ANDEAN COMMUNITY

PATENT EXAMINATION MANUAL

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This Document prepared by the General Secretariat of the Andean Community with the assistance of the national industrial property offices of Bolivia, Colombia, Ecuador and Peru; and in cooperation with the WIPO International Bureau.

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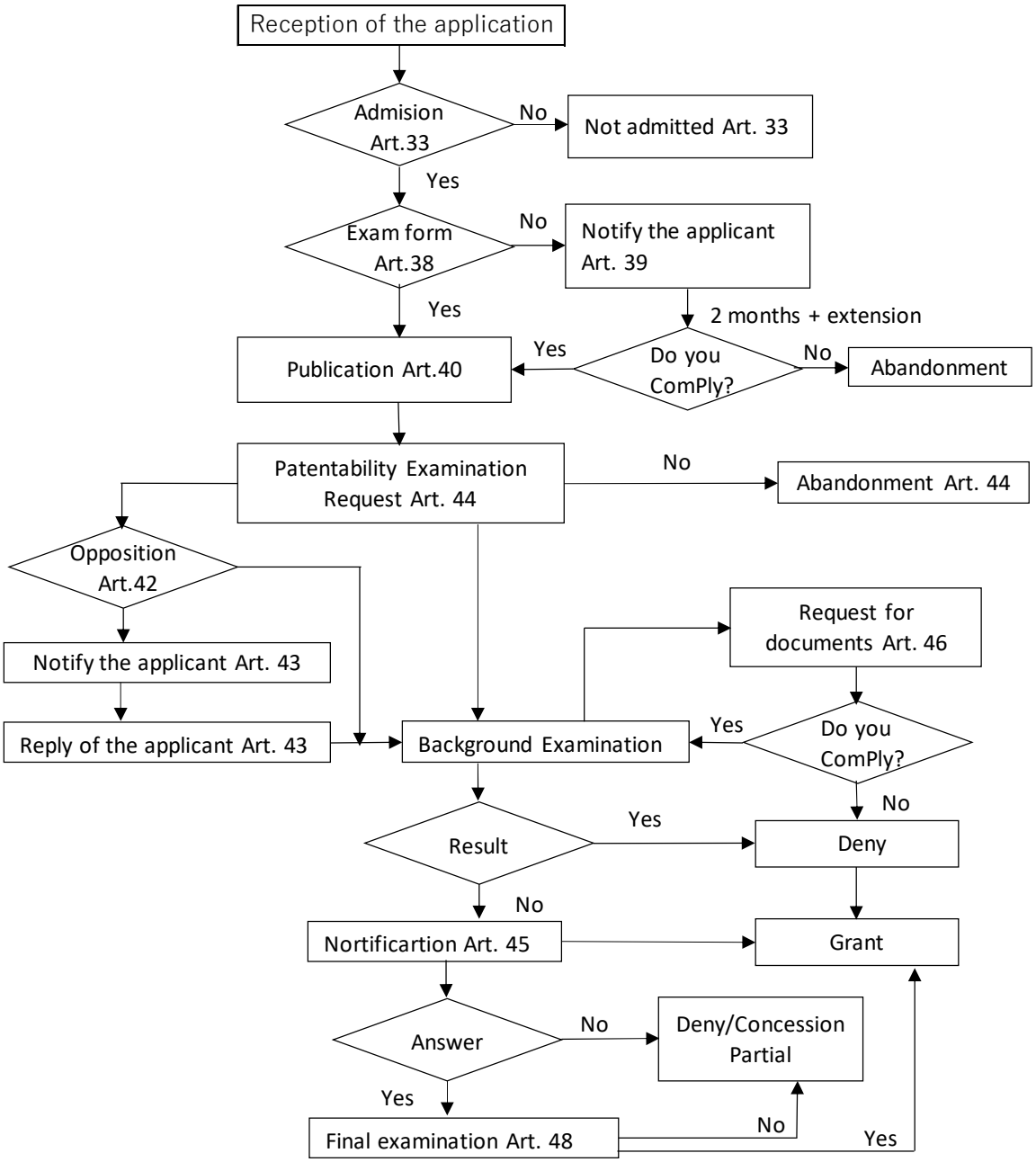
CHAPTER I INTRODUCTION

1. GENERAL SCHEME OF THE PROCESS

The processing and examination of a patent application in accordance with Decision 486 is illustrated below.



2. PROCESSING OF THE PATENT APPLICATION

2.1 Acceptance to processing and granting of the filing date

Once the patent application has been submitted, it is examined whether it meets the minimum requirements to be accepted for processing and a filing date is assigned. If an essential requirement is missing by this date, the applicant will be notified that his application is missing the requirement and cannot be accepted to process or obtain the said filing date (Article 33 of Decision 486).

2.2 Examination of the application form

Once the submission date has been assigned to the application, within 30 business days from that date, the competent national office examines whether the application complies with the formal requirements established in Articles 26 and 27 of Decision 486.

If any requirements are missing, the applicant will be notified. The applicant has a period of two months following the date of notification to comply with the missing requirement. This period may be extended only once and for the same period if the applicant requests it in writing (Article 39 of Decision 486).

The extension must be requested at any time before the expiration of the term to be extended. Said extension will be understood to be granted automatically for the respective period and will be computed from date to date, without requiring an express pronouncement by the competent national office.
If within these deadlines the applicant does not complete the requirements, the application is considered abandoned.

2.3 Publication of the application

The application is published 18 months from the date of submission or, where applicable, from the priority date invoked, once the formal examination requirements have been passed. At the request of the applicant, publication may be brought forward (Article 40 of Decision 486).

An application for a patent for an invention is confidential and cannot be consulted by third parties before 18 months have elapsed from its filing date, unless there is written consent from the

applicant. Once this period has elapsed, the application file automatically becomes public and could be consulted by anyone, and if applicable, obtain a simple copy of it after justifying the reason for what they need.

Anyone who proves that the applicant for a patent has intended to assert against him the rights derived from the application, may consult the file, and if applicable, obtain a simple copy of it, before its publication and even without the consent of the applicant. (Article 41 of Decision 486).

2.4 Opposition

The publication is carried out with the objective that third parties become aware of the application for a patent for an invention, so that whoever has a legitimate interest can present a one-time reasoned opposition that could distort the patentability of the invention (Article 42 of Decision 486).

An opposition to the grant of the patent can be filed within a period of 60 business days from the date of publication. This period can be extended for another 60 days at the request of the opponent to allow time for the opposition to be duly supported (Article 42 of Decision 486).

The extension must be requested at any time before the expiration of the term for which you wish to extend. The extension is understood to be granted automatically for the respective period, counted from the first business day following the day on which the original term expires, without requiring an express pronouncement by the competent national office.

In accordance with its local legislation, the office will notify the applicant of the opposition that has been presented so that, within a period of 60 business days, extendable for another equal period, they can present their response or relevant documents, or modify the claims or description if you deem it appropriate.

The decision on oppositions will be made at the substantive examination stage of the application (Chapter III. Substantive Examination).

2.5 Application for patentability examination

The applicant must request that it be examined whether the invention is patentable, within a period of six months from the publication of the application, regardless of whether oppositions have been filed (Article 44 of Decision 486) and this request must be accompanied by the respective payment of the rate for this concept. If the patentability examination is not requested within the indicated period or the corresponding fee is not paid, the application is abandoned.

2.6 Patentability of the invention

The competent national office will examine whether the invention is patentable (Articles 14, 15, 16, 17, 18, 19, 20 and 21 of Decision 486). If it finds that the invention is not patentable or that it does not comply with any of the requirements established in the Decision for the grant of the patent, it will notify the applicant one or more times as it deems necessary (Article 45 of Decision 486).

If the applicant does not respond to the notification within the period of 60 days extendable for 30 days from the date of notification (Article 45 of Decision 486), or if despite the response the impediments to the concession remain, the office will deny the patent.

If necessary and in accordance with local legislation, for the purposes of the patentability examination and at the request of the competent national office, the applicant shall provide, within a period not exceeding three months, documents relating to the patentability examination of one or more applications foreign companies referring totally or partially to the same invention (Article 46 of Decision 486).

If the final examination is favorable, the patent title is granted. If it is partially favorable, the title is granted only for the accepted claims. If it is unfavorable, the patent is totally denied (Article 48 of Decision 486).

3. FUNCTIONS OF THE EXAMINER

In national offices there are two types of examiners: those in charge of the formal examination of the application and those responsible for the substantive or patentability examination, whose functions will be detailed in Chapters II and III.

CHAPTER II EXAMINATION OF FORM AND PROCEDURAL ASPECTS PRIOR TO THE SUBSTANTIVE EXAMINATION

1. CONTENT OF THE APPLICATION

Decision 486 establishes the following provisions:

"**Article 26.**- The application for a patent shall be filed with the competent national
office and shall contain the following:

(a) the request;
(b) the description;
(c) one or more claims;
(d) one or more drawings, where necessary for the understanding of the invention, which shall be considered an integral part of the description;
(e) the abstract;
(f) such powers of attorney as may be necessary;
(g) proof of payment of the prescribed fees;
(h) where applicable, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom of which any of the member countries is the country of origin;
(i) where applicable, a copy of the document accrediting the licensing or the authorization of the use of the traditional knowledge of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin, in accordance with the provisions of Decision 391 and such of its amendments and implementing regulations as are in force;
(j) where applicable, the certificate of deposit of biological material;

and

(k) where applicable, a copy of the document attesting the assignment of the right to the patent by the inventor to the applicant or to his principal."

2. REQUEST

"**Article 27.**- The request forming part of the patent application shall be set down on a form and shall contain the following:

(a) a request that a patent be granted;
(b) the name and address of the applicant;
(c) the nationality or domicile of the applicant. Where the applicant is a legal entity, its place of incorporation shall be specified;
(d) the name of the invention;
(e) the name and domicile of the inventor where he is not the applicant;
(f) where applicable, the name and address of the legal representative of the applicant;
(g) the signature of the applicant or of his legal representative; and
(h) where applicable, the date, number and office of filing of any application for a patent or other title of protection that may have been filed or obtained abroad by the same applicant or his principal and that refers entirely or partly to the same invention as is claimed in the application filed in the member country."

3. FUNCTIONS OF THE FORM EXAMINER

- Verify compliance with the necessary requirements for the admission of the application (Article 33 of Decision 486);
- Verify compliance with the formal requirements indicated in Articles 26 and 27 of Decision 486 (Article 38 of Decision 486);
- Request any missing documentation from the applicant;
- Prepare reports on compliance or non-compliance with formal requirements, as applicable with your local legislation;
- Guide the user to properly comply with the formalities of a patent application;
- Pre -classify requests according to the International Patent Classification (hereinafter "the IPC"); and
- Publish the request.
- The competent national offices will use their respective national forms for the processes planned before them.

4. APPLICATION ADMISSIBILITY PROCEDURE

"**Article 33.**- The date of receipt of the application by the competent national office shall be considered the filing date thereof, provided that its contains at least the following at the time of receipt:

(a) a mention that the grant of a patent is applied for;
(b) the particulars identifying the applicant or the person filing the application, or which enable the competent national office to communicate with that person;
(c) a description of the invention;
(d) drawings if they are relevant; and
(e) proof of payment of the prescribed fees.

Failure to comply with any of the requirements specified in this Article shall cause the competent national office to regard the application as not having been accepted for processing, and no filing date shall be assigned to it."

The competent national office will verify that the patent application meets the minimum requirements necessary for granting the filing date (Article 33 of Decision 486), and will carry out the documentary examination.

Requests must be submitted in writing and in Spanish, in accordance with local legislation. Depending on each office, the copy will preferably be presented in electronic format, upon payment of the corresponding fee. Depending on each office, the virtual parties table can be used, or the electronic submission platform or portal for applications in digital format, when available.

If the application includes drawings of the invention, it will be verified that the related or mentioned drawings are indeed annexed to the application. If the drawings are not found or if they are necessary to understand the invention, the application will not be accepted for processing and the applicant will be informed immediately.

5. EXAMINATION PROCEDURE OF PATENT APPLICATION FORM

Decision 486 establishes the following provisions:

"**Article 38.**- The competent national office shall, within the 30

days following the filing date of the application, examine whether it fulfills the conditions of form provided for in Articles 26 and 27."

The formal examination will consist of the verification of:

5.1 Petition
The request is in the form required by each competent national office.
The form examiner will verify:

5.1.1 Application
The type of application to be processed, checking the box corresponding to "Invention Patent" or "Utility Model Patent".

5.1.2 Applicant
If the applicant is a natural person: indicate his or her name, address, nationality and complete address.
In the event that the applicant is a legal entity: the examiner must also verify that its place of incorporation is indicated.

5.1.3 Representative or attorney
In the case of a request from a natural or legal person acting through a legal representative or attorney-in-fact, the form examiner must verify that the power of attorney complies with the requirements of the national law of the Member Country and that the request indicates its name and direction.

In the case of legal entities, the examiner must also verify that the existence and representation of the same is accredited in accordance with the practice of each office.

5.1.4 Inventor
The name and address of the inventor will be verified. The inventor's data can be indicated inside or outside the application form. The form examiner will verify that the inventor is always one or more natural persons. There is a possibility that there may be co-inventors in an application.

5.1.5 Title of the invention
The title, name or denomination of the requested invention, which

complies with the applicable standards.

5.1.6 Proof of payment

The presence of proof of payment of the established fees and their amount.

5.1.7 Annexes to the application

The effective presence of the annexes mentioned in the application.

5.1.8 Signature

The signature of the owner, his legal representative or attorney on the application.

5.1.9 Language

The request written in Spanish (Article 7 of Decision 486).

5.2 Description

In the form exam, the examiner does not perform an exam to verify the content, clarity and understanding of the description. However, you must verify the presence of a document that appears to be a description of the invention, and verify that this document is sufficiently legible.

5.3 Claims

In the formal examination, the examiner does not verify the claims regarding their clarity, conciseness, and support in the description. The form examiner only verifies the presence of a part of the application that contains one or more claims (claim chapter). These requirements will be verified in the background exam.

5.4 Drawings

If the application mentions drawings, the examiner will verify their existence and that they are separate from the description. The drawings related to the application or request or which, without being related, were mentioned in the description, must be attached to the application. If any drawing mentioned in the application is missing, this fact will be indicated in the file.

5.5 Summary

The form examiner will verify that the application contains a summary of the invention that meets the applicable standards. The abstract must indicate the technical field to which the invention belongs.

5.6 Powers

When the applicant is represented by a representative, it will be verified that the respective document accompanies the application. The power of attorney document must comply with the internal rules and practices of the Member Country.

5.7 Copy of the access contract to genetic resources or license contract for the use of traditional knowledge

In the event that the invention had been obtained or developed from genetic resources or their derivatives, from traditional knowledge, originating in any of the Member Countries, the existence of a contract or other document that accredits legitimacy or legal access will be verified. to those genetic resources or traditional knowledge, in accordance with the regulations applicable in the respective country, issued by the Competent National Authority (hereinafter ANC). The access document must be presented with the formalities that each Member Country stipulates necessary. More information about the contract for access to genetic resources is found in Annex III of this manual.

5.8 Certificate of deposit of biological material

In the case of inventions referring to a product or a process related to a biological material and cannot be described in a way that can be understood and executed by a person trained in the technical matter, the examiner will verify that the certificate of deposit of the respective material has been presented. issued by an authority or institution for the deposit of biological material, and, where applicable, any information referring to digital verification means of said authority or institution. Each Member Country will have the power to request or dispense translation when said document is in a language other than Spanish. Likewise, the certificate of deposit of the material, and where appropriate the translation, must be presented with the formalities that each Member Country stipulates necessary.

In accordance with Article 29 of Decision 486, the deposit must be made no later than the date of submission of the application, or, where applicable, on the date of submission of the application whose priority is invoked. If it is evident that the applicant has not made the timely deposit of the biological material, the examiner will not request the certificate, since it would not be possible to accept a late deposit. Therefore, the examiner will verify that the application includes the certificate of deposit and that it complies with the provisions of Article 29 of Decision 486.

Deposits must be made with an international depository authority in accordance with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Process, 1977, or with another depository institution recognized by the national office competent to these effects.

According to the definitions of the aforementioned treaty:
"(vii) "depositary institution" means an institution which provides for the receipt, acceptance and storage of microorganisms and the furnishing of samples thereof;
(viii) "international depositary authority" means a depositary institution which has acquired the status of international depositary authority as provided in Article 7;"

The certificate of deposit must indicate the name and address of the depository institution, the date of the deposit and the deposit number assigned by such institution. Eventually, the certificate of deposit may be accompanied by information that allows verification by digital means, depending on the institution.

In view of Article 29 of Decision 486, depository institutions recognized by the competent national office may be biological resource centers or national or international culture collection centers and must fulfill at least the following functions:

1. Store and preserve the type of biological material that is the subject of the patent application to maintain its viability and purity for subsequent use;
2. Perform the identification and characterization of the samples for the purposes of their conservation;

3. Store in the long term of said material for later use;
4. Provide samples of said material to any interested person;
5. Provide a certificate of deposit.

The biological materials that can be deposited in one of the depository institutions for biological material depend on each authority or depository institution. Those materials include, but are not limited to:

- cells (including bacteria, fungi, cell lines and plant spores)
- seeds that can be dried to a low moisture content and stored at -20 °C or lower
- genetic vectors such as plasmids or bacteriophage vectors or viruses containing a gene or DNA fragments
- organisms or systems used to produce a protein from a gene, including:
  - viral, bacterial, yeast, plant or animal cell cultures
  - yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, viruses, plant tissue cells, spores and hosts containing materials such as vectors, cellular organelles, plasmids, DNA, RNA, genes and chromosomes
  - purified nucleic acids
  - deposits of materials such as “naked” DNA, RNA or plasmids.

If the certificate of deposit is not presented or indicated where it can be obtained, the office will notify the applicant to present the respective document, or prove its existence.

The deposit of biological material will only be valid for the purposes of granting a patent if it is done under conditions that allow any interested person to obtain samples of said material no later than the date of expiration of the period provided for in Article 40 of Decision 486. In this way, the biological material deposited in any of the deposit institutions referred to here must be publicly accessible, no later than the date of publication of the patent application. Where applicable, the relevant provisions of the aforementioned Budapest Treaty Regulations will apply.

5.9 Document of transfer of rights from the inventor to the applicant

In cases where the inventor is different from the applicant, the formal examiner will verify that the document accrediting the transfer of the right to the patent from the inventor to the applicant has been presented in accordance with the formalities and practices of each Member Country, or that the application clearly explains the manner or title by which the applicant acquired the right to the patent from the inventor. For example, in the case of an employment or contractual relationship, the applicant must indicate that such a relationship exists. In cases of hereditary succession, the existence of the executed will or final court ruling will be verified.

5.10 Language

The examiner will verify that the documents mentioned in Sections 5.2 to 5.9 of this Chapter are in the language accepted by the competent national office or, if not, accompanied by a simple translation in said language (Articles 7 and 8 of Decision 486).

For verification of compliance with Articles 26 and 27 of Decision 486, and in accordance with local practice. This list will be the basis of the notification to the applicant.

6. RESULTS OF THE FORM EXAMINATION

"**Article 39.**- If it emerges from the examination as to form that the application does not meet the conditions specified in Articles 26 and 27, the competent national office shall inform the applicant accordingly, so that he may meet those conditions within a period of two months following the date of notification. That period may be extended once by an equal amount at a request of a party without any loss of priority.

If, on the expiry of the period specified, the applicant has not met the conditions mentioned, the application shall be considered abandoned and its priority shall be lost. The competent national office shall nevertheless respect the confidentiality of the application."

If the deficiencies notified to the applicant are not corrected within two months following the notification or its extension, the formal examiner will prepare a resolution or official letter declaring the abandonment indicating the reasons for it. The application declared abandoned will lose its priority. In any case, the competent national office will maintain its confidentiality if the abandonment occurs before the publication of the application (see point 7, below).

The decision to abandon the application may be subject to the corresponding legal remedies, in accordance with the provisions of the internal legislation of the Member Country.

7. PUBLICATION OF THE APPLICATION

7.1 Steps prior to publication

In accordance with its local practice, the national office will verify that the formal examination is favorable and will assign the application the international classification, in accordance with the IPC corresponding to the requested invention, where relevant.

The office shall verify that the extract to be published contains the bibliographic data of the application, an abstract or an extract that in general terms contains the claim or claims.
The office will then verify if there was a request for advance publication or prior publication (Article 40 of Decision 486), as well as the existence of an invocation of priority in order for it to be indicated in the publication.

7.2 Publication

"**Article 40.**- When 18 months have elapsed following the filing date of the application in the member country, or where applicable following the priority date claimed, the file shall be declared public and may be inspected, and the competent national office shall order the publication of the application pursuant to national legislation.

Notwithstanding the provisions of the foregoing paragraph, the applicant may request publication of the application at any time, provided that the examination has been completed.

In such a case the competent national office shall order such publication."

"**Article 41.-** A patent application may not be consulted by third parties until 18 months have elapsed from the filing date, except where the written consent of the applicant has been obtained.

Any person who proves that the applicant for a patent has sought to assert rights deriving from the application against him may consult the file prior to publication, even without the consent of the said applicant."

Publication will be carried out in accordance with the legislation and practice of the competent national offices.

8. REQUEST FOR SUBSTANTIVE EXAMINATION

"**Article 44.-** Within a period of six months following the publication of the application, regardless of whether or not oppositions have been filed, the applicant shall request that the invention be examined for patentability. Member countries may charge a fee for the conduct of that examination. Where the said period expires without the applicant having requested examination, the application shall lapse."

The applicant must request in writing to examine whether the invention contained in his application is patentable or not. To request this examination, the applicant for an invention patent has a period of six months from the date of publication. If payment of a substantive examination fee is required, the examination request must be accompanied by proof of respective payment, when feasible. The request for examination and proof of payment are integrated into the file and the application is ready to be examined at the merits stage.

9. OPPOSITION

"**Article 42.**- Within a period of 60 days following the publication date, any person having a legitimate interest may file one reasoned opposition contesting the patentability of the invention.
At the request of a party, the competent national office shall grant one additional period of 60 days for the substantiation of the opposition.
Reckless oppositions may be punished if national legislation so provides."

"**Article 43.**- Where opposition has been filed, the competent national office shall notify the applicant so that he may, within 60 days, present his arguments, submit documents or revise the claims or description of the invention if he sees fit.
At the request of a party, the competent national office shall grant one additional period of 60 days for the response."

The office will verify that the opposition, if any, is incorporated into the file and has been presented within the period provided for in Decision 486.

In this case, it will notify the patent applicant and make available a simple copy of the document and its annexes. The response to the opposition will be incorporated into the file and it will be verified that it has been made within the period provided for in the Decision.

In accordance with local legislation, the additional term must be requested at any time before the expiration of the term you wish to extend. Said extensions will be understood to be granted automatically for the respective period, counted from the first business day following the day on which the original term expires, without requiring an express pronouncement by the competent national office.

CHAPTER III SUBSTANTIVE EXAMINATION

1. FUNCTIONS OF THE BACKGROUND EXAMINER

The substantive examiner is a professional who is trained in the analysis of patentability requirements in a certain field of technology, in order to define whether the claimed object is susceptible to being protected with a patent. Its functions are the following:

- Pre- classification (if it had not been carried out before) and definitive classification of the invention in accordance with the IPC;
- Background search and preparation of the search report, in order to establish the state of the art relevant to the invention;
- Requirement of documentation from the applicant, if necessary;
- Preparation of the patentability examination of the invention;
- Pronouncement on compliance with patentability requirements and on the granting or denial of the patent;
- Preparation of technical reports related to the patentability of the invention (in cases of reconsideration, modifying act, appeal, complaint for infringement, request for nullity or when required);
- Guidance to the applicant to comply with the technical requirements related to their application; and
- Support the analysis to clarify whether the technical matter of the invention has been developed from GR. or TK, if applicable, in accordance with Annex III.

2. VERIFICATIONS PRIOR TO THE SUBSTANTIVE EXAMINATION

The competent national office, before starting the examination, will verify the general situation of the file, which includes:

a. that the application has been published;
b. that the application has not fallen into abandonment, withdrawal or expiration;
c. the request for the substantive examination and the payment of the corresponding fee, if applicable;
d. If the priority of a foreign application is claimed, the examiner will limit himself to reviewing within the documents related to priority:

i. mention that one or more priorities are invoked, indicating the date, office and, if possible, the number of the priority request(s);
ii. that the application being examined has been submitted to the competent national office within a period of 12 months from the day following the first invoked priority application (Article 9 of Decision 486);
iii. that the priority document provided corresponds to the document(s) stated in the application;
iv. a copy of the priority application certified by the respective office (no legalization is required) (Article 10 of Decision 486);
v. a certificate of the date of submission of the priority application(s), issued by the respective office (legalization is not required).
vi. priority rate, if applicable, in accordance with domestic legislation;
vii. requirements iii), iv), v) and vi) have been provided at the time of the application or within the maximum period (non-extendable) of 16 months from the date of the initial application;
viii. verify the correspondence of the technical content of the application being examined with the content of the claimed priority.

e. that, where appropriate, the opposition, the respective notifications and responses appear;
f. that, if made, the modifications or amendments to the description, claims and drawings appear; and
g. whether or not there is a division or merger of the application; If this occurs after publication, no new publication will be required.

3. DESCRIPTION

3.1 Requirements of Article 28 of Decision 486

"**Article 28.**- The description shall disclose the invention in a manner sufficiently clear and complete to be understood and for a person skilled in the corresponding technical field to be able to carry it out. The description of the invention shall state the name of the invention and include the following information:
(a) the technological sector to which the invention relates or

applies;

(b) the previous technology known to the applicant that may be useful for understanding and examining the invention, and references to earlier documents and publications relating to the said technology;

(c) description of the invention in terms that allow the technical problem and the solution provided by the invention to be understood, with an explanation of the differences and possible advantages in relation to the earlier technology;

(d) an account of the drawings, if any have been filed;

(e) a description of the best method known to the applicant of carrying out the invention or putting it into practice, with the use of examples and references to the drawings where the latter are relevant; and

(f) a mention of the way in which the invention meets the condition of industrial applicability, if this is not clear from the description or the nature of the invention."

