

1. REPORT ON EXHAUSTION OF PATENT RIGHTS

Exhaustion of patent rights is regulated with the article 152 of industrial property code.

Article 152 states *“After the products forming the subject of protection of industrial property right are put on the market by right owner or by third parties with his consent, actions related to these products shall remain outside the scope of the right.”*

If the product is put on the market by the right owner or by the third parties on his consent the patent right is exhausted. There is no territorial limitation in the article 152. If the product is put on the market anywhere in the world the patentee's exclusive right is exhausted on the product which is marketized.

To illustrate if a patent owner company X has sold its product Y to a country Z, a company A can buy the product Y in the country Z and import the product into country B even the patent owner X has also patent protection in country B.

2. REPORT ON SUFFICIENCY OF DISCLOSURE FOR PATENTS IN THE AREA OF INORGANIC AND ORGANIC CHEMISTRY INCLUDING PHARMACEUTICALS

The article 92 of industrial property code states that *“The invention shall be disclosed in a sufficiently clear and complete manner, which provides that the invention would easily be carried out by the skilled person in the art, with description, claims and drawings, which are referred in description or claims of the patent application.”*

The implementing regulations of industrial property code rule 75 states that *“ the description should be drafted clearly and detailed manner in order to enable skilled person in the art to apply the invention. The subject matter of invention should be explained without concealing anything.”*

In other words, the disclosure of the claimed invention should be clear enough for a person skilled in art to reproduce the invention without undue burden of experimentation.

Sufficiency of disclosure is not only criteria for the grant of a patent but also it is reason of post grant appeal and invalidation trial if the subject matter is not sufficiently disclosed. In other words even patent is granted it can be invalidated on the grounds of insufficient disclosure.

The chemical and pharmaceutical inventions must be compliant with articles and rules of industrial property code regarding the sufficiency of disclosure. In addition to general provisions regarding to the sufficiency of disclosure, the chemical and pharmaceutical inventions should satisfy further needs. Since the predictability of chemical inventions is low, it is frequently required to provide evidence to demonstrate the technical effect. It is difficult for skilled person in the art to predict a new chemical to be used in the treatment of a specific disease. Therefore, description of chemical and pharmaceutical inventions frequently requires the experimental evidence, which supports the alleged technical effect.

The typical patent applications in pharmaceutical and chemical inventions may be summarized as follows

- Chemical compounds defined by Markush Formula;
- Esters, ethers, salts, N-oxides;
- Stereoisomers (enantiomers, diastereomers, Cis-trans and E-Z isomerism);
- Pro-drugs;
- Compositions and formulations;
- Polymorphic forms and crystalline, co-crystals, hydrates, solvates;
- New use of a known compound;
- Manufacturing process of chemical products

Chemical compounds defined by Markush Formula

Chemical compounds defined by the Markush formula should satisfy following requirements

- The embodiments should have a common use or property;
- such possible embodiments should share common structure;

Since the predictability of chemical inventions is low and Markush claims are used for protection of several variant in single invention, sufficient number of examples for different alternatives should be provided to prove that the generalization of compounds with the Markush claims can be possible.

Non-Unity objection may be raised when some of the claimed compounds are not novel.

Stereoisomer

If the invention is related to the pure form of one enantiomer, sufficient experimental data should be provided how the enantiomer is isolated from the racemic mixture. It is recommended to compare the invention with the prior art and explain the differences between the prior art the claimed invention. If there is further technical effect, the alleged technical effect should be supported with experimental data.

Compositions and Formulations

The active ingredient should be served to patients in different form of drugs. There are several patent filings with regard to compositions and formulations. If the use of an active ingredient for the treatment of a disease is known, it is not necessary to demonstrate the in vitro or in vivo studies. However, if the formulation is related to overcoming technical prejudice, the presence of experimental data is recommended to prove the technical effect. Alleged technical advantages without presenting experimental data will not be taken into the consideration for the assessment inventive step.

