National Group: **German Group**

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?

   Answer:
   Yes, industrial applicability.

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

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

   Answer:
   § 1 (1) German Patent Act (PatG) / Art. 52 (1) European Patent Convention (EPC) set out that industrial applicability, besides novelty and inventive step, is a prerequisite for patent protection. According to § 5 PatG / 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 details of these provisions have been elaborated by jurisprudence and case law.

   German law is intended to be the same as the EPC in this respect. Said provisions were taken almost word by word from Art. 3 of the Strasbourg Convention.

   The term industrial applicability is typically construed in a broad manner. It is considered sufficient that the invention **can be** manufactured or used in any kind of industry. Thus, one such possibility shall be sufficient. The term "industrial" is also not to be construed narrowly and can be regarded as being the opposite of private. In both German national law and the EPC there is no separate requirement for "utility" or usefulness.

However, it should be noted that there are specific provisions in the German Patent Act and the EPC that set out further requirements for patentability and industrial applicability in particular. This is especially true with regard to the human body and its elements as laid down in § 1a PatG / Rule 29 EPC that transpose Directive 98/44/EC on the legal protection of biotechnological inventions (the "Biotech Directive").

There are further exceptions from patentability laid down in § 2, § 2a PatG and Art. 53 EPC with regard to "ordre public or morality" and – besides others – for medical and microbiological processes. In particular, it is laid down in § 2a (1) no. 2 PatG / Art. 53 lit c) EPC 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 be excluded from patent protection, whereas, however, the exemption shall not apply to products, in particular substances or compositions, for use in any of these methods. Said provisions intend to ensure that in the area of medicine, as far as surgery, therapy and diagnosis are concerned, no process patents may be issued in order to allow therapeutic professions to choose between appropriate methods.

In practice, with regard to prosecution and invalidation proceedings, industrial applicability may in general only become an issue with regard to chemical substances and biotechnological inventions, whereas it plays a very insignificant role in other fields of technology.

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:
On (a): As a general rule, no explicit disclosure or proof of industrial applicability is required. According to § 10 (2) no. 5 PatV (Rules for patent matters before the German PTO) / Rule 42 (1) lit. f) EPC that further specify § 1 PatG / Art. 57 EPC, the description shall "*indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable*". These cases may be considered as exceptional.

The Examination Guidelines of the EPO make reference to "industrial application" as follows:

> "*4.9*
> *Industrial application*
>
> *The description should indicate explicitly the way in which the invention is capable of exploitation in industry, if this is not obvious from the description or from the nature of the invention. The expression "capable of exploitation in industry" means the same as "susceptible of industrial application", and indeed identical expressions are used in the French and German texts of the EPC. In view of the broad meaning given to the latter expression by Art. 57 (see G-III, 1), it is to be expected that, in most cases, the way in which the invention can be exploited in industry will be self-evident, so that no more explicit description on this point will be required; but there may be a few*

instances, e.g. in relation to methods of testing, where the manner of industrial exploitation is not apparent and must therefore be explicitly indicated."

Also, in relation to certain biotechnological inventions, i.e. sequences and partial sequences of genes, the industrial application is not self-evident. The industrial application of such sequences must be disclosed in the patent application (see G-III, 4)."

§ 1a (3) PatG / Rule 29 (3) EPC that transpose Directive 98/44/EC set forth that "*the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application*". According to Recital 23 of Directive 98/44/EC, the specific protein that is being produced as well as its function shall be mentioned. In the EPO guidelines it is stated in this regard:

"4.
Sequences and partial sequences of genes

In general it is required that the description of a European patent application should, where this 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 recognise that its contribution to the art could lead to practical exploitation in industry (see T 898/05). In relation to sequences and partial sequences of genes, this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application. A mere nucleic acid sequence without indication of a function is not a patentable invention (EU Dir. 98/44/EC, rec. 23). In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could e.g. be that the sequence exhibits a certain transcription promoter activity."