The description of the invention fulfills an important function, which is to disseminate the technical teaching of the invention. To do this, the invention must be described in a sufficiently clear and complete manner so that it is possible to understand it and so that a person trained in the corresponding technical subject can execute it. These two requirements complement each other since the understanding of the invention is what the person trained in the corresponding technical subject can understand about the invention and be able to evaluate the contribution made to the technology, while the execution includes being able to carry out step step by step invention.

The person trained in the technical matter is a person trained in the technological field to which the invention belongs (for greater detail see the glossary in Chapter VI). Their level of knowledge is higher than the level of knowledge of the general public, but does not exceed what can be expected from a suitably qualified person. This is the person with average knowledge in the technological field, but it is not necessary for them to be a highly specialized expert.

Given that the general requirements of the description are clarity and sufficiency, the examiner must determine whether the

information provided in the description allows a person trained in the technical subject matter of the application to clearly understand the technical problem and the proposed solution, and if this is sufficient to reproduce the invention. When the examiner identifies that the description is not clear or sufficient, he or she must immediately notify the applicant.

3.1.1 Clarity

The disclosure of the invention must be made in terms that allow understanding of the technical problem and the solution provided by the invention. The advantages that exist with respect to the state of the art can also be presented. It is the applicant's responsibility to provide the information in the description clearly.

The description must be written in the usual technical language of the technological field to which the invention belongs. If a term has a meaning different from that commonly given to it in the respective technical field, this must be indicated, and signs and symbols accepted in the field in question must be used for mathematical and chemical formulas.

3.1.1.1 Measurement units

The units of measurement must express their correspondence in the International System of Units (SIU). The unit of measurement is a particular magnitude, defined and adopted by convention, with which other magnitudes of the same nature are compared to quantitatively express their relationship with this magnitude.

3.1.1.2 Formulas of new compounds

If the object of the invention is related to new chemical compounds, the description must disclose the structural chemical formulas of said compounds and/or define them by their chemical name (IUPAC name). If this is not done, the examiner must raise an objection due to lack of clarity and/or lack of descriptive sufficiency.

3.1.1.3 Stages of a new synthesis process

If the object of the invention is a new process for synthesizing a compound, the description must mention the essential steps and conditions of the compound synthesis process. If this is not

done, the examiner must raise an objection due to lack of clarity and/or lack of descriptive sufficiency.

3.1.1.4 Own names, registered trademarks, trade names

The use of proper names, registered trademarks, trade names or similar to refer to the subject matter of the invention is not accepted within the description, unless they are defined in the description. However, where such words have become internationally accepted as standard descriptive terms and have acquired a precise meaning within the particular technical field, they may be permitted without further identification of the product to which they relate.

3.1.1.5 Drawings and reference numbers

If the application includes drawings, these must be briefly detailed within the description, for example: “Figure 1 shows a side view of the packaging machine; Figure 2 shows a partial view of the first phase of operation of the machine of Figure 1; Figure 3 shows a partial view of the second phase of operation of the machine of Figure 1”.

Likewise, when referring to the drawings, the name of each element must be followed by a reference number, for example: "the packaging machine (10) comprises two rollers driven by the motor (11) to support and rotate the roll (13)”. Reference to the drawings should not be permitted without mentioning the name of the element depicted in the drawing, for example, as follows: “10 comprises two rollers driven by 11 to support and rotate 13.”

The description and drawings must be consistent with each other when referring to signs, symbols or reference numbers.

3.1.2 Sufficiency

The purpose of the description is to ensure that, on the one hand, the application is described with sufficient technical information in detail so that a person trained in the respective technical field can implement or reproduce it, and on the other hand, that the description makes known the contribution or technological advance in the respective technical field. The description must indicate the way in which the invention satisfies the condition of being capable of industrial

application, if this is not evident from the description or the nature of the invention.

The invention can be considered sufficiently described if one or more examples, alternative embodiments or variations are provided that enable the person versed in the technical subject to, by applying his general technical knowledge, be able to put the invention into practice in the entire claimed area and not just some particular modalities claimed, without requiring an inventive effort to do so. However, the presentation of examples relating to all the particular species of the invention or to each claimed alternative will not be necessary to find a sufficiency of the description, as long as said species are mentioned in it.

3.1.2.1 Lack of sufficiency of the description

When the claimed subject matter is excessive in scope and the preferred embodiments or alternative embodiments are not sufficient to cover the subject matter covered within the scope of the claims, it will be understood that a person normally versed in the art would not be able to reproduce the invention and therefore, the description is not enough. In such a case, the examiner will consider that only some embodiments are sufficiently described.

The inclusion of additional new examples in the context of the correction of an objection due to lack of sufficiency may not be admitted, as it will be considered an expansion of the matter disclosed in the initial application, which is not permitted by Article 34 of the Decision 486.

It may happen that the description is not sufficient, to the point that it is impossible for a person skilled in the art to execute the invention. In these cases, the applicant will not be able to correct the failure, since any addition of information would constitute an extension to what was initially presented, which is not allowed according to the aforementioned Article 34. In such case, the examiner must notify an objection alleging lack of sufficiency of the description. This includes, for example, cases where successful reproduction of the invention depends on chance; that is, when the person skilled in the art follows the

instructions for executing it and finds that the supposed results to be achieved are unrepeatable or unpredictable, or that success was obtained in an uncertain and unreliable manner (see example 1 of Section 1 of Annex IV).

There could be the case of inventions whose reproduction in practice is impossible because they go against the natural laws of physics. The typical case that exemplifies this situation is a perpetual motion machine. In these cases, the description would always be insufficient and the patent must be denied.

3.1.2.2 Sufficiency of the description of biological material

When the invention refers to a product or a process that involves a biological or genetic material and the invention cannot be described in a way that can be understood and executed by a person trained in the technical field, the description must be complemented with a deposit of said material, as mentioned in Section 5.8 of Chapter II of this manual. It should be noted that not always when the invention refers to biological or genetic material will it be necessary for the applicant to present a deposit certificate. The deposit must only be complied with when the description of the invention requires complementation with the deposit of said material or when said deposit is necessary to interpret the scope of the claims in accordance with Articles 30 and 51 of Decision 486 (see Section 4.6 of Chapter III, related to clarity and claims).

The examiner will consider that the biological material is not sufficiently described when:

- the biological or genetic material that is claimed, or that was necessary to reproduce or execute the invention, was not known by a person trained in the relevant technical field (biotechnology); or
- the biological or genetic materials to which the invention relates cannot be described sufficiently so that a person skilled in the art can reproduce or execute that invention.

The examiner will consider that the material is sufficiently described when:

- the biological material is known by a person trained in the relevant technical field (biotechnology); or

- the applicant has included in the application sufficient information to identify the characteristics of the biological or genetic material; or
- the biological material is already stored in some recognized deposit institution.

In addition, the description presented should contain adequate information of the properties of these biological materials, including information on the taxonomy of biological materials and distinctive characteristics in comparison with well-known biological materials, for example, biochemical characteristics, morphological as well as taxonomic characteristics.

If the references to the biological material do not correspond to what is indicated above, the examiner must assume that the biological material is not accessible to the public, and, therefore, the invention is not sufficiently described, and must therefore be objected based on the provisions of Article 28 of Decision 486.

Finally, there are cases of biotechnological inventions, where nucleotide or amino acid sequences are described, in which the presentation of the respective list is necessary, as mentioned in Section 6 of Chapter III of this manual. The sequence listing must be attached to the application on the submission date, as it constitutes a fundamental part of the description. In accordance with the practice of each national office, the patent application may be declared inadmissible if the list is not attached.

3.1.2.3 Markush type formulas

If an invention refers to a Markush formula, of the type "A-B-C-D", the examiner may present a request for lack of clarity and/or lack of descriptive sufficiency, according to Article 28 of Decision 486, which express that the information in the description is not sufficient to synthesize all the compounds formed by the combination of the variables of the formula and may suggest to the applicant to limit the application. (see example 11 of Section 4 of Annex IV).

3.1.2.4 Polymorph

As mentioned in Section 7.6.1 of this Chapter, countries are

responsible for technically and scientifically determining patentability requirements for all inventions, including polymorphs and other crystalline forms. Therefore, for a polymorph to be considered sufficiently described, the application must contain the following information:

a. At least one process for obtaining the seed crystal or first polymorph with sufficient detail of all essential steps and experimental conditions so that the person ordinarily skilled in the art can, by putting them into practice, arrive at the claimed polymorph; and
b. The description of the polymorph, using techniques available for this purpose, such as:
   - The 2 theta values of the single crystal X-ray diffraction pattern (single crystal XRD) and the respective figure; or
   - The 2 theta values of the X-ray powder diffraction (XRPD) pattern and the respective figure; and other technical data, such as those obtained by thermal analysis methods or spectroscopic methods, that allow characterizing a certain polymorph, such as:
     – Thermal analysis methods:
     (a) Differential scanning calorimetry (DSC), or
     (b) Differential thermal analysis (DTA), or
     (c) Thermogravimetric analysis (TGA), or
     (d) Hot phase microscopy (HSM);

     – Spectroscopic methods:
     (a) Raman, or
     (b) Infrared (IR), or
     (c) Carbon-13 nuclear magnetic resonance (13C-NMR).

Single crystal X-ray diffraction provides a complete supramolecular description of the crystalline structure from a "near perfect" single crystal sample, as well as data that allows to calculate or predict the diffraction pattern obtained from the powder of such a material, thus representing a sufficient technique to characterize the crystalline structure of a solid compound (polymorph). In this regard, if a certain polymorph has been characterized using this technique, the description of other techniques with the same purpose will be optional.

If single crystal X-ray diffraction data is not provided, provide

powder X-ray diffraction (XRPD) data, which is an important analytical tool for differentiating crystalline forms as it provides a "fingerprint" of the crystal lattice. Also, XRPD data should be provided from the initial application along with data from: (i) DSC, DTA, TGA or HSM; or (ii) spectroscopic methods cited in b. (compare examples 3 and 6 of Section 1 and 9 and 10 of Section 4 all in Annex IV).

It is important to present figures corresponding to the diffractograms of each polymorph, where the scanning region must comprise from 0° to 40° 2 theta for organic compounds (small molecules) and from 0° to more than 50° 2 theta (for example, up to 90°, up to 120°, or up to 150°) for inorganic compounds, as justified in each particular case. It is suggested that each diffractogram shows the relative intensities (Y axis) as a function of the 2 theta angles (X axis) with their respective data tables. It is suggested that the diffractogram shows the most relevant relative intensities to characterize the polymorph.

As with other inventions, in the case of polymorph, the description must disclose the technical problem faced by the forms existing in the state of the art and the solution provided by the polymorph that is the subject of the application, which must be supported by evidence that allows us to establish that, in fact, the problem has been resolved.

The description will be considered not sufficient to describe the polymorph when:

- does not clearly describe the preparation procedure of the claimed polymorph;
- they do not include all the preparation processes disclosed in the application, they involve the seeding of crystals but the preparation of the seed crystals is not described; or
- The essential parameters used in said processes are omitted.

3.1.2.5 Pharmaceutical compositions containing a new compound

If the object of the invention is a new compound, the patent applicant has the right to claim pharmaceutical compositions characterized by containing that new compound, but is not obliged to use examples of how to design and prepare specific compositions containing the new compound because “the solution

provided by the invention", that is, the object of the invention is "the new compound". It is understood that a person versed in pharmaceutical matters is capable of designing and preparing specific compositions containing the new compound, with the information disclosed in the application and with his general knowledge of the state of the art. In this case, the description will be considered to meet the sufficiency requirement.

3.1.2.6 New compound synthesis processes

Likewise, if the object of the invention is a new compound, the applicant has the right to claim the process of synthesis or obtaining the new compound, as long as said process has been described in such a way that a person versed in the matter technique can reproduce it and regardless of whether it is a process analogous to another process already known in the state of the art.

3.2 Modifications to the description

A modification that entails expanding the protection that would correspond to the disclosure contained in the initial request will not be accepted, in application of Article 34 of Decision 486. Without prejudice to the above, the following will be accepted:

i. relevant documents of the state of the art not cited, as long as they do not include interpretations, clarifications or comments of the applicant, regarding the described invention;
ii. adaptations of the description to the claims, taking into account the requirements of the first paragraph of Article 34; and
iii. others of a similar nature

3.2.1 Correction of material errors

The correction of material errors will be admitted. The following are considered material errors:

i. the correction of a grammatical or calculation error; and
ii. the correction of a quote, reference, formula or name as long as it is obvious.

3.2.2 Modifications derived from drawings

There are cases where modifications are based on details that are only found in the original application drawings. Within this

context, a figure that only serves to give a schematic explanation of the principle of the object of the invention, without representing it in every detail, cannot be understood as an intentional exclusion of missing characteristics.

The way a particular feature is represented in the drawings may be incidental. The person skilled in the art must be able to clearly and unequivocally recognize from the drawings, in light of the complete description, that the added feature deliberately results from technical considerations aimed at solving the technical problem involved (see example 2 of Section 1 of Annex IV).

3.2.3 Additional effects and examples

An amendment by introducing additional examples must be examined very carefully in the light of Article 34 of Decision 486. The same applies to the introduction of statements of new effects of the invention, not mentioned above, such as new technical advantages.

Example of additional effect:

If the originally filed invention relates to a process for cleaning woolen clothing that involves treating the clothing with a particular fluid, the applicant may not introduce later in the description a statement that the process also has the advantage to protect clothing against moth damage.

However, in certain circumstances, new effects or examples presented later, even when not incorporated in the description, may be taken into account by the examiner as evidence in support of the patentability of the claimed invention. An additional example may be accepted as evidence that the invention can be readily applied throughout the claimed field, based on the information provided in the originally filed application. Similarly, a new effect can be considered as evidence in support of the inventive step, provided that this new effect is implicit or at least related to an effect disclosed in the originally filed application and to some technical feature(s) initially disclosed. The treatment of this type of information is discussed in greater detail in Section 11.9 of Chapter III of this manual.

3.3 Suggested wording of the technical report (in case of extension)

"The modifications made to the description, page _____, lines _____ /in the claim(s), received on day xx/xx/xx expand the content of the application as it was initially submitted. The reasons are as follows:

i) first argument; and

ii) second argument

In response to the prohibition enshrined in Article 34 of Decision 486, the previous modification is not admissible, since it implies an expansion of the protection that would correspond to the disclosure contained in the initial request.

Any additional information that the applicant wishes to provide in relation to the invention (e.g. advantages with respect to the known state of the art, comparative examples, etc.) and that was not in the initially submitted application, must be provided by the applicant in a separate document and not incorporated into the text of the request."

4. CLAIMS

4.1 Requirements of Article 30 of Decision 486

"**Article 30.-** The claims shall define the subject matter to be protected by the patent. They shall be clear and concise and entirely supported by the description.

The claims may be either independent or dependent. A claim shall be independent where it defines the subject matter to be protected without reference to another, earlier claim. A claim shall be dependent where it defines the material to be protected by reference to an earlier claim. A claim that refers to two or more earlier claims shall be considered a multiple dependent claim."

A patent application must contain one or more claims. The claims are an essential part of the application since they define the invention to be protected and delimit the scope of that protection, as established in Article 51 of Decision 486:

"**Article 51.-** The scope of the protection conferred by the patent shall be determined by the content of the claims. The description

and drawings and any biological material deposited, shall be used for their interpretation."

Three fundamental requirements of the claims are derived from Article 30 of Decision 486: that they be clear, concise and that they are supported by the description, in such a way that:

- can be compared and differentiated from the prior art in order to verify patentability requirements; and
- the extent of the patent holder's rights can be determined unambiguously.

These requirements apply to each claim individually, as well as to all of them as a whole.

4.2 Content of the claims

The claims, as well as the description, may contain chemical or mathematical formulas, but not drawings. Claims may contain tables, but only if their content makes the use of tables desirable.

Likewise, the claims must contain all the essential technical characteristics of the invention. They define the solution to the technical problem that the invention tries to solve.

For the purposes of the examination, the inclusion of terms relating to non-technical aspects, such as commercial advantages, is not taken into account as a technical feature of the invention, since the result or end achieved of the invention is not an essential feature for these purposes. Notwithstanding this, the inclusion of non-technical elements may affect the clarity of the claim.

A claim must include not only a list of elements, but also indicate the functional relationship between them when for the person versed in the matter this does not appear obviously from the definition of the element itself.

4.2.1 Structural and functional characteristics

A category of technical characteristics in a claim, perhaps the most intuitive, is that which is defined by its structure, composition or form. These are called structural features.

However, those technical characteristics defined by the function they perform are allowed, as long as in that technical field it is easy to find a way to carry it out. These are called functional characteristics. In an independent claim a functional characteristic, in general, cannot be the only technical characteristic. It must be accompanied by at least one other structural or functional technical characteristic.

Example of functional characteristic:
"…element to increase the pressure of a fluid in a hydraulic circuit…"
It is an undefined element of technique that is only specified by the function it performs. But it is much more likely that in a claim, this element of technology will appear in a claim as a "pump" that suggests a more structural physical element. The fact that it is worded in this way or another does not change its nature as a functional characteristic; it remains an undefined element of technology since there can be many types of pumps: bladed, geared, electric, etc. Any pump would be valid and also in the technical sector it would not be difficult to find one that fulfills the function.

4.2.2 functional characteristics "Means plus function"

A formal way of writing a functional characteristic that tries to identify its nature is called "means plus function." This type of writing always includes the word "media" to then indicate the function performed by those media.

In the previous example of the pump, it would be: "means to increase the pressure of a fluid". The word "means" creates a certain lack of definition that, to avoid generalizing and in case of doubts for third parties, is interpreted as being limited to the means that appear as examples in the description or dependent claims or to those means that an expert in the field of that technical sector could clearly use as equivalents.

This way of writing a technical characteristic makes it more general and expands its scope of protection. They have the drawback that the definitions are somewhat artificial, moving them away from technical language towards a more legal language that can create a certain confusion, especially when several of

these characteristics of means plus function are present in the same claim.

Examples of "means plus function" functional characteristics
- Injection media
- Means for detecting an end-of-stroke position
- Means for lifting a stack of trays

4.3 Form of claims
Although Decision 486 does not define the way in which claims must be presented, they can be presented through a structure that consists of two parts: a preamble and a characteristic part.

The preamble will first indicate what the subject of the invention is (device, process, composition, compound, etc.) and the technical characteristics necessary to define the invention but which together form part of the state of the art. The latter only applies to independent claims.
The characteristic part defines the characteristics that, in combination with the preamble, are intended to be protected, that is, the elements that the invention adds to the state of the art.

The division between the preamble and the characteristic part may change during the substantive examination in view of the state of the art that can be found.

Example of a claim with two parts:
"Composition comprising A, B and C, characterized in that the concentration of A is less than 3%."

In this case, the form of the claim is appropriate since compositions comprising components A, B and C are already known in the state of the art (preamble) and the contribution of the invention is the limiting concentration of A (characteristic part) which is not in the state of the art.

The purpose of the two-part structure (preamble - grammatical link - characteristic part) is to allow the person skilled in the art to clearly see which characteristics necessary for the definition of the claimed object are part of the prior art. However, if this is sufficiently clear from the indication of the

state of the art made in the description, the two-part form should not be insisted upon.

Example of a claim without two parts:
"Camera that includes automatic distance correction."

In this case it is not necessary to write the claim in two parts since the common technical characteristics are already implicitly described in the term "camera".

In some cases the nature of the invention may be such that the two-part form is not suitable, for example because it would give a distorted or misleading impression of the invention or the prior art.

Examples of the type of invention that may require a different presentation:

a) the modification, as opposed to addition, of a known chemical process, for example, by omitting a substance or substituting one substance for another;
b) a complex system of functionally interrelated parts, the inventive level refers to changes in several of these or in their interrelationships; and
c) when the invention is a new chemical compound or group of compounds.

In examples a) and b), the two-part form may be artificial and inappropriate, while in examples c) it could result in an excessively long and complicated claim.

Other cases are also likely to arise in which the applicant can put forward compelling reasons for formulating the claim in a different way.

4.4 Categories of claims

"**Article 14.-** The member countries shall grant patents for inventions, whether of goods or of processes, in all areas of technology […]".

There are fundamentally two categories of claims: those that refer to a product and those that refer to a process.

4.4.1 Product claim

Product claims are used for substances and compositions, as well as articles, machines, mechanisms, systems, systems of devices that cooperate with each other as a combination of devices, kits of parts, electronic circuits, etc.

Example of composition product claim:

Food composition to make a pizza dough, essentially characterized by being made up of a mixture of ingredients by weight that, subjected to a subsequent hydration process, gives rise to a professional pizza dough, the composition includes:

- a soft wheat flour in a percentage between 50% and 99%;
- salt in a percentage between 0.5% and 10%;
- a brewer's yeast in a percentage between 0.1% and 20%;
- and is complemented with at least one of the ingredients listed below, in a percentage between 0% and 10%: rye flour; wheat bran; wheat semolina; potato starch; modified starch; dietary fibers; soy and derivatives; vital wheat gluten; alpha amylase; L-cysteine; L-ascorbic acid; glucose oxidase; milk powder; omega 3 powder; milk serum protein; pentosans; xylanase; malt flour; starter powder sourdoughs; lactic acid.

It is worth mentioning that there are product claims that are defined in terms of a manufacturing process, which are explained in greater detail in Section 4.6.8 of Chapter II of this manual.

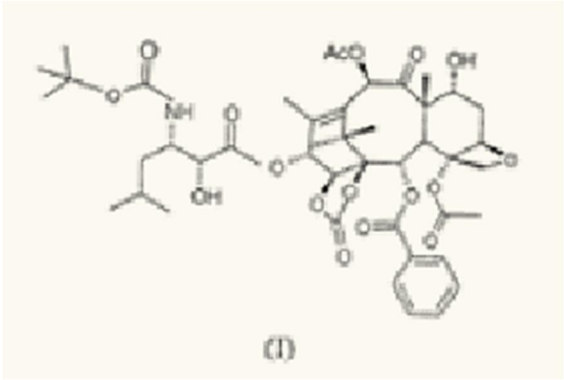
4.4.2 Process claim

Process claims are used with respect to inventions that involve an orderly and coherent sequence of steps or phases to obtain a product, or the use of any material product to carry out a process, which does not consist solely of the use of such product. These activities can be carried out on material products, energy, other processes (for example, control processes) or on living beings, when legislation allows it.

Example of process claim

“Synthesis process of a crystalline form of the potassium salt of the formula compound (I)

Which understands:



(I)

1) Mix a potassium base, in an organic solvent and water, together with the free acid corresponding to the formula salt(I), in an organic solvent and water;
2) cool the resulting suspension;
3) isolate the crystals resulting from the resulting suspension;
4) wash the isolated crystals with an organic solvent and water; and
5) Dry isolated crystals, to give crystalline potassium salt(I) under conditions that correlate with the stability domain of the monohydrate form or the dehydrated form, respectively, of potassium salt;
6) and where the compound of formula(I) is an individual stereoisomer or any mixture of stereoisomers".

It is essential that the claim studied leaves no doubt as to the category to which it belongs. If the words used are such that it is not possible to determine to which category a claim belongs, a lack of clarity must be objected.

In the field of computer-implemented inventions (hereinafter CII) the claims must define all the characteristics that are essential for the technical effect of the process that the computer program must carry out when it is executed. Some models for drafting CII claims can be found in Section 7.7.6.2 of Chapter III of this manual.

Many inventions need claims from more than one category to obtain complete protection. In a set of claims, each change in category identifies a claim as independent, even when the claim refers to a preceding one. It is important to note that the set of claims always has to comply with the unity of invention requirement (see Section 9 of Chapter III).

4.5 Type of claims

Article 30 of Decision 486 also defines the type of claims indicating that they may be independent or dependent.

4.5.1 Independent claims

An independent claim defines all the essential features of the invention and is self-sufficient. It is possible to find more than one independent claim in a category or in different categories in the same application.

If the independent claim is very general and does not mention the characteristics that are essential because it leaves them in some dependent claim, the objection must be presented to the applicant for lack of clarity and support in the description, and request that the characteristics be incorporated into the main claim relevant essential characteristics.

4.5.2 Dependent claims

A dependent claim is one that refers to a previous claim and contains all the characteristics of that claim (if possible, this fact is indicated at the beginning of the claim). In a dependent claim the expression "characterized by" must be understood as "further characterized by". That is, if claim 3 depends on claim 2 and this on claim 1, claim 3 is the sum of the characteristics of claim 1 plus claim 2 plus claim 3, since by itself it would have no meaning.

A dependent claim may refer to one or more independent claims, to one or more dependent claims, or to dependent and independent claims at the same time, provided that the dependence is clear and there are no contradictions.

Dependent claims may refer to particular characteristics of an element of the independent claim, regardless of whether said element is found in the preamble or in the characteristic part of the independent claim or may define new elements.

A dependent claim is patentable if the independent claim from which it is derived is also patentable, even if it defines elements already known from the prior art. Patentability is derived from the independent claim.

Example of type of claims:
Independent claim. "1. Composition that includes A, B and C, characterized in that the concentration of A is less than 3%."
Dependent claim. "2. Composition according to claim 1, characterized in that the concentration of A is less than 2%."

In a statement of claims, there are often several dependent claims that define preferred embodiments or different ways of executing the same invention, which is why it is common to find a few independent claims, each with its respective dependent claims.

4.5.3 Claims that refer to a claim from another category (false dependencies).

The relationship that exists between claims is not always one of dependency. One claim may refer to another, but not depend on it. This way of writing the claims gives coherence to the claims chapter, because it explains that there is a relationship between the claimed objects. This type of wording is called "false dependency," in order to emphasize that there is actually no dependency between those independent claims and, therefore, it is acceptable.

One such case is when a claim in one category refers to a claim in another category.

Example of claims with "false dependencies":
Claim "1. A product…"
Claim "2. A process for manufacturing the product of claim 1…"
Claim "3. An apparatus for carrying out the process of claim 2…"

In this case, claim 2 informs that the process has the purpose of obtaining the product of the preceding claim, but does not mean that it is dependent on it. That is, compliance with the patentability requirements of claim 1 does not imply recognition of the patentability of claim 2. The examiner must evaluate the patentability of this last claim despite having established that claim 1 is novel and inventiveness.

