

**National Group:** Polish Group

**Title:** Questionnaire Apotex Inc. v Sanofi-Aventis  
Proposed AIPPI intervention – Supreme Court of Canada appeal

**Contributors:** Marek Lazewski

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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.

#### **Answer: (c)**

Industrial applicability requirement in Poland is based on the statute and much of its understanding is shaped by jurisprudence.

As to the statute, the requirement is defined in Art. 24 and 27 of the Industrial Property Law Act dated June 30, 2000 (Dz.U. [Journal of Laws of 2013, item 1410 as amended]):

#### *Article 24*

*Patents shall be granted – regardless of the field of technology – for any inventions which are new, which involve an inventive step and which are susceptible of industrial application.*

#### *Article 27*

*An invention shall be considered as susceptible of industrial application, if by means of that invention a product may be produced or a process may be used, in a technical sense, in any kind of industry, including agriculture.*

As to jurisprudence – the industrial applicability is a statutory requirement; therefore, a patent can be refused based on the fact that it does not meet this requirement. According to the Polish case law the industrial applicability requirement covers aspects relating to the nature of the invention and aspects relating to the sufficiency of disclosure, i.e. the application must

disclose the invention in a manner sufficiently clear and complete for it to be carried out and it must be clear that the invention can be realized with repeatable results. Therefore, the industrial applicability is quite broadly interpreted in Poland.

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?

In order to satisfy the industrial applicability requirement **(a) and (b)** must be present in the patent application.

According to the wording of the Polish regulations (see point 2) the industrial applicability requirement relates most of all to the nature of the invention. In other words, the industrial applicability should be acknowledged when the invention as such can be used in any human activity of technical character. However, the industrial applicability requirement is assessed by the Polish examiners in conjunction with the sufficiency of disclosure, i.e. the Polish Patent Office is of the opinion that the invention meets the industrial applicability requirement *'when it can be used (carried out) in a repeatable manner with the same results'* (according to the website of the PPO). Therefore, the application must disclose all the technical means necessary to realize the invention and additionally it must contain working examples illustrating the invention.

As mentioned above, the industrial applicability is assessed in conjunction with the sufficiency of disclosure. The latter requirement is quite strictly interpreted in Poland, especially in certain technical fields, such as pharmacy. Some examiners are of the opinion that the working examples should serve not only the purpose of illustrating the invention, but also of proving that the applicant indeed realized the invention. If such examples, containing experimental data, are not present, sufficiency of disclosure is questioned, and consequently the examiner comes to the conclusion that the industrial applicability requirement is not met.

4. Is the basis for any disclosure required in the patent specification:
  - (a) statute;
  - (b) jurisprudence; or
  - (c) both?

**Answer: (c)**

According to the Polish regulations the description *"(...) shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. (...) it shall also present the invention in a detail manner, describe the figures in the drawings (if any), and indicate the way or ways of carrying out or exploiting the invention claimed using examples."*

The wording of the regulation is quite general and there is no special emphasis on the experimental data/examples. However, as explained above the disclosure is a very strict requirement in Polish Patent Office practice, interpreted even to the extent that the application should prove that the applicant indeed realized the invention and that it indeed achieves the claimed result.

## **B. Prosecution**

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

**Answer: YES**

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

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

**Answer: (c)**

The industrial applicability is a statutory requirement, but there is no explicit regulation concerning the need to demonstrate the applicability. It can be, however, inferred from the wording of the regulations that all aspects of the invention must be disclosed on the filing date. It is a bit disputable to what extent the very broad interpretation of industrial applicability is indeed warranted by statute. There has been little case law in particular regarding the allowability of post filing evidence. It is possible that the current practice of the Office will be (at least to some extent) restricted by administrative court as part of their judicial review of the PPOs practice.

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

The industrial applicability requirement should be demonstrated in the patent application, therefore, it must be demonstrated on the filing date at the latest (see also comments to the question 8).

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?

As explained above in point 3, the industrial applicability requirement is, in fact, interrelated with the sufficiency of disclosure requirement. If the nature of the invention is, generally speaking, technical and the application discloses means for realizing the invention, and it is supported by working examples (with detailed experimental data) both requirements are met.

(a) In reasonable circumstances post filing evidence can be used, but never as the sole evidence. Post filing evidence can only be used when it develops and supplements the evidence already disclosed in the application or as additional data supporting statements present in the description. The post filing evidence can never be included in the patent specification, they are only added to the case file. The practice of the Patent Office as to allowability of post-filing evidence is not very coherent.

(b) As discussed above, the application must contain examples illustrating the invention, including precise technical data which support statements relating to the industrial applicability, e.g. in case of pharmacy they should demonstrate that the invention was indeed realized and that it exhibits the desired properties.

## 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]*

Poland has a bifurcated trial system – infringement and invalidation claims are recognized in separate proceedings.

Patent invalidation action must be initiated before the Polish Patent Office in Warsaw on the basis that ‘the statutory requirements for the grant of a patent have not been satisfied’. This means, the lack of novelty, inventive step and industrial applicability can form grounds for revocation, whereas it is not clear if e.g. insufficient disclosure alone would form a ground for revocation.

A patent validity attack cannot be successfully carried out in an infringement case pending before a common court. Although, pending invalidation proceedings before the Polish Patent Office may influence the infringement case in a psychological aspect.

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?

See comments to the 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?

See comments to the question 8.