If a new formulation is developed, the working example should be provided so that person skilled in the art could put into the practice.

Polymorphic forms and crystalline

In order to comply with the sufficiency of disclosure requirements for the patents related to polymorphic forms it is recommended to present the analytic results such as XRD, which characterizes the polymorph. It is also suggested to demonstrate the production method of

new polymorphic form. Technical effect should be discussed in detail in the description of invention.

New Use of a known compound

If a new use of known compound invented, it is essential for inventor to provide an evidence to show that the compound can be used for the specific disease. The experimental evidence can be presented either in vitro or in vivo.

Manufacturing process of chemical product

If a new chemical compound is synthesized, it is recommended for applicant to demonstrate all the production steps. To illustrate it is essential to demonstrate the necessary reactions, process parameters such as operating temperature and pressure, the catalyst that is used for the reaction. Working examples should be provided. The sufficiency of disclosure is also linked with the assessment of inventive step. The problem solution approach is used for the assessment of inventive step. The description of invention should be clear enough to demonstrate the technical effect caused by the differentiating features. The technical effect caused by the differentiating features may help the subject matter of invention to qualify for inventive step.

3. REPORT ON SUFFICIENCY OF DISCLOSURE FOR PATENTS IN AREA OF MICROORGANISMS

National Patent Legislation

Industrial Property Law No. 6769, Article 92:

“(1) The invention shall be disclosed in a sufficiently clear and complete way, which provides that the invention would easily be carried out by the skilled person in the art, with description, claims and drawings, which are referred in description or claims of the patent application.

(2) If the invention relates to a biological material or includes the use of a biological material, which is not accessible by the public and cannot be adequately identified to enable a skilled person in the art to practice the invention, in case this material is deposited, it shall be considered that the invention has been explained in accordance with the first paragraph.

(3) If the biological material deposited in accordance with the second paragraph is no longer accessible in the depositary authority; in case this material is redeposited in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure that we agreed to be the part of, with the Decree of the Council of Ministers dated 5/8/1997 and numbered 97/9731, and if a copy of the document issued by the depositary authority regarding the receipt of the material is sent to the Institution by specifying the number of the patent application or document within four months from the date of filing, this access shall be considered uninterrupted.

(4) The basis of the claims shall be the description; the claims shall define the subject for which protection is requested, be clear and concise and shall not exceed the scope of the invention defined in the description.

(5) The abstract shall be for technical information purposes only. It shall not be used for other purposes, especially in determining the scope of protection or in the implementation of the third paragraph of Article 83.

(6) The conditions for the deposit of biological material shall be determined by the regulation.”

Regulation on the Implementation of the Industrial Property Law No. 6769, Article 81:

“(1) If the invention relates to a biological material or includes the use of a biological material, which is not accessible by the public and cannot be adequately identified to enable a skilled person in the art to practice the invention, the invention is deemed to have been disclosed in accordance with Article 92 of the Law, provided that the following conditions are met:

a) Depositing a sample of the biological material to an international depositary authority established in accordance with the Budapest Treaty or a depositary authority recognized by the Institution, on or before the date of application.

b) Containing information available to the applicant on the characteristics of the biological material deposited at the time of application.

c) Indication of the name of the depositary authority and the accession number given to the biological material deposited by that depositary authority in the patent application.

(2) If the biological material deposited in accordance with the first paragraph is no longer accessible in the depositary authority; in case this material is redeposited in accordance with the Budapest Treaty, and if a copy of the document issued by the depositary authority regarding the receipt of the material is sent to the Institution by specifying the number of the patent application or document within four months from the date of filing, this access shall be considered uninterrupted.

(3) The information in the subparagraph (c) of the first paragraph shall be given within the period specified below, whichever expires first:

a) Within sixteen months from the date of submission of the application or the priority date, if any, or, if it cannot be submitted within this period, before the completion of the necessary technical preparations for the publication of the application.

b) Until the date of the request for publication of the application according to the first paragraph of Article 97 of the Law.

c) Within one month after the Institution's notification to the applicant that there is a right to examine the application file pursuant to the second paragraph of Article 102 of the Law.

