



Further Study on the Sufficiency of Disclosure (Part II) (SCP/35/5)

Standing Committee on the Law of Patents (SCP)

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Presentation by the Secretariat

Sufficiency of disclosure

Applying general principles to certain technologies

- Further Study on Sufficiency of Disclosure (Part I) (SCP/34/5)
 - Microorganisms
 - Inventions that forms the AI technologies and inventions that involves the use of AI
- Further Study on Sufficiency of Disclosure (Part II) (SCP/35/5)
 - Chemistry
 - Biotechnology } *Experimental and less predictable art*

- *Legal principles as well as general guidance re. sufficiency of disclosure apply to all fields of technology.*
- *The further study to be read together with SCP/22/4 (Study on Sufficiency of Disclosure).*

Predictability of the art and sufficiency of disclosure

A person skilled in the art shall be able to “**carry out**”/”**perform**” the invention on the basis of the information disclosed in the application/description/specification, without “**undue burden**”/”**any inventive effort**”/”**undue experimentation**”.

Chemical/biotech inventions ...

Physical structure \leftrightarrow Technical effects?

Physical structure \leftrightarrow Properties, Usage?

In general, plausibility/credibility of the claimed invention more scrutinized than other fields.

- It must be plausible/credible that the full scope of the claimed invention would work and produce the claimed technical effect.
- Broad claims (ex. generalization of examples disclosed, numerous alternatives) require sufficient support.
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Undue burden/efforts/experimentation

- Case-by-case analysis, but some factors that may be considered in determining whether carrying out the claimed invention requires “undue” efforts for a person skilled in the art

The level of predictability of art	Nature of the invention	The breadth of the claims
Amount of guidance provided (explicit/implicit)	Common general knowledge	Amount and nature of additional experimentation required

- Qualitative and quantitative aspects are taken into account.
 - e.g. Reasonable trial and routine experiments
 - Certain errors or omission
 - Extent of working examples

Examples from some jurisdictions in SCP/35/5.

Supportive evidence and data

- Applicants may submit evidence to demonstrate that the application sufficiently disclose the claimed invention (e.g., experimental data and results).
 - To confirm the information already contained in the application as filed

- Evidence obtained after the filing date

Some offices allow applicants to rely on evidence that had not been public or experimental data that had not been obtained before the filing date to demonstrate sufficiency of disclosure.

- Such evidence can be used only to back up the disclosure in the application as filed

Examples from some jurisdictions in SCP/35/5.

Sufficient disclosure for carrying out the claimed invention

- How to make the claimed invention?

- Starting material
(or apparatus for manufacturing the claimed invention)
- Intermediate compounds

- How to use the claimed invention?

- Disclosure of claimed invention for medical use

- The effectiveness of the claimed therapeutic use of the compound plausible/credible?
 - Technical data, pharmacological study or other evidence
 - Representative examples covering the full scope of claims

The level of disclosure required depends on what can be considered undue burden for a person skilled in the art and common general knowledge

Examples from some jurisdictions in SCP/35/5.

Certain chemical inventions – Issues addressed

Markush claims

Broad claim covering many alternatives and disclosure of proportionate, representative working examples.

Stereoisomers and enantiomers

- Characterization and configuration of stereoisomers
- Process for isolating enantiomers

Composition and formulation

Clarity of the definition of compounds in the claims (e.g., general statement, definition solely by its use, form of administration etc.

Polymorph and Crystalline

Physical and chemical characterization of polymorph forms through appropriate techniques

Prodrugs

Functional definition of prodrugs and metabolites

Thank You