National Group: **CHINA**

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?

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

Answer：Yes.

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

   (a) statute;
   (b) jurisprudence; or
   (c) both.

Answer: (c).

Article 22 and Article 26 of Chinese Patent Law is the statute that the utility or Industrial applicability requirement based on.

The utility or industrial applicability requirement is basically required by Article 22 of Chinese Patent Law which describes that: practical applicability means that the invention or utility model mode can be made or used and can produce effective results.

In addition, Article 26, paragraph 3 of Chinese Patent Law describes that: the description shall set forth the invention or utility model in a manner sufficiently clear and complete so as to enable person skilled in the relevant field of technology to carry it out.

For the jurisprudence, please refer to the answer to question 3 which mainly comes from the Patent Examination Guideline as well as to answers 8and 12.

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?

Answer:

1. As for patent application in the field except for chemistry, pharmaceutics and biotech, there is no special requirement for the specification, as long as a skilled person in the art can reproduce the patented product or method.

2. As for a chemical product invention, the use and/or its technical effect of the product shall be completely described. Even the structure of the compound has been confirmed for the first time, at least one use of the compound shall be described.

If a person skilled in the art is unable, on the basic of the prior art, to predict that the use and/or its technical effect stated in the invention can be carried out, the description shall sufficiently provide qualitative or quantitative data of experimental tests for the person skilled in the art to be convinced that the technical solution of the invention enable the use of to be carried and/or the effect as expected to be achieved.

As for the property data showing the effect of the invention, the method used to measure it shall be specified when various measuring methods for it in the prior art yield different results. If it is a special method, it shall be explained in detail to enable a person skilled in the art to carry it out.

3. As for use invention of a chemical product, the description shall describe the chemical product to be used, the method for using the product and the effect to be achieved to enable a person skilled in the art to carry it out. If a person skilled in the art can not predict the use according to the prior art, the description shall sufficiently provide data of experimental tests for a person skilled in the art to be convinced that the product is useful for said use and can solve the problem or achieve the technical effect expected.

4. For a new pharmaceutical compound or pharmaceutical composition, not only its specific medical use or pharmacological action, but also its effective amount, and method of application shall be described. If a person skilled in the art is unable, on the basis of the prior art, to predict that said use or action stated in the invention can be carried out, qualitative or quantitative data of the laboratory test (including animal test) or clinical test shall be sufficiently provided for the person skilled in the art to be convinced that the technical solution of the invention can solve the technical problem or achieve the technical effect as expected.

5. For an invention of a gene, a vector, a recombinant vector, a transformant, a polypeptide or a protein, a fused cell, a monoclonal antibody, etc., the description will describe the use and/or technical effect of the product, and specify the technical means, condition, etc. which is needed to obtain said effect.

For example, the applicant shall submit evidence in the description to show that the gene that has the special function.

6. For an invention of a process for producing a gene, a recombinant vector, a transformant, a polypeptide or a protein, a fused cell, a monoclonal antibody, etc., the

description shall describe said process in a manner sufficiently clear and complete so as to enable a person skilled in the art to prepare the product by using said process and at least one use of said product shall be described in the description when said product is novel.

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)]

Answer: (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.]

Answer:
Usually, for an application in the field except for chemistry, pharmaceutics and biotech, the answer is 'no'.
However for an application in the field of chemistry, pharmaceutics and biotech, the answer is "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)]

Answer: (c)

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

Answer: the filing day.

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?

Answer:
(a) The post filing evidence except for evidence used for common knowledge in the art such as text book, manual book and the like, can not be used.
(b) The applicant can rely upon the utility or industrial applicability being soundly predicted to demonstrate. However, the applicant should prove, with evidence, that the utility or industrial applicability being soundly predicted.

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]

Answer:
Yes.
However, the court can not invalid a patent right in a civil case.
The defendant has to invalid a patent right though an invalidation procedure before a patent reexamination broad which is settled within the SIPO (State Intellectual Property Office)). Lack of utility or industrial applicability is a basis for a validity attack during the invalidation procedure.

10. Is such attack permitted by reason of:

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

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

Answer: (a)

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

Answer: The filing day.

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?

Answer:
(a)The post filing evidence except for evidence used for common knowledge in the art such as text book, manual book and the like, can not be used.
(b)The patentee can rely upon the utility or industrial applicability being soundly predicted as opposed to demonstrated. However, the right holder may have to prove that the utility or industrial applicability can be soundly predicted.