Patentability Criteria and Patent Grant Procedures at Country Level

Geneva

October 27, 2015

Tomoko Miyamoto
Head, Patent Law Section, WIPO

Patentability criteria in patent systems

- Formality requirements
  - Form and contents of patent application and other documents required
  - Procedural requirements (ex. time limits)
- Unity of invention
- Patentability criteria
  - Patentable subject matter
  - Novelty
  - Inventive step
  - Industrial applicability
  - Sufficiency of disclosure
- Prohibition of double patenting

Compliance with all requirements are necessary to obtain patent protection

WIPO
WORLD INTELLECTUAL PROPERTY ORGANIZATION

Certain aspects of national/regional patent laws

http://www.wipo.int/scp/en/annex_ii.html

Requirements under more than 100 national/regional patent laws on the selected aspects

- Prior Art
- Novelty
- Inventive Step (Non-obviousness)
- Grace Period
- Sufficiency of Disclosure
- Exclusions from Patentable Subject Matter
- Exceptions and Limitations to the Rights

Certain aspects of national/regional patent laws
http://www.wipo.int/scp/en/annex_ii.html

- The wording of various countries' statutes are similar with respect to certain requirements, but not the same.

ex. Inventive Step (Non-obviousness)

- The invention is not "obvious" to "a person skilled in the art" [having regard to the prior art][from the state of the art].
- The invention could not "easily have been made" by "a person with ordinary skill in the art" on the basis of the prior art.

