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.

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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?

   Yes, requirement for industrial applicability. There is no Danish jurisprudence specifically dealing with industrial applicability. For all practical purposes, Danish practice will follow the practice of the EPO

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

   The requirement is based on statute, i.e.Patents Act Section 1.1 and Art 57 EPC: An invention shall be considered as susceptible of Industrial application if it can be made or used in any kind of industry, including agriculture. The criterion mainly serves to distinguish from phenomina of "non –technical " nature and does not encompass a requirement for "usefulness".

   Also, a body of case law has been handed down by the Boards of Appeal of the EPO. Generally speaking, Art. 57 has seldom been a problem, except in more speculative cases of gene technology. A clear message is that each case is decided on its own merits.

3. What must be disclosed in the patent specification to satisfy the industrial applicability requirement? In particular, must the patent specification disclose:

   (a) the industrial applicability;

   Yes, in general it is required that the description of an EP patent application should, where it is not self-evident, indicate the way in which the invention is capable of exploitation in industry. The invention claimed must have such a sound and concrete technical basis that the skilled person can recognize that its contribution to the art could lead to a practical exploitation in industry (see T898/05) Guidelines G III-2

(b) a basis (eg test data) to prove or demonstrate that the industrial applicability is achieved;

Test data may mainly be required to substantiate that "the problem of the invention has been solved" (i.e to justify inventive step (Art 56 EPC) or sufficient disclosure (Art 83 EPC)The more so if a selection invention or "new medical use " is claimed

(c) a basis (eg test data) and/or a line of reasoning from which the industrial applicability may be predicted?

If there are no pertinent data in the application as filed, some EPO case law has required that it was "plausible" that the invention was ready (Art 56 EPC) or worked (Art 83EPC), in which case it was permissible to file post-published evidence, but not as the sole basis. This line of reasoning probably comes close to the "sound prediction" under Canadian law

4.Is the basis for any disclosure required in the patent specification:

Both statute and jurisprudence;

B. Prosecution

5. Is it necessary to demonstrate utility or industrial applicability during prosecution?

'yes'

6. Is the requirement to demonstrate utility or industrial applicabilitiy 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?

The industrial applicability must be apparent from the application 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?

This is case dependent. If e.g. an industrial applicability has been rendered plausible (soundly predicted) by in silico analysis (see T898/05) post filing

evidence is likely to be accepted

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?

(c)

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

The filing date or priority date as applicable

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?

Both, according to circumstances