



National Group: Singapore

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.

Both. The need for Utility is covered in case law, while the requirement for Industrial Applicability is statutorily defined.

Industrial applicability as a requirement is based on statute in Singapore under Section 13(1) the Patents Act (Cap 221, 2005 Rev. Ed.).¹

Under the Patents Act, in order for an invention to be patentable, it must possess novelty, inventive step and be capable of industrial application. Therefore, industrial applicability is an additional requirement for patentability.

Section 16 of the Patents Act provides guidance on industrial applicability. It provides that “*an invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture.*” (emphasis added)

This excludes any “*invention of a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body shall not*

¹ Adopted from the English Patents Act 1977.

be taken to be capable of industrial application.” However, products used in a method of treatment or diagnosis can be capable of industrial application.

Utility is not defined as a specific requirement of patentability under the Patents Act. However, it was considered by the Singapore Court of Appeal in *Merck & Co Inc v Pharmaforte Singapore Pte Ltd* [2000] SLR(R) 708 (“*Merck*”).

The Court of Appeal followed the position in the pre-1949 UK Patents Act, which similarly did not contain a requirement for utility. They found that although there was no provision allowing revocation on the basis of inutility, the court was not precluded from considering the question of utility in determining patentability.

The court quoted the following passage from Alsop’s Patent (1907) 24 RPC 733 which it felt was pertinent:

“In considering the validity of a patent for a process it is, therefore material to ascertain precisely what the patentee claims to be the result of the process for which the patent has been granted; the real consideration for which he gives for the grant is the disclosure of a process which produces a result, and not the disclosure of a process which may or may not produce any result at all. If the patentee claims protection for a process for producing a result and that result cannot be produced by the process, in my opinion the consideration fails. Similarly, if the patentee claims a process producing two results combined and only one of these results is in fact produced by the process, there is a partial failure of consideration ... and such partial failure of consideration is sufficient to avoid the patent ... Objections to patents on [this ground] are sometimes treated as objections for want of utility, and when so treated the **well known rule is that the utility of an invention depends upon, whether by following the directions of the patentee, the result which the patentee professed to produce can in fact be produced.** Want of utility in this sense must be distinguished from want of utility in the sense of the invention being useless for any purpose whatsoever. In the case of an invention not serving any useful purpose at all, the patent would no doubt be void, but not entirely for the same reason. It would probably be void at common law on the ground that the King’s prerogative could not be properly exercised unless there were some consideration moving to the public, and the public could not be benefited by the disclosure of something absolutely useless.”

It further quoted with approval the old English case of *Lane Fox v Kensington & Knightsbridge Electric Lighting Co Ltd* [1892] 3 Ch 431 where Lindley LJ opined:

“The utility of the alleged invention depends ... on whether by [directions in the complete specification] the effects which the patentee professed to produce could be produced ... Utility is often a question of degree, and always has reference to some object. Useful for what? It is a question which must be always asked and the answer must be, useful for the purposes indicated by the patentee.”

Utility also appears to be linked to the fundamental principle that discoveries are not in themselves, patentable. A mere discovery, for instance, of a naturally occurring material or microorganism would be a discovered, which is not patentable unless new use is found. In *Kirin-Amgen v Hoechst Marion Roussel* [2005] RPC 9, the invention related to the production of erythropoietin by recombinant DNA technology. In this case, erythropoietin had been a particularly elusive goal because it had been difficult to obtain sufficient quantities to carry out the necessary research. The prior art disclosed the N-terminal sequence of erythropoietin (with two incorrect base

residues). The application in question claimed a DNA sequence and a recombinant polypeptide. The Court considered that the invention did not lie in the DNA sequence – this was considered to provide information only – but there was patentable subject matter in the isolation and the process of making erythropoietin.

To summarize, Singapore does appear to recognize “utility” as an implicit requirement, although it is not specifically mentioned in the legislation.

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?

(a) Disclosure of Industrial Applicability

Rule 19(5)(f) of the Patent Rules (1/1995, 2007 Rev. Ed.), states that the patent specification at the point of application shall include a description which, *inter alia*, “indicate(s) explicitly, when it is not otherwise obvious from the description or the nature of the invention, the way or ways in which the invention satisfies the condition in section 13(1)(c) [of the Patents Act] of being capable of industrial application.” (emphasis added)

(b) Disclosure of a basis to demonstrate the achievement of industrial applicability

There appears to be no statutory requirement for the disclosure of such a basis. That said, in the absence of authority considering the matter in reported cases, it remains an open legal question whether such disclosure is necessary.

However, the Patents Rules, Patents Act and Intellectual Property Office of Singapore (IPOS) guidelines and reported case law are silent on the precise form such support should take (e.g. whether test data is required).

(c) Disclosure of a basis to predict industrial applicability

See answer to question (b).

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)]

- (a) statute

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)]

(a) Statute.

7. Is there a material date by which the utility or industrial applicability be demonstrated? Presumably, the application for an invention must meet the patentability requirements as at the priority date of the application, and it should be demonstrated that industrial applicability resides in the invention as at that date. During the prosecution process, the applicant will have the opportunity to satisfy the Registrar as to the industrial applicability of the invention.
8. What evidence is required to demonstrate utility or industrial applicability? For example:
 - (a) can post filing evidence be used; and/or
The Applicant may submit data or evidence after the date of filing in order to address objections (including industrial applicability objection) raised by the Examiner. Whether the data or evidence will be admitted depends on the technological field and individual case. Generally, as long as support could be found in the original disclosure (no new teaching), the submitted data may be considered by the Examiner.²
 - (b) can the applicant rely upon the utility or industrial applicability being soundly predicted as opposed to demonstrated?

It is an open question whether a sound prediction is sufficient, without more, to demonstrate industrial applicability; the Patents Act, Patents Rules and Guidelines issued by the Intellectual Property Office of Singapore (IPOS) do not state the type of evidence required, and there have been no reported cases on the issue. However, presumably there must be industrial applicability as a question of fact.

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]

² Intellectual Property Office of Singapore, “**Examination Guidelines for Patent Applications at IPOS**”, http://www.ipos.gov.sg/Portals/0/Patents/Examination%20Guidelines%20for%20Patent%20Applications%20at%20IPOS_Feb%202014.pdf

Yes.

Is such attack permitted by reason of:

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

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

Statute.

- (a) Is there a material date by which the utility or industrial applicability must be demonstrated?

In the context of litigation, there is no deadline prior to a trial which such Industrial Applicability must be demonstrated.

If the validity of a patent is challenged by application to the Registrar, or raised as a defence or counterclaim in the course of an infringement suit, the patentee would have to demonstrate the Industrial Applicability at trial.

- (b) What evidence may the patentee adduce in response? For example:

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

During the course of a trial, a patentee can submit evidence including expert evidence, ,and experiments, subject to rprocedural requirements.

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

Yes, but the predictions cannot be too vague or speculative.

There have been no reported cases in Singapore which considered the question of whether a sound prediction was sufficient, without more, to demonstrate utility or industrial applicability.

At least in the field of genomics, in the absence of Singapore authority, the UK position, as decided by UK Supreme Court, may be persuasive.

In the 2011 case *Human Genome Sciences v Eli Lilly* [2011] UKSC 51, Lord Neuberger did not disturb the Technical Board of Appeal of the European Patent Office's (EPO) decision in *T 1329/04 Factor-9/John Hopkins*, which indicated that:

“Where a patent discloses a new protein and its encoding gene...The absence of any experimental or wet lab evidence of activity of the claimed protein is not fatal” and that “A “plausible” or “reasonably credible” claimed use, or an “educated guess”, can suffice”.

(emphasis added)

However, the UKSC in *Human Genome* held that the objection was there made out as the proposed applications for the subject matter of the patent were “vague and speculative” and no practical

method of exploitation was disclosed. It cautioned against allowing “patenting too far upstream“, agreeing with the EPO’s Technical Board of Appeal that “the purpose of granting a patent is not to reserve an unexplored field of research for an applicant.“

The applicability of this case beyond the narrow confines of genomics is also unclear. In summary, patentees can rely on sound predictions of Industrial Applicability.