



National Group:

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.

(c).

The Israeli Patents Law provides, in section 3, that for an invention to be patentable it must, *inter alia*, satisfy the utility requirement.

The requirement under Israeli law with respect to the utility of an invention is that the patent application will promise that the invention satisfies its stated purpose. Proving such promise may be required at the opposition stage, if an opposition to the patent application is indeed filed on this ground, or when the patent is challenged after grant, as well as in infringement proceedings.

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?

At the time of submission of the patent application, and in order to satisfy the utility requirement, the specification must disclose the purpose which the invention seeks to achieve. The patent application must also include a promise that it does indeed achieve same, and provide a basis from which the utility of the invention may be predicted. As a matter of principle, the application need not include proof with regard to achievement of the invention's purpose, but it is conceivable that demonstrating that the utility is achieved will be required; for example, where the promise seems, *prima facie*, unreliable, or if there exists any reason to believe that the promise is untrue.

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.]

Not as such, unless the examiner is of the opinion that the promise is untrue on its face. In practice, evidence submitted - when necessary - to prove inventive step may sometimes also satisfy the utility requirement.

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)]

(b).

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

The utility of the patent must be demonstrated by reference to the state of the art at the date of submission of the patent application.

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?

We are not aware of any Israeli case law dealing with this specific issue; however, it is believed that the requirement under Israeli law for demonstrating the utility of a patent when undergoing prosecution proceedings, is not materially different from that needed to be demonstrated in litigation proceedings: applicant will be able to use post-filing of positive and concrete evidence (see Q12).

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?

The utility of the patent must be demonstrated by reference to the state of the art at the date of submission of the patent application.

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?

It is believed that, for the purpose of proving the utility of an invention, when that becomes an issue in litigation, it will not be sufficient for the patentee to provide a mere assumption - even if relatively strong - that the invention does satisfy its stated purpose, but it will be necessary to prove satisfaction of the purpose by means of positive and concrete evidence. In one case, which concerned a device for a crib intended to prevent "Sudden Infant Death Syndrome", an Israeli District Court held that in order to prove the utility of the invention, an expert opinion will need to be submitted, or - alternatively - the patentee must provide physical-theoretical evidence. It is assumed that, in practice, mere theoretical evidence will not suffice.