

PATENT OFFICE OF THE REPUBLIC OF POLAND

Information on the requirements of inventive step and sufficiency of disclosure

Inventive step

1. The definition of a person skilled in the art

There is no definition of a person skilled in the art in the Industrial Property Law of 30 June 2000. The Patent Office applies the definition of a person skilled as provided for in the *Guidelines for examination in the European Patent Office. (Part G, chapter VII -3)*

2. Methodologies employed for evaluating the inventive step

The Patent Office employs the methodologies for evaluating the inventive step as established in the *Guidelines for examination in the European Patent Office*. The Office also employs the *Guide for Inventors*, in which the methodologies employed by experts, as well as procedures applied are described in detail

There is no single universal search strategy suitable for all applications of inventions and utility models. The manner in which examination is carried out should be adapted to the specifics of a particular application based on experience and expert knowledge. In the first place, you can consider the documents referred to in reports of searches carried out in other patent offices (if any), the documents referred to in the description of the state of the art and found in the collections of Polish patent literature. The search should be directed primarily to find technical solutions that might indicate a lack of novelty or reported inventive step of the invention and classified according to the IPC to the technical fields in which finding them is most likely to occur. The results of the search should be evaluated and analyzed, on regular basis, for the purpose of making possible changes or broadening the scope of the search.

In case of not finding in the patent literature technical solutions destroying the novelty or inventive step, the search can be limited to determining the general state of the art, so-called. "technological background "of an invention, which may include the technical solutions described in the a non-characterising portion of the independent claim, in the description of the state of the art of the application, or those relevant for a given technical field. The search should be completed at the stage in which finding further documents which may constitute the state of the art is unlikely, as well as in the case of finding a technical solution destroying novelty. The search is carried out primarily in computer databases available on the Internet and in internal databases and collections of patent literature of the Polish Patent Office. The search is performed in professional retrieval system EPOQUENET. In addition, the most famous online database currently includes Espacenet, DEPATISnet.,

Conducting search in these databases requires the identification of search criteria, which generally include – the number of the publication, patent classification symbol, keywords or combinations of these words, the name or the family name of the applicant, the name of the inventor, etc. In order to reduce the amount of documents for search, various combinations of search criteria are used, which are often described in the instructions for use of the database. The most commonly used criterion of keywords and IPC classification symbols. Before starting the search it is advisable to create a set of keywords characterizing the invention under examination (preferably in English) and then to use different combinations thereof. In many cases it is helpful to use a combination of sets of keywords and classification symbols.

In case of a need to include the information contained in the technical literature and inaccessible in computer databases, selected publications are ordered in the library or, if necessary, abroad. If the application includes a product and process adapted especially for the preparation of this product and its features meet the requirements of patentability, it is no longer necessary to examine the application - as to inventive step with respect to the process, assuming that all the technical features defining the product are the result of the application of the claimed process. This also applies when the use of the product is claimed, when the product is patentable and is used in accordance with the use of its technical features claimed.

3. Having regard to the prior art, the level of inventiveness (obviousness) to meet the inventive step requirement

For detailed information, please consult:

Guidelines for examination in the European Patent Office, Part G, chapter VII, pkt.3 person skilled In the art and pkt. 5 problem-and- solution approach

and Guide for Inventor:

http://www.uprp.pl/uprp/_gAllery/25/87/25870/PORADNIK_WYNALAZCY_INTERNET.pdf) section 9.8 – available only in the Polish language.

Sufficiency of disclosure

Sufficiency of disclosure is regulated in Article 33 (1) of the Industrial Property Law of 30 June 2000:

1. Subject to Article 93⁶(1), the description referred to in Article 31(1)(ii) shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. In particular, the description shall contain the title of the invention designating the subject matter of the invention, specify the technical field to which the invention relates, as well as indicate the background art known to the applicant; 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 Patent Office attaches great importance to the examples of the ways in which an invention is carried out or used. A broad scope of protection sought should be adequately illustrated in the description of the application. Providing one example only is insufficient. Pharmaceutical inventions should include relevant research data made before the filing date. Support by the description, in particular by examples of carrying out the invention, of the entire scope of protection as defined by the claims, is a mandatory condition for obtaining a patent. This does not mean, however, that the scope of protection should be limited to the examples.