Similarly, claim 3 defines the apparatus with which the process of claim 2 is carried out and is independent of it. Therefore,

the examiner must advance the patentability study of claim 3, even if he has already established that claim 1 meets the patentability requirements.

Another case is when a claim refers to another claim of the same category, but its statement does not necessarily imply that all the characteristics of the claim to which it refers are included in it.

Example of claims with "false dependencies", which do not include all the characteristics of the claim to which they refer:
Claim "1. A system that comprises a device…;"
Claim "5. An apparatus according to claim 1…"

Claim 5 refers to claim 1, which is of the same category and is independent of it, but does not contain all the characteristics of claim 1. So, in this case, it is necessary to evaluate the patentability of claim 5., although the novelty and inventive level of claim 1 have already been accepted.

4.6 Clarity and interpretation of claims

The claims must clearly define the object for which protection is requested because according to the clarity of the claims it will be possible to determine whether the invention is new, inventive and capable of industrial application.

Additionally, the claims must be interpreted in the same way, both for the purposes of search and examination. Each claim must be read as giving the words the meaning and scope they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise. However, the claims must be clear on their own.

4.6.1 Terms used

The meaning and scope of the words of the claims must be what is normally given in the technical area of the application and must be clear to the person skilled in the art by simply reading the claims. If the word has a special meaning given by a definition in the description, this definition must be included in the claim, whenever this is practicable.

Example of terms used:

Application: A "homogeneous" copolymer of A and B obtained by the continuous addition of monomers A and B according to the described process is claimed.

In the state of the art, another NON-continuous process is known for the production of the same copolymer. It is not mentioned whether the polymers thus obtained will be "homogeneous" or not. The word "homogeneous" is thus the only technical characteristic to distinguish the two products (novelty), although it does not have a well-defined meaning in this field.

However, in the description the homogeneous copolymer is defined by the composition and distribution of the individual monomers along the chain. Comparative tests submitted by the applicant were able to prove that the copolymers prepared according to the prior art method did not have this composition and distribution.

Result: *The application was considered new and inventive. The definition of the term homogeneous, however, had to be included in the independent product and process claims.*

4.6.2 Inconsistency between claims and description

Any inconsistency between the claims and the description initially presented must be avoided since the description must serve to interpret the claims (Article 51 of Decision 486). There are several common cases of inconsistency:

- Verbal inconsistency: the description says that the invention is limited by some characteristics and the claims are not thus limited. These inconsistencies are resolved by alleging lack of clarity (Article 30 of Decision 486) and modifying the description or claims so that they agree;
- Inconsistency regarding essential characteristics: when it is clear from the description that a characteristic is essential for the invention (it is part of the solution to the problem to be solved) and it is not found in the claims. In this case it is alleged that the claims do not define the subject matter to be protected (Article 30) and the introduction of these essential characteristics in the claims is requested; and
- General phrases that imprecisely suggest that protection extends to other possible variations or modifications or that a product is also protected when the claims are only procedural. In this case, clarification must be requested, otherwise it

must be deleted.

4.6.3 Imprecise or relative terms

Imprecise terms such as “approximately”, “around” cannot be accepted since in that case the scope and scope of protection of the claim is no longer precise and does not allow a comparison with the state of the art. They can be allowed for non-essential characteristics when justified and as long as they allow the state of the art to be distinguished without ambiguity (novelty, inventive step).

For the same reasons, relative terms such as “larger”, “thin”, “source” are not allowed since they do not have a precise meaning. In no case can these terms be used to distinguish the invention from the prior art. In these cases, these expressions must be replaced by precise terms or specific ranges of values.

4.6.4 Trademarks and trade names

Trademarks and trade names are distinctive signs whose use for commercial purposes requires the authorization of the owner or holder. These distinctive signs should not be used in a patent application as the generic or common designation of a product or a technical procedure as this would have the detrimental effect of 'diluting' the distinctive force of the sign. Nor should they be used in a context (a patent application) that allows it to be assumed that there is a commercial link between the patent applicant and the owner of the distinctive sign. Furthermore, these distinctive signs may refer to products or processes whose characteristics may change over time, even if the sign is maintained. For these reasons, it is not permitted to use trademarks, trade names or other signs in a patent application or in the description or claims.

4.6.5 Optional terms in a claim

Expressions of the type “preferably”, “for example”, “such as”, “in particular” preceding a characteristic in a claim must be interpreted as non-limiting, that is, the characteristic is merely optional and does not limit the scope of the claim (in particular when analyzing novelty and inventive level). If they cause confusion in the claim, you should allege lack of clarity and suggest that the optional or preferred features become a

dependent claim.

4.6.6 Definition by the result to be achieved

The claims must define the invention by its essential, structural or functional characteristics. It is not accepted that the claim defines the invention by the result to be achieved (for example: "Distillation apparatus characterized in that it has an efficiency of 99%"), since in reality this would be equivalent to reiterating the technical problem to be solved and the scope of the claim would encompass not only the solution proposed by the applicant, but any present or future alternative that would achieve that result.

The result to be achieved is not a technical characteristic of the invention. It may appear in the claim, but always accompanied by the technical characteristics that define the invention, and as long as it does not detract from the clarity of the claim. If this were the case, the paragraph referring to the result to be achieved must be removed (see example 10 of Section 1 of Annex IV).

4.6.7 Definition by parameters

A product claim, for example a chemical compound, can be characterized by its general chemical structure and radicals (Markush formulas), by its specific chemical formula, by its IUPAC name, by its international non-proprietary name (INN), as a product of a process or exceptionally by its parameters when there is no other way to claim the invention.

Parameters are characteristic values of measurable properties (for example, melting point) or defined as mathematical combinations of several variables.

Characterization of a chemical compound solely by its parameters will not be permitted, unless the invention cannot be otherwise defined. In any case, the parameter must be able to be determined and measured unambiguously by standard methods known in the field in question or clearly described in the application.

For example, in inventions related to polymorph the compound cannot be defined only by its crystalline nature, since it would

not be possible to define the scope of the invention to be protected. For such cases, in addition to the name and chemical structure of the compound, it must be characterized by its single crystal X-ray diffraction pattern or powder X-ray diffraction pattern (with the most relevant 2-tether values of intensities) and other complementary techniques, since it is a characteristic that will allow the invention to be defined, as well as to compare and differentiate it from the state of the art (see example 3 of Section 1 of Annex IV).

Claims defined in this way must include parameters that can be determined and measured clearly and reliably by means of indications included in the description, or by objective processes recognized in the art (see example 4 of Section 1 of Annex IV).

The same is true for a characteristic related to a process that is defined by its parameters. This eventuality may occur, for example, in the case of macromolecular chains. Objections could be raised alleging lack of clarity when parameters not recognized in the art are used, or that apparatus not available to measure those parameters is used. The examiner must take into account the fact that the applicant may attempt to use unusual parameters to avoid a possible objection of lack of novelty.

When unclear or unusual parameters are defined, clarification of said parameters should be requested. For example, a comparison with known parameters, as long as this does not extend the content of the original request (Article 34 of Decision 486). The parameters must be able to be determined in a clear, precise and unambiguous manner by means of objective processes usual in the art. The method for measuring the parameter values must be included in the claim, except when the person skilled in the relevant technical subject matter knows which method should be used or when all methods reach the same result.

When parameters are not commonly used in the field of invention, two types of situations may arise:

(i) The unusual parameter measures a property of the product/process for which another parameter generally recognized in the field of invention is used.

(ii) The unusual parameter measures a property of the product/process that was not measured before in the field of the invention.

Cases in which an unusual parameter of type (i) is used and a direct conversion of the unusual parameter to the parameter generally recognized in the art is not possible, or an apparatus not accessible is used to measure the unusual parameter are in principle objectionable on the grounds reason for lack of clarity, since no meaningful comparison can be made with the state of the art.

The use of unusual parameters is allowed in the type (ii) situation if it is evident from the application that the trained person would not face difficulties in performing the tests presented and would therefore be able to establish the exact meaning of the parameter and perform a meaningful evaluation (comparison with the state of the art). Furthermore, the burden of proof that an unusual parameter is a genuine distinctive feature with respect to the prior art rests on the applicant.

Example of an unusual parameter admissible in type (ii) situation:
The description explains that the abrasive action of very fine grade sandpaper is improved if strips with abrasive grain are alternated with strips without abrasive grain. Claim 1 contains an unusual parameter of type (ii) that measures the ratio between the widths of the abrasive strips and the non-abrasive strips within a certain length of the sandpaper.

The person skilled in the art has no problem establishing the exact meaning of the parameter, measuring it and determining its genuine distinctive feature compared to the state of the art.

4.6.8 Product defined by its manufacturing process

When a product claim is defined by the procedure used to obtain the product, the claim as a whole is understood as a product claim and must be treated as such.

Product claims defined in terms of a manufacturing process are admissible only if the products as such meet the requirements for

patentability, that is, when among other things they are new and inventive and when they cannot be defined by their structural characteristics. A typical case is polymers, which should preferably be written in the form "Product X obtainable by process Y".

A product does not become new simply because it is produced by a new process. That is to say, a claim of this nature lacks novelty if in the state of the art there is a product substantially identical to the claimed product, even if its production process is not disclosed. In these cases, the burden of proof of a supposedly different characteristic in the product defined by its manufacturing process falls on the applicant, who must provide evidence that the modification of the process results in a product different from the known one, e.g. by demonstrating that there are clear differences in the properties of the products. However, the examiner must present reasoned arguments to support the alleged lack of novelty of a product claim defined by its manufacturing process (see example 5 of Section 1 of Annex IV).

When a product can only be defined by the process by which it is obtained, or when the manufacturing process is presumed to give the final product different characteristics, the examiner will take into account the stages of the procedure when defining the object of the search and evaluating the patentability of the invention in relation to the state of the art.

Example of a product claim defined by its manufacturing process:
Polymers containing chemically bonded metal atoms.

Claim 1. A polymer containing tungsten and/or chemically bonded metallic molybdenum atoms obtained by reaction of i) an unsaturated or saturated dicarboxylic acid or its anhydride with ii) a metal complex product of the carbonyl-tungsten reaction and/ or carbonyl-molybdenum with pyrrolidine.

Claim 2. A polymer as defined in claim 1, wherein one mole of said dicarboxylic acid or anhydride is reacted with one mole of said metal complex to obtain a thermoplastic polymer.

Claim 3. A polymer as defined in claim 1, wherein two moles of

said dicarboxylic acid or anhydride are reacted with one mole of the metal complex to obtain a product containing carboxylic terminal groups and subsequently produce copolymerization of the product.

Claim 4. A polymer as defined in claim 1 that is further reacted with a cross-linking agent to form a thermosetting resin.

Claim 5. A resin obtained by reacting the polymer of claim 1 with a polyalcohol cross-linking agent.

These types of claims can be challenged at the examiner's discretion, for example, by requiring the applicant to define the claimed invention based on its essential characteristics.

4.6.9 Claims characterized by a use

The claims that in the preamble refer to a product or procedure but the characteristic part describes only the use of said product or procedure, are not the subject of a patent because they refer to a use, not patentable according to the interpretation of the Andean Court in Process 89-AI-2000, which does not recognize uses as patentable subject matter. In the same way, a product or a process will not be the subject of a patent when said product or procedure was known in the state of the art and a use different from that originally disclosed was attributed to it.

It should be noted that if the preamble of the claim states "The use of a certain product or procedure" it will not be the subject of a patent either, in accordance with the interpretation indicated above (see uses in Section 7.4 of Chapter III).

Thus, in the case of second uses, in the face of this type of claims characterized for a use different from that initially known, the competent national office must notify the applicant that his invention is not accepted because the uses are not patentable in accordance with the Andean community jurisprudence interpreting Decision 486, and demonstrate that the product or procedure is included in the state of the art, and therefore falls within the exception of Article 21. Therefore, the respective analysis of novelty must be made, together with the

objection relating to use.

4.6.10 References to the description or drawings

The claims must not make express reference to the description or drawings if it is not strictly necessary. Expressions such as "as described on page 3", "according to example 4", "as indicated in Fig. 7" are not allowed.

If the claims need to refer to the drawings to be clearer, the presence of reference signs in parentheses is allowed after the characteristic mentioned in the claim. For example, the case of a piece illustrated in a figure and whose shape is practically impossible to describe precisely, in which case the reference sign of said element will be indicated, but not that of the figure.

Example of claim with references:

"A structured panel (1) formed from two layers (2, 3)…"

4.6.11 Limitations or waivers ("disclaimers")

In general, the object of a claim should be defined by positive characteristics. However, the scope of a claim could be limited by means of a "waiver", a "limitation" or an "exclusion", that is, by expressly subtracting from the protection claimed an element clearly defined by its technical characteristics, but if the "exclusion" is very extensive or does not allow the scope of protection to be clearly defined, it must be withdrawn and the claim defined positively. These limitations are only used when it is not possible to define the subject of the claim by positive characteristics. There is nothing ambiguous or vague about a limitation or "disclaimer" since it defines an object that is not present in the claimed invention.

Examples of waivers, limitations or "disclaimers":

- "cosmetic composition characterized in that it does not contain stearic acid…"
- "in which the compound lacks water…"
- "said homopolymer is devoid of proteins, soaps, resins and sugars present in the rubber obtained from the rubber tree…"
- "incapable of forming a colorant with said oxidized developer…"

The examiner will accept the disclaimer when the applicant uses it to:

a. Restore novelty, eliminating an element, whereby the object of the application already differs from the object of the state of the art.
b. Withdraw an element that is not an invention or an element that is excluded from patentability:

But the examiner will not accept the disclaimer when the applicant uses it to:

a. Exclude variants (modalities) that do not work or to correct insufficient description.
b. Make the request inventive by excluding that element. [Request that is not inventive when it has that element].
c. Exclude an item that was not explicitly excluded from the description. [Although the description did not mention that element].

4.6.12 Open and closed type terms (transitional phrases)

Depending on the "transitional phrases" used in the writing of the claims, there are two types of claims: 'open' and 'closed', which the examiner must take into account when evaluating novelty.

Open claims include components that are not mentioned in the claims. An open claim contains transition words such as: 'comprises...'[comprende...], 'includes...'[incluye...], 'contains...'[contiene...], 'is composed of...'[está compuesta de...], 'is characterized by ...'[se caracteriza por...].

On the other hand, closed claims are those that exclude any other component that is not mentioned in the claims. A closed claim contains transition words such as: 'consisting of...'[que consiste en/de...], 'constituted by...'[constituido por...], 'consisting of... '[consta de...].

Both 'open' and 'closed' claims must be supported by the description.

Structure of open and closed type claims:

If for a composition A+B+C there is no other component reported

in the description, it should not be presented as an open claim. If the independent claim of a composition is A+B+C and the following claim is A+B+C+D; Since claim A+B+C is open, the claim that contains component D must be a dependent claim on the first. If the object of an application is A+B+C and, in addition, it could have D, said claim should not be drafted as a closed claim, unless the claimed object is limited to A+B+C+D.

4.6.13 Conciseness

The conciseness requirement of Article 30 of Decision 486 applies both to each individual claim and to the set of claims. The purpose of this requirement is to avoid excessive complexity for the examiner when analyzing the claims and to prevent third parties from not being able to clearly see the scope of the claims due to their excessive number and complexity.

The number of necessary claims must be considered taking into account in each case the nature of the invention to be protected. For clarity, the claims are numbered consecutively.

There may be two or more independent claims of the same category if the invention cannot be protected in a more appropriate (concise) way, for example, using dependent claims. It should be taken into account that the scope of protection of two independent claims of the same category may be different, even if they appear similar. For example, a new and inventive chemical product can be claimed in the same application for its chemical formula and its manufacturing process.

If the invention is a new and inventive product, the application may include two or more claims covering processes for its manufacture. The single inventive concept that is common to all claims is the inventive new product.

However, where it is clear that there are an excessively high number of independent claims that could be formulated with dependent claims or that have the same scope, a lack of conciseness must be objected to.

As for dependent claims, their role is to avoid unnecessarily repeating all the characteristics again for each claim. The

number of dependent claims must be reasonable depending on the alternatives to be protected; it must be objected if there is a multiplicity of claims of a trivial nature. One should also object for lack of conciseness if there are a large number of possible alternatives within a claim.

In conclusion, when evaluating the conciseness of the claims the examiner must apply the following criteria:

- Observe inappropriate repetitions of terms or elements within the same claim.
- Object to duplicate or redundant claims.
- Object to the excessive number of claims that do not provide any additional element to what has already been claimed.
- In those cases where there are multiple independent claims, the examiner must evaluate whether it is possible to reduce their number, through the use of dependent claims.

4.6.14 Support in the description

According to Article 30 of Decision 486, the claims must be supported by the description. This means that the object of each claim must have its basis and support in the description, and its scope must not exceed what is justified by the content of the description and the drawings.

Regarding the disclosure contained in the initial application, the examiner must apply a "full content" criterion to the application. This criterion allows admitting the existence of an element of disclosure, even if it does not appear in the most suitable place within the request.

For example, if there are characteristics of the invention that are clearly expressed in the claims initially presented and not in the description, they are allowed to be incorporated as is into the description to support the claims and thus comply with the requirements of Article 30 of Decision 486. This modification does not represent an extension as long as the initial claims have been presented with the description, in accordance with Article 26 of Decision 486. In these cases, the examiner will indicate to the applicant the inclusion of the present technical characteristics in the claims, as part of the description, so that they comply with being supported by the description (see

examples 6 and 7 of Section 1 of Annex IV).

Example of a claim without possible support in the description: "A specific method for the treatment of flexible materials to obtain certain special characteristics of them."

Only the method for treating flexible materials of type A is described in the specification.

It is well known to the person skilled in the art that the claimed method is inappropriate for the treatment of flexible materials of type B. In this circumstance and unless the applicant can demonstrate that the method is also applicable to all materials described in the Claim 1, this must be limited exclusively to the materials described in the description. If the applicant could not demonstrate this, there would be serious reasons to consider that claim 1 is not supported by the description.

Now, claims are usually generalizations of the content disclosed in the description. A generalization is permitted as long as it covers all variants or specific modes disclosed in the description. To determine whether the generalization is appropriate, the examiner must rely on the prior art. When the invention corresponds to a new technological field, a greater generalization can be admitted than when the invention refers to an advance within a known technology.

For claims expressed in generic terms, it must be examined whether they are sufficiently supported in the description. When a claim includes a very broad generalization that would lead one to believe that the applicant is speculating and the technical effect is difficult to determine, it can be assumed that its scope goes beyond the content disclosed in the description and that it lacks the required support.

If it is found that one or more specific terms or options included in the generic terms do not solve the technical problem with the proposed solution, nor achieve the same technical effects, then it must be concluded that it is not supported by the description. In this case, the applicant must be invited to

modify the claim by restricting it.

Example of a claim that is a broad generalization:
"Method for producing aromatic compounds consisting of…"

The description contains only a method for producing a specific aromatic compound, without involving any other type, and a person skilled in the art cannot derive the method for producing other types of aromatic compounds. In this case it must be considered that there is a lack of support in the description. It could only be considered that there is support in the description if a relationship between the method for producing the aromatic compound and the method for producing aromatic compounds of the other types were indicated in it, such that the person skilled in the art could use that method to produce aromatic compounds of all other types. Therefore, all the claimed matter must be justified and supported by the description.

4.7 Suggested wording of technical report (clarity)
The claims do not meet the requirements of Article 30 of Decision 486 because the ____ claim(s) do not clearly define the subject matter to be protected. The claim defines the subject matter of the invention by the result to be obtained. This definition would only be admitted under the conditions established in Section 3.1.1 of Chapter III. In this case, however, it is not admitted since it is possible to define the object of the claim(s) by the technical characteristics of the invention (specify) (page ____ lines ____ of the description).

The terms used in the claim(s) ____ are (are) vague and indefinite/do not have a recognized meaning, so that they do not allow the subject matter of the invention to be clearly determined. From the description, pages __, lines __, it appears that the characteristic(s) is(are) essential to carry out the invention since the independent claim(s) do not contain this(s) technical characteristic(s), these do not meet the requirements of Article 30 of Decision 486.

5. DRAWINGS

5.1 Form and content

The drawings, plans, figures and graphic representations are intended to contribute to a better understanding and dissemination of the invention. Therefore, they must meet the following requirements:

- have a direct relationship with the description of the invention;
- allow you to visualize and understand the methods of execution described;
- the relationship between the description and the drawings must be made through reference signs that are found on both elements and correspond;
- if the description mentions any figure, it must necessarily be included in the application;
- figures or drawings that have not been described in the application cannot be considered;
- symbols or numbers that have not been mentioned in the description cannot be considered;
- as far as possible, texts or signs should not be included in the drawings, plans or figures;
- schematic and flow diagrams (flowcharts) are considered drawings; and
- must be numbered individually and consecutively.

5.2 Extension

The absence of a figure or drawing mentioned in the report will not necessarily imply the insufficiency of the description. However, the subsequent incorporation of said missing figure or drawing will require a detailed analysis by the examiner in order to determine whether it incorporates additional technical characteristics to those described in the originally presented description and, based on this, establish whether or not there is an extension of the protection originally disclosed in the initial application.

On the other hand, the a posteriori introduction in the claims of some characteristic of the drawings originally presented not mentioned in the description will not necessarily imply an extension of the disclosure as long as its appreciation is

sufficiently clear. This point is explained in greater detail in Section 3.2.2 of Chapter III. (see example 2 of Section 1 of Annex IV)

When the invention that is the subject of an application refers to nucleotide or amino acid sequences, the description must contain a list of sequences, which must be presented in a separate chapter of the description under the title "List of sequences", which will be considered part of the description. The sequence listing not only includes sequence information, but may also include descriptive information about each sequence known as “annotations.”

In the description of claims the sequences presented in the sequence listing will be indicated by their identification number even if the sequence or other additional or modified representations of the sequences are included in the text or drawings accompanying the description.

6. LIST OF SEQUENCES

6.1 ST.26 Standard

Sequence listings must follow the submission standards for amino acid and nucleotide sequence listings established by WIPO. WIPO members agreed that starting in 2022 all sequence listings that are part of a patent application filed nationally and internationally must comply with Standard ST.26.

The new standard for the presentation of nucleotide and amino acid sequence listings using 'extensible markup language' (XML) is Standard ST.26. This standard was developed by the Committee on WIPO Standards (CWS).

Standard ST.26 defines how to disclose in a patent application the nucleotide and amino acid sequences that must appear in a sequence listing, the representation of those disclosures, and the document type definition (DTD) when sequence listings They are presented in XML.

The idea behind converting ASCII text-based listings to XML is to make it easier to search for sequence data for an invention, both

in an intellectual property office and in publicly available databases (e.g., the International Nucleotide Sequence Data Collaborative, or INSDC).

6.2 Advantages of the ST.26 Standard

Some advantages of Standard ST.26 are noted below:

- Acceptance of a single sequence listing worldwide.
- Guidance to ensure consistency between intellectual property offices regarding the application of sequencing rules.
- Clarification on what sequence disclosures should or can be included in a sequence listing and how they should be represented.
- Improved quality in terms of presentation, thanks to the structure of sequence listings in XML format.
- Greater automation of data validation and simplification of the processing process for intellectual property offices.
- Data compatibility with INSDC database supplier requirements.
- Normalization of the following data:
  - Feature annotations
  - Feature Locations
  - Qualifiers and qualifier values
  - Presentation of sequence variants
- The requirement to include additional sequence types (nucleotide analogues, D amino acids, branched sequences) means that more sequence data will be searchable. Additionally, this confers specificity to the sequences disclosed under the ST.26 format.

6.3 Changes to Standard ST.26

The most notable change is the transition from text format to XML format. Some other changes incorporated in this standard are the following:

- The inclusion of nucleotide analogues, D-amino acids, branched sequences and other modified amino acids.
- The specific exclusion of sequences with less than 10 nucleotides or 4 amino acids.
- Changes in requirements for gapped sequences, branching sequences, and variant positions.
- The inclusion of annotations, not only with characterization keys, but also qualifiers.

Example of glucagon sequence listing:

Glucagon is a hormone that raises the level of glucose in the blood. The pancreas produces glucagon and releases it when the body needs more blood sugar to send to the cells. It is 29 amino acids long and helps release stored glucose into the blood.

A sequence listing for the glucagon peptide would show like this according to the Standard previous ST.25:

```
<210>  1
<211>  29
<212>  PRT
<213>  Homo sapiens

<400>  1

His Ser Gln Gly Thr Phe Thr Ser Asp Tyr Ser Lys Tyr Leu Asp Ser
1               5                   10                  15

Arg Arg Ala Gln Asp Phe Val Gln Trp Leu Met Asn Thr
            20                  25
```

The same list of sequences in the new ST.26 standard would be shown:

```
<SequenceData sequenceIDNumber="1">
     <INSDSeq_length>29</INSDSeq_length>
     <INSDSeq moltype>AA</INSDSeq moltype>
          <INSDQualifier_name>ORGANISM</INSDQualifier_name>
          <INSDQualifier_value>Homo sapiens</INSDQualifier_value>
          <INSDQualifier name>MOL_TYPE</INSDQualifier name>
          <INSDQualifier_value>protein</INSDQualifier_value>
     <INSDSeq sequence> HSQGTFTSDYSKYLDSRRAQDFVQWLMNT </INSDSeq sequence>
```

6.4 Content of Standard ST.26

Standard ST.26 is a WIPO consultation document in various languages and its structure includes:

- Main body on inclusion or representation requirements.
- Annex I with controlled vocabulary based on the INSDC.
- Annex II includes document type definitions (DTD) in accordance with Standard ST.26.
- Annex III includes examples of sequence listings (XML file) in accordance with Standard ST.26.
- Annex IV is a subset of characters from the basic Latin alphabet for use in an XML instance conforming to Standard

ST.26.

- Annex V includes requirements on the exchange of INSD data.
- Annex VI is a guidance document with examples.
- Appendix to Annex VI shows an XML file that includes all sequences disclosed as an example in Annex VI.
- Annex VII compiles recommendation for the transformation of the sequence listing of Standard ST.25 in accordance with Standard ST.26.

