



**National Group:** AIPPI-US Division

**Title:** Response to AIPPI Questionnaire  
Apotex-Inc. v Sanofi-Aventis

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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, utility

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

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

ANSWER:

The utility requirement means that an invention must be useful for a particular purpose. The patent disclosure must assert a specific and substantial utility that is credible or the invention must have a readily apparent, well-established utility.

The basis for the utility requirement in the U.S. is both statutory and jurisprudential. First, Article I, § 8, cl. 8 of the United States Constitution empowers Congress “[t]o promote the progress of science and *useful* arts.” (emphasis added). Under 35 U.S.C. §101 (2014), an invented or discovered process, machine, manufacture, or

composition of matter or improvement thereon must be “useful”. Related U.S. statute 35 U.S.C. §112 further addresses the specification requirements, including, in part, the sufficiency of disclosure needed to make and use the invention. Issues that other countries may address solely under their utility requirements, e.g., claim breadth/operability, the U.S. addresses most often under our sufficiency analysis. Post-filing evidence in support of sufficiency, e.g., enablement, may be allowed.

It is important to note, though, that despite the statutory basis for the utility requirement in the U.S., aside from determining what constitutes patentable subject matter, the issue of utility is not often challenged in the U.S. Recent Supreme Court cases addressing 35 U.S.C. §101 issues related to patentable subject matter, not utility.

The utility requirement is further defined by U.S. case law. See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, (Fed. Cir. 1996) (“For over 200 years, the concept of utility has occupied a central role in our patent system . . . . Consequently, it is well established that a patent may not be granted to an invention unless substantial or practical utility for the invention has been discovered and disclosed.”).

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 (e.g. test data) to prove or demonstrate that the utility or industrial applicability is achieved; and/or
  - (c) a basis (e.g. test data) and/or a line of reasoning from which the utility or industrial applicability may be predicted?

ANSWER:

In order to satisfy the utility requirement, the claimed invention must have and the specification should disclose: 1) a specific utility, i.e., provide a well-defined and particular benefit to the public; 2) a “substantial” utility, i.e. a significant and presently available benefit to the public; and 3) a credible utility, i.e. it can be used by a person of ordinary skill in the art to achieve the specific and substantial utility asserted. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005) and Manual of Patent Examining Procedure (“MPEP”) § 2107.03.

Although U.S. patent law includes a utility requirement, a patent may still be valid even if the specification does not explicitly disclose or assert the utility of the claimed invention, e.g., if the claimed invention has a “well-established” utility. In the event that the specification does not include an indication of the invention’s utility, the utility requirement is nonetheless satisfied if “(i) a person of ordinary skill in the art would immediately appreciate why the invention is useful . . . .” and “(ii) the utility is specific, substantial, and credible.” MPEP, §2107.02 (Jun. 2014).

In addition, as necessary, evidence, including test data, can be used to demonstrate that the utility is achieved. Such evidence is not strictly necessary in view of the criteria discussed above, but can be presented at any time to show a specific, substantial, and credible utility for the claimed subject matter at the time the application was filed.

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) both.

**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:

Yes. utility

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) both.

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

ANSWER:

Utility is based on the information available at the time of filing. If the application contains a credible utility, there is no material date by which that utility must be *demonstrated*. Although applications are not often rejected for lack of a credible utility, once an application is rejected on utility grounds, which must be by a *prima*

*facie* showing that the claimed invention lacks utility, supported by sufficient evidence for factual assumptions, the burden of proof shifts to the applicant, who must: “[p]rovide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing.” MPEP § 2107.01 (Jun. 2014).

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:**

Post-filing evidence is admissible to establish that utility existed at the time of filing. MPEP, § 2107 (Jun. 2014) (permitting the examiner to consider evidence “that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established at the time of filing” and which includes any “evidence of record . . . that is probative of the applicant’s assertions”). Predictive and correlative evidence is also admissible. *Nelson v. Bo’loler*, 626 F.2d 653, 856-57, (CCPA 1980). Applicants may rebut a utility rejection by submitting any one or combination of claim amendments, argument and reasoning, or post-filing evidence in the form of an affidavit or declaration under 37 U.S.C. 1.132 or a printed publication. MPEP 2017.02(VI).

**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, lack of utility

10. Is such attack permitted by reason of:

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

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

**ANSWER:**

(c) both

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

ANSWER:

No, anytime during the life of the patent or its period of enforceability. Patentees may submit evidence in support of the asserted utility when/if it is challenged.

However, accused infringers may be effectively estopped to challenge utility of the infringed patent, since their use of the infringed patent would presumptively prove utility. *Phillips Petroleum Co. v. U.S. Steel Corp.*, 673 F. Supp. 1278, (D. Del. 1987), *aff'd*, 865 F.2d 1247, (Fed. Cir. 1989) (“lack of practical utility cannot co-exist with infringement and commercial success.”)

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:

Post-filing evidence is admissible. Predictive and correlative evidence is also admissible.