

National Group: Slovenia

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

Contributors: Urban Vrtačnik, Jakob Gašperin – AIPPI Slovenia

Date: June 9th, 2014

Questions

A. Utility or industrial applicability requirement

1. Does your national law have a utility or industrial applicability requirement for patentability?

Yes.

Article 10 ZIL-1 (Industrial Property Act) says; “patent could be issued for any invention, from any technical field, which is new and industrially applicable”.

Generally speaking SIPO (Slovenian Intellectual Property Office) does not substantially test mentioned condition of industrial applicability before granting a patent except from:

- (1) formal requirements of patent application including description of the manner of industrial applicability (without requirement to provide evidence for such applicability) – Article 4/I/3; Rules on the contents of the patent application and on the division of patents (Rules)*
- (2) prima facie examination that the patent (as claimed) may be applicable for industrial use (without requirement to provide evidence at this stage of registration) –Article 88/II/b of the ZIL-1 (Industrial Property Act).*

In addition the patent holder shall provide evidence on industrial applicability in 9 years since the patent is granted. Otherwise the patent protection expires after 10 years since the patent was granted (Article 91/I,III of the ZIL-1).

2. Please briefly describe the utility or industrial applicability requirement, including whether it is based on:
 - (a) statute;**
 - (b) jurisprudence; or
 - (c) both.

Invention is industrially applicable, if the invention may be used or produced in any commercial (business) activity, including the farming (agriculture) –Article 15; Industrial Property Act.

Jurisprudence is not a formal source of law in Slovenia, however it may further determine and provide argumentation on some legal standards (including industrial applicability) for the law to be used consistently and equally for all individuals participating in legal disputes. Jurisprudence is thus important in the process of practical implications of rules of law.

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 (if not obvious from patent specification);**
 - (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?

Article 87/II of Industrial Property Act states that patent specification must also include a manner of industrial applicability if such applicability is not obvious from the description or the sole nature of invention.

In addition the patent specification shall include, according to the Article 4 of Rules (*Rules on the contents of the patent application and on the division of patents*), the presentation of the problem, information on the state of the art or of other solutions available by that time and their deficiencies which have been known to the applicant, together with a description of the new solution to the problem. The invention shall be described in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art to which the subject-matter of the invention relates.

Patentee must himself issue the proof of industrial applicability of his patent in 9 years since the patent is registered. Otherwise the patent is not protected after 10 years. (91 ZIL-1)

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

B. Prosecution

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

A manner of industrial applicability must be demonstrated in the patent description (Article 4 of the Rules), the invention shall be described in a manner sufficiently clear and complete (Article 87/II of the Industrial Property Act).

In addition patentee must himself issue the proof of industrial applicability of his patent in 9 years since the patent is registered. Otherwise the patent is not protected after 10 years. (91 ZIL-1)

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

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

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

It shall be demonstrated (in the extent as described above) when filing patent application. Formal deficiencies can be cured before the rejection from SIPO (Article 85/IV of the ZIL-1 and Article 4 of the Rules), while not meeting requirements subjected to prima facie examination (Article 88/I/b of the ZIL-1 as described above) lead to imminent refusal of application (Article 88/IV of the ZIL-1).

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?

The answer refers to evidence requirement under Article 91/I,III of the ZIL-1.

C. Litigation

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

Yes. If the invention does not cover all the conditions for patentability it may be subjected to special nullity claim (Article 112/I/b of the ZIL-1). The nullity of the patent may be also claimed as objection in the infringement litigations (according to the case-law in relation to certain types of patents in certain circumstances).

10. Is such attack permitted by reason of:

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

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

According to Article 122a of the ZIL-1, the procedural rules of Civil Procedure Act (ZPP) apply if not defined otherwise. Therefore the evidence may be presented until the end of the first hearing in front of the court. In the nullity litigations, evidence must be proposed or presented by the claimant, whereas in the infringement cases specific evidence on the lack of industrial applicability shall be provided by the defendant if the infringement claims are based on the valid (granted) patent. The patent holders also benefit from the opportunity of early evidence submission to SIPO according to the Article 91/I/4 of the ZIL-1 connected with Article 121 of the ZIL-1, to be able to reach declaratory decision of SIPO (meeting full requirements of patentability, Article 93 of the ZIL-1) before the expiry of the 9 year period and thus improve litigation position as claimant in infringement cases.

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?

A definite answer cannot be given. In nullity claims the burden of proof lies on the claimant, whereas the patentees (even not required to do so) usually provide their own evidence to support industrial applicability (post filing evidence or demonstrating applicability in other ways). The court makes full assessment of proofs and determines whether the claimant has succeeded to prove non-applicability. If validity of the patent is contested in infringement cases, the burden of prove (for the valid patents) is the same as it is described above (infringing party), however in reality evidence procedure may depend on the type of the patent (national, EP, PCT, ect.) and the stage of the registration (grant, opposition procedure, patent valid after declaratory decision, etc.)