6.5 Preparation of XML sequence listings

Under Standard ST.26, the applicant must provide the sequence listing as an XML 1.0 format file. For their part, intellectual property offices must validate in accordance with the document type definition (DTD), and those operational standards derived from the content of this standard. Therefore, to support the implementation of ST.26, WIPO has developed a tool called "WIPO Sequence" to create, edit and validate the sequence listing in XML format.

"WIPO Sequence" is a free desktop tool with a simple interface and is available for download on the WIPO website along with the corresponding user manual. Sequence information can be saved in a project, validated and then output to a sequence listing in ST.26 format. Data can be imported from ST.26 format sequence listings, ST.26 format projects, ST.25 format sequence listings, multi-sequence format files, RAW format files, and FASTA format files. Validation of sequence listings can also be performed in XML format. Relevant characterization keys, qualifiers, and organism names can be easily selected from drop-down menus. Applicant and inventor information can be stored in a database of individuals and organizations. It is possible to export and import XLIFF files used by translators. This new software to compile the new sequence listings will eliminate the old "PatentIn" software.

7. PATENTABILITY

7.1 Patentability requirements

For the substantive examination of patent applications, it is necessary to take into account Articles 14, 15, 16, 17, 18, 19, 20 and 21 of Decision 486.

"**Article 14.-** The member countries shall grant patents for inventions, whether of goods or of processes, in all areas of technology, provided that they are new, involve an inventive step and are industrially applicable."

The substantive examination of an application for a patent for invention is based on the verification of compliance with the conditions legally established in Article 14, namely: novelty (Articles 16, 17 - special cases - and 21), inventive level (Article 18) and industrial application (Article 19). The examination begins by determining whether the claims presented in the application contain any matter that cannot be patented either because they are not considered inventions (Article 15) or because, being inventions, they are excluded by the Decision (Article 20), in this sense, The matter indicated by said articles must be eliminated from the claims so that they can be examined by the authority.

7.2 They will not be considered inventions (exclusions)

Decision 486 does not contain a definition of the concept of "invention." However, Article 14 only allows patents to be granted for inventions, product or process, in all fields of technology. Although this provision does not define what an invention is, it clarifies that all inventions necessarily fall within one of those two general categories of "product" or "process."

Product inventions are all those that take shape in a tangible object or physical entity. They include, for example, inventions consisting of chemical compounds, molecules, compositions, apparatus, machines, artifacts, circuits, devices, tools, systems, among others.

Procedural inventions are all those of intangible nature, defined

as steps, processes or stages to obtain a technical result, such as a product. They include, for example, processes and methods, among others.

This means that, for the purposes of granting patents, any invention will always be a 'product' or a 'procedure', regardless of whether the applicant uses any of the aforementioned terms in the description or claims.

Although Decision 486 does not contain an explicit definition of the term 'invention', its Article 15 expressly determines which matters cannot be considered an invention:

"**Article 15**.- The following shall not be considered inventions:
(a) discoveries, scientific theories and mathematical methods;
(b) the entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germ plasm of any natural living being;
(c) literary and artistic works or any other work protected by copyright;
(d) plans, rules and methods for the pursuit of intellectual activities, the playing of games or the conduct of economic and business activities;
(e) computer programs or software as such; and
(f) methods of presenting information."

In principle, all inventions must have a technical character since they are aimed at solving specific technical problems in the physical world, and are not associated, for example, with aesthetics, the presentation of information, as such, and abstraction. In addition to having a technical nature, inventions must involve creative or transformative human activity. To the extent that the requested subject matter does not imply said creative or transformative activity, it will not be considered an invention even if an arduous research task has been carried out.

7.2.1 Discoveries

A discovery is a finding of matter or energy existing in nature, whose existence was unknown. Conceptual definitions of the laws of nature, for example, an explanation of the force of gravity,

the functioning of light or subatomic particles, are also discoveries. These materials and information are not considered inventions because they are not the product of a creative activity of a human being that uses, modifies or takes advantage of the forces of nature (matter and energy). However, an invention can be developed from a discovery if, through human intervention, nature is used or modified to develop a new technical solution.

A discoverer identifies something that already exists in nature, and can even identify, isolate, purify and characterize previously unknown matter. On the other hand, an inventor modifies the discovered or known matter to give it practical application and solve a specific technical problem.

Finding a substance that is in nature is a discovery and cannot be considered an invention. For its part, if said substance found in nature has to first be isolated from its environment and processed to obtain it, this process of obtaining it could be an invention that can be patented if it meets the patentability requirements: novelty, inventive level and industrial application. industrial in accordance with articles 16, 18 and 19 of Decision 486.

If a new property of a known substance or material is found, it would be a discovery, therefore, it would not be considered an invention. However, if the inventor took advantage of such a property to make a product, this would be an invention that can be patented. For example, the discovery of a material capable of resisting mechanical shock would not be an invention, but a railway sleeper made of that material is an invention that could be patentable.

On the other hand, if a substance has been isolated from nature and is characterized by its structure or parameters and its existence had not been previously recognized, it is considered a discovery whenever said substance has not been modified by human intervention, but that has only been isolated and characterized.

The subject of an application consisting of a chemical compound that exists in nature is a discovery and, therefore, is not

considered an invention. Now, a composition that contains said natural compound combined with excipients may be considered an invention since that composition is not found in nature. However, the patentability of that invention will depend on compliance with the established patentability conditions. Similarly, if said compound existed in nature, but had undergone chemical modification through human intervention, the compound thus modified may be considered an invention.

In the same way, if a microorganism that naturally produces an antibiotic is discovered in nature, neither the microorganism nor the antibiotic will be considered inventions, since both are products of nature. However, if that microorganism or antibiotic is used as part of a pharmaceutical formulation that has a medical application, then the pharmaceutical formulation as a whole could be considered an invention that would be patentable if it meets the requirements of novelty, inventive step and industrial application.

In the field of biotechnology and genetic engineering, the biological and genetic matter existing in nature constitutes a discovery and must be excluded from patentability because it is not an invention. Man is limited to recognizing the existence of that matter and some of its characteristics that occur spontaneously, which cannot be considered a human creation.

Examples of products from nature:

1. Diamond, well known as a precious gem, is the hardest of the minerals and can scratch other materials. The diamond itself cannot be patented, but devices that use it can. Such is the case of the diamond scalpel used in surgery, which was a revolutionary invention in medicine.

2. The identification of an extract from a plant or a resin from the bark of a tree, or the identification in said extract or resin of new chemical components, even when they could be isolated or separated from their natural environment, are not considered inventions but a discovery of matter existing in nature. However, if the object of the patent application consists of a product obtained by the chemical modification of the extract, or if it consists of a composition that, in addition to

containing the extract, is made up of other components, such product and such composition are considered matter that may be the subject of patentability examination.

7.2.2 Scientific theories and mathematical methods

Scientific theories and mathematical methods are purely abstract principles and concepts that lack technical character. These theories and methods allow theoretical or mathematical problems to be defined and solved. However, the problems raised and the solutions provided do not imply an intervention or modification of the physical or natural world.

An example of a scientific theory is the theory of semi-conductivity that explains a phenomenon in physics, but cannot be characterized as a solution to a technical problem. However, the properties of semi conductivity can be exploited by an inventor to make semiconductor articles that utilize those properties. Such items and the process for manufacturing them can be considered inventions and would be patentable.

Likewise, a mathematical formula to calculate or obtain a temperature alone would not be an invention; However, if within a process to obtain a product, said formula is used to obtain the temperature required to carry out said process, the process can be considered as an invention different from the mathematical method that was used to carry it out.

On the other hand, mathematical methods as such lack industrial applicability since they are ideal constructions of a series of steps or rules for the deduction of results that are carried out and specified on the intellectual level, without intervening or modifying the physical world.

Thus, mathematical reasoning, equations, theorems and algorithms — the latter being a variant of the methods — do not have a technical nature and are not considered inventions, which is why they cannot be patented.

It is important to mention that when a technical means applies or performs a mathematical method or an equation; and said invention, seen as a whole, solves a technical problem, it must

be evaluated whether the application should be considered an invention.

7.2.3 All or part of living beings as they are found in nature, natural biological processes, biological material existing in nature or that which can be isolated, including genome or germplasm of any natural living being.

The examiner must take into account that all living matter or part of any living being and substances existing in nature are not inventions in accordance with Article 15 of Decision 486. Thus, biological or genetic material existing in nature, even When it is isolated, it is not considered an invention.

"Article 15.- The following are not considered inventions:
(b) the entirety or part of living beings as encountered in nature, natural biological processes, biological material existing in nature or which may be isolated, including the genome or germ plasm of any natural living being;" [emphasis added]

In relation to this "absence of invention", the Court of Justice of the Andean Community (TJCA) specified the following in ruling 21 IP-2000.

"Biological material, cells or their components that already exist in nature, even when isolated by microbiological processes, are not considered "inventions", without prejudice to the fact that patents may be granted on isolation processes, as well as on the other microbiological processes, such as cultivation, selection or mutation of microorganisms or others of a physicochemical nature, but as long as they meet the objective conditions of novelty, inventive level and industrial application.

However, the possibility of patenting inventions related to biological material does not undermine the above, since the aforementioned exclusion only includes materials as they are found in nature, but not those that have been modified or obtained through biological processes in which there is a relevant human activity, in which case we could speak of life "created" by man with the use of biotechnology."

7.2.3.1 All or part of living beings as found in nature

All living matter and substances existing in nature are not inventions. New pharmaceutical and food products that are obtained from matter found in nature can be patentable as long as they are products resulting from human intervention and do not constitute matter in their natural state. The genome or germplasm of any natural living being, including humans, is not patentable. Living beings and their parts are not considered inventions, so plants and their parts (flowers, fruits, leaves, seeds), as well as animals, are not considered inventions.

Examples of "the whole or part of living beings" that are not considered patentable subject matter:

- An oleaginous plant that comprises…
- A mature seed harvested from the plant…
- A seed, comprising a lipid…

For example, the simple extract of plants is not considered an invention since the components of the extract are materials existing in nature. On the other hand, if the object of the application consists of the product obtained as a result of the chemical modification of the extract or if it consists of a composition that, in addition to containing the extract, is made up of other components, such product and such composition are considered invention and may be subject to patentability examination. The extraction process by which the extract has been obtained is susceptible to being considered an invention and subject to patentability examination.

For their part, extracts from genetically modified plants are considered inventions and are susceptible to patenting, only if said extracts have a different chemical composition than those obtained from the original plant from which the genetically modified comes and meet the other requirements. of patentability (see example 1 of Section 2.3 of Annex IV).

Examples of chemical markers that can characterize plant extracts:

A plant extract is a complex mixture of various compounds from said plant. It is because of this complexity that an extract is difficult to describe by the specific identity of its components.

Plant extracts are commonly defined by chemical markers that characterize them (e.g. Herb MaRS criteria, pharmacopeia-defined criteria, etc.). There are various ways to categorize chemical markers of plant extracts, among which the following are exemplified:

1) therapeutic components,
2) bioactive components,
3) synergistic components
4) characteristic components,
5) main components,
6) correlative components,
7) toxic components,
8) general components coupled with chromatographic profiles (fingerprinting). The chromatographic profiles (fingerprints) and characteristic patterns of said extracts can be established using multiple techniques, both chromatographic and spectroscopic.

7.2.3.2 Natural biological processes

Biological processes, in general, are processes that are carried out by living beings or that occur within living beings. Examples of biological processes are photosynthesis, composting and fermentation.

Natural biological processes are understood to be those in which there is no human activity or intervention (exclusively biological processes) and which are therefore not considered inventions.

In addition to the 'natural biological processes' that are not considered inventions according to subsection b) of Article 15 of Decision 486, there is subsection c) of Article 20 of Decision 486 that considers essentially biological processes as non-patentable inventions. However, the latter are distinguished from the former in that they do have human intervention, although this intervention does not affect the final result. For more information on essentially biological processes and inventions involving biological processes, see Section 7.3.3.

For a process or procedure to be distinguished from a replica of a natural biological process, the process must include at least

one technical stage that includes human intervention and this is novel and essential to carry out the process whose result is an effect. different from what would occur spontaneously in nature.

7.2.3.3 Biological material existing in nature or that which can be isolated, including genome or germplasm of any natural living being

For the purposes of this manual, we will define biological matter as matter that contains self-reproducing or reproducible genetic information in a biological system.

The simple isolation of biological material that exists in nature, even when isolated by microbiological processes, is not sufficient to be considered an invention. Without prejudice to the foregoing, patents may be granted on isolation processes, as well as on other microbiological processes, such as those for the cultivation, selection or mutation of microorganisms or others of a physicochemical nature, provided that they meet the objective conditions of novelty, level inventiveness and industrial application.

Example of natural protein:

1. A wild protein that has been isolated and has also been characterized by means of its amino acid sequence, its secondary or tertiary structure, its characteristics of molecular weight, polarity, pH, etc., is not considered an invention because it is the protein as it is found in nature. In this case, only the characteristics of the protein were identified, but the protein was not modified to obtain a product different from the wild protein. For example, "a transmembrane GGG protein characterized because it is found in the Ebola virus and because it binds to the anti-GGG antibody."

For their part, new pharmaceutical, biotechnological or food products that are obtained from matter found in nature are not excluded from patentability, because the matter as it exists in nature is not claimed.

7.2.4 Genome or germplasm

The genome or germplasm of any natural living being, including the human being, if it were not modified by man, would not be patentable because it is biological material existing in nature or material that can be isolated. It is considered a "product of nature", not a human invention.

Genome is understood as the totality of the genetic information (genes) that a particular organism has. For example, the genome of a potato or a sunflower could not be patented. For its part, germplasm is understood as the set of genes that is transmitted through reproduction to offspring through gametes or reproductive cells.

Likewise, in ruling 21-IP-2000, the TJCA has indicated that "the proteins that make up the human body, the genes or the DNA sequences are not susceptible to protection through patents."

Likewise, any synthetic biological material, such as genomes, germplasm, proteins, genes, DNA sequences, etc., that is identical to that found in nature, by itself, regardless of its method of obtaining or manufacturing, it cannot be considered an invention since it cannot be distinguished from that originating in nature.

Example of biotechnology and genetic engineering:

Synthetic nucleotides and proteins per se, including antibodies, that are exactly identical to naturally occurring matter are not considered an invention because they identically reproduce naturally occurring material. However, the technical processes used to obtain said synthetic nucleotides can be considered patentable inventions when they allow solving technical problems or represent a technical alternative for obtaining them.

Complementary DNA (cDNA) is constructed by biotechnological methods entirely from messenger RNA (mRNA). It is well known that naturally occurring DNA molecules, coming from eukaryotic organisms (especially higher eukaryotes such as plants and animals), contain introns (which are non-coding regions); while mRNA molecules (product of post-transcriptional modifications of the primary transcript of said DNA molecules) do not contain said

introns. Consequently, cDNA obtained from eukaryotic mRNA is an artificial molecule that does not contain the introns of the naturally occurring eukaryotic DNA from which it comes. Thus, to the extent that obtaining said cDNA molecule involves creative or transformative human activity, then said molecule is not excluded from patentability according to Article 15, section b) of Decision 486.

For its part, a recombinant protein is considered an invention, but if the sequence of said protein matches the sequence of the protein existing in nature, it will not be patentable, even if the invention consists of said protein having been obtained from recombinant DNA or complementary DNA. However, the subject matter surrounding the obtaining of said protein is considered an invention and the patentability examination could proceed with at least:

a) Recombinant DNA;
b) Complementary DNA
c) The vector that contains the gene;
d) The host cell transformed with the vector;
e) The processes for obtaining the gene, the vector, the host cell; and
f) The procedure for obtaining the protein.

7.2.5 Literary and artistic works or any other protected by copyright

Literary and artistic works are not technical solutions that solve technical problems in the physical world. They are personal expressions of the author's creative genius and do not have a technical nature or utilitarian purpose. Since these works lack a technical character in the aforementioned sense, they could not be considered inventions for the purposes of patent legislation. However, literary and artistic works can be protected as such by copyright if they meet the conditions of the relevant legislation.

7.2.6 The plans, rules and methods for the exercise of intellectual activities, games or economic-commercial activities

They are intellectual creations of an abstract nature. Thus, for example, the method of solving a crossword puzzle, the rules of a children's game or a board game, or the plans to organize a

commercial operation or carry out a business. They are not technical solutions that allow solving a technical problem in the physical world. Since they lack a technical nature, they cannot be considered inventions for the granting of patents. However, some elements of the plans, rules and methods for the exercise of intellectual activities and games, for example, written texts and instructions or special material for playing, could be protected as literary works or as industrial designs by the respective legal regulations.

As with mathematical methods, if a technical means carries out a task that is considered an intellectual activity or economic activity, the application must be evaluated as a whole and whether it solves a technical problem or not. If such a technical solution does exist, the application is an invention. Examples of the latter are when a machine makes a decision on its own; Deciding is considered an intellectual activity typical of man, but carried out by a machine it could have a technical effect.

7.2.7 Computer programs and software as such

See section 7.7 of this Chapter.

7.2.8 Ways of presenting information

Any representation of information characterized only by the content of the information is not patentable.

This applies if the claim is directed to the presentation per se of the information (example: an acoustic signal, a spoken or written speech, a visual display, the arrangement of information on an airport screen, the insert of a medicine), to the information stored in a medium (example: a book characterized by its content, a recording tape characterized by the recorded piece of music, a traffic sign characterized by the prevention message, a compact disc characterized by the data or program recorded), or a process and apparatus for the presentation of information (example: a recorder characterized only by the recorded information, a computer characterized by the stored data).

7.3 Exceptions to patentability

If the subject matter of protection constitutes an invention, the examiner must determine, prior to evaluating the patentability requirements, whether it is not contained within the prohibitions contemplated in Article 20 of Decision 486.

"**Article 20.**- The following will not be patentable:

(a) inventions the commercial exploitation of which on the territory of the member country concerned has necessarily to be prohibited in order to protect law and order or morality. To that end the commercial exploitation of an invention shall not be considered contrary to law and order or morality solely owing to the existence of a legal or administrative provision that prohibits or regulates such exploitation;

(b) inventions the commercial exploitation of which in the member country concerned has necessarily to be prohibited in order to protect the health or life of persons or animals, or to preserve plants or the environment.

To that end the commercial exploitation of an invention shall not be considered contrary to the health or life of persons or animals or liable to prejudice the conservation of plants or the environment solely on account of the existence of a legal or administrative provision that prohibits or regulates such exploitation;

(c) plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes;

(d) therapeutic or surgical methods for the treatment of human beings or animals, and also diagnostic methods applied to human beings or animals."

Subparagraphs a) and b) of Article 20 prohibit the patenting of inventions whose commercial exploitation is against public order or morality and of those inventions whose commercial exploitation must be prevented to safeguard the health or life of people and animals and the preservation of the environment and plants. In this regard, see sections 7.3.1 and 7.3.2 below.

The patentability prohibitions provided for in literal c) of Article 20 are due to public policy reasons of the Member Countries of the Andean Community. These countries do not grant

patents to inventions of plants, animals and essentially biological processes for their production.

7.3.1 Inventions whose commercial exploitation must be prevented to protect public order or morality

In application of Article 20, paragraph a), of Decision 486, the examiner must object to inventions whose exploitation must be prevented to protect public order or morality. This prohibition implies a prior determination by each Member Country to identify those products or processes whose commercial exploitation would be prohibited in the respective territory due to being contrary to public order or morality. A marketing ban resulting from other reasons, for example the need to comply with certain regulatory authorizations, would not bring such products or processes within this prohibition.

For example, if in a country the commercial exploitation of certain addictive, hallucinogenic or euthanasia compositions, methods for the manufacture of certain drugs or torture process is prohibited for reasons of public order, the office of that country must object to the granting of a patent for such a product or process.

In the area of biotechnological inventions, a Member Country could determine that certain products or processes related to the genetic identity of the human being are contrary to morality, in which case they would fall within the scope of this patenting prohibition.

For example, a Member Country could determine that the commercial exploitation of the following products and processes is prohibited, in which case they could be excluded from patenting: Processes for cloning human beings, that is, processes, including the embryo division technique, designed to create a human being with the same genetic information as another living or dead human being.

- Process to modify the genetic identity of the germ line of human beings; for example, germline gene therapy that affects the individual and their offspring, because it alters their genetic heritage.

- Use of human embryos for industrial or commercial purposes and products that were obtained by a method that involved the destruction of a human embryo.
- Processes that modify the genetic identity of animals and may cause suffering without medical benefit for the man or the animal.
- The human body in its stages of formation and development, or the total or partial sequence of germ cells.
- Processes to produce chimeras from germ cells or totipotent cells of humans and animals.

7.3.2 Inventions contrary to the health or life of people or animals; or to the preservation of plants or the environment

Article 20, paragraph b), of Decision 486 mentions: ”b) inventions whose commercial exploitation in the respective Member Country must necessarily be prevented to protect the health or life of people or animals, or to preserve plants or environment. For these purposes, the commercial exploitation of an invention will not be considered contrary to the health or life of people, animals, or to the preservation of plants or the environment solely because there is a legal or administrative provision that prohibits or that regulates said exploitation.”

In application of this prohibition, the competent national office may object or deny an invention when the patent application contains information that leads to the definitive conclusion that any exploitation of the claimed subject matter would harm the life, health or preservation of human beings, animals or plants, or the environment, within the framework of Andean regulations.

7.3.3 Plants, animals and the essentially biological processes to produce them

Article 20, paragraph c), of Decision 486 indicates the following as an exception to patentability:

“Article 20.- The following shall not be patentable:

…

(c) plants, animals and essentially biological processes for the production of plants or animals that are not non-biological or microbiological processes; and …"

Plants and animals are not patentable, including transgenic plants and animals. These plants and animals can be obtained by essentially biological processes or by non-biological or microbiological processes. For the purposes of this manual the terms “process” and “procedure” are used synonymously.

The non-biological or microbiological procedure for obtaining it could be patentable as long as it is not the mere result of isolation activities. Likewise, biological material subject to transformation may be subject to patentability as long as it does not constitute a plant or animal. Nor are parts of transformed plants patentable that can give rise to the complete plant, for example, a modified seed or a plant cell modified with a transgene.

“Essentially biological processes” are understood to mean any biological process in which, while human activity exists to carry it out, it does not affect the final result. In this way, the patentability of a biological process will be conditioned to the intensity or relevance of the technical intervention of man in the various stages of the procedure.

To determine whether a process is considered an “essentially biological procedure,” it is necessary to examine whether said process can be carried out by technical or non-technical methods.

For example, in a process where the exchange of a single nucleotide in the genome of a plant is carried out, said change can be carried out by a process that is essentially biological, such as a natural allele, or by a technical procedure through mutagenesis. directed. For this example, in the claim it is important to make the due distinction to confirm that the procedure used is not an essentially biological process but rather a technical one.

Examples of technical processes:
Processes for obtaining transgenic plants and mutants induced by techniques such as, for example, targeted mutations with CRISPR/Cas9 or random mutagenesis such as UV-induced mutation, are considered technical processes.

In this way, a process for the mere fact of including stages of a biological nature would still be considered an invention. In this case, the examiner must determine the degree of human intervention in said process. If it is considered a non-biological or microbiological procedure, the substantive examination of the process may continue, analyzing its novelty and inventive level.
When an essentially biological step is the only difference between the claimed subject matter and the state of the art, it will be concluded that the claimed object is not new.

Examples of essentially biological processes:

- The method for the production of plants that have trait X, the method comprises crossing plants A and B and selecting the progeny that has marker X.
- The process to use an animal (transgenic) for breeding.
- The introgression of a gene X (transgenic) in a plant, that is, introducing it into the genome through crossing and selection.
- The plant breeding method through crossing complete genomes and selecting plants that include the embryo rescue stage.

For their part, non-biological or microbiological processes for the production of plants or animals will be patentable, since they use technical methods such as a microbiological process carried out to genetically modify the cell of a plant, for example, to make it genetically resistant to a pesticide.

In general, microbiological processes are processes that involve, are carried out, or result in microbiological material. In this way, the microorganisms or their parts are used to create or modify products or to obtain new microorganisms for specific uses (see section 7.5 of Chapter III referring to 'Patentable and non-patentable biological material').

Examples of patentable microbiological processes:
A process for the production of compost (fertilizer) or a process for cleaning oil tanks or petroleum products using strains of microorganisms with high biodegradable power would be considered patentable inventions.

Comparative examples of patentable and non-patentable processes for obtaining plants and animals:

I. Patentable processes:

a) Process for the production of a corn plant that includes the recombinant gene X, which consists of the transformation and regeneration of the transgenic plant

b) Process to produce animal X, which consists of transformation with the chimeric gene Y...

II. Non-patentable processes:

c) Process for the production of a corn plant X, which consists of crossing plants Y and W through pollination and selection.

d) Process to produce animal X, which consists of crossing...

Processes a) and b) would be patentable because they contain a technical step (transformation, regeneration) in the understanding that they do not occur in nature, while processes c) and d) are natural biological processes and, therefore, not patentable.

Technical processes that copy a process of nature are also not patentable.

For example, a method for pollinating plant X, which consists of cutting ... introducing the pollen, etc., would not be patentable because, although carried out artificially, it would be the same and achieve the same results as the natural process (processes c and d).

Notwithstanding the prohibition regarding the patenting of plants, an invention referring to a plant variety could be protected under the common regime for the protection of plant varieties established by Decision 345 of the Andean Community, provided that it complied with the established conditions. in that special regime.

7.3.4 Therapeutic, surgical and diagnostic methods

In application of Article 20, subsection d) of Decision 486, the examiner must object to the patenting of inventions that specifically claim a therapeutic, surgical or diagnostic method applicable to human beings or animals.

In general, therapeutic, surgical and diagnostic methods for human beings or animals are not considered inventions susceptible of industrial application, since the action of a human being on the body of another human being, or on that of an animal, and the professional relationship between a doctor and his patient, are not considered "industrial" acts. Furthermore, for reasons of public policy, it is not desirable that a doctor or surgeon (or a company in the health care sector) be able, by means of an invention patent, to prevent other doctors from using and applying the same surgical and diagnostic methods.
Therapeutic methods are the set of practices and knowledge aimed at curing diseases or malfunctions of the body. However, this exclusion does not apply to substances, compositions, instruments or apparatus used in such methods.

