

National Group: Sweden

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

Contributors: The Swedish Group through Jonas Westerberg

Date: 9 June 2014

Questions

A. Utility or industrial applicability requirement

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

Yes, a requirement for industrial applicability exists.

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

The requirement is based on statute. Section 1 of the Patents Act provides that a patent can be granted for an invention with industrial applicability. It is a separate patentability requirement distinct from novelty and inventive step.

For a general description of said requirement and Swedish law on the subject matter please see a copy of the national report on Q180 for Sweden, which is still relevant (although the Biotechnology Directive 98/44/EU has since been implemented in Sweden and some references to the EPC in the report uses old (EPC 1973) Article/Rule numbers).

In summary the precise scope of the industrial applicability requirement is not clear, it is very rarely used to refuse patent applications or revoke patents and in case law the Court of Appeal has in an older case (1984) concluded that the concept of industrial applicability “*was hardly intended to exclude from patentability inventions other than those that are completely without practical significance*”.

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?

Section 8 of the Patents Act requires that the patent specification contains information on how the invention can be applied in industry unless this follows already from the nature of the invention. In respect of inventions concerning (part of) gene sequences this information is mandatory. There is no further specification of how this requirement shall be met and as noted in the Swedish report on Q180 it is very uncommon that a patent application is refused due to lack of industrial applicability.

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

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

(a)

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?

Information on industrial applicability shall be included in the patent application as filed. However, the applicant is allowed to amend and complete the specification and drawings of the application prior to grant in case it is necessary in order to comply with i.a. the requirement in Section 8 of the Patents Act to show industrial applicability (Section 19 of the Patents Decree). However, such amendments must not cause the claims to cover something which does not have support in the 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?

There is no specific type of evidence specified in the statute. As noted above there is no requirement for any evidence or information in respect of industrial applicability at all in case this quality is evident from the nature of the invention. Post filing evidence can be used within the limits stated in the answer to question 7 above.

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?

Facts and evidence invoked in support of industrial applicability must normally be presented at the latest prior to start of the main hearing in the court of first instance. The court can dismiss further facts invoked after the commencement of the main hearing and on appeal there is an even stricter prohibition against the submission of new facts and evidence.

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?

There is no limitation in respect of the form of evidence that can be invoked (written, oral, expert, objects etc.) and the court shall decide the matter based on a free evaluation of all the evidence presented. As noted above and in the Swedish report on Q180, attacks on validity based on lack of industrial applicability are very rare.