



National Group: Australia

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

Contributors:

Date:

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.

(c) Both.

There are two components to the test of utility under Australian laws.

1. *Australia has an explicit requirement of “usefulness” as specified by the Patents Act 1990. There are currently two usefulness tests in Australia based on the date that examination is requested of a complete patent application:*
 - a. *where examination is requested prior to 15 April 2013, the Patents Act 1990 requires under s18(1)(c) that the invention must be “useful”. The courts have interpreted “useful” to mean that the claimed invention must be able to produce the results that are promised in the specification (see Martin Engineering Co v Trison Holdings Pty Ltd (1989) 14 IPR 330 and Pracdes v Stanilite (1995) 35 IPR 259).*
 - b. *where examination is requested post 15 April 2013, the amended Patents Act 1990 requires under s7A and s18(1)(c) that an invention is taken not to be useful unless “a specific, substantial and credible use for the invention (so far as claimed) is disclosed in the complete specification”. As this is a recent amendment, there is as yet no jurisprudence on this issue.*

2. *Australia also requires that the invention claimed be to a manner of manufacture (s18(1)a of the Patents Act 1990 for standard patents and s 18(1A)a for innovation patents), which imposes an additional requirement of usefulness. The courts have interpreted s18(1)(a) to mean that the invention must be one that “offers some advantage which is material” and “its value to the country is in the field of economic endeavour.” (National Research Development Corp v Commissioner of Patents (1959) 102 CLR 252, 275.)*
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?

Pre 15 April 2013, the specification must disclose a manner of manufacture and must disclose the claimed invention such that it can in fact produce the results that are promised.

Post 15 April 2013, in addition to this requirement, the specification must disclose “a specific, substantial and credible use” It appears from the external legislative materials (explanatory memoranda) that this requires:

- *there must be a specific use to the subject matter and the claimed invention can provide a well-defined and particular benefit to the public.*
- *the claimed invention must show that it is useful to the public as disclosed and does not require further research to identify or reasonably confirm a real world use.*
- *use is credible unless there is evidence that the invention does not operate to produce the results claimed by the patent application or there is reason to doubt the objective truth of the statement in the specification.*

The courts have yet to consider this requirement.

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) Both

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. For patent applications for which examination is requested after 15 April 2013, usefulness is a ground of examination, opposition and revocation.

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)]

(a) Statute

Once there is jurisprudence on the newly defined usefulness requirement it is expected that the jurisprudence will be applied by IP Australia during examination.

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

Yes. For applications for which examination is requested before 15 April 2013, utility must be shown at the date of the invention (not later than the grant date). For patents filed after 15 April 2013, there must be "a specific, substantial and credible use" for the claimed invention disclosed in the complete specification at the date of the invention which is not later than the grant date.

The addition of data to establish utility post-filing is likely to be considered to add of new matter. However, additional post filing evidence (e.g. tests) could presumably be adduced based on data disclosed in the specification 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?

For applications for which examination was requested before 15 April 2013, post filing evidence could be taken into account to establish utility. However, knowledge from after that date could not be taken into account. The onus is on the party seeking to establish that a patent is not valid to prove inutility.

For patents for which examination is requested after 15 April 2013, there must be "a specific, substantial and credible use" for the claimed invention disclosed in the complete specification.

To the extent that the current definition places an emphasis on what is disclosed in the specification, this is a new test to be applied by IP Australia. It is expected that, over time, the question of whether (a) post filing evidence can be used to demonstrate utility (or the converse) will be addressed by the courts.

It appears from the explanatory memoranda that a specification will not meet the requirement if further invention would be required to ascertain the use or to put it into practice. The explanatory memoranda suggests that this "ensures that the public is given sufficient information in the specification to understand how the invention is useful and how to put that use into practice".

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) Both

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

Yes. For patents for which examination was requested before 15 April 2013, it must be shown that the invention was useful at the date of the patent (which is not later than the date of grant).

For patents for which examination was requested after 15 April 2013, there must be “a specific, substantial and credible use” for the claimed invention disclosed in the complete specification at the date of the invention, which is not later than the grant date. The addition of data after filing to establish utility is likely to be considered to be the addition of new matter. However, additional post filing evidence (e.g. tests) could presumably be adduced based on data disclosed in the specification as filed.

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?

Pre 15 April, the patentee could adduce post-filing evidence and there was no requirement that utility be demonstrated in the specification itself (and the onus was on the party seeking to invalidate the patent to show inutility).

As set out above, there is no jurisprudence on the post 15 April 2013 definition of usefulness and thus it is unclear how the new law will be applied.