Prophylactic or preventive treatments are also considered therapeutic methods (for example: vaccination or immunization against diseases, removal of bacterial plaque from the teeth, etc.). In this sense, to determine whether the claimed subject matter falls within this exclusion, the examiner must verify whether what is being treated or prevented with the claimed method is a disease understood as such.

If the method involves the administration of a product (compound or pharmaceutical composition, for example) to a human or animal subject for the purpose of preventing, curing or alleviating a disease, or correcting or repairing the consequences thereof; then the claimed subject matter is a therapeutic method. To the extent that the method does not involve the administration of a product to a human or animal subject, the request should not be considered a therapeutic method.

Surgical methods, understood as "those that involve intervention with instruments of any type on the human or animal body," are also not patentable. For example, a new technique to perform a heart transplant, or the surgical use of lasers to correct myopia.

Diagnostic methods are understood as "those that try to discover and individualize a pathological situation, to propose the curative procedure that is necessary" in order to overcome the

condition. It covers any method or procedure intended to determine the presence of a medical condition in a patient (or animal), or to project the evolution of that condition over time.

In vivo diagnostic methods are not considered patentable. For the analysis of in vitro and/or ex vivo diagnostic methods, each Member Country has defined its practice based on its local legislation and interpretation of the standards.

Example of a non-patentable diagnostic method:
Title: Anti-cgrp antibodies and compositions thereof

Claim 2. An in vivo imaging method that detects the presence of CGRP-expressing cells, comprising administering a diagnostically effective amount of at least one anti-human CGRP antibody or antibody fragment according to claim 1.

Claim 3. The method of claim 2, wherein said administration further includes administration of a radionuclide or fluorophore that facilitates detection of the antibody at disease sites that express CGRP.

Comment: *Claim 2 defines a diagnostic method applied to a human being or animal, since the method involves the administration of the anti-CGRP antibody to the patient, this antibody upon entering the body will interact with the cells that express CGRP, then through the Images obtained from the patient's body will observe this interaction. The detection of the antibody-CGRP cell interaction will be facilitated with the administration of a radionuclide or a fluorophore, as indicated in claim 3, this diagnostic method will allow the detection of diseases such as cancer, among others. Therefore, claims 2 and 3 are affected by article 20 d) of Decision 486.*

7.3.4.1 About methods for obtaining information from the human or animal body

In addition to the diagnostic methods that are excluded from patentability according to Article 20, paragraph d), there are other methods related to diagnosis but that serve only to obtain information from the human or animal body (data, images, physical parameters, physical quantities, etc.) These methods or processes

in themselves do not allow deciding on the application of a therapeutic or prophylactic treatment to a patient, which is why they would not be included within the exclusion of 'diagnostic methods'. These methods and processes would be patentable (for example, taking an x-ray, magnetic resonance imaging, measuring blood pressure).
To determine whether a method for obtaining information from the human or animal body is not a diagnostic method, the method must not include steps that allow it to be implicitly or explicitly concluded that the patient has a disease or needs a specific surgical, therapeutic or prophylactic treatment.

In this way, said method to obtain information from the human or animal body can be carried out by a technician or a doctor acting as a technician and without the necessary intervention of the treating doctor.

7.3.4.2 About cosmetic methods

Cosmetic methods are associated only with aesthetic effects, which is why they can be patented. If the claimed cosmetic method contains one or more therapeutic method steps, it would not be patentable. When the support of the description allows it, claims referring to therapeutic steps that are part of a cosmetic method may be eliminated or canceled as long as the remaining claimed material allows obtaining the technical effect of the invention.

In the case of methods carried out with a product that has a therapeutic and cosmetic application, only the claims directed to the cosmetic method will be patentable, since the mention of any therapeutic benefit must be excluded from the patent.
A method to remove dental plaque is not considered a cosmetic method because the result cannot be seen from the outside. A cosmetic effect of a product that cannot be distinguished from a therapeutic effect would fall within the exclusion of patentability.

7.3.4.3 About non-therapeutic methods

In addition to therapeutic, surgical and diagnostic methods that are not patentable, there are other methods related to health sciences or biological sciences that can be considered patentable inventions.

A method that relates to the operation of a device associated with the body of a human or animal may be patentable, if there is no functional relationship between the steps of the method performed by the device and the therapeutic effect of the device on the body.

The application of a prosthesis to the body would be a method of treatment or prophylaxis, which is why it would not be patentable. However, the prosthesis and its manufacturing procedure carried out outside the body are patentable. In this way, although the manufacturing process of said prosthesis includes taking measurements on the body and the use of some part of the body as a model, can be patentable, because the manufacturing process itself does not imply a therapeutic, surgical or diagnostic method. This is the case, for example, of the manufacture of a dental prosthesis and of the dental prosthesis itself.

On the other hand, some methods practiced on animals are not considered treatment methods, such as hormonal treatment of farm animals (sheep, pigs, cows, etc.) when carried out with the aim of increasing the fertility of females, weight of the animals, or milk production, which is why these methods can be patentable. In these cases, the claim must explicitly mention that it is a "non-therapeutic" method. Likewise, if the claim refers only to the non-therapeutic treatment of animals, it is advisable to specify that it concerns "animals other than humans."

7.3.4.4 About contraception methods

Contraception methods are considered to have no 'industrial' application because they are used in the private and personal sphere of human beings. The fact that for some people contraception is related to professional activities does not confer an industrial character to an essentially private and personal act.

Likewise, the treatment of a subject with a composition that has both contraceptive and therapeutic effects, for example, when the therapeutic effect is to avoid the side effects of the contraceptive, is not patentable both for including a therapeutic method and for including a method of contraception that lacks industrial application.

7.3.4.5 On masked therapeutic, surgical and diagnostic methods. Often, claims in the pharmaceutical and biotechnology area contain claims for the use of a product or procedure for therapeutic, surgical or diagnostic purposes, and uses and second uses in any technical area are exceptions to patentability (see section 7.4 regarding Applications).

The examiner will analyze whether said use claims can also be objected because they are therapeutic, surgical or diagnostic methods. If a 'use' claim for a product or procedure is characterized by reference to a therapeutic, surgical or diagnostic method, this claim will be considered a therapeutic, surgical or diagnostic method excluded from patentability under Article 20, subsection d.) of Decision 486.

The above will also apply when a product or procedure is characterized by reference to its use in therapeutic, surgical and diagnostic methods.

It will be considered that including claims such as "to be administered to mammals, preferably human" and "that are previously combined to its administration", refers to uses of products or procedures and the therapeutic, surgical and diagnostic methods (see section 7.4 referring to uses).

7.4 Uses

In the Andean framework, claims of use and second uses of a product or procedure are not the subject of a patent since it has been interpreted that said uses are not included within the patentable subject matter in accordance with Article 14 of Decision 486. This is follows from ruling 89-AI-2000 of the TJCA.

In the case of claims of second uses of a product or procedure, Article 21 of Decision 486 is also relevant.

"**Article 14.-** The member countries shall grant patents for inventions, whether of goods or of processes, in all areas of technology, provided that they are new, involve an inventive step and are industrially applicable.

…

Article 21.- Products or processes that are already patented and

included in the state of the art within the meaning of Article 16 of this Decision may not form the subject matter of a new patent owing to the fact of having a use ascribed to them different from that originally provided for in the first patent”

In this way, the examiner will consider that claims whose preamble mentions the 'use' of a product or procedure do not refer to patentable subject matter.

Likewise, the examiner will take into account that the product or procedure claims must be characterized by their technical characteristics, so references to a 'use', for the purposes of Articles 14 and 21 of Decision 486, will not be considered characteristics. techniques.

The general structure of a 'use' claim is illustrated in the following table:

PREAMBLE	CHARACTERISTICS
- The use of product X - The use of process X - The compound of claim X	- in ... - as ... - for
- Use of product X	- As a medicine - As a medicine for the treatment of disease and - For the treatment of the disease and - To prepare a medicine - To prepare a medication for disease treatment and

In the same way, a product or a process will not be the subject of a patent when said product or procedure is known in the state of the art, but a use other than that originally disclosed is attributed to it.

When a claim refers to a product in its preamble, but only describes the usefulness of said product in its characteristic part, then said claim defines use (see claims characterized by a use in Section 4.6.9 of Chapter III).

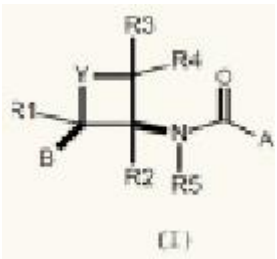
For example, a claim for “a transistor to be used in an amplifier circuit” will be equivalent to a claim for use of the transistor,

for which the examiner must notify the applicant that the uses are not patentable according to the cited articles.
Another example is a claim worded as "substance

Upon finding a use claim, the examiner must notify the applicant that the uses are not patentable in accordance with Article 14 of Decision 486. If it is a second use, he must make the request in accordance with Article 21 of the Decision 486 and must demonstrate that the product or procedure is included in the state of the art, therefore, the novelty test will be applied to said product or procedure (Article 16 of Decision 486).

It is common to find claims of use in the pharmaceutical, chemical and biotechnology area, so some common examples that the examiner can find are cited. When finding a use claim, the examiner must analyze whether it can also be objected for being characterized by reference to treatment, surgical or diagnostic methods which are explicitly excluded from patentability pursuant to Article 20, subsection d), of Decision 486.

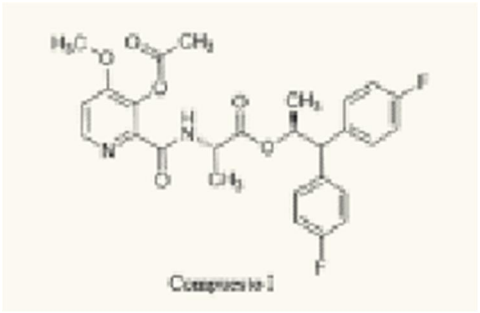
Examples of claims of 'use' in the pharmaceutical area (excluded):
- Use of the Antisense oligonucleotide of SEQ ID NO: 1 for the treatment of muscular dystrophy.
- Use of a formula compound (I)



(I)

To control or prevent the infestation of vegetables, tomato and potato plants by pathogenic organisms selected among Sphaerotheca fuliginea, Leveillula taurica, Sclerotinia sclerotiorum, Cercospora and Fusarium oxysporum, Sclerotinia sclerotiorum, Cercospora and Fusarium oxysporum.

- A method for controlling fungal diseases in a row crop that is at risk of becoming diseased comprising the steps of: contacting at least a part of a plant and/or an area adjacent to a plant with a composition comprising compound I.



where said compound is effective against a plant pathogen.

- The use of a fusion polypeptide according to any of the claims 1 to 16 in the treatment of a tumor in which the first domain of the fusion polypeptide binds to cancer cells.
- Use of a formula compound (I), specific inhibitor of the complement factor B (CFB), to treat, prevent or improve a disease associated with the deregulation of the alternative route of the complement.
- A formula compound to which it is in amorphous state and adequate for use in the form of injectable dosage, where the formula A compound is characterized by a D90 less than 40µm.
- A method to increase tolerance to abiotic stress or reduce the consequence of abiotic stress in a plant or part of it, which includes contacting a plant or part of it with a composition that includes an effective amount of a dicarboxylic acid from HOOC -R -COOH formula, where R is alkyne C5 to C14.
- Comment: The claiming method is equivalent to defining the use of a dicarboxylic acid of HOOC -R -COOH (where r is alkyne C5 - C14) to increase tolerance to abiotic stress or reduce the consequence of abiotic stress in a plant or part of the same; So define, clearly, the use of a product.
- A method for inhibiting p70S6K, characterized in that a system expressing p70S6K is contact with at least one compound of formula (I) under conditions such that the p70S6K is inhibited. p70S6K is inhibited.
- Comment: As drafted the claim is intended to protect the use of the compound of formula (I) to inhibit p70S6K.

Examples of first and second use claims of a substance characterized by its use in treatment, surgical or diagnostic methods (excluded):

First use:

- The use of substance X for the treatment of the disease Y.
- The use of product X as a medicine.
- Composed of Formula X or its pharmaceutically acceptable salts to be used in the treatment of an X pathology.
- The pharmaceutical composition that includes the compound and, which is used to prevent or treat cancer.
- Use of the Z peptide for the preparation of a medication for the treatment of hepatitis B.
- A compound, according to any of the claims 1 to 25 to use in a medical treatment procedure.
- The use of the compound of formula (AI) in the elaboration of a medication to treat or prevent a disease or condition mediated by the FXR in a subject.
- Trans-4-{2-[4-(2,3-Dichlorophenyl)-piperazin-1-yl]-ethyl}-N,N-dimethylcarbamoyl-cyclohexyl amino and its pharmaceutically acceptable salts for use in the treatment of primary negative symptoms of schizophrenia.

Second use:

- When x is already known to be used as medication: the use of product X as a herbicide.
- It is known that compound X is active for arthritis treatment:
- Use of compound X to prepare a medication for hypertension treatment.
- Use of the formula compound (I) for the manufacture of a medicine for healing or preventive treatment of erectile dysfunction.
- Comment: Formula (I) includes the drug Sildenafil which a was known to treat angina pectoris, therefore, a second use is sought to be patented.
- A pharmaceutical composition comprising from 1.5 mg to 6 mg of pioglitazone and a pharmaceutically acceptable carrier, vehicle or excipient.
- Comment: To the extent that the terms "bearer", "vehicle" and "excipient" are very general and nonspecific (both in their function and in its nature), then the product is essentially characterized by the doses of pioglitazone. In that sense, the requested matter is equivalent to defining a dose range of pioglitazone, and the pharmaceutical composition requested would only reflect the benefits of said active compound.

The status of the technique reveals dosing forms that omitted 15 mg and 30 mg of pioglitazone, and its usefulness for the treatment of type 2 diabetes mellitus.
The description of the invention refers to the usefulness of pioglitazone in the low doses claimed for the treatment of Alzheimer's disease.
While the determination of effective doses for specific treatment may imply an arduous research task, this does not imply creative human activity even if the new therapeutic utility were apparently surprising. Thus, the new therapeutic utility
(Treatment of Alzheimer's disease) remains attributable, clearly, to the active pioglitazone compound.
Therefore, the new therapeutic property related to a pharmaceutical composition that includes pioglitazone in low doses implies a new therapeutic use, so the invention is related to a second use.

For more information about uses, see examples 1 - 3 in section 2.1 of Annex IV.
The claims can also involve uses in the preamble or in the characteristic part, but implicitly, and must be objected by art. 14. Thus we have the following examples:

Example 1: "A kit to administer a glucagon agonist to a patient who needs it":
Comment: Of your writing it is understood that it aims to protect the use of the kit in the administration of a glucagon agonist to a patient who needs it.

Example 2: "A composition to treat bladder cancer, brain cancer, breast cancer and bone marrow cancer, characterized in that it includes an excipient and a therapeutically effective amount of an omitted formula (I) of claim 1"
Comment: While the word use is not explicit, by the phrase "to treat bladder cancer, brain cancer, breast cancer and bone marrow cancer" it is understood that it is sought to protect "the use of the composition that includes an excipient and a therapeutically effective amount of a compound of formula (I) of claim 1, to treat bladder cancer, brain cancer, breast cancer and bone marrow cancer", so it is referred to a use and is objected by art. 14.

Example 3: "A pharmaceutical composition to treat systemic lupus erythematosus that includes the antibody of claim 1 and pharmaceutically acceptable excipients"
Comment: As written, this claim aims to protect the use of composition, which includes the antibody, to treat systemic lupus erythematosus. It even is related to a treatment method.

Example 4: "A pharmaceutical composition that comprises one or more agents of CD33 union according to claim 1, for the treatment of malignments cell malignments and myelodysplastic syndrome (MDS)."
Comment: As written, this claim aims to protect the use of the pharmaceutical composition that includes an antibody of claim 1 in the treatment of myeloid cells and myelodysplastic syndrome (MDS).

It should be noted that, in the case of examples 2 to 4, removing the phrases related to use would overcome the objection under Article 14.

7.5 Patentable and non-patentable biological material

Biotechnological inventions refer to:
- Products consisting of or containing biological material; or
- Processes that produce, process or use biological material.

'Biological material' is any material that contains genetic information and can reproduce itself or be reproduced in a biological system.
For its part, a microbiological process is any process that involves, is carried out in or results in microbiological material.

7.5.1 Microorganisms

Microorganisms are organisms that can only be seen through a microscope. The concept of microorganisms includes bacteria, protozoans, algae and fungi, as well as organelles, bacteroids, viroids, bacteriophages, spores and viruses.

The patenting of microorganisms is an exception to the prohibition of patentability of plants and animals provided for in Article 20, literal c), of Decision 486. This exception is

part of the international regulations in force in accordance with the TRIPS Agreement, Article 27, paragraph 3, section b).
In this way, microorganisms existing in nature or extracted from it are not patentable in accordance with Article 15, literal b), of Decision 486. However, they could be patentable when they are modified and as long as they meet the criteria of patentability under this Decision.

The applicant may use the following definitions when the description does not specifically define another. A "mutant" refers to any organism that differs from the strain of origin (parent strain) by a modification in the genome caused by one or more mutations. A "variant" refers to a strain that differs in some way (often minimal differences) from another particular organism. In the case of claims for modified microorganisms, the examiner will consider that the terms "mutant" and "variant" are not clear, so their specific definition must be requested, taking into account the initial disclosure.

When a microorganism cannot be described in a way that can be understood and reproduced by a person skilled in the art, the description must be supplemented by a deposit of said material to satisfy the requirement of sufficiency of the description (see Section 3.1.2.2 of the Chapter III, referring to sufficiency).

In this sense, the examiner must consider that it will not always be necessary to have the deposit certificate for any biological material that is mentioned in the description, it is only necessary when the description of the invention requires complementation with the deposit of said material (see Section 5.8 of Chapter II) or when such deposit is required to clearly delimit the scope of the claims in accordance with Articles 30 and 51 of Decision 486 (see Section 4.6 of Chapter III).

For example, a mutant microorganism may be sufficiently described in the description when it is a mutant of another known microorganism and its mutation process is reproducible in accordance with the description; but for an unknown microorganism and/or when the mutation process is not reproducible, it will be necessary to have its deposit certificate.

A modified microorganism must be claimed indicating type of microorganism involved, the modification (sequence introduced or mutation carried out) or the name of the microorganism along with its biological deposit number.

The claim of a microorganism can be characterized in the following ways:

- A microorganism characterized by its deposit number, genus name and, if possible, species or strains. "Streptococcus Y-1 mutant NRRL 234567"
- A microorganism characterized by its deposit number could include other characteristics, such as function or activity. "Xanthomonas campestris NRRL B 1459 that is capable of producing the polysaccharide of claim X"
- A microorganism characterized by a product of a process capable of being repeated (genetic engineering processes) "A strain of recombinant yeast Pichia pastoris capable of biosynthesizing the enzyme extracellular endoglucanase, characterized in that the strain carries a recombinant vector pPICZaA that comprises DNA that encodes endoglucanase which has the sequence indicated in SEQ ID NO. 1 from the fungus strain Aspergillus niger VTCC-F-021"

7.5.2 Cell lines

Cell line is a general term applied to a defined population of cells that can be maintained in culture for an extended period, retaining the stability of certain phenotypes and functions. Cell lines are widely used in processes to obtain metabolic products of mainly chemical and pharmacological application, so cell lines can have industrial application.

To analyze the patentability of a cell line, the patentability exclusions of Article 20, subsection c) of Decision 486 must be taken into consideration (see Chapter III, Section 7.2.3 on exclusions to the patentability of plants and animals) since The cell lines that are the subject of a claim must not be able to give rise to a new individual to avoid falling into the indirect protection of plants and animals, including humans. Furthermore, by analogy, the examiner will apply the patentability criteria applicable to microorganisms (see Chapter III, Section 7.5.1 on microorganisms).

Like bacteria and viruses, cell lines are patentable as long as they have industrial application and have not been obtained by simple isolation from nature or, even having been obtained by non-biological or microbiological processes, are identical to those found in nature. Cell lines usually require deposit in a microorganism deposit institution to sufficiently explain the invention (see Chapter II, Section 5.8 regarding Deposit Certificate).

Cases of cell line inventions:

- A cell line that was obtained from cells isolated from nature is not considered an invention for the purposes of granting a patent.
- Plant cell lines, even when modified, are not patentable since they have the necessary capacity to allow the growth and development of a new plant without any type of fusion of sexual cells or gametes.

For information on the case of stem cells, see example 1 in Section 2.4 of Annex IV.

7.5.3 Genetically modified organelles (mitochondria, ribosomes, etc.)

An organelle is a subcellular structure that carries out one or more specific jobs in the eukaryotic cell, just as an organ does in the body that has a distinct structure, macromolecular composition and function. Some examples of organelles are the nucleus, mitochondria, chloroplast, Golgi apparatus.

For the purposes of the patentability analysis, the examiner will consider cellular organelles as parts of microorganisms and their patentability is analyzed in a manner analogous to that of microorganisms.

7.5.4 Expression vectors

An expression vector is a virus or plasmid that carries a DNA sequence to a suitable host cell and there directs the synthesis of the protein encoded by the sequence. A recombinant vector is an expression vector that carries an inserted fragment of DNA. The recombinant vector can be described by specifying at least the type of vector and the recombinant sequence it contains.

Expression vector example:
Recombinant plasmid vector comprising the nucleotide sequence SEQ ID NO: 123

7.5.5 Host cell

A host cell refers to a cell that incorporates or is infected by a virus or other type of microorganism. Expression vectors are a means of transferring genes, allowing a host cell to be specifically modified to induce gene expression.

Host cells can be described like any other microorganism by their accession number, although it is also usually relevant to describe them by their function or activity.

Example: EP1794299B1

1. An unnatural bacterial cell containing:

i) a DNA sequence that encodes a marker protein whose expression is to be regulated and, operatively associated with it,

ii) a DNA sequence that encodes parts of an RNA sequence II, and
   a) that is complementary to an RNA I sequence that is transcribable from a plasmid with a ColE1 origin of replication,
   b) comprising only two loops, and
   c) which is present upstream of the marker gene encoding said marker protein together with a ribosome binding site that is upstream or downstream of parts of said RNA II sequence,

wherein the parts of the RNA II sequence are designed and positioned so as to ensure sufficient RNA-RNA interaction of the complementary sequences, so that when the plasmid with a ColEI origin of replication is present, the RNA I transcribed from the itself binds to the host mRNA to a sufficient extent to inhibit the translation of the mRNA transcribed from the DNA sequence of i).

7.5.6 Primers, probes and antisense RNA.

Primers, probes and antisense RNA are biological material that uses fragments of DNA or RNA. They are widely used as tools in genetic engineering and detection and identification of organisms and microorganisms. These biological materials can be described by specifying at least their nucleotide sequence and preferably,

the functional characterization of the sequences being claimed should be indicated. The patentability analysis of these biological materials will be subject to local criteria and practice.

7.5.7 Transgenics

The term 'transgenic' refers to organisms or microorganisms to which exogenous genes were transferred horizontally through processes similar to an infection. For example, a transgenic cell that is genetically modified through the use of expression vectors comprising exogenous genes.

Its patentability will be subject to the provisions corresponding to the type of organism or microorganism to which the invention corresponds. For example, a transgenic animal or a transgenic plant will not be considered patentable as they are excluded by the provisions of Article 20, subsection c) of Decision 486.

For its part, a microorganism to which genes were transferred, for example, through the insertion of a plasmid for the overproduction of an antibiotic compound, may be patentable as long as it meets the conditions provided for in Decision 486.

7.5.8 Epitopes and antigens.

Antigen is a molecule that is capable of provoking an immune response; these can be defined by its complete amino acid sequence or by the amino acid sequence of its epitope.

An antigenic determinant (epitope or epitopes) is a specific region of a molecular antigen that binds to an antibody or T cell receptor.

If the epitope is a “linear epitope” (i.e., the antibody interacts with continuous amino acids in the antigen), it should be defined as a clearly limited fragment using closed wording (e.g., epitope consisting of).

If the epitope is “nonlinear” or “discontinuous” (i.e., the antibody interacts with multiple distinct segments of the primary amino acid sequence of the antigen), it is necessary to clearly identify the specific amino acid residues of the epitope.

The method for determining this discontinuous epitope must also be indicated in the claim and the application must provide a disclosure that allows the skilled person to determine whether other antibodies bind to this epitope. The application must also allow production by showing that it does not have an undue burden of additional antibodies that bind to the same epitope.

7.5.9 Monoclonal antibodies

A monoclonal antibody must be characterized based on its function and structure. Additionally, it can be defined by specifying the hybridoma that produces it. In the event that the antibody is characterized by the hybridoma that produces it, the latter must be identified by its deposit number.

The structure of the antibody must indicate the amino acid sequence of the heavy and light chain variable regions, the sequences of the complementarity determining regions (CDRs) of the heavy and light chains, or the sequences of the complete heavy and light chains.

Antibody example:

Antibody molecule that binds to XXXX comprising a heavy chain variable region with SEQ ID NO: XXX and a light chain variable region with SEQ ID NO: YYY.

7.5.10 Biological marker

Biomarker or biological marker is that substance used as an indicator of a biological state. The detection or measurement of biological markers provides information about a subject.

Biological markers, as a product, are susceptible to patentability as long as they do not correspond to a matter existing in nature. (see example 8 of Section 4 of Annex IV).

7.5.11 Gene therapy products

Products used in gene therapy processes may be considered inventions eligible for patentability as long as they are characterized as products and do not contravene the provisions of Articles 15 and 20 of Decision 486.

7.6 Chemistry and Pharmacy

7.6.1 Polymorph

Ruling 604-IP-2016 of the TJCA defines polymorph as patentable subject matter but only to the extent that they meet the patentability requirements demanded by Article 14 of Decision 486. Likewise, in accordance with Articles 28 and 30, the Support for the claims must be stated clearly and sufficiently in the description and its analysis will be case by case. This ruling concludes that:

"4.11. In this sense, this Court has considered that the national patent office must carry out a very specific analysis in order to determine whether a polymorph has an inventive level or not, since it cannot validate that invention patent rights extend beyond the time determined in the Andean regulations. Therefore, in order to safeguard the right to health and access to medicines, it is the responsibility of the national offices to technically and scientifically determine each of the patentability requirements for polymorph."

