

Questionnaire Apotex-Inc. v Sanofi-Aventis

National Group: Belgium

Title: Questionnaire Apotex-Inc. v Sanofi-Aventis

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Questions

5. 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;

In accordance with article 7 under the Belgian Patent Act of 28 March 1984 (hereafter "BPA") for a Belgian patent (application) (hereafter "BE patent")

This requirement is in line with article 57 under the European Patent Convention (hereafter "EPC") for an European patent validated in Belgium (hereafter "EP/BE patent"). This Article defines and explains the nature of the requirement in Art. 52(1) EPC that the subject-matter has to be "*susceptible of industrial application*".

Article 57 EPC- Industrial application

An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.

As defined by case law of the Boards of Appeal of the EPO, the notion of "industry" implied that an activity was carried out continuously, independently and for financial gain (T144/83). Merely because a substance could be produced in some ways did not necessarily mean that this requirement was fulfilled, unless there was also some profitable use for which the substance could be employed (T870/04).

A basic principle of the patent system is that exclusive rights could only be granted in exchange for a full disclosure of the invention, which includes the need to indicate how to exploit the invention. This indication must have "a sound and concrete technical basis", as a "speculative indication of possible objectives that might or might not be achievable

by carrying out further research with the tool as described was not sufficient to fulfil of the requirement of industrial applicability" (T1452/06).

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;

Under the BPA, such disclosure is only needed if the industrial applicability is not self-evident from the description or nature of the invention (Royal Decree 2 December 1986 Art. 9§1 7°)

Under the EPC, such disclosure is only needed if the industrial applicability is not self-evident from the description or nature of the invention (EPC Rule 42(f).)

In the special case of genes, a special rule has been inserted in the EPC: Rule 29(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

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,

but only if an objection is raised by the Office and the grant depends on the Office being satisfied that the requirement was met.

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?

NO,

the requirement must be met at the filing date, but the demonstration can be given later when required.

8. What evidence is required to demonstrate utility or industrial applicability? For example:

(a) can post filing evidence be used; and/or

YES,

as long as this post filing evidence is based on the disclosure of the patent.

(b) can the applicant rely upon the utility or industrial applicability being soundly predicted as opposed to demonstrated?

YES,
as the BPA as well as the EPC uses the term 'can be made or used'. (see T1452/06 cited above)

(b)

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

Under the BPA such validity attack on a BE or EP/BE patent is allowed by Art 49 §1 1).
Under the EPC such validity attack on a EP/BE patent is a ground for opposition by Art 100.

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

NO

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

- (a) can post filing evidence be used; and/or

YES,

as long as this post filing evidence is based on the disclosure of the patent.

(b) can the patentee rely upon the utility or industrial applicability being soundly predicted as opposed to demonstrated?

YES,

as the BPA as well as the EPC uses the term 'can be made or used'. (see T1452/06 cited above)