Questionnaire

Apotex-Inc. v Sanofi-Aventis

1. Introduction

In *Apotex Inc. v Sanofi-Aventis*, the Supreme Court of Canada has granted leave to Apotex Inc to appeal the validity of a Canadian pharmaceutical patent that claims clopidrogel bisulfate (Sanofi-Aventis' Plavix). The appeal will relate to the Canadian disclosure requirements for patent validity. Specifically, it will relate to the disclosed utility - industrial applicability in some jurisdictions - or "promise" of the patent.

This is a very topical issue. Disclosure requirements to demonstrate utility or industrial applicability is the subject of a workshop at the Toronto Congress in September this year.

While recognizing that this is an area which is not completely harmonized at an international level, the Bureau considers that a limited intervention by AIPPI to bring international standards of utility (or industrial applicability) to the attention of the Supreme Court of Canada could assist the Court.

It is not intended that AIPPI take a position on the substantive legal issues to be decided by the Supreme Court. AIPPI's intervention would simply present the current law in different jurisdictions.

To that end, the Bureau seeks the urgent input of the Groups in relation to the questions in section 5 below. Responses are required by **9 June 2014**.

2. Background - utility and the "promise of the patent"

Section 2 of the Canadian *Patent Act* defines an "invention" as "…any new and *useful* art, process, machine, manufacture or composition of matter..." or improvement therein.

Under Canadian law, an invention is "not useful" if the invention will not work, either in the sense that it will not operate at all or that it will not do *what the specification promises it will do*.

Generally, there is no obligation to disclose the utility of the invention in the patent. However, if the skilled person would understand the patent to contain an explicit promise

of a specific result, the patentee will be held to the promise made. If not, no particular level of utility is required - a "mere scintilla" of utility will suffice.

Depending on the nature of the invention, it may be necessary that the patent disclose or promise a particular utility. For example:

- A patent claiming a new use of a known compound presumably promises that the compound is useful for the claimed purpose.
- In the case of a selection patent claiming compounds falling within a previously disclosed genus, patentability resides in identifying an advantage possessed by the selected compounds over the genus. The selection patent must promise an advantage in the sense that, if the advantage is not promised, the patentee will not be able to rely on the advantage to support the validity of the patent. [1]
- Similarly, if an advantage is needed to establish inventiveness, the advantage might be considered a promised utility. [2]

Although issues of promised utility have most commonly arisen in the context of patents concerning pharmaceutical products, issues can arise in any technical discipline, including patents concerning mechanical inventions. [3]

If a patent is challenged on grounds of lack of utility, the patentee must be able to show that *as of the Canadian application filing date* (i.e. the PCT international filing date), the utility of the invention had been demonstrated or could be "soundly predicted". [4]

Thus, there are three key questions to be answered:

(1) Does the patent promise a specific result (i.e. utility)?

(2) Was this utility demonstrated at filing?

(3) If not, was this utility soundly predicted?

With respect to demonstrated utility, the patentee may be able to rely on data obtained before the filing date that is not disclosed in the patent. [5] The threshold for demonstrated utility can be high, particularly in pharmaceutical cases. In some cases, pre-filing clinical studies have been found to be insufficient to constitute demonstrated utility on the basis that the study e.g. was not of sufficient scale or duration. [6]

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1 *Eli Lily Canada Inc. et al. v Novopharm Limited* 2010 FCA 197 (olanzapine) at para. 78.

2 *Hoffmann-La Roche Limited v. Apotex Inc.* 2011 FC 875 (mycophenolate mofetil) at para. 22.

3 *Bell Helicopter Textron Canada Limitée v. Eurocopter* 2013 FCA 219.

4 *Sanofi-Aventis v. Apotex Inc.* 2013 FCA 186 (clopidogrel), at para. 46.

5 *Teva Canada Ltd. v. Pfizer Canada Inc.* 2012 SCC 60 (sildenafil) at para. 42. The patent referenced but did not disclose the results of a pre-filing clinical trial demonstrating the use of sildenafil citrate to treat erectile dysfunction.

6 See e.g. *Eli Lilly & Co. v. Teva Canada Limited* 2011 FCA 220 (atomoxetine) at para. 31-43.

If utility has not been demonstrated at the Canadian filing date, the sound prediction test is applied. For a "sound prediction", there must be:

(a) a factual basis for the prediction;

(b) a sound line of reasoning which can be articulated and from which the desired result can be inferred from the factual basis; and

(c) proper disclosure. [7]

The factual basis and line of reasoning for a sound prediction must be disclosed in the patent or be within the common general knowledge of the person of ordinary skill in the art. [8] A sound prediction requires "a reasonable *prima facie* inference of utility." [9] Sound prediction does not mean a certainty, and presupposes that further work remains to be done. [10]

Because demonstrated utility and sound prediction are assessed as of the Canadian application filing date, post-filing data are not relevant to demonstrated utility or to a sound prediction of utility – a bare speculation, even if it afterwards turns out to be correct, is insufficient. [11]

It has become common in attacking the validity of Canadian patents to assert that the patent makes a promise of utility that was not demonstrated or soundly predicted at the Canadian filing date, such that the patent is invalid even if the claimed subject matter would be understood to serve some useful or practical purpose – i.e. possess a "scintilla" of utility.

3. *The present case – Sanofi-Aventis v Apotex Inc*

The patent in question claims clopidogrel bisulfate *per se*.