Polymorph can be defined as the ability of a substance to exist in two or more crystalline phases that present different arrangements and/or conformation of the molecules in the crystal.

Polymorph are each of the different crystalline forms of the same compound, which result from the different arrangements of the molecules in the solid state, that is, their chemical composition is the same but their properties are different. Such properties are physical (hardness, density, electrical or thermal conductivity), physicochemical (adsorption, stability, melting point), chemical (reactivity, stability, solubility, specific surface), technological (magnetism, refraction, reflection and absorption of light), pharmacological (bioavailability, ineffectiveness, toxicity, contraindications, side effects), etc.

Pseudopolymorph are crystalline forms of a chemical compound that contain solvent molecules in their structure (that is, molecules that in their natural state are in a liquid state at normal conditions of pressure and temperature; for example, water). That is, pseudopolymorph are crystalline forms of a solvated compound.

The solvated compound is also known as a solvate. When the solvent is water, then the solvate is specifically a hydrate.

More information about polymorph is found in sections 3.1.2.4 and 11.11.1.5 of this Chapter and examples 8 and 9 of section 1; and example 10 of section 4, all of them in Annex IV.

Member Countries are responsible for technically and scientifically determining the patentability requirements applicable to the analysis of polymorph.

7.6.2 Prodrugs and metabolites

Prodrugs are pharmacologically inactive derivatives that are metabolized, through a chemical or enzymatic process, to release the pharmacologically active compound (active metabolite) in vivo in the patient's body after administration. In these cases, the active metabolite is responsible for the pharmacological effect in vivo and its structure partially differs from the prodrug from which it is derived. Prodrugs are designed to: (a) direct the release of the active metabolite at the specific site of action, thus reducing its adverse effects; (b) improve oral bioavailability in case of poor absorption in the gastrointestinal tract; (c) improve the biopharmaceutical or pharmacokinetic properties of the pharmacologically active compound; among others.

In accordance with the above, prodrug claims may be considered patentable subject matter as long as they meet the patentability criteria and the prodrug is clearly defined.

Metabolites are compounds that are generated in vivo as product of the metabolism of an organic molecule, and can be intermediates or finals. By extension, it also refers to compounds that are generated in vivo by metabolism of a drug. Therefore, in the case of prodrugs, the active compound that is released in vivo represents its active metabolite.

However, metabolites obtained from a drug or prodrug will not be considered patentable subject matter, to the extent that they are obtained within the body of the subject to whom said drug is administered, as a result of a natural biological process.

Member Countries are responsible for technically and scientifically determining the patentability requirements applicable to the analysis of prodrugs.

7.6.3 Other derivatives of chemical compounds: salts, cocrystals, complexes, hydrates, solvates, esters, among others.

In a similar way to polymorph, it is possible to consider other forms of chemical compounds as patentable matter if the patentability conditions provided for in Decision 486 are met. The support of the claims must be set out clearly and sufficiently in the description and its analysis. It will be case by case.

When the compound is known in the state of the art, it may be considered a selection invention or a new product, depending on the practice of each office, and its patentability will be subject to the applicable patentability requirements.

Below, the various crystalline forms in which a chemical compound can be found are presented in an illustrative manner

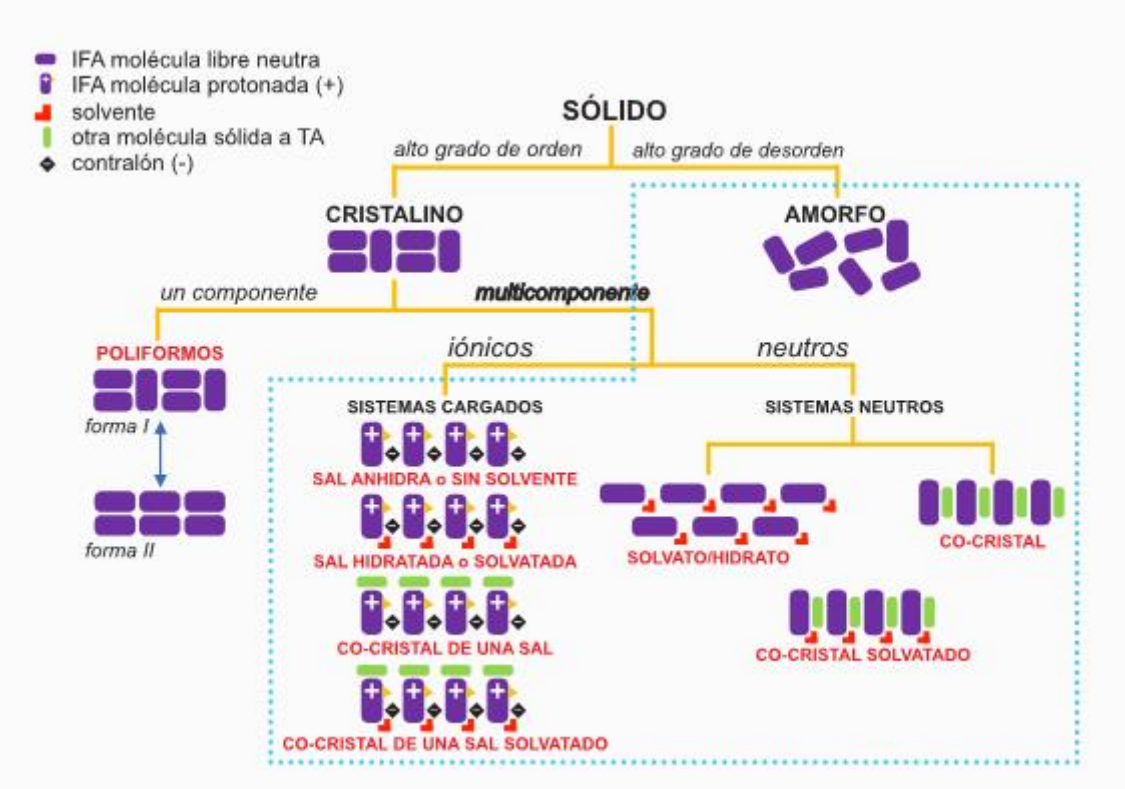


Figure 1. Diversity of crystalline solids. The systems that are found within the box with the light blue dotted line are called

"pseudo-polymorphic" by some authors, although as can be seen in the classification, each of them They present a rational name based on their composition.

Member Countries are responsible for technically and scientifically determining the patentability requirements applicable to the analysis of chemical compounds.

7.6.4 Stereochemistry of pharmaceutical compounds

The stereochemistry of a drug has a large impact on how that drug interacts with an enzyme or receptor. There are various types of isomerism classification that include positional, geometric, optical and diastereomeric.

In this category are optical isomers (enantiomers), geometric isomers (cis-trans isomer), diastereoisomers (isomers that differ only in the position of a functional group), tautomers, etc. The following figure illustrates the classification of isomers in organic chemistry.

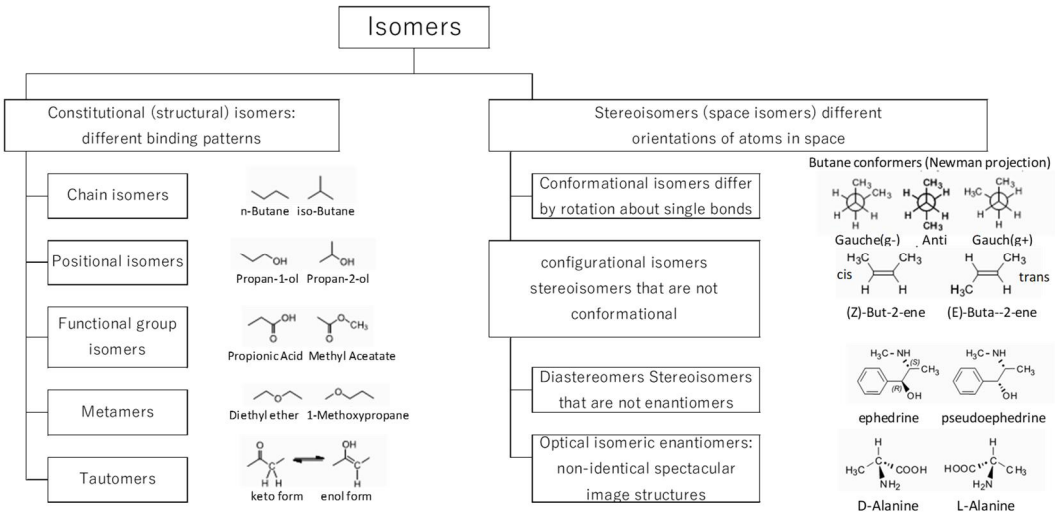


Fig. 2. Classification model of isomers.

The support of the claims must be stated clearly and sufficiently in description and its analysis will be case by case.

Member Countries are responsible for technically and scientifically determining the patentability requirements applicable to the analysis of new forms of compounds.

7.7 Computer-implemented inventions (CII)

7.7.1 Definitions of CII

7.7.1.1 Definition of CII

A computer-implemented invention (hereinafter referred to as CII) is one that involves the use of a computer, computer or computer network or other electronically programmable device, where the invention has one or more features that are realized in whole or in part by means of of a computer, computer or computer program. The synergy between these elements must always produce a technical effect that is part of the solution to the technical problem posed.

Examples of CII:

A cycle control process for a washing machine, a control process for a vehicle braking system, a smart watch, a touch screen gesture recognition component, a cryptographic algorithm for encrypting communication data, balancing loads on a computer network, resource allocation algorithms for a processing system, among others.

7.7.1.2 Other definitions related to CII

The terms “computer program”, “software” and “algorithm” are often used in relation to the patentability of subject matter in the field of information technology.

A “computer program” or “computer program” is a sequence of computational steps that can be effectively performed by a computer, where its steps are written in a systematic notation known as a programming language. Generally, a computer program refers to code in the programming language that is used.

Therefore, a computer program is a component of an invention implemented by a computer, consequently, an CII will always have a computer program embedded within it, but a computer program is not an CII, it is simply an encoding of a certain way, for a computer or other programmable device to perform some desired function.

For its part, the term “software” is commonly used as a synonym for computer program. However, software is a broader term that

applies to the non-physical logical components of a computer system that allow it to execute its tasks; Therefore, it may additionally involve other elements such as software, databases, storage media for a program, a set of programs, a series of instructions, etc., as well as all types of documentation that accompanies the program.

Based on the above we can see that, although as mentioned above the term software is often interpreted as synonymous with the term computer program, there is no word in Spanish that is exactly equivalent to the term software, so the latter should be considered as an Anglicism that is clear to a technician in the matter.

Finally, an "algorithm" can be defined as a systematic and sequential procedure for carrying out a task in a finite number of steps. In the computational context, the term algorithm is frequently used in relation to a suitable set of steps to solve a problem or provide an "output" from a specific set of "inputs." In this context, the term algorithm describes the concept that forms the basis for a computer program.

The physical implementation of an algorithm can be carried out either through a computer program that runs or is executed on a computer, potentially in combination with specific circuits, or through specific circuits alone, such as processors or programmable devices. In this way, when an algorithm is implemented totally or partially in a computer program, and when executed it solves a technical problem, it defines the underlying concept of an invention called "computer-implemented invention."

7.7.1.3 Technical nature

The CII must be evaluated considering all the physical and non-physical elements as a whole, since precisely the set and interaction of all of them are part of the specific solution to the problem posed. The object of the claim must be considered in its together, in order to decide whether the claimed object has a technical character. If not, there is no invention. Therefore, technical character is understood as all the particularities of the invention that contribute to solving a technical problem posed.

For its part, the technical effect is related to the solution to the technical problem through essential characteristics of the invention, which contributes to establishing its technical character.

Examples of what could be considered to have a technical nature in the field of CIIs:

a) The processing of parameters or control values of physical data of an industrial process;
b) Processing that affects the way a computer operates such as saving memory, increasing speed, security of a process, data transfer rate, etc.;
c) The physical characteristics of an entity such as memory, port, database, etc.

Purely abstract concepts, devoid of technical implications, are considered non-technical.

Examples of technical effect in the field of CIIs:

a) Obtain greater processing speed;
b) Achieve a reduction in hard disk access time;
c) The most efficient use of memory;
d) Have more effective data compression techniques;
e) Improve the control of a robotic arm;
f) Improve signal reception/transmission or processing.

On the other hand, it can be considered that those characteristics referring only to abstract issues are considered non-technical. Likewise, the simple processing of non-physical data through the computer could be considered as such, when there is no technical effect provided by the invention as a whole.

Examples of administrative (non-technical) issues:

Sales, insurance, marketing, selection among job candidates, administration, monetary values, business data, transfers or financial transactions as such.

CII claims generally comprise technical and non-technical characteristics, each characteristic must be evaluated to see if, in the context of the invention, it contributes to the technical character of the claimed object, as this is relevant to assess

the inventive step.

7.7.2 Study on the patentability of CIIs

Within the framework of the Andean Community, patents are granted for inventions (Article 14 of Decision 486). Some inventions with certain subjects and activities are excluded from patentability (Article 20 of Decision 486). Computer programs as such are not considered inventions and therefore are not patentable (Article 15 of Decision 486). CIIs, as their name suggests, are considered inventions that use computer programs. CIIs can be patentable within the framework of the Andean Community. It remains to be determined whether these inventions meet the patentability criteria of Article 14 of Decision 486.

It should be noted that throughout this manual reference is made to some jurisprudential interpretations issued by the Boards of Appeal of the European Patent Office (EPO) with respect to concepts and arguments about CIIs, which may be applicable in the corresponding and as long as they are not contrary to what is established by Decision 486 of the Andean Community. An extract from each of the EPO's jurisprudential interpretations can be found in Section 2 of Annex II.

7.7.2.1 Eligibility

First of all, in the study of CII it is necessary to determine whether the patent application includes an object that can be considered as eligible material for the patentability study. To determine said eligibility, it is necessary to verify that the subject matter to be protected is an invention. Although Decision 486 does not provide a definition of what is meant by an invention, Article 15 provides a non-exhaustive list of elements that may not be considered inventions.

Therefore, the provisions of Article 15 must be interpreted in light of the description and claims, to understand what is considered ineligible subject matter for the patentability study. According to the aforementioned article, the following are not considered inventions and are therefore excluded from patentability:

a. discoveries, scientific theories and mathematical methods;

b. the whole or part of living beings as they are found in nature, natural biological processes, biological material existing in nature or that which can be isolated, including genome or germplasm of any natural living being;
c. literary and artistic works or any other protected by copyright;
d. the plans, rules and methods for the exercise of intellectual activities, games or economic-commercial activities;
e. computer programs or software, as such;
f. nor the ways of presenting information.

In contrast to this list of exceptions, an invention, within the meaning of Article 14 of Decision 486, must have a concrete application and contain technical characteristics, in any field of technology.

If the invention includes any of the listed materials, it must be considered whether the claimed material as a whole has a specific application and contains characteristics techniques. At this point it is important to note that, if the claimed subject matter meets these criteria, the claimed subject matter is eligible for the patentability study and cannot be challenged under Article 15 of Decision 486.

If the application includes at least one technical characteristic related to a physical element (hardware), it cannot be considered that the invention falls within the assumptions of Article 15, as it does not refer only to said matter. In other words, the fact that an CII includes features considered non-technical or features related to the prohibitions of Article 15, or that the application is implemented in a field that could be interpreted as non-technical, is not a sufficient reason to discard it from the possibility of protection, since the invention must be evaluated as a whole, that is, considering the implementation of said non-technical characteristics in the so-called technical characteristics or physical elements and interpreting them in light of the description to determine if it is considered as ineligible matter. for the patentability study.

To carry out this point, the following guidelines must be considered:

a. The subject matter of the claim must be considered as a whole, in order to decide whether the claimed subject matter is of a technical nature;
b. The technical character is evaluated without taking into account the state of the art.

In the case of CIIs, the technician in the matter, when facing a specific problem in search of satisfying a specific need relying on computational means, requires the configuration of different physical and non-physical elements such as software and hardware in a specific way to that they can interact. And in order for this fact to confer a technical character on the CII, it is necessary to analyze the scope of the subject matter to be protected and the proposed solution, interpreting them in light of the description to determine whether it is considered eligible or ineligible subject matter.

By virtue of the above, we can generally consider that CIIs meet the definition of an invention and must be aimed at solving a technical problem, therefore providing a solution to the problem posed through technical characteristics.

7.7.2.2 Patentability examination for CII applications

If it has been determined as indicated in the previous paragraph that the patent application includes an object that can be considered eligible material, its patentability can be examined. Now, it must be ensured that the claimed invention falls within the two categories of claims that are acceptable in accordance with Article 14 of Decision 486, that is, product claims or process claims.

A product claim may include an apparatus, a machine, a mechanism, a tool, a device, a system, a composition, among others. Similarly, a process claim may include a process, method, or sequence of steps.

Subsequently, to grant a patent you must meet the patentability requirements established in Articles 16, 18 and 19 of Decision 486, that is:

- that is new
- that has an inventive level

• that is susceptible to industrial application
The steps to examine the CII are as follows:
• Disclosure and clarity of claims

Article 28 of Decision 486 establishes that the description must disclose the invention in a manner sufficiently clear and complete for its understanding and so that a person trained in the corresponding technical subject can execute it and that allows the understanding of the technical problem and the solution provided. for the invention.

The claims must contain all the essential technical characteristics of the invention which define it. These essential characteristics define the solution to the technical problem that the invention attempts to solve.

• Determine the closest state of the art
To determine the state of the art in CIIs, it is important to consider the technical field in which the invention is implemented as a whole and not only base the patentability analysis on the physical elements involved, such as computers, servers, networks, etc

• Novelty Exam
It is feasible that a combination of technical and non-technical characteristics appear in a claim in the field of CII. Non-technical features may even form an important part of the claimed subject matter.

If the closest prior art contains all the features of the claim, both technical and non-technical, the subject matter of the claim is not new. Consequently, the application is not patentable.

If there is any difference, that is, there is something new, go to the next step.

• Examination of the Inventive Activity
As mentioned above, it is feasible for a combination of technical and non-technical characteristics to appear in an CII claim, which is usually known as mixed type inventions. Non-technical features may even form an important part of the claimed subject

matter. However, the presence of an inventive step under Article 18 of Decision 486 requires a non-obvious technical solution to a technical problem.

To examine the inventive activity, the problem-solution approach is followed. Application of the problem-solution method to mixed type inventions that contain technical and non-technical characteristics:

I. The characteristics that contribute to the technical character (technical contribution) of the invention are determined on the basis of the technical effects achieved in the context of the invention;

II. Differences with the closest state of the art are identified. The technical effects of these differences, in the context of the claim as a whole, are determined to identify from these differences those characteristics that contribute to the technical character and those that do not. In this way you have to:

   a. If the differences do not contribute to the technical character, the inventive step is challenged. The reasoning behind the objection is that the subject matter of a claim cannot be inventive if there is no contribution of the technical character to the prior art. Since there is no technical nature, it can be argued that the object to be protected is an alternative to what is already revealed in the state of the art.

   b. If the differences include features that contribute to technical character, the following applies:

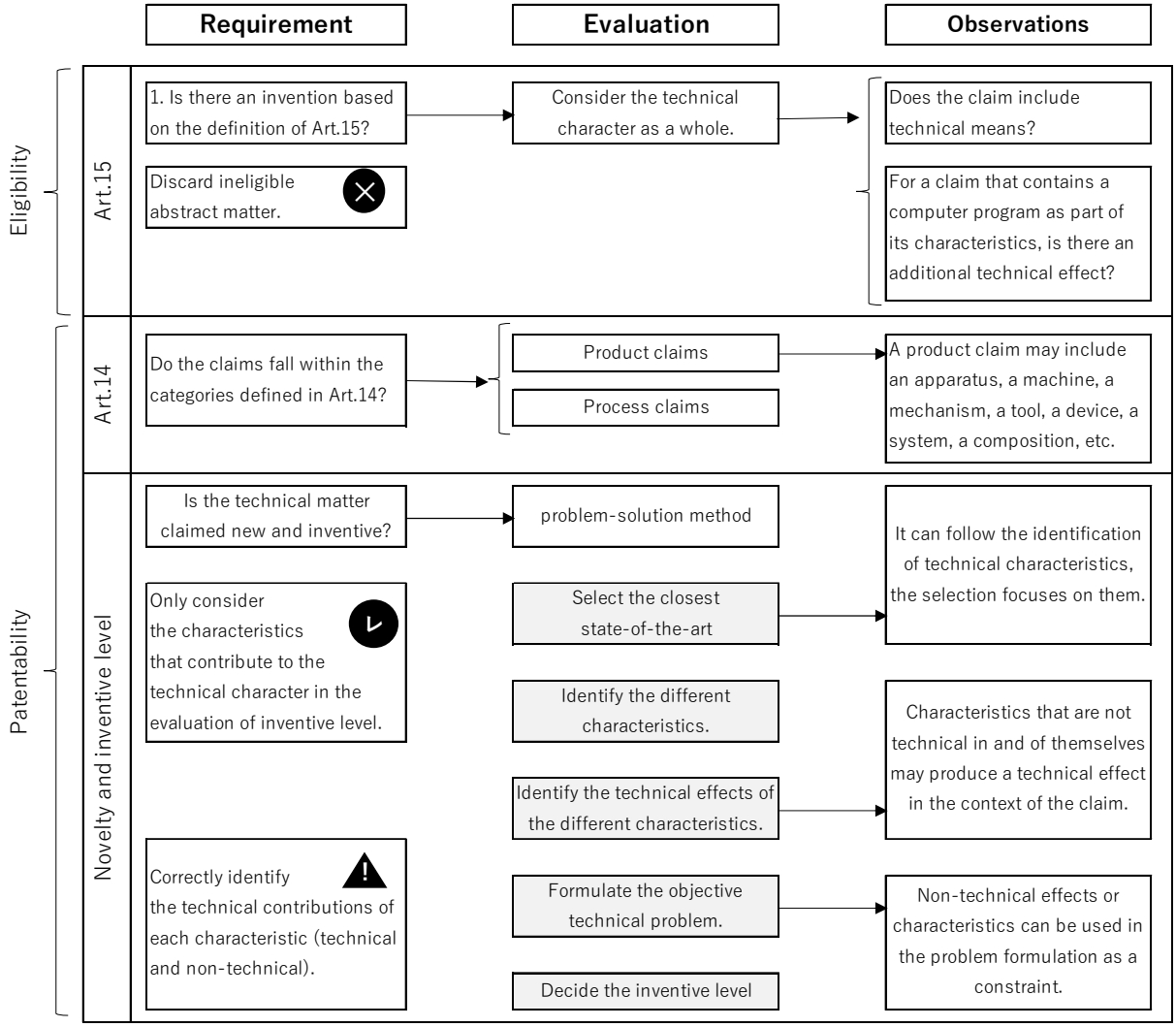
      - The objective technical problem is formulated on the basis of the technical effects achieved by these features. Furthermore, if the differences include features that do not contribute to technical character, these features, or any non-technical effects achieved by the invention, may be used in the formulation of the objective technical problem as part of what is given to the expert, in particular as a restriction that must be met.

      - If the claimed technical solution to the objective technical problem is obvious to the person skilled in the art, an inventive step is objected.

It is important to consider that, although the application may or may not designate the technical problem as such, the application as a whole must be considered to determine this. In other words, even when reading the application, it is understood that the problem solved is related to fields that could be interpreted as non-technical, the application as a whole and particularly the claimed subject matter must be evaluated to determine if a technical problem is resolved.

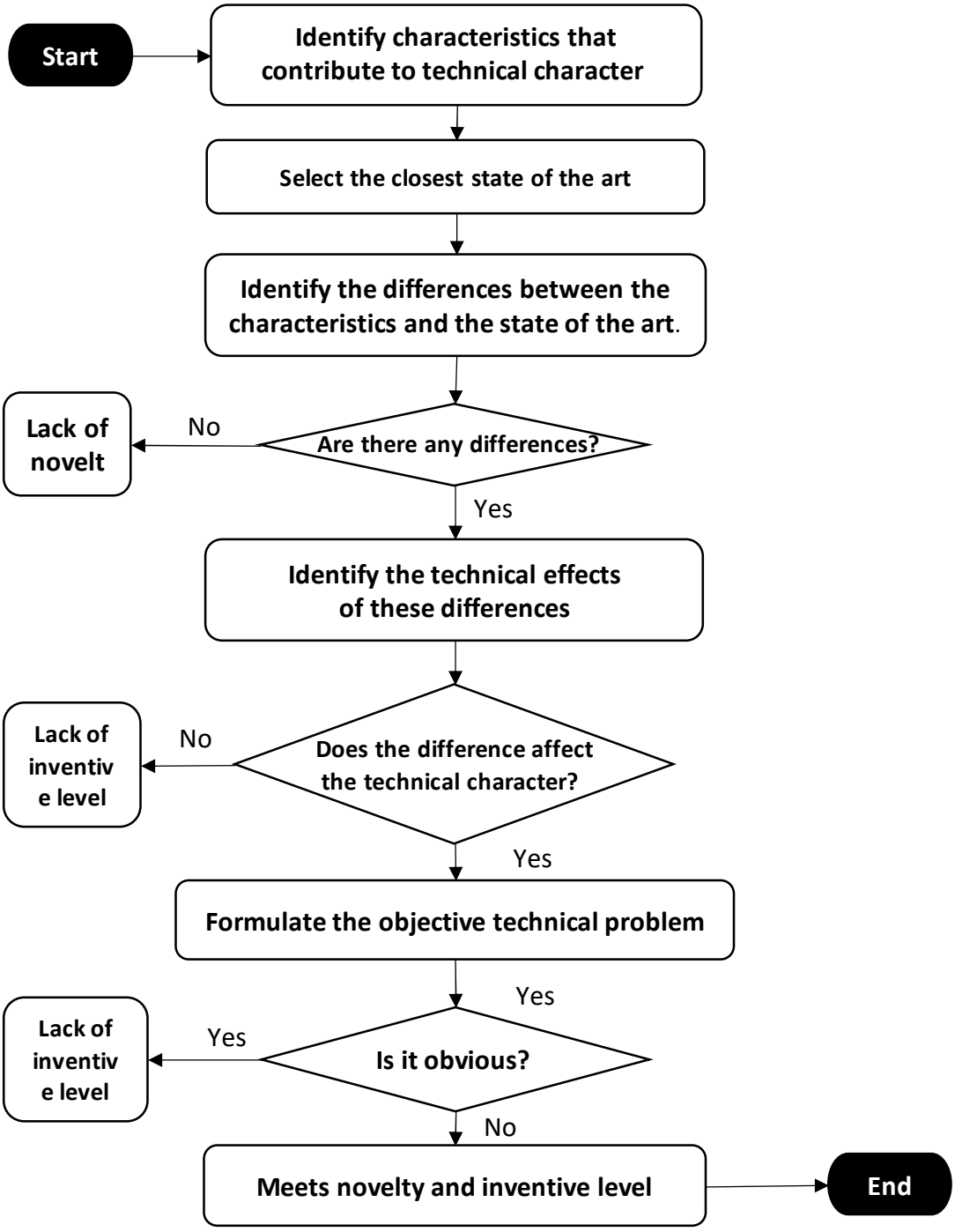
If it is determined that said characteristics that distinguish the invention from the closest state of the art solve a technical problem, that is, it is evaluated whether the solution proposed by the claims, considered as a whole, meets the requirements of novelty, inventive level and if they are susceptible to industrial application, established in Decision 486.

