

National Group: Hungarian

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.

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

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

The industrial applicability requirement is based both on statute and jurisprudence in our country.

According to the Hungarian Patent Act, industrial applicability is a major prerequisite of patentability. Article 1 says: "(1) Patents shall be granted for any inventions in any field of technology that are new, involve an inventive step and are susceptible of industrial application."

Article 5(1) of the Patent Act reads as follows: "(1) An invention shall be considered susceptible of industrial application if it can be made or used in any sector of industry or agriculture."

Paragraph 5 of Chapter III of the Manual of Patent Examination (available only in the Hungarian language), issued by the Hungarian Intellectual Property Office (in the following: HIPO), deals in detail with industrial applicability in the following subparagraphs:

5.1 Definition of industrial applicability

5.2. Judgment on industrial applicability

5.2.1. Definition of "industry"

5.2.2. Definition of "applicability"

5.3 Judgment on medical, surgical and diagnostic methods

This latter subparagraph provides guidance in the respect what is considered to be an industrial application by the HIPO. In this respect it is worth to refer to the repealed (in 2007) Article 5(2) of the Patents Act which reads as follows:

"(2) In particular, the therapeutic or surgical procedures for the treatment of the human body or animals, as well as diagnostic procedures to be carried out on the human body or animals shall not be deemed susceptible of industrial application. However, this provision shall not apply to any product used in such procedures, in particular to any material (compound) and mixture."

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?

Although it is up to the HIPO and/or the relevant courts to decide whether industrial applicability is satisfactorily disclosed in a patent application and/or patent, the practice and the jurisprudence mostly requires the satisfaction of condition (c) as defined above. Our court practice demonstrates that the reasoned predictability of industrial applicability may effectively be questioned if the invention is doubtful to fulfill its declared goal as disclosed originally in the 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)]

(c)

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.]

Yes.

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)]

(c)

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

It is worth to cite Article 60(1) of the Patent Act in this respect:

"A patent application shall disclose the invention in a manner sufficiently clear and detailed for it to be carried out by a person skilled in the art on the basis of the description and the drawings. The industrial applicability of a sequence or a partial sequence of a gene shall be disclosed in the patent application."

Apart from the last sentence of this Article it is necessary, in our view, at least to define clearly the industrial applicability of the invention in the original patent application as filed.

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, e.g. new test data can be used in the prosecution but can't be inserted into the patent specification in view of a ban on introducing new matter. According to the best knowledge of the draftsmen of this report the problem of "predicted versus demonstrated" did not arise in our jurisprudence but we tend to state that, at least in certain "predictable" technical fields (e.g. new pharmaceutically active compounds) a sound prediction should suffice, while in other more uncertain technical fields (e.g. surprising apparatuses for energy production) demonstration may be required.

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]

Yes.

10. Is such attack permitted by reason of:

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

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

(c)

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

See our answer re point 7 above.

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?

See our answer re point 8 above.