On (b), (c): German law (§ 34 (4) Patent Act) as well as the EPC (Art. 83) contain provisions according to which the invention must be disclosed in the application in a manner sufficiently clear and complete for it to be carried out by the skilled person. Technically, this provision does not refer to the criterion of "industrial application", but there are certainly overlaps. In particular, questions arise as to whether experimental data have to be presented with the application or whether this may happen at a later stage during prosecution or even in invalidation proceedings (opposition or nullity actions).

As a general rule, it would be fair to say that the application must at least contain one example which shows the invention. In that case it would be possible to further support this with additional data. On the other hand, if an application seems rather speculative and the later filed test results serve the purpose to show that the invention is working at all, this may be seen as an insufficient disclosure.

In practice, one will find this discussion rather in the context of sufficient disclosure and inventive step than with regard to industrial applicability. As mentioned above, biotech cases are being treated differently.

For biotech inventions concerning the complete or partial sequence of a gene § 1a (4) Patent Act contains the clear requirement that the use of the sequence for which the industrial applicability is described must be part of the patent claim. Consequently, the industrial applicability must be disclosed already when filing the patent claims.

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

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

Answer:
(a), see above.

B. Prosecution

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

   Answer:
   As a general rule: No, unless it does not already follow from the description. Please see exceptions set out above, see A., No. 3

6. Is the requirement to demonstrate utility or industrial application during prosecution based on:

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

   Answer:
   (a), see above

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

   Answer:
   It depends on the subject matter of the invention.

   It should be noted first that in principle the material date for the existence of an industrial applicability is the priority and the filing date respectively. If demonstration of industrial applicability is to be demonstrated under the conditions set forth above, it should be filed with the application since post filing may give rise to inadmissible broadening. Besides, according to the practice of the Federal Supreme Court, evidence may be provided post filing of the application. However, with regard to inventions subject to Directive 98/44/EC and as set forth in § 1a (3) PatG / Rule 29

para 3 EPC industrial application of a sequence or a partial sequence of a gene must already be disclosed in the patent application and therefore at the filing date.

Again, a distinction must also be made between an application for which only further evidence is produced and a purely speculative application for which no evidence is provided at the filing 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?

Answer:
Yes to both, depending on the technical field concerned by the application.

Since industrial applicability is to be interpreted in a broad manner under the German / EPC regime, as a general rule, the threshold to demonstrate industrial applicability – if necessary at all – is rather low. It shall be more relevant in cases concerning inventions in the chemical or biotechnological field. However, also in these cases, it appears to be sufficient to describe/identify the substance/protein and its effects (see above, question 3). As to (a) and (b) it is referred to the answers above, in particular to question 7.

C. Litigation

9. Is lack of utility or industrial applicability a basis for a validity attack in litigation?

Answer:
Yes.

10. Is such attack permitted by reason of:

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

Answer:
(a) According to § 21 (1) no. 1 Patent Act. Again, § 21 (1) no. 2 Patent Act also allows the nullification for insufficient disclosure. There is again a very close overlap in practice.

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

Answer:
Yes, with regard to some inventions, in particular those subject to Directive 98/44/EC on biotechnological inventions; No strict material date for other inventions, see above, question 7

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:
As explained above, it has to be noted that in nullity and opposition proceedings, as a general rule, industrial applicability does not play a role. Only in exceptional cases where industrial application may not already be derived from the description as well as in chemical and biotechnological cases it might become relevant. Since in some cases – as explained above – industrial applicability must be shown in the application, post filing evidence does not appear to be allowable for the patentee in order to establish industrial applicability (for the first time). However, in these cases, it shall be allowable to file additional evidence post filing in order to further confirm industrial applicability as mentioned/demonstrated in the application/specification. The latter shall be true for other inventions as well. Also, patentee shall be allowed to post file evidence in order to strengthen patentee´s argument that industrial applicability can evidently be derived from the description or the nature of the invention.