The Canadian Federal Court of Appeal held that the patent was a proper selection over a prior art genus, and that the advantages as to the therapeutic index of the claimed compound over the genus patent had been demonstrated.

The Court of Appeal held that there was no explicit promise for use in humans, despite description in the patent of suitable dosage forms and doses covering ranges useful in humans.

In January 2014, the Supreme Court of Canada granted Apotex Inc leave to appeal. The Supreme Court is expected to address issues regarding the assessment of the promised utility of a patent.

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7 *Apotex Inc. v. Wellcome Foundation Ltd.* 2002 SCC 77 (AZT) at para. 70.

8 *Eli Lilly Canada Inc. v. Apotex Inc.* 2009 FCA 97 (raloxifine) at para. 15; *Eli Lilly and Company v. Teva Canada Limited* 2011 FCA 220 (atomoxetine) at para. 57; *Eurocopter supra*. at para. 155.

9 *Lilly* (olanzapine), *supra.*, at para. 85.

10 *Wellcome Foundation, supra*. at para. 77.

11 *Wellcome Foundation, supra.* at para. 84.

4. Timing

The expected hearing date for the Supreme Court appeal is 4 November 2014.

Any application by AIPPI for leave to intervene is likely to be due by **23 June 2014**. The application must set out the submissions AIPPI would wish to make on the appeal.

Accordingly, answers to the questions below are required by **9 June 2014** in order to analyse the responses and decide whether they provide sufficient information that would justify an application by AIPPI to intervene.

5. Questions

A. Utility or industrial applicability requirement

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

   [Please just answer 'yes' or 'no. If 'no', you do not need to answer the remaining questions.]

Yes
The industrial applicability requirement shall be distinguished from the utility requirement which does not exist in French law.

2. Please briefly describe the utility or industrial applicability requirement, including whether it is based on:

   (a) statute;

   (b) jurisprudence; or

   (c) both.

The industrial applicability requirement is based on both statute and jurisprudence.

The industrial applicability requirement is provided for by statute:

- for a French designation of European patent, Article 52 of the European Patent Convention Article 57 of the European Patent Convention,:
  "*European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application*." (Article 52 of the European Patent Convention),

  "*An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.*"
  (Article 57 of the European Patent Convention),
- for a French patent, Article L. 611-10 and Article L. 611-15 of the French intellectual property code:
  "*Inventions, in all technological fields, which are new and which involve an inventive step and which are susceptible of industrial application, shall be patentable.*" (Article L. 611-10 of the French intellectual property code),

  "*An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture*."
  (Article L. 611-15 of the French intellectual property code).

The absence of industrial application constitutes a grounds of invalidity of the patent according to Article L. 613-25 a) of the French intellectual property code and Article 138 a) of the European Patent Convention: accordingly the French courts assess the fulfilment of this condition when it is challenged by a party claiming the revocation of the patent.

The threshold to meet the industrial application requirement is low:

- the term "*industry*" is construed very broadly: it covers any kind of technical or commercial activity,
- the word "*application*" is also very broad: it suffices that the subject-matter of the invention can be manufactured or used in any kind of industry.

In addition, it is enough that the invention is "*susceptible*" of industrial application, *i.e.* that an application is possible, without the need to demonstrate an actual application.

According to the legal writings and case law, there is no requirement of utility, quality of the result, or improvement.

Lack of industrial application is rarely admitted by the courts.

In case a serious doubt exists about the possibility to implement the invention, the sufficiency requirement could be more relevant.

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?

Requirements as to the content of the patent specification with regard to industrial application are very limited.

It is enough to mention the technical field of the invention and the way in which the invention is industrially applicable, when it is not obvious from the description or the nature of the invention.

Article R. 612-12 of the French intellectual property code, concerning French patents, indicates that:

> *"The description shall contain:*
>
> *1°. A statement of the technical field to which the invention relates;*
>
> *[…]*
>
> *6°. A statement of the way in which the invention is capable of exploitation in industry if such exploitation is not obvious from the description or the nature of the invention.*

Rule 42 of the Implementing Regulations to the European Patent Convention applying to the French designations of European patents has almost the same wording:

> *"(1) The description shall:*
>
> *(a) specify the technical field to which the invention relates;*
>
> *[…]*
>
> *(f) indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.*
>
> *[…]"*

For completeness, please note that specific requirements exist concerning inventions relating to sequences and partial sequences of genes: Article 5 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions and Rule 29 Implementing Regulations to the European Patent Convention provide that "*the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application*".

Article L. 611-18 of the French intellectual property code, implementing Article 5 of Directive 98/44/EC, provides more broadly that for all elements of the human body the *"use must be disclosed in the patent application in a concrete and precise manner"*.

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.]

No, unless requested by the office.

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?

It shall be demonstrated at the date of the patent application or of the claimed priority if any.

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?

Any evidence that the invention was "*susceptible*" of industrial application at the time of filing is enough to fulfil the industrial application requirement.

Later evidence can also be taken into account to supplement prior evidence, but not as the sole basis to demonstrate industrial applicability.

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)]

(a) statute

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

It shall be demonstrated at the date of the patent application or of the claimed priority if any.

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?

Any evidence that the invention was "*susceptible*" of industrial application at the time of filing is enough to fulfil the industrial application requirement.

Later evidence can also be taken into account to supplement prior evidence, but not as the sole basis to demonstrate industrial applicability.