The aforementioned requirements and evaluations are summarized in the following summary table:



7.7.2.3 Diagram of the novelty and inventive level exam for CII

To facilitate the visualization of the examination of novelty and inventive level with the problem-solution method in the field of CII, the following diagram is presented:



To exemplify the application of the problem-solution method in the field of CIIs, refer to examples 1, 2, 3 and 4 of Section 2.2 of Annex IV.

7.7.3 Specific considerations of CII according to Article 15 of Decision 486

7.7.3.1 Mathematical methods

Mathematical methods play an important role in solving technical problems in all fields of technology. However, pure mathematical methods are excluded from patentability under Article 15, subsection a) due to lack of technical character.

The exclusion applies if the claim is directed to a purely abstract mathematical method and the claim does not require any technical means.

Examples of pure mathematical method:

a) A method for performing a Fourier transform on abstract data that does not specify the use of any technical means.
b) A method or formula for calculating the area of a polygon, an algebraic formula, or a logarithmic method. A purely abstract mathematical concept, for example, a geometric object or a graph with nodes and edges, is not a method, but it is not an invention either because it is non-technical.

If a claim refers to a method that involves the use of technical means, for example, a computer or a device, and when analyzing the scope of the subject matter to be protected and the proposed solution, interpreting them in light of the description to determine if their object has a technical character as a whole and consequently can be considered an invention.

Merely specifying the technical nature of the data or parameters of the mathematical method may not be sufficient by itself to define an invention. Even if the method were not considered a purely abstract mathematical method, it may still fall within the excluded category of methods for the exercise of intellectual activities if it does not involve the use of technical means.

Once it is established that the claimed subject matter as a whole is an CII, it is examined in relation to the other patentability requirements, in particular novelty and inventive step.

For the evaluation of the inventive level, all the

characteristics that contribute to the technical character of the invention must be taken into account. When the claimed invention is based on a mathematical method, it is evaluated whether the mathematical method contributes to the technical nature of the invention.

A mathematical method can contribute to the technical character of an invention, that is, contribute to producing a technical effect that has a technical purpose, by applying it to a field of technology or by adapting to a specific technical implementation. The criteria to evaluate these two situations are explained below.

7.7.3.1.1 Applications to a field of technology

When assessing the contribution of a mathematical method to the technical character of an invention, consideration must be given to whether the method, in the context of the invention, has a technical purpose.

Examples of technical purpose that can be supported by a mathematical method:

a) control a specific technical system or process, for example, an X-ray apparatus or a steel cooling process;
b) determine from measurements a required number of passes of a compaction machine to achieve a desired material density;
c) analyze audio for noise removal or estimate the quality of a transmitted audio signal;
d) analyze image or video to detect people in a digital image;
e) source separation in voice signals; speech recognition, for example, mapping a voice input to a text output;
f) data encoding for reliable and/or efficient transmission or storage (and corresponding decoding), for example, error correction encoding of data for transmission over a noisy channel, compression of audio, image, video or data of sensors;
g) encrypt electronic communications; generate keys in a cryptographic system;
h) optimize load distribution in a computer network;
i) determine the energy expenditure of a subject by processing data obtained from physiological sensors;
j) provide an estimate of the genotype based on an analysis of

DNA samples;

k) provide a medical diagnosis through a system automated that processes physiological measurements.

A generic purpose such as "controlling a technical system" is not sufficient to confer a technical character on the mathematical method. The technical purpose must be specific.

The claim must be functionally limited to the technical purpose, whether explicitly or implicitly. This can be achieved by establishing a sufficient link between the technical purpose and the steps of the mathematical method, for example, by specifying how the input and output of the sequence of mathematical steps relate to the technical purpose so that the mathematical method is causally related to a technical effect.

To exemplify the analysis of a mathematical method that contributes to the technical nature of an CII, refer to example 4 of Section 2.2 of Annex IV.

Defining the nature of data input in a mathematical method does not necessarily imply that the mathematical method contributes to the technical nature of the invention. Whether the mathematical method serves a technical purpose is determined primarily by the direct technical relevance of the results it provides.

7.7.3.1.2 Technical implementation

A mathematical method may also contribute to the technical character of the invention independently of any technical application when the claim is directed a specific technical implementation of the mathematical method and the mathematical method is particularly adapted to that implementation in the sense that its design is motivated by technical considerations about the internal workings of the computer.

Technical implementation example:

Adapting a polynomial reduction method to exploit word size changes coincident with the computer hardware word size is based on such technical considerations and can help produce the technical effect of an efficient hardware implementation of such a method.

7.7.3.1.3 Computational efficiency

If the mathematical method has no technical purpose and the claimed technical implementation does not go beyond a generic technical implementation, the mathematical method does not contribute to the technical character of the invention. In such a case, it is not sufficient for the mathematical method to be algorithmically more efficient than prior art mathematical methods to establish a technical effect.

However, if it is established that the mathematical method produces a technical effect because it has been applied to a field of technology or adapted to a specific technical implementation, the computational efficiency of the steps that affect that established technical effect will be taken into account when evaluating the inventive level.

7.7.3.2 Artificial intelligence and machine learning

The US National Institute of Standards and Technology (NIST) defines 'artificial intelligence' technologies and systems as: “comprising software and/or hardware that can learn to solve complex problems, make predictions, or perform tasks that require human-like sensors (such as vision, speech, and touch), perception, cognition, planning, learning, communication, or physical action.” However, for patent applications, artificial intelligence is also defined as comprising one or more of these eight technologies mentioned above, as long as it maintains a unity of invention. These components span software, hardware, and applications, and a single patent document may contain multiple AI component technologies.

Artificial intelligence and 'machine learning' are based on computational models and algorithms for classification, clustering, regression and dimensionality reduction, such as neural networks, genetic algorithms, support vector machines, k-means, kernel regression and discriminant analysis. Such computational models and algorithms are abstract mathematical in nature, regardless of whether they can be trained using training data. Therefore, the concepts presented in the previous point for mathematical methods generally also apply to these computational models and algorithms.

Terms such as “support vector machine,” “reasoning engine,” or “neural network” may, depending on the context, simply refer to abstract models or algorithms, so they do not necessarily imply the use of a technical means in and of themselves. This must be taken into account when examining whether the claimed object is of a technical nature as a whole.

Examples of CII on artificial intelligence and machine learning in technology applications:
The method that incorporates a neural network into a cardiac monitoring device to identify irregular heartbeats constitutes a technical contribution.

Classification of digital images, videos, audio or speech signals based on low-level features (e.g., edges or pixel attributes for images) are other typical technical applications of classification algorithms.

When a classification method has a technical purpose, the steps of generating the training set and training the classifier may also contribute to the technical character of the invention if they support the achievement of that technical purpose.

To exemplify more cases in the field of CII related to artificial intelligence, refer to examples 5, 6, 7 and 8 of Section 2.2 of Annex IV.

7.7.3.3 Computer programs
Pure computer programs or software are not considered inventions under Article 15(e) of Decision 486, if they are claimed as such.

The prohibition of Article 15, paragraph e), is directed primarily towards a set of instructions expressed by words, lines of code, plans or in any other form; and not to prohibit products or processes, such as devices, systems and methods that involve a computer program, software, or its application. This is fundamental in the evaluation of CII, since currently many inventions involve the implementation of a software, computer program or its implementation through some device or in a stage of the process.

To fulfill a technical character, a computer program must produce an “additional technical effect” when executed on a computer. An “additional technical effect” is a technical effect that goes beyond the “normal” physical interactions between the software and the physical components or hardware on which it runs. The normal physical effects of program execution, for example the circulation of electrical currents in the computer, are not in themselves sufficient to confer technical character on a computer program.

Examples of other technical effects that confer technical character to a computer program are the control of a technical process or the internal functioning of the computer itself or its interfaces.

The presence of an additional technical effect is evaluated without reference to the state of the art. It follows that the mere fact that a computer program serving a non-technical purpose requires less computing time than a prior art program serving the same non-technical purpose does not by itself establish the presence of an additional technical effect.

Likewise, comparing a computer program to the way a human being would perform the same task is not an adequate basis for evaluating whether the computer program is technical in nature.

If an additional technical effect of the computer program has already been established, the computational efficiency of an algorithm that affects the established technical effect contributes to the technical character of the invention and therefore to the inventive step, for example, when the design of the algorithm is motivated by technical reasons.

A computer program cannot have a technical nature simply because it has been designed to be executed automatically by a computer. “Additional technical considerations” are needed, typically related to technical considerations of the internal and/or external functioning of the computer, that go beyond simply searching for a computer algorithm to perform a task. They must be reflected in claimed characteristics that cause an additional technical effect.

A computer program and a computer-implemented method are different from each other. The former is a sequence of computer-executable instructions that specify a method, while the latter refers to a method that is actually performed on a computer.

Claims directed to a device or system cannot be objected under Article 15, since they generally contain within their characteristics technical means, such as a computer, that have a technical nature.

On the other hand, the methods or processes must be evaluated under the view of Article 15. The mere fact that they mention that they are implemented or executed by a computer does not confer them technical character. The stages of said method must transform a defined element, be it matter, or energy, or process information data, provided that this is determined after analyzing the scope of the matter to be protected and the proposed solution, interpreting them in light of the description.

Claims that include a computer program in their wording should not be rejected outright, since they must be evaluated as a whole and the fact that they include the computer program does not mean that they seek protection for the program as such.

However, claims worded as: “A computer program…” or “A computer program product…” would clearly fall into subsection e) of Article 15 of Decision 486, even though they do not claim the code as such.

7.7.3.3.1 Information modeling

Information modeling is a non-technical intellectual activity, typically carried out by a systems analyst in an early stage of software development, to provide a formal description of a real-world system or process. Consequently, the specifications of a modeling language, the structure of an information modeling process or the maintenance of models are also not technical in nature.

Now, if an information model is used intentionally in the context of an invention to solve a specific technical problem, it can contribute to the technical character of the invention. Features

that specify how the model is actually stored, for example using relational database technology, can also make a technical contribution.

7.7.3.3.2 Programming activity

The activity of programming understood as writing code is an intellectual, non-technical activity, to the extent that it is not used in the context of a specific application or environment to causally contribute to the production of a technical effect.

Example of a non-technical programming activity:
Reading a data type parameter from a file as input to a computer program, rather than defining the data type in the program itself, is simply a programming option when writing code, which per se is not technical.

The same applies to object naming naming conventions to facilitate intelligibility and manageability of program code.

7.7.3.3.3 Programming languages

Defining and providing a programming language or programming paradigm, such as object-oriented programming, does not by itself solve a technical problem, even if its particular syntax and semantics allow the programmer to develop a program more easily. The invention must be evaluated to define whether or not it has a technical effect. An example of the absence of contribution to the technical nature for this type of CII is found in example 9 of Section 2.2 of Annex IV.

7.7.3.3.4 Recovery, data formats and structures

A data structure or data format implemented by a computer embedded in a medium or as an electromagnetic carrier wave has a technical character as a whole.

A data structure or format contributes to the technical character of the invention if it produces a technical effect. This can happen if the data structure or format is functional data, that is, if it has a technical function in a technical system, such as controlling the operation of the device that processes the data. Functional data inherently comprises the corresponding technical characteristics of the device. On the other hand, cognitive data

is data whose content and meaning are only relevant to human users and do not contribute to producing a technical effect.

Examples of data retrieval and structure with contribution to technical nature:

1. A recording medium for use in an image retrieval system store encoded images along with a data structure defined in terms of line numbers and addresses that tell the system how to decode and access the image from the recording medium. This data structure is defined in terms that inherently comprise the technical characteristics of the image retrieval system, namely, the recording medium and a reading device for retrieving images therefrom on which the recording medium is operative. It therefore contributes to the technical character of the recording medium, whereas the cognitive content of the stored images, for example a photograph of a landscape, does not.

2. An index structure used to search a record in a database produces a technical effect because it controls the way the computer performs the search operation.
Another example related to the recovery of structures is available in example 10 of Section 2.2 of Annex IV.

7.7.3.3.5 Database management systems

Database management systems are computer-implemented systems to perform the technical tasks of storing and retrieving data using various data structures for efficient data management. A method carried out in a database management system is a method that uses technical means, so it is not excluded from patentability.

The features that specify the internal workings of a database management system are typically based on technical considerations. Therefore, they contribute to the technical nature of the invention and are taken into account for the evaluation of the inventive level. For example, technical considerations are involved in improving system performance and query response times by automatically managing data using multiple data stores with different technical properties, such as different levels of consistency or performance.

Database management systems execute structured queries, which formally and precisely describe the data to be retrieved. Optimizing the execution of such structured queries with respect to the necessary computing resources contributes to the technical nature of the invention, since it involves technical considerations relating to the efficient exploitation of the computing system.

However, not all features implemented in a database management system necessarily make a technical contribution by virtue of this fact alone.

Example of a feature in a management system without technical contribution:
A feature of a database management system for accounting costs related to the use of the system by different users does not constitute a technical contribution.

7.7.3.4 Plans, rules and methods for the exercise of intellectual activities.
The exclusion from patentability of plans, rules and methods for the exercise of intellectual activities under Article 15, subsection d) of Decision 486 refers to instructions directed to the human mind on how to carry out cognitive, conceptual or intellectual processes, for example, how to learn a language.

If a method claim comprises a purely mental realization of all the steps of the method, it falls into the category of methods for the exercise of intellectual activities, and its subject matter would not be considered an invention. This applies regardless of whether the claim also includes modalities and whether the method is based on technical considerations.

In general, the complexity of a method is not relevant to qualify it as a method for the exercise of intellectual activities as such. If technical means, for example a computer, are necessary to carry out the method, they must be included in the claim as an essential characteristic.

A claimed method is not considered a method for the exercise of intellectual activities if it requires the use of technical

means, for example, a computer or a measuring device to carry out at least one of its steps, or if it provides a physical entity such as the resulting product. For example, if it is a method of manufacturing a product that includes the design stages of the product and a manufacturing stage of the product thus designed.

Once it is established that the claimed method as a whole is not excluded from patentability under Article 15 of Decision 486, it is examined with respect to the patentability requirements, in particular novelty and inventive step.

When a claim defining a method for the exercise of intellectual activities specifies that the method is carried out by a computer; Not only the use of a computer, but also the steps carried out by the computer can make a technical contribution if they are based on technical considerations and have a technical purpose.

A method that comprises steps involving the use of technical means may also specify steps that the user of the method must carry out mentally. These mental steps contribute to the technical character of the method only if, in the context of the invention, they contribute to producing a technical effect for a technical purpose.

A method may specify steps that result in the selection of a product from a family of products based on various criteria, as well as a manufacturing step for the selected product. If such selection steps are carried out mentally, they contribute to the technical character of the method only to the extent that a technical effect can be derived from the characteristics characterizing the subfamily of selected products on the generic family of suitable products. If the selection steps are based on purely aesthetic criteria, they result in a non-technical selection and therefore do not contribute to the technical character of the method.

Example of method with technical contribution:
In a method for attaching a controller to a Coriolis mass flowmeter, the steps that specify how to select the position of the controller to maximize the performance of the flowmeter make

a technical contribution insofar as they define that particular position.

7.7.3.5 Plans, rules and methods for playing games.
In accordance with Article 15, subsection d), of Decision 486, the plans, rules and methods for playing games are excluded from patentability because they lack technical character. The exclusion applies to the rules of traditional games, such as sports, card or board games, as well as the rules of games underlying mechanized and electronic games such as gaming machines or video games.

The rules of the game define a conceptual framework of conventions and conditions that govern player behavior and how a game evolves in response to the players' decisions and actions. They comprise the setting of the game, the options that arise as the game unfolds, as well as the objectives that define progress in the game. Players typically perceive or accept them as rules and instructions that serve the explicit purpose of playing the game. The rules of the game are therefore abstract in nature, purely mental and only make sense in the context of the game.

Example of game rule:
A condition that requires two randomly drawn numbers to match to win is a rule of the game.

Contemporary games, and particularly video games, are often characterized by complex interactive and narrative elements of a virtual game world. Such game elements govern how the game develops on its own, for example, evolving characters and stories, as well as how it proceeds in interaction with players. Since these elements are conceptual in nature, they qualify, in a broader sense, as rules for the game.

Example of an object that specifies technical means to implement the rules of the game on a technical basis:
When implementing the rule of matching random numbers, the use of a computer that calculates a pseudorandom sequence, or of mechanical means such as cubic dice or uniformly sectored reels, may be sufficient to avoid a lack of technicality objection.

The inventive level of a claim that comprises a combination of rules of the game and technical characteristics is examined according to the problem-solution approach for mixed type inventions. As a principle, the inventive level cannot be determined solely on the basis of the rules of the game themselves, no matter how original they may be, or by their mere automation, rather it must be based on additional technical effects of a technical implementation of the game, that is, technical effects that go beyond those already inherent in the rules.

Examples of network game implementation:
1. A network implementation of a game of chance such as bingo, in which numbers physically drawn by an operator undergo random mapping before transmission to remote players, makes a technical contribution since the encoding of results has the technical effect of securing a data transmission, analogous to encryption, without bearing on the actual game.

2. A reduction in memory, network capacity, or computational resources achieved by limiting the complexity of a game does not overcome a technical constraint by a technical solution. Rather than solving the technical problem of improving the efficiency of an implementation, such a limitation would, at best, prevent it.

The inventive level of an implementation must be evaluated from the point of view of the expert, usually a game engineer or programmer, who is tasked with implementing the rules of the game established by a game designer. The simple writing of claims is related to the inventive level, when in said writing non-technical elements of the game are paraphrased ("computational means of victory" to monitor the number of game tokens) or abstracted ("objects" instead of "game tokens") using terms that are technical only on the surface.

The rules of the game are often designed to entertain and maintain the interest of players through psychological effects such as amusement, suspense, or surprise. Such effects do not qualify as technical effects. Likewise, leading to a balanced, fair or fun game are psychological effects, not technical ones. Therefore, the rules and corresponding calculations that

determine a game's score or a skill rating for players, even if computationally complex, are generally considered non-technical.

A highly interactive game, as in video games, involves technical means to detect user input, update the game state, and output visual, audio, or haptic information. Cognitive content that informs the player about the current state of the game at a non-technical level, for example, about the score of a game, the disposition and the card suits, status, and attributes of a game character are considered non-technical information. This is equally valid for instructions presented on game boards or cards, such as “return to the starting point.”

An example of a technical context in which the way information is presented can provide a technical contribution is the interactive control of real-time maneuvers in a game world, the visualization of which is subject to conflicting technical requirements.

Features that specify how to provide information to the user typically constitute a technical contribution. A mapping of parameters obtained from known input mechanisms to parameters of a computer game qualifies as a game rule in a broader sense if it reflects the choice of the game designer, established for the purpose of defining the game or making it more interesting or challenging. For example, a condition that specifies that a swipe gesture on a touch screen determines both the power and spin of a virtual golf shot may be considered a technical contribution.

A case about video games is included in example 11 of Section 2.2 of Annex IV.

7.7.3.6 Plans, rules and methods for the exercise of economic-commercial activities

The object or activities that are of a financial, commercial, administrative or organizational nature fall within the scope of plans, rules and methods for the exercise of economic-commercial activities, which are excluded from patentability under Article 15 of the Decision 486, subsection d), because it lacks technical character. In the rest of this section, these topics or activities will be included in the term “economic-commercial method”.

Examples of economic-commercial activities:
Financial activities typically include banking, billing, or accounting. Marketing, advertising, licensing, rights management and contractual agreements, as well as activities involving legal considerations, are of a commercial or administrative nature. Managing personnel, designing a workflow for a business process, or communicating publications to a target user community based on location information are examples of organizational rules. Other typical activities of business activity concern operations research, planning, forecasting and optimizations in business environments, including logistics and task scheduling. These activities involve collecting information, setting goals, and using mathematical and statistical methods to evaluate information to facilitate managerial decision making.

If the claimed subject matter specifies technical means, such as computers, computer networks or other programmable devices, to execute at least some steps of an economic-commercial method, this would imply a technical nature and could be considered an invention. However, the mere possibility of using technical means is not sufficient to avoid exclusion, even if the description reveals a technical embodiment.

Terms such as “system” or “means” should be carefully examined in light of the description, because a “system” could, for example, refer to a financial organization and “means” to organizational units if it cannot be inferred from the context that these terms refer exclusively to technical entities.

Once it is established that the claimed subject matter as a whole is not excluded from patentability, it is examined with respect to novelty and inventive step. Examination of the inventive step requires an evaluation of the characteristics that contribute to the technical character of the invention.

When the claim specifies a technical implementation of an economic-commercial method, the features that contribute to the technical character of the claim are in most cases limited to those that specify the particular technical implementation.

Characteristics that are the result of technical implementation

choices and that are not part of the economic-commercial method contribute to the technical character and must be duly taken into account.

Example of characteristics resulting from technical implementation choices with contribution to technical character:
The claim defines a computerized network system that allows customers to obtain audiovisual content on selected products using computers installed in each point of sale of a company, all connected to a central server with a central database that stores the audiovisual content as electronic files. The distribution of electronic files from the central server to the points of sale could be technically implemented either by allowing the download of individual files directly from the central database to the computer at the request of a customer or, alternatively, by transferring a plurality of electronic files selected to each point of sale, storing these files in a local database of the point of sale and retrieving the corresponding file from the local database when a customer requests audiovisual content at the point of sale.

Choosing an implementation between these two options is the responsibility of a technically qualified person, such as a systems engineer, rather than, for example, specifying that the set of audiovisual content offered is different for each point of sale, which would normally be within the competence of an expert in economic-commercial activities.

The features of the claim that specify either of these two possible technical implementations contribute to the technical character of the invention, while the features that specify the economic-commercial method do not.
Conclusion: *Therefore, those characteristics must be taken into account.*

In the case of claims directed to a technical implementation of an economic-commercial method, a modification of the underlying economic-commercial method intended to circumvent a technical problem, rather than addressing this problem in an inherently technical manner, is not considered to make a technical contribution on the state of the art. In the context of an

automation of an economic-commercial method, effects that are inherent to the economic-commercial method do not qualify as technical effects.

Examples of automation of the economic-commercial method without technical contribution:

1. An automated accounting method that avoids redundant accounting requires fewer computing resources in terms of computing workload and storage requirements. These advantages, to the extent that they result from a reduction in the number of operations to be carried out and the amount of data to be considered due to the commercial specification of the accounting method, are inherent to the accounting method itself, so they do not qualify as technical effects.

2. An electronic auction that is carried out by successively lowering the price until the price is set by the remote participant who first transmits a message. Because messages may be received out of order due to possible transmission delays, each message contains timestamp information. Changing the auction rules to avoid the need for timestamp information is equivalent to circumventing the technical problem of transmission delays instead of solving it with technical means.

3. A method for carrying out electronic financial transactions with credit cards at a point of sale, the administrative decision to dispense with the need to obtain the name or address of the buyer to authorize the transaction can result in savings of time and reduce data traffic. However, this measure in itself is not a technical solution to the technical problem of the bottleneck of the bandwidth of the communication lines and the limited capacity of the server computers, but rather an administrative measure that does not contribute to the technical nature of the claimed matter.

Conclusion: *These examples correspond to the simple automation of economic-commercial methods that lack technical contribution, so they would not be considered patentable.*

The mere fact that the input to an economic-commercial method is real-world data is not sufficient for the economic-commercial

method to contribute to the technical character of the claimed object, even if the data relates to physical parameters (for example, distances geographic locations between points of sale.

The mere possibility of fulfilling a technical purpose is not sufficient for a method to contribute to the technical character of the invention. For example, a claim for a "method of resource allocation in an industrial process" encompasses pure business processes and services in finance, administration or management, without limiting the method to any specific technical process due to the broad meaning of the term "industrial". The result of an economic-commercial method may be useful, practical or salable, but that does not qualify as a technical effect.

The characteristics of economic-commercial methods, for example administrative characteristics, can be found in different contexts.

Example of an administrative characteristic without technical effect, as context in the formulation of the technical problem: A medical support system can be configured to deliver information to the doctor based on data obtained from the patient's sensors and only if such data is not available, based on data provided by the patient. Prioritizing sensor data over patient-provided data is an administrative rule. Establishing this is the responsibility of an administrator, for example, the clinic director, rather than an engineer. As an administrative rule without technical effect, it does not contribute to the technical character of the claimed object, but can be used in the formulation of the objective technical problem as a constraint that must be met when evaluating the inventive step.

Another example of CII related to economic-commercial methods is example 12 of Section 2.2 of Annex IV.

7.7.3.7 Ways of presenting information.

The ways of presenting information within the meaning of Article 15, subsection f) of Decision 486 are understood as the transmission of information to a user. They can refer to both the cognitive content of the information presented and the form of presentation. It is not limited to visual information, but also

covers other presentation modalities, for example, audio or haptic information. However, it does not extend to the technical means used to generate such ways of presenting information.