(4) By submitting the information in subparagraph (c) of the first paragraph to the Institution, it is deemed that the applicant gives unconditional and irrevocable consent for the deposited biological material to be made available to the public.

(5) The deposited biological material shall be accessible to everyone upon request from the date of publication of the patent application, and before this date, to persons authorized to examine the application file in accordance with the second paragraph of Article 102 of the Law. This access is achieved by providing the requester with a sample of this biological material.

(6) A copy of the biological material shall be provided, unless the applicant or patentee expressly indicates that he or she has waived that biological material, or any derivatives thereof, until the date on which the patent right expires or the patent application is rejected, withdrawn, deemed withdrawn. It shall be given on the condition that the requester undertakes not to give a biological material, or any derivatives thereof, to third parties and to use this material for experimental purposes only. If the requester uses the biological material under the compulsory license, this commitment shall not be sought.

(7) The request in the fifth paragraph shall be made to the Institution with an announced form. In this form, the Institute confirms that a patent application has been made regarding the deposited biological material and that the requestor is authorized to receive a copy of this material. This request is made to the Institute even after the patent is granted. The Institute sends a copy of the approved request to the depositor and the patent application or patent owner."

Practice at TURKPATENT

Patent applications regarding microorganisms should enable a skilled person in the art to practice the invention. However, it is practically difficult to describe a microorganism in words and the problem arises if the microorganism has never been known before. Additionally, patent offices are not equipped for working independently with microorganisms. For this reason, in order for the invention to meet the sufficiency of disclosure requirement, the applicant should deposit a sample on or before the filing date to any international depositary authority under Budapest Treaty.

The depositary authorities recognized by TURKPATENT, currently, consist of international depositary authorities established in accordance with the Budapest Treaty, of which Turkey has been a member. Budapest Treaty eliminates the need to deposit multiple samples of the same microorganism in different countries.

The applicant should indicate the name of the depositary authority and the accession number given to the microorganism deposited by that depositary authority in the patent application. However, it should be noted that the accession number from an international depositary authority cannot replace the written description. In order to comply with the sufficiency of disclosure requirements, the applicant should also provide the information available to the applicant to characterize the microorganisms as exhaustively as possible at the time of the application. Distinctive morphological, biochemical and taxonomical characteristics are examples to the information that the applicant can provide in order to characterize the microorganisms.

As the claims should define the subject for which protection is requested in a sufficiently clear and concise way, it is strongly recommended that the claims related to protecting microorganisms should also include the name of the depositary authority and the accession number given to the microorganism deposited by that depositary authority, the name of genus, and if possible, of species and strains.

Industrial Property Law No. 6769,

<https://www.mevzuat.gov.tr/MevzuatMetin/1.5.6769.pdf>

Regulation on the Implementation of the Industrial Property Law No. 6769,

<https://www.mevzuat.gov.tr/mevzuat?MevzuatNo=23528&MevzuatTur=7&MevzuatTertip=5>

4. REPORT ON SUFFICIENCY OF DISCLOSURE FOR PATENTS IN ARTIFICIAL INTELLIGENCE

Artificial Intelligence (AI) refers to an intelligence technology similar to human implemented by means of ordinary computer programs. Therefore, inventions that are related to artificial intelligence models can be evaluated as computer implemented inventions. CII (computer implemented inventions) which have an implementation of artificial intelligence methods are generally considered as mixed inventions, that defined as having both technical and non-technical features. TURKPATENT have decided to bring a systematic approach to computer-implemented inventions to assess patentability criteria for these type of applications. Turkish Patent and Trademark Office stated that if the claims about computer-implemented inventions contain only technical features (not a mixed-type invention), the search process should be done as usual. Whether the claims does not have any technical features, the search and/or examination report should not be prepared; since the claims does not comprise any patentable subject-matter. Most of the cases are mixed inventions, where the claims comprise both technical and non-technical elements. In cases where technical and non-technical features are combined, non-technical features are evaluated for assessment of inventive step due to their contribution to the solution of the technical problem.

