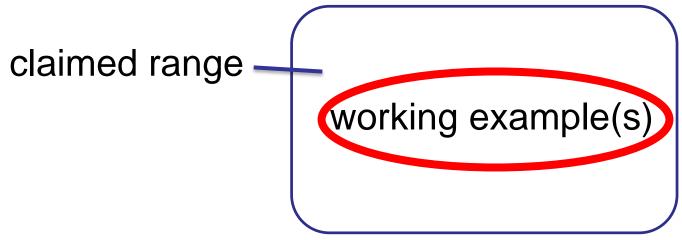
Not necessary to explain how to practice the claimed invention based on the specification and technical knowledge in the art.



Enablement requirement TIPS 2

Claiming Broader than the working example;

Show the reason why one skilled in the art is easily able to conceive the target effect based on a theory or technique implicitly or explicitly described in your specification or known in the art.





In the IP High Court, I once argued an remarkable effect of a specific protein (Protein B) claiming an inventive step.

Working example 12 proteins C-N having an remarkable effect were already patented. (Patented claim only covers proteins C-N.)

JPO examiners usually consider that an effect of a claimed invention of a chemical substance would be observed only within the range of a working example(s).

We filed a divisional application claiming protein B, not described in the working examples in the original specification.

The name of protein B is explicitly described in the original specification.

The divisional application was rejected in JPO examination and JPO trial confirmed the rejection.



In the IP high court, we explained a remarkable effect of protein B conceivable from working example proteins C-N and asserted an inventive step of protein B based on the remarkable effect unpredictable from known art.

With respect to the conceivable remarkable effect of protein B, we analyzed the results of working example proteins C-N and compared amino acid sequence of protein B to those of proteins C-N according to common technical knowledge at the filing.

Among proteins C-N, we showed similarity of the 3D structures and hydrophilic and hydrophobic partial areas thereof, which rationally cause the target activity of protein B having a similar 3D structure and hydrophilic and hydrophobic partial areas.

In addition, we showed newly obtained result of working example of protein B.

The above argued analysis, theory and technology was neither mentioned nor described in the original specification. • • • We failed.

When contribution of the specific 3D structures, hydrophilic and hydrophobic partial areas of working example proteins C-N necessary for the target effect (=analysis of working examples) are mentioned in the specification, the decision might be different.

Commonly known possible <u>mechanism regarding</u> <u>a target effect</u> described in a specification might be helpful.



With respect to a substance invention whose effect is unpredictable, such as bio-tech chemistry, it is usually difficult to broaden range of the claimed invention from an originally described working example(s).

*Additional working example is only acceptable when it supports an originally described working example(s). =A new working example showing an effect not mentioned in the original working example should NOT be acceptable.



Mechanical or electrical invention

The above explanation about the enablement requirement is not applied in mechanical or electrical invention.

That is because, effect of a mechanical or electrical invention is <u>predictable based on a structure</u>.

The effect is directly related to the mechanical or electrical structure in these inventions.



Enablement requirement (conclusion)

Pioneering invention should be able to claim a broader range than conventional inventions, so, unpredictable effect should be approved in a broader range, with substances similar to the working example(s).

With respect to the enablement requirement, an exemplary description or mention of a mechanism or theory of effect helps to broaden claimed range. Mentioning a literature showing known knowledge might be helpful.



Enablement requirement (conclusion)

Recently, the JPO patent allowance decision rate has increased to more than 75 %.

JPO examiners favor to patent allowance.

Please be optimistic about obtaining a chemical or bio-tech patent in Japan with tips on the enablement requirement provided here.

* * Explain your claimed effect is conceivable based on a working example(s) described in an original specification.