Furthermore, the transmission of information to a user must be distinguished from technical representations of information directed to a technical system that will process, store or transmit that information. Characteristics of data coding schemes, data structures, and electronic communication protocols that represent functional data other than cognitive data are not considered ways of presenting information.

When evaluating exclusion from patentability under Article 15 of Decision 486, the claimed subject matter must be considered as a whole. In particular, a claim directed to the use of any technical means to present information could imply a technical nature and could be considered an invention. However, the mere possibility of using technical means is not enough to avoid exclusion. Once it is established that the claimed subject matter as a whole is not excluded from patentability under Article 15 of Decision 486, it is examined with respect to the other patentability requirements, in particular novelty and inventive step.

During the assessment of the inventive level, the characteristics related to the ways of presenting information are analyzed to determine whether, in the context of the invention, they contribute to producing a technical effect with a technical purpose. Otherwise, they make no technical contribution and cannot support the presence of inventive step. To determine whether a technical effect occurs, the examiner evaluates the context of the invention, the task being performed by the user, and the actual purpose pursued by the particular way of presenting information.

A feature that defines a way of presenting information produces a technical effect if it credibly helps the user perform a technical task through an assisted human-machine interaction process. Such a technical effect is considered credible if the assistance to the user in performing the technical task is objectively, reliably, and causally related to the feature. This

would not be the case if the supposed effect depended on the user's subjective interests or preferences.

Examples of ways to present information without technical contribution:

a) Some users find it easier to understand data when it is displayed as numerical values, while others may prefer a color-coded display. Therefore, the choice of one way or another of displaying the data is not considered to have a technical effect.
b) Some users find it easier to understand audio information transmitted as a musical scale rather than spoken words, it is an issue that only addresses the user's cognitive abilities.
c) Allowing the user to establish parameters that determine the information to be presented or to select the form of its presentation does not constitute a technical contribution if it simply adapts to the subjective preferences of the user.

It can be difficult to determine the extent to which a particular way of presenting information can be considered to credibly support the user in completing a technical task. It can be simplified during the assessment of the inventive step by comparing the invention with the state of the art, allowing the analysis to be limited to the characteristics that differentiate it. This comparison may reveal that potential support for the performance of the technical task is already achieved in the state of the art, with the consequence that the differentiating features do not provide any technical contribution, for example, if they refer only to the subjective non-technical preferences of the user.

7.7.3.7.1 Categories of information presented

It can be commonly considered that a characteristic related to the way of presenting information allows specifying:

a. the cognitive content of the information presented, that is, defining “what” is presented;
b. the way in which the information is presented, that is, defining “how” the information is presented.

It should be noted that these categories are not intended to be exhaustive. Additionally, there are cases where a feature falls

into both categories.

Example of a way to present information with both categories:
A “display a customer's last name in capital letters” step in a claimed method defines both the cognitive content of the information presented (a customer's last name) and the form of its presentation (in capital letters). Such a feature can be considered to consist of two features: the displayed text is a customer's last name (which belongs to the first category) and the displayed text is displayed in capital letters (which belongs to the second category). The form of presentation itself could convey additional cognitive information. For example, the capitalized part of a first name can, by convention, indicate which part is the surname.

What information is presented?
If the cognitive content of the information presented to the user relates to an internal state prevailing in a technical system and allows the user to correctly operate this technical system, it has a technical effect. An internal state prevailing in a technical system is a mode of operation, a technical condition or an event that is related to the internal functioning of the system, can change dynamically and is automatically detected. Its presentation usually urges the user to interact with the system, for example, to avoid technical failures.

Predetermined information about the technical properties or potential states of a machine, specifications of a device, or operating instructions do not qualify as an internal state prevailing in the device. If the predetermined way of presenting information only has the effect of helping the user with the non-technical tasks that precede the technical task, it does not make a technical contribution.

Example of effect without technical contribution:
The effect of not requiring the user to know or memorize a sequence of buttons to operate before setting up a device is not a technical effect.

Non-technical information, such as the state of a casino game, a business process, or an abstract simulation model, is intended

solely for the user for subjective evaluation or non-technical decision making. It is not directly linked to a technical task. Therefore, such information does not qualify as an internal state prevailing in a technical system.

How is the information presented?
A characteristic in this category usually specifies the form or arrangement in which information is transmitted to the user. An example is a diagram designed solely to convey information. Specific technical characteristics related, for example, to the way in which audio signals or images are generated are not considered a way in which information is presented.

The features that define a display of information in a particular diagram or design are not normally considered to make a technical contribution, even if the diagram or design conveys information in a way that a viewer may intuitively regard as particularly attractive, lucid, or logical.

For example, dealing with the limited space available on a screen is part of designing ways to present information for human viewing, so it is not a technical indication in and of itself. The general idea of providing an overview of a plurality of images in a limited display area by displaying a single image and sequentially replacing it with other images is not based on technical considerations, but is a matter of layout design.

On the other hand, if the way information is presented credibly helps the user perform a technical task through an assisted human-machine interaction process, it produces a technical effect.

Examples of ways to present information with technical effect:
a) Displaying multiple images side by side in low resolution and allowing the selection and display of an image in a higher resolution conveys information to the user in the form of a technical tool that allows the user to perform the technical task of searching and retrieving interactively stored images more efficiently. Storing digital images at different resolutions gives rise to the technical effect of allowing simultaneous general viewing of several images.

b) In a football video game, the particular way of conveying to the user the location of the nearest teammate by dynamically displaying a guide mark on the edge of the screen when the teammate is off-screen produces the technical effect of facilitate an assisted human-machine interaction by resolving conflicting technical requirements: displaying a magnified portion of an image and maintaining an overview of an area of interest that is larger than the viewing area.
c) In the context of a visual aid to a surgeon, if, in the course of surgery, the current orientation of a medical patella implant is displayed in a manner that credibly assists the surgeon in correcting the position of the implant. More precisely, this is considered to provide a technical effect.

7.7.3.7.2 Effects that depend on human physiology

When a way of presenting information produces an effect in the user's mind that does not depend on psychological or other subjective factors, but on physical parameters that are based on human physiology and can be precisely defined, that effect can be classified as a technical effect. The way information is presented makes a technical contribution to the extent that it contributes to this technical effect.

Examples of ways to present information with technical contribution to the effect based on human physiology:

a) Displaying a notification on a screen of a plurality of computer displays near the user's current focus of visual attention has the technical effect that it is more or less guaranteed to be viewed immediately (compared to, for example, an arbitrary location on one of the screens). In contrast, the decision to show only urgent notifications (compared to, for example, all notifications) is based solely on psychological factors and therefore does not provide any technical contribution. Minimizing information overload and distraction is not considered a technical effect per se.
b) Showing an image stream in which the parameters of delay and change in content between successive images are calculated based on the physical properties of human visual perception to achieve a smooth transition is considered a technical contribution.
c) If information (such as a visual or auditory stimulus) is

presented to a person for the purpose of producing in that person a physiological reaction (such as an involuntary gaze) that can be measured in the context of the evaluation of a medical condition (such as a visual, hearing, or brain damage), the way information is presented can be considered to produce a technical effect.

Another example of CII related to technical contribution to the effect based on human physiology is example 13 of Section 2.2 of Annex IV.

7.7.3.7.3 Effects that depend on the mental activities of the user

When the claimed subject matter includes the characteristic of presenting information to a user, whether from category a) or b), an evaluation by the user is involved. Although such evaluation is a mental act, the mere fact that mental activities are involved does not necessarily imply that the subject matter is non-technical.

Example of mental activity that integrates the solution to the technical problem:

In the side-by-side image example discussed above, the user makes an evaluation based on an overview of low-resolution images in order to objectively locate and recognize a desired image. This mental evaluation can be considered an intermediate step that directs the image search and retrieval process, making it an integral part of a solution to a technical problem. Such a solution is neither based on facilitating the human tasks of understanding, learning, reading or memorizing nor on influencing the user's decision about which image should be searched. Provides a mechanism for entering a selection that would not be possible if the images were not displayed in that specific layout.

On the other hand, if the choice or design of the information presented is aimed exclusively at the human mind, in particular to help the user make a non-technical decision, no technical contribution is made. For example, which product to buy according to a diagram showing the properties of the products or an advertising campaign (see example 14 of Section 2.2 of Annex IV).

7.7.3.7.4 User interfaces

User interfaces, particularly graphical user interfaces (GUIs), comprise features for presenting information and receiving information in response as part of the human-computer interaction. The features that define user input are more likely to be technical in nature than those that concern only the output and display of data, because input requires compatibility with a machine's default protocol, while output may be determined largely by the subjective preferences of a user. Features relating to the graphical design of a menu that are determined by aesthetic considerations, subjective user preferences, or administrative rules do not contribute to the technical character of a menu-based user interface.

Functions that specify a mechanism that allows user input, such as entering text, making a selection, or sending a command, are typically considered a technical contribution.

GUI example with technical contribution:

Providing in a GUI an alternative graphical shortcut that allows the user to directly set different processing conditions, such as starting a printing process and setting the number of copies to be printed by reciprocally dragging and moving a document icon over a printer icon, makes a technical contribution.

GUI example without technical contribution:

Supporting user input by providing information that only facilitates the user's mental decision-making process during this task (for example, helping the user decide what to enter) is not considered a technical contribution.

When the actual achievement of effects such as simplifying user actions or providing more convenient input functions for the user depends exclusively on the user's subjective abilities or preferences, such effects may not form the basis of an objective technical problem to be solved. (see example 15 of Section 2.2 of Annex IV).

Example of GUI effects that are not considered a technical problem:

A reduction in the number of interactions required to make the

same entry is not credibly achieved if it materializes only for some usage patterns that occur depending on the user's level of experience or subjective preferences.

Ways of presenting information, such as gestures or keystrokes, that simply reflect the user's subjective preferences, conventions or rules of the game and from which a physical ergonomic advantage cannot be objectively established, do not make a contribution technique. However, performance-oriented improvements to input detection, such as enabling faster or more accurate gesture recognition or reducing the processing load on the device when performing recognition, do make a technical contribution.

7.7.4 Specific considerations of CII according to Article 20 of Decision 486

After verifying that the claimed subject matter is considered an invention in light of Article 15, it must be analyzed whether the invention falls within the exceptions to patentability according to Article 20 of Decision 486.

Consequently, for an application to be objected as an exception to patentability, the invention to be protected must fall under any of the literals (a – d) of Article 20. When this happens, the claims that cover inventions excepted from patentability are not examined for any of the other requirements necessary to grant the patent.

7.7.4.1 CII of therapeutic, surgical and diagnostic methods

The CII may fall under literal d) of Article 20 of Decision 486, which refer to therapeutic or surgical methods for human or animal treatment, as well as diagnostic methods applied to humans or animals are exempt from patentability.

To carry out the analysis of this type of applications, it is important to analyze the invention as a whole and even take as reference the information contained in the description of the application, since it allows the real scope of the invention to be defined.

Example – method of electrical and magnetic tissue stimulation by spatial scanning:
Therapeutic method focused on humans where, through electromagnetic stimulation of tissues, the aim is to influence the body with electromagnetic fields. Electromagnetic fields can induce cellular regeneration and/or degeneration, allow the rehabilitation of damaged or paralyzed muscle groups, or facilitate the treatment of central nervous system dysfunction (fibromyalgia, chronic pain, attention deficit, bipolarity, chronic fatigue, sleep, depression, anxiety among others).
The steps of the claimed method focus on treating tissues in a patient for stimulation purposes, where electromagnetic transducers are adjusted and positioned in a volume containing a tissue, such as the arm, abdomen or knee, in order to activate these transducers via electrical signals and stimulate the tissue.

In this case, the claimed methodology corresponds to a therapeutic method and therefore, it is an invention excluded from patentability according to Article 20, literal d), taking into account that it includes a stage of adjustment and positioning of transducers on the tissue of a patient to perform stimulation or treatment of a person.

Example – method for positioning a drilling element and performing said drilling:
Surgical method that seeks, through artificial vision, to determine where in a patient's body it is most convenient to perform a perforation with a surgical drill bit. Once the location of the perforation is determined, the incision is made.

The method includes the stages of capturing information from the patient's body through a camera system, subsequently, with the images received, a map of the possible places where the incision can be made is created, then the perforation site is determined taking into account the parameters/data obtained from the patient and finally, the incision is made using a common surgical drill.

In this case, although most of the stages of the method refer to determining a perforation site in surgery from the images obtained from a patient, the stage that indicates the objection

by this article is that of using the result of the algorithm to make the incision using a common surgical drill. Taking into account the above, the claimed method corresponds to a surgical method applied to the human body regardless of the purpose for which it is designed.

Example – methods for active detection of prostate cancer:
Method to predict whether a patient suffers from prostate cancer through the evaluation of multiple parameters obtained directly from the patient.

The mentioned method comprises the steps of connecting the subject to a system that obtains blood samples and identifies different parameters associated with the characteristics of the blood, comparing the identified parameters with values obtained from patients who previously suffered from prostate cancer that are stored in a database, establishing a probability function of a prostate cancer event based on the comparison made and finally verify if said probability function exceeds a previously defined threshold to diagnose the existence or not of the disease.

This case is included in the exclusion of Article 20, literal d) because it corresponds to the diagnosis of a patient's condition while the patient is connected to a system or device. In this method, the stages that cause said objection are those that correspond to the connection of the patient to the system or device and the stage of diagnosing the disease from the information obtained from the blood obtained while the patient remains connected to the system.

An example of CII related to clinical diagnosis through the presentation of information is included in example 13 of Section 2.2 of Annex IV.

7.7.5 Hybrid cases with chemistry and biotechnology
Hybrid files are usually particular cases where the essential characteristics claimed in the claims refer to a particular technical field, but require the use of elements or knowledge from another technical field, without this causing the invention to deviate from its objective or posed problem.

In these cases, it is recommended to carry out the substantive examination jointly between examiners from the different technical fields related to the matter to be protected.

Example – improved compositions and methods for prediction related to the presence of prostate cancer:
The invention seeks to develop methods for the identification of prostate cancer and methods for evaluating the need for invasive biopsies of prostate tissue.

The proposed methods claim the steps of subjecting a blood plasma sample from the subject to an immunoassay that measures a level of total prostate specific antigen (tPSA). The measured level is compared to a threshold to determine the probability that the prostate tissue biopsy exhibits detectable prostate cancer, where said determination is made based on the tPSA level and other parameters. Additionally, in other embodiments of the invention the use of a computer and its corresponding method is claimed to determine the probability of an event associated with prostate cancer, in this case the steps of entering the information of the measured levels of the sample through an input interface and on said information applying an algorithm that uses a logistic regression model to determine the probability of an event associated with prostate cancer and finally, said result is displayed through an output interface.

In this case, it is evident that the main object of the invention is to determine the probability of an event related to prostate cancer from a series of measurements of levels of antigens and other substances that are considered relevant, so said invention belongs to the field of chemical sciences. However, since in some modality's devices such as computers and methods implemented by said computers are claimed to perform probability calculations from the application of different algorithms, it is necessary to have an examiner from the field of electronics to study said modalities together and thus perform a correct analysis of the claimed invention.

Example – biosensor system for the detection of Ochratoxin A (OTA) in coffee for domestic consumption:
The invention proposes a device for the detection of Ochratoxin A

(OTA) in coffee or other foods using biological and chemical techniques.

The invention claims a system that contains different elements such as processors, electrodes, communications modules, input and output devices, among other typical elements of electronic systems. Particularly, the detection part occurs through an arrangement of electrodes that allow the fixation of the peroxidase enzyme from Ipomoea batatas. Once detection occurs, it is possible to determine the presence of the substance of interest.

In this case, it is clear that the main object of the invention is to determine the probability of an event related to prostate cancer from a series of measurements of levels of antigens and other substances that are considered relevant, so that said invention belongs to the field of chemical sciences. However, since in some modalities devices such as computers and methods implemented by said computers are claimed to perform probability calculations from the application of different algorithms, it is necessary to have an examiner from the field of electronics to study said modalities together and thus perform a correct analysis of the claimed invention.

Some other examples of hybrid cases are included in examples 5 and 8 of Section 2.2 of Annex IV.

7.7.6 Drafting of the CII

7.7.6.1 Recommendations for writing the CII description

As mentioned in the definition of CII, the claims of this type of invention involve computers, computer networks or other programmable devices, whereby at least one characteristic is realized by a program.

In the particular case of CIIs, lists or program portions written in programming languages cannot be described as the only disclosure of the invention. As in other technical fields, the description must be written substantially in plain language, possibly accompanied by flowcharts or other elements that facilitate the understanding of the invention so that it can be

understood by an expert in the field who is not considered a specialist in any specific programming language, but who has general programming skills. Brief excerpts from programs written in commonly used programming languages may be accepted if they serve to illustrate an embodiment of the invention.

Other points to consider when writing the description of the CII are listed below:

- Include physical elements such as a computer, processors, servers, etc., or other physical element and the function they perform, in the description so that it can be a weighting factor to consider that an invention is not abstract.
- Clearly define in the description the technical problem being solved, trying to separate it from merely administrative, financial, commercial and mathematical issues.
- Include in the description how the proposed solution is technically reached.
- Clearly describe in the application how the technical effect is achieved.
- Clearly indicate in the application the technical contribution of the invention.

7.7.6.2 Models for drafting CII claims

Claims directed to CII must define all characteristics that are essential to the technical effect of the process that the computer program must carry out when it is executed. One objection that may arise is when the claims contain listings or portions of the computer program. As mentioned in the previous point, brief excerpts from the programs can be accepted in the description.

These types of claims are known as declarative claims, in which they follow the fate of the procedure to which they are linked. Below, some cases regarding the claims of the CII are analyzed.

7.7.6.2.1 Cases in which all steps of the method can be fully implemented by generic data processing means

A common case of CII is where all steps of the method can be carried out entirely by computer program instructions executing on media that, in the context of the invention, provide generic data processing functions.

Example of generic data processing means:

a) Personal computer
b) Server
c) Smartphone
d) Smart tablets
e) Programmable microprocessors
f) Display devices or screens with processing means
g) Printing devices with processing media
h) Sensors and devices with processing means

In CIIs, different claim models are possible, but the set of claims typically begins with a method claim. Other claims may be included in other categories with the object corresponding to that of the method to obtain complete protection of the invention.

Method claim model 1 (claim 1)

1. A computer-implemented method comprising steps A, B
2. A method carried out by a computer that includes steps A, B, ...

Apparatus/device/system claim model 2 (claim 2)

1. A data processing apparatus/device/system comprising means for carrying out [the steps of the] method of claim 1.
2. A data processing apparatus/device/system comprising means for performing step A, means for performing step B,...
3. A data processing apparatus/device/system comprising a processor adapted/configured to perform [the steps of] the method of claim 1.

In wording model 2, the characteristics of the device of the means plus function type (“means for ...”) are interpreted as means adapted to carry out the respective stages/functions, rather than merely means suitable to carry them out. There is no particular wording preference between “comprising means for”, “adapted to”, “configured for” or equivalents. In this way, novelty is conferred on an unprogrammed data processing apparatus or a data processing apparatus programmed to perform a different function.

Machine and operating procedure model 3

1. A machine that, among other elements, includes a computer program that integrates and interacts with parts of the machine, performing certain actions or functions.
2. A procedure that describes the operation (or the manufacturing process) of the machine, in whose steps there are actions carried out by a program, detailing in the actions the interaction between the program and the elements of the machine.

When evaluating the novelty and inventive step of a set of claims as defined above, one should begin with the method claim. If the subject matter of the method claim is considered novel and inventive, the subject matter of the other claims in a set formulated according to the previous models will normally be new and inventive as well, provided that they include the characteristics corresponding to all those that ensure patentability of the method.

However, when the invention is made in a distributed computing environment or involves interrelated products, it may be necessary to refer to the specific characteristics of the different entities and define how they interact to ensure the presence of all essential characteristics, rather than making a mere reference to another claim as in drafting model 2. In such cases, other independent claims for interrelated products and their corresponding methods may also be permitted.

If user interaction is required, an objection under Article 30 of Decision 486 may arise if it is not possible to determine from the claim what steps the user performs.

A claim for a computer-implemented data structure may be admissible, not only if it is drafted according to models 1 and 2, but may be defined by its own technical characteristics, for example, by a well-defined structure, possibly with references to the corresponding method or system in which it is used. However, a computer-implemented data structure does not necessarily include characteristics of the process by which it is generated. It is also not necessarily restricted by a method in which it is used. Therefore, a claim for a computer-implemented data structure generally cannot be defined simply by reference to a

method or as a result of a process.

7.7.6.2.2 Cases in which one or more steps of the method define additional devices and/or specific means of data processing

Where a method claim includes steps defined as performed by devices other than generic data processing means, a device claim and/or corresponding computer program may need more than a mere reference to the method claim as in the wording of the previous point. Furthermore, if not all features of the method claim are reflected in claims in other categories that relate to the method, such other category claims must be interpreted and examined separately with respect to novelty and inventive step.

Particularly in applied fields such as medical devices, measurement devices, optics, electromechanics or industrial production processes, method claims frequently involve steps of manipulation or interaction with technical physical entities through the use of computer control. These procedure steps may not always be fully performed by the computer and the procedure claim may recite specific technical means for carrying out some of the steps.

In these cases, an objection under Article 30 of Decision 486 may arise if the claims do not define which steps are carried out by the data processor or by the additional devices involved, as well as their interactions. The same applies if specific data processing means are required (for example, a particular parallel computer architecture) as opposed to generic data processing means.

Example 1 of drafting CII with specific means of data processing:

1. A method for determining blood oxygen saturation on a pulse oximeter, comprising:
- receiving first and second electromagnetic radiation signals from a portion of tissue perfused with blood corresponding to two different wavelengths of light in an electromagnetic detector;
- normalizing said electromagnetic signals according to steps A, B and C to provide standardized electromagnetic signals;
- determining the oxygen saturation based on said normalized electromagnetic signals according to steps D and E.

2. A pulse oximeter having an electromagnetic detector and means adapted to execute the steps of the method of claim 1.

Remarks: *In this example, the method claim comprises a step that is defined as executed by specific technical means (the electromagnetic detector in a pulse oximeter).*

On the other hand, if the method claim defines the subsequent processing, by generic computational means, of data received from specific technical means, such as sensors, it is not necessary that the device claim (for example, a computer) referring to the method includes those specific technical means. In this case, the specific technical means listed in the method are not necessary to carry out the steps of the method and the writing models presented above may be appropriate.

Example 2 of writing CII with specific means of data processing:
1. A computer-implemented method for determining blood oxygen saturation, comprising:
- receiving data representing first and second electromagnetic radiation signals acquired by an electromagnetic detector from a portion of tissue perfused with blood corresponding to two different wavelengths of light;
- normalizing the data representing said electromagnetic signals according to steps A, B and C to provide normalized data;
- determining the oxygen saturation based on said normalized data according to steps D and E.

2. A data processing apparatus comprising means for carrying out the method of claim 1.

Remarks: *In this example, the invention is based on additional processing of acquired data to determine blood oxygen saturation. The data may be received, for example, from a data file that stores data previously acquired by the electromagnetic detector. Therefore, such a method can be carried out by generic data processing means, for example, in the form of a desktop computer. The claim does not specify that the electromagnetic detector is a necessary feature to receive the input data. Therefore, the device claim defined by reference to the method claim also need not include the pulse oximeter or an electromagnetic detector.*

Finally, as with any essential feature, if specific technical means are essential to the definition of the invention, they must be present in all independent claims.

7.7.6.2.3 Cases in which the invention is carried out in a distributed computing environment

Another common type of CII is performed in a distributed computing environment.

Examples of CII in a distributed computing environment:

a) A networked client (for example, a smartphone) and a server system, which accesses the storage or processing resources of a cloud computer,
b) devices in a peer-to-peer network that perform file sharing,
c) an augmented reality environment with displays mounted on the user's head,
d) autonomous vehicles that interact on an ad hoc network,
e) the maintenance of a distributed ledger using blockchain technology.

For such distributed environment CIIs, the set of claims may comprise claims directed to each entity of the distributed system and/or to the overall system and corresponding methods. However, each independent claim must meet the patentability requirements, in particular the novelty, inventive step and clarity requirements. For example, if the invention lies in the implementation of a computing cloud using virtual machines that allow adaptation to changes in the workload by automatically assigning resources, a client device that accesses cloud resources can be already known in the state of the art. The set of claims must also meet the unity of invention requirements.

It may be necessary to refer to the specific characteristics of different entities and define how they interact to ensure the presence of all essential characteristics. When referring to the interaction between the different entities, special care must be taken that the claim is clear. In some situations, it may be necessary to limit the claim to the combination of the entities. If the distribution of the steps of a method among the entities involved is essential to the invention, it will be necessary to define which step of the method is carried out by which entity to

comply with the requirements of Article 30 of Decision 486. Otherwise, this can be left undefined in generic CII claims.

Example of writing CII in a distributed computing environment:

1. A transmitting device comprising means for encoding data by performing steps A and B and means for transmitting the encoded data to a receiving device.
2. A receiving device comprising means for receiving encoded data from a transmitting device and means for decoding the data by performing steps C and D.
3. A system comprising a transmitting device according to claim 1 and a receiving device according to claim 2.

Observations: The problem addressed by the invention is the transmission of data over a network. The transmitting device encodes the data using an algorithm comprising steps A and B and the receiving device performs the complementary function of decoding the data using an algorithm comprising steps C and D. Novelty and inventive step must be evaluated for each independent claim individually. For example, if encoding according to steps A and B allows encoding to a known encoding format in a more efficient manner and decoding according to steps C and D is conventional, it may be that only claims 1 and 3 be new and inventive.

Other points to consider when drafting CII claims are listed below:

- In the claims, it is recommended to include said physical elements linked to the different steps or functions; however, this is limited by the scope of the description.
- Do not write claims pursuing a computer program as such, it is advisable to write method or system claims instead.
- Include in the claims clearly the technical solution to the problem raised, clearly indicating it in the preamble.
- Use different models for writing claims.

7.8 The Kit of Parts

A product in the form of a kit of parts has the ability to be produced or used in any type of industry, which is why it is susceptible to industrial application. However, it is important to clearly distinