



National Group: JAPAN

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?

YES.

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

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

Statute.

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?

This is a complicated issue, of course. To state the most simplified conclusion, if the invention is directed to a new chemical compound, a statement of utility may suffice, but it is preferable to have experimental data. For the invention directed to pharmaceutical use of a known compound or substance, wet lab data (v. hypothetical or prophetic data) is required. Prediction alone does not work under normal circumstance.

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

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

(b)

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?

(c)

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

The filing or priority date.

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?

If we consider Plavix (small molecule and a selection from known genus),

(a) Probably no.

(b) Probably no.

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?

(a)

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

Most likely, the filing or priority date.

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?

If we consider Plavix (small molecule and a selection from known genus),

- (a) Probably no.
- (b) Probably no.