- Terminology, semantics and interpretations

Prior art, grace period and novelty

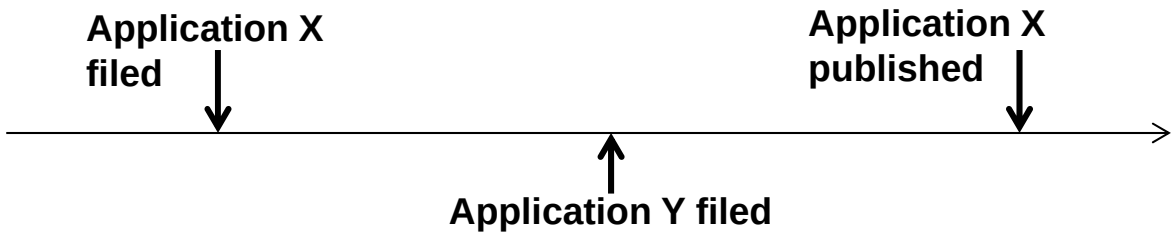
Principle

Novelty: The invention does not form part of the prior art

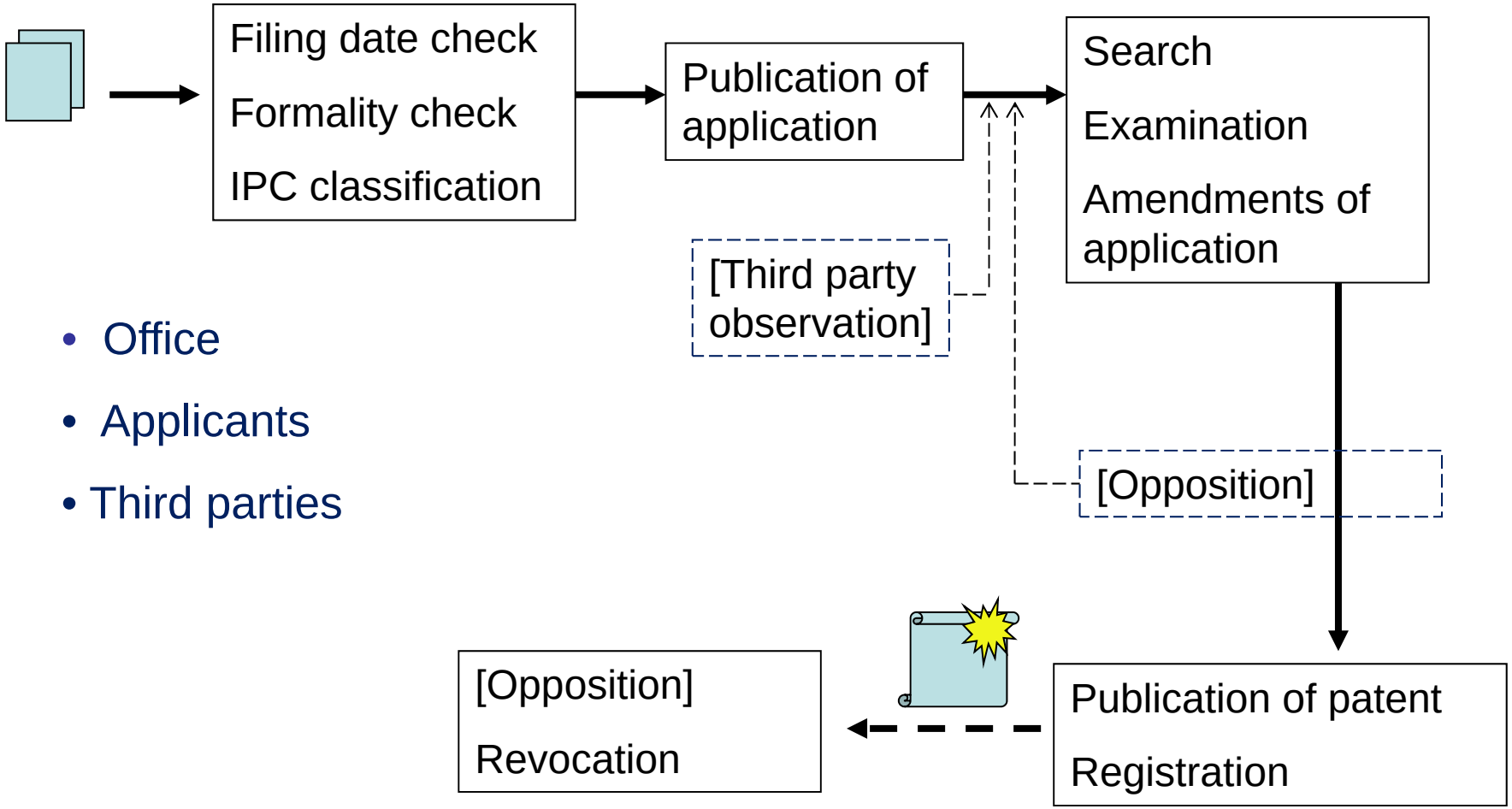
- Prior art = any knowledge made available to the public before the filing date of the relevant patent application

However:

- Publication of the claimed invention by the applicant in a scientific journal before the filing date destroys novelty of his patent application?
- Even if Application X has not been published before the filing date of Application Y, should it destroy the novelty of Application Y? How about inventive step?



Patentability criteria and patent procedures



- Office
- Applicants
- Third parties

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Chemical inventions

- Patent laws and regulations are technology neutral (chemical inventions are considered in the same light as other technical inventions).

←→ Predictability in the art may be different in various technical fields

The ability of a person skilled in the art to readily extrapolate known results/knowledge to the claimed invention.

→ In general, inventions in the fields of chemistry and biology is considered less predictable than mechanical or electrical inventions.

Predictability in the art affects the questions such as :

- What degree of disclosure is required by an applicant?

- What degree of inventiveness is required to be considered as not obvious?

Sufficiency of disclosure

An applicant must disclose the invention in a sufficiently clear and complete manner for the invention to be carried out by a person skilled in the art. (enabling disclosure requirement)

- In many countries, the application/specification/description must provide sufficient information so that a person skilled in the art can, on the basis of the information disclosed in the application as filed and the common general knowledge in the art, perform the invention without "undue burden", "any inventive effort" or "undue experimentation".
- Reasonable amount of trial and error is generally admissible.

Undue burden?

Factors to be considered include the breadth of the claims, the amount of direction provided in the application, the level of predictability in the art, among others.

Sufficiency of disclosure

- Example: China

The enabling disclosure requirement is not met when, for e.g. :

- the description sets forth only a task and/or an assumption, or simply expresses a wish and/or a result, providing no technical means that a person skilled in the art can implement;
- the description sets forth a concrete technical solution but without experimental evidence, while the solution can only be established upon confirmation by experimental results. For example, in general, the invention of a new use for a known compound requires experimental evidence in the description to validate the new use and effects thereof: otherwise, the requirement of enablement cannot be met.

- Working examples or prophetic examples?
- Experimental data?
- Association between an *in vitro* example and alleged *in vivo* therapeutic utility ?
- Post-filing date evidence (ex. support therapeutic utility)?