The main issue that offices have encountered about AI and machine learning algorithms that their basic idea are pure mathematical methods. Their basic and general purposes (classification, clustering, regression, dimensionally reduction) are considered as merely abstract applications to some general data. Whether applying this type of algorithms for training or models which ate trained does not change this abstract nature of data. Although terms which are frequently used in AI and machine learning algorithms like ““support vector machines” or “neural networks” sound very technical, these terms are defined as mathematical words and still abstract mathematical models in patent terminology.

There are two possibilities of how such abstract mathematical models can be taken into account and can be actually claimed for a patent application and a patent can be obtained for these subject-matters. First one is serving a specific purpose: it’s crucial that the aim must be specific; general technical purpose e.g. controlling some kind of machine which is not in a specified manner does not help for contributing to the solution of the technical problem. The other option for patentability of AI is specific implementation. This needs to be a detailed implementation such as specific use of cache memory or something. For these kind of applications, unlike the first option; applicant do not have to limit the invention for a specific field, since they are technical by their nature.

Sufficiency of disclosure is one of the main obstacles that AI-related applications have to overcome for patentability of the invention. According to Industrial Property Code in Turkey, *“The invention shall be disclosed in a sufficiently clear and complete manner, which provides that the invention would easily be carried out by the skilled person in the art, with description,*

claims and drawings, which are referred in description or claims of the patent application (Article 92 (1)). As mentioned above, AI algorithms have to make a technical effect to the invention for assessing these features for inventive step. If the applicant claims that an AI model is specifically trained for a certain specific purpose (e.g. using machine learning algorithms for elevation of a projectile and making it at a desired point at a calculated point of time), in order to derive a credible technical effect, a person skilled in the art needs information how the model is actually trained. So, a person skilled in the art would need details about training data of implemented AI model. Also, explaining the weights of the trained model would be very useful to cope with sufficiency of disclosure problem in AI inventions.

For inventions using AI models, such as supervised learning; the application can contain information about model details – e.g. model architecture with hyper parameters-, displaying how the model can be trained or used, examples of inputs and outputs of AI model and examples of training data. Moreover, experimental data to these examples would be very useful for an examiner to comprehend the invention in a complete way. Data results can be a significant proof that the model is a valid approach to achieve the invention.

Purely black-box inventions, which are defined as models created directly from data by an algorithm, and even those humans who design them, cannot understand how variables are being combined to make predictions; lack most likely sufficiency of disclosure. Having a black-box AI algorithm in an invention means that the applicant might not explain the inputs and outputs of the system and assessing any technical effects derived from this system would not be possible. Remaining on an abstract general level instead of detailing the AI system also causes sufficiency of disclosure problems. One of the main issues about AI-related applications, terms of artificial intelligence are used in description and claims but no details are provided with these terms and their implementations to the process of the invention. What these algorithms mean are not explained in a detailed way by most of the applications. In addition, some applications indicate that any AI algorithm can be used for their invention and leads a sufficiency of disclosure problem hence the person skilled in the art would not understand the purpose and technical problem which the invention claims to solve. Remaining on an abstract general level instead of detailing the AI system.

For AI-related, applications whose have a sufficiency of disclosure problem, TURKPATENT assumes these mathematical method features do not have any interaction with technical features of the claim and do not take into account when assessing inventive step. This problem is mentioned in the examination notifications at “inventive step” or “observation” sections. Applicant can transmit a letter to explain the necessary details of the artificial intelligence model and some test results about data that can be a proof for validity of the model. Adding these details and further technical effect that AI model provides to the invention after filing may be a problem in Industrial Property Code of Turkey, because it is clearly stated that applicant cannot go beyond the scope of the protection of the invention after filing date (Article 103 (1)). So it is ideal for applications that explaining details and technical effect of the AI models for invention with first filing.