Patent claims must be formulated in a manner which makes the subject of the protection sought fully understandable and the scope of the protection claimed unambiguous. It cannot be more broad than the scope of the protection supported by the description of the invention. The patent claims for a pioneering invention may be drafted in a more general manner than those for the invention, which merely improves the known technique. The actual lack of disclosure in the description constitutes the uncorrectable defect within the same application (Decision of the Board of Appeal in PPO, No. App. 1898/98).

Relevant court decisions follow:

1. Administrative Court in Warsaw – VI SA/Wa 982/12, 2012-10-30

The correctness of the application is one of the conditions for the grant of the patent. Industrial applicability includes four essential requirements: the requirement of completeness, the requirement of suitability for use, the requirement of repeatability of the result of using the invention and the requirement of sufficient disclosure

<http://orzeczenia.nsa.gov.pl/doc/426C2E72B8>

**2. Supreme Administrative Court, Chamber of Commerce – II GSK 405/13,
2014-06-04**

Thus, the first instance court made it clear that the criteria of patentability, including the industrial applicability of the invention should be examined on the date of filing of the technical solution, and therefore research data confirming the synergistic effect of the claimed combination should be submitted to the authority on the filing date of the patent application.

<http://orzeczenia.nsa.gov.pl/doc/A233EFDC9B>

3. Administrative Court in Warsaw – VI SA/Wa 1134/10, 2011-02-24

The court shared the Patent Office's assessment regarding the allegation of insufficient disclosure, i.e. which is the requirement of applicability indicated in Article 10 of IP Law. The requirement of applicability of the invention is to be understood as the possibility of its realization, in the entire scope as claimed, leading to obtaining the declared benefits. Confirmation of such a possibility should be documented in the examples of use of the invention.

<http://orzeczenia.nsa.gov.pl/doc/B9900DDD09>

4. Administrative Court in Warsaw – VI SA/Wa 112/08, 2008-05-09

In case of a medical invention it is very important that its disclosure not only makes possible to implement the invention but also includes an indication that the implementation of the technical solution is safe for its customers.

<http://orzeczenia.nsa.gov.pl/doc/B5BF60B041>

5. Supreme Administrative Court, Chamber of Commerce – II GSK 1472/10 2012-02-23

Application of the technical solution is represented in the disclosure of its technical features (parameters of the phases of its realization) which will allow the product to be applied without a need to reach the intended results through trial and error and experiments due to the lack of the necessary data.

<http://orzeczenia.nsa.gov.pl/doc/B27DE69066>

6. Administrative Court in Warsaw – VI SA/Wa 2264/10, 2011-02-03

It is therefore not possible to obtain a patent for only the concept of the technical solution . Lack of the specific example of the application of the method referred to in the title of the invention filed by the plaintiff prevented, according to the Court, its re-enactment. The presence of such an example in the application is a *sin a qua non* for assessing the patentability of the invention filed. It should also be emphasized that the preliminary draft proceedings of clinical trials as described in the patent application cannot serve as a basis for granting a patent for a technical solution, neither proves the level of inventive step involved. In addition, at the filing date there is no evidence of implementation of the concept. In these conditions, it is to be admitted that the Office is right when claiming that with the information contained in the patent application P [...] a person skilled in the art is not in a position to embody the concept, and the lack of an example illustrating the invention filed by the plaintiff demonstrates the irreparable defect and, consequently, the application must result in a refusal to grant a patent.

In addition, it has to be noted that, although it explicitly follows from the abovementioned provisions that the patent claims should be fully supported by the description of the invention, the plaintiff failed to meet this requirement, and therefore the Office was obliged to refuse to grant a patent for the invention as filed.

<http://orzeczenia.nsa.gov.pl/doc/9349AE6ACA>

7. Supreme Administrative Court, Chamber of Commerce – II GSK 271/12,

2011-02-03

The court found that the inclusion in the application of biological tests in confirmation of the efficacy of the drug is required under the law. The invention relating to a composition (pharmaceutical agent, pharmaceutical combination) must include experimental material documenting the discovered properties associated with the intended use. The use of insulin as a medicament for the treatment of a new disease - burns, should be confirmed by the example of its application in the treatment of burns. The provisions of the IPLaw explicitly stipulate that the invention should be disclosed no later than at the filing date. After that date it is not possible to add the missing example of the new application of insulin in the patent application.

<http://orzeczenia.nsa.gov.pl/doc/09D883FAF6>