National Group:	**The Netherlands**
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

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 legal basis for the requirement can be found in Art. 27 TRIPs agreement, Art. 1 & Art. 3 Strasbourg Patent Convention, Art. 57 European Patent Convention (hereinafter: "EPC"), and in Art. 2(1) Dutch Patent Act 1995 (hereinafter: "DPA"). Although in the footnote (5) of the TRIPs provision, member states are allowed to interpret the requirement as meaning "useful", both the Dutch and European statute provisions follow the Strasbourg Convention (Art. 3) in that an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry including agriculture.

   In applying the Dutch requirement of industrial applicability, the Dutch courts usually follow the interpretation of the counterpart provision in the EPC and the case law of the Boards of Appeal of the European Patent Office (hereinafter: "EPO"). Amongst others, the Boards of Appeal, have emphasized in various cases that the industrial applicability requirement is related to the (other) requirement for patentability (Art. 83 EPC), that the invention is disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, wherein the notion "industry" is to be interpreted broadly to include all manufacturing, extracting and processing activities of

enterprises that are carried out continuously, independently and for financial (commercial) gain.

Articles 52 and 53 EPC specify that some subject-matter and activities are excluded from patentability. In the previous version of the EPC (EPC1973), Art. 52(4) provided that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body shall not be regarded as susceptible of industrial application. This led to discussions regarding the patentability of inventions in the medical arena, such as inventions pertaining to dosage regimen . The new version of the EPC (EPC2000) still excludes the same methods of medical treatment from patentability, but no longer links this exclusion to industrial applicability. The Enlarged Board in G2/08 emphasized that Art. 53(c) EPC 2000 just states that patents shall not be granted in respect of methods of treatment, and that, for instance, dosage regimen claims are at least allowable in regard of the industrial applicability requirement. This has somewhat limited the discussion; however, under Art. 57 EPC (2000) and as confirmed by the Enlarged Board in G1/03, subject-matter may be excluded from patentability for non-technical reasons. If a method for contraception is claimed, this may be considered not to be susceptible of industrial application when applicable to human beings only in the private sphere (T 74/93, OJ EPO 1995, 712), whereas the application to domestic animals, e.g. for breeding purposes, is patentable.

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?

    Rule 42(1) (f) EPC stipulates that the description should indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable.

    In case the invention is concerned with a sequence or partial sequence of a gene, the application must specify the function and industrial applicability of the sequence or partial sequence. (Art. 25(3) DPA and Rule 29(3) EPC: the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application). This requirement has been introduced in the law in the implementation of the EC Biotechnology Directive, recital 23 (which results in national law being interpreted accordingly): a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention, and article 5(1): simple discovery of an element of the human body including a sequence or partial sequence of a gene, cannot constitute patentable inventions.

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

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

    (c)

B. Prosecution

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

   Yes

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

   Neither the DPA nor the EPC stipulates when the applicant must provide evidence which demonstrates the utility or industrial applicability of the invention.

   For Dutch national applications, there is no substantive examination. A novelty search report is drawn up which is provided to the applicant together with a preliminary opinion on the patentability of the invention. This opinion may or may not contain a statement on the industrial applicability of the claimed invention. The applicant has the opportunity to file amendments to his application in reaction to the novelty search report and preliminary opinion, but is not obliged to. At the same time, he may comment on the preliminary opinion, including any statement about industrial applicability that it contains. These comments will become part of the public file. A patent will be granted on the basis of the amended application, in case amendments are filed, or on the basis of the original application.

   For European patent applications, in most cases it is sufficient that the industrial applicability of the invention is indicated in, or can be derived from the description of the application. There is only a need to do more in case, during prosecution, the industrial applicability of the invention is challenged by the examiner. If that happens, the applicant will have to convince the examiner of the industrial applicability of the invention within the time limit set by the EPO.

   In case the applicant is required to demonstrate the utility or industrial applicability of the invention, there is no basis in Dutch law that stipulates what is the material date by which the industrial applicability must have been demonstrated. On the basis of (old) Dutch case law and case law from the Boards of Appeal of the EPO (see T 1109/10, Reasons 2, also quoted below) - which Dutch courts generally follow on fundamental questions like this - it must be held that the material date is the priority or application date.

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?

   Based on case law from the Boards of Appeal of the EPO:

Sub (a): The patentee can adduce post filing evidence. However, as was held in decision T 1109/10: "*The assessment of this requirement of the EPC has to be carried out from the position of a skilled person at the relevant filing date, i.e. without the benefit of hindsight provided by post-published documents. Reference to such documents may be permitted* ***for confirmatory purpose only*** *if industrial application was demonstrated in the patent application*."

Sub (b): The patentee can in our view rely upon the industrial applicability being soundly predicted (with reference to Rule 42(1) EPC) in that such prediction provides a sound and concrete technical basis from which the skilled person can recognize that the claimed contribution to the art could lead to practical exploitation in industry.

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?

    First of all, it is noted that in Dutch patent litigation, such as a revocation action, the party arguing lack of industrial applicability will bear the burden of proof. Hence, that party will have to demonstrate that the invention is not susceptible of industrial application. Of course, depending on the nature of the claimed invention and/or the evidence submitted regarding lack of industrial applicability, the patentee may be forced to provide evidence to the contrary. In this respect we note, with reference to our response to Question 3, that if the way in which the invention is industrially applicable is already obvious from the description or nature of the invention, there would be no particular need to provide additional evidence.

    There is no provision in Dutch law that expressly defines the material date for the determination of industrial applicability. However, as indicated in answer to question 7, on basis of (old) Dutch case law and case law from the Boards of Appeal of the EPO, it must be held that the material date is the priority or application date.

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?

    Pursuant to Article 152 of the Dutch Code of Civil Procedure, evidence can be provided by any means, and the valuation thereof is to the court, unless provided otherwise by law.

    Most certainly such means can comprise information or data that were already available before the application or priority date of the patent, but not disclosed in the

patent. In respect of the above specific examples, the following is added hereto, particularly based on case law from the Boards of Appeal of the EPO:

Sub (a): The patentee can adduce post filing evidence. However, as was held in decision T 1109/10: "*The assessment of this requirement of the EPC has to be carried out from the position of a skilled person at the relevant filing date, i.e. without the benefit of hindsight provided by post-published documents. Reference to such documents may be permitted* ***for confirmatory purpose only*** *if industrial application was demonstrated in the patent application.*"

Sub (b): The patentee can in our view rely upon the industrial applicability being soundly predicted (with reference to Rule 42(1) EPC) in that such prediction provides a sound and concrete technical basis from which the skilled person can recognize that the claimed contribution to the art could lead to practical exploitation in industry.
