



**National Group:** BRAZIL

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

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## Questions

### A. Utility or industrial applicability requirement

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

*[Please just answer 'yes' or 'no'. If 'no', you do not need to answer the remaining questions.]*

**Ans: Yes**

2. Please briefly describe the utility or industrial applicability requirement, including whether it is based on:
  - (a) statute;
  - (b) jurisprudence; or
  - (c) both.

**Ans: (a)**

**According to Article 15 of Law 9,279/96, inventions and utility models are considered to be susceptible of industrial application when they can be made or used in any kind of industry.**

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?

**Ans: (a), (b) and (c)**

**According to Normative Instruction 30/2013 issued by the Brazilian Patent Office, specifically in Article 2<sup>nd</sup>, item X, industrial utilization should be clearly indicated in the specification when it is not evident to predict the same from the invention's description.**

4. Is the basis for any disclosure required in the patent specification:

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

*[Please just answer (a), (b) or (c)]*

**Ans: (a)**

## **B. Prosecution**

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

*[Please just answer 'yes' or 'no'. If 'no', you do not need to answer questions 6-8 but please answer question 9.]*

**Ans: Yes, it will be necessary to demonstrate industrial application in case it is contested by the examiner during the substantive examination of the application or during a patent invalidity procedure.**

6. Is the requirement to demonstrate utility or industrial application during prosecution based on:

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

*[Please just answer (a), (b) or (c)]*

**Ans: (a)**

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

**Ans: Not specifically. In the administrative sphere, in case of office actions there is a 90 day period to file a response. In case of patent invalidity request, the applicant will have 60 days to contest and in case of rejection decision the applicant will have 60 days to appeal against such decision.**

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?

**Ans: Our local rules do not specify the accepted evidence. Therefore, all legal means are, in principle, acceptable.**

## **C. Litigation**

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

*[Please just answer 'yes' or 'no'. If 'no', you do not need to answer questions 10-12]*

**Ans: Yes**

10. Is such attack permitted by reason of:

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

*[Please just answer (a), (b) or (c)]*

**Ans: (a)**

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

**Ans: In principle, all defense arguments shall be submitted by the patentee within the 60 day period to file a response. However, evidence that substantiate such arguments may be demonstrated at a later stage.**

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?

**Ans: All means accepted by our law. Therefore, the patentee may use all means available to demonstrate the industrial application, provided that such means are not contrary to our legal framework.**