



**National Group:**

**Title:** Questionnaire Apotex Inc. v Sanofi-Aventis  
Proposed AIPPI intervention – Supreme Court of Canada appeal

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**Date:**

## Questions

### A. Utility or industrial applicability requirement

1. Does your national law have a utility or industrial applicability requirement for patentability?

Yes

2. Please briefly describe the utility or industrial applicability requirement, including whether it is based on:

- (a) statute;
- (b) jurisprudence; or
- (c) both.

The statute prescribes that a patentable invention must be suitable for industrial application and that the industrial application requirement is met when the invention can be manufactured or used in any type of industry, including agricultural industry (Art. 45 and 49 of the Italian IP Code)

3. What must be disclosed in the patent specification to satisfy the utility or industrial applicability requirement? In particular, must the patent specification disclose:

- (a) the utility or industrial applicability;
- (b) a basis (eg test data) to prove or demonstrate that the utility or industrial applicability is achieved; and/or
- (c) a basis (eg test data) and/or a line of reasoning from which the utility or industrial applicability may be predicted?

There isn't any specific requirement which obliges utility or industrial applicability to be explicitly disclosed in a patent application, but it should be inferred from the specification [therefore in some cases (b) or (c) may be sufficient to meet the utility or industrial applicability requirement]. Additional arguments and evidence may be supplied at any stage, provided that they refer to the disclosure as filed. An objection

of lack of utility or industrial applicability is raised when there is a high presumption that the invention cannot work as disclosed.

4. Is the basis for any disclosure required in the patent specification:
- (a) statute;
  - (b) jurisprudence; or
  - (c) both?

There is not such a requirement in relation to disclosure.

## **B. Prosecution**

5. Is it necessary to demonstrate utility or industrial applicability during prosecution?

Yes

6. Is the requirement to demonstrate utility or industrial application during prosecution based on:
- (a) statute
  - (b) jurisprudence; or
  - (c) both?

(a)

7. Is there a material date by which the utility or industrial applicability be demonstrated?

The utility or industrial applicability requirement must be met at the filing date of the patent application.

8. What evidence is required to demonstrate utility or industrial applicability? For example:
- (a) can post filing evidence be used; and/or
  - (b) can the applicant rely upon the utility or industrial applicability being soundly predicted as opposed to demonstrated?

Post filing evidence may be used during the prosecution of the patent application only to integrate the original disclosure of industrial applicability (Art. 172.2 C.P.I.). In certain cases, a sound prediction of industrial applicability may be sufficient to meet the statutory requirement.

## **C. Litigation**

9. Is lack of utility or industrial applicability a basis for a validity attack in litigation?

Yes

10. Is such attack permitted by reason of:

- (a) statute;
- (b) jurisprudence; or
- (c) both?

(c)

11. Is there a material date by which the utility or industrial applicability must be demonstrated?

The utility or industrial applicability requirement must be met at the filing date of the patent application.

12. What evidence may the patentee adduce in response? For example:

- (a) can post filing evidence be used; and/or
- (b) can the patentee rely upon the utility or industrial applicability being soundly predicted as opposed to demonstrated?

Post filing evidence may be used only to integrate the original disclosure when the industrial applicability of the invention or sound predictability thereof is already set forth in the patent application as filed.

There isn't any specific standard for proving utility or industrial applicability. The higher is the presumption of lack of this requirement, the more will be amount of evidence required.

### **Abstract**

The Italian IP Code provides utility/industrial applicability requirement, which is met when an invention can be manufactured or used in any kind of industry. It is not necessary that the utility/industrial applicability is explicitly disclosed in a patent, but it should be inferred from it. The requirement at issue must be met at the filing date of the patent application.

It is necessary to demonstrate it during prosecution and its lack can also be a basis for a validity attack in litigation. In particular, an objection of its lack is usually raised when it is maintained that the invention cannot work as disclosed.

There is not any specific standard to demonstrate the requirement under discussion. Post filing evidence may be adduced by the patentee, provided that it refer to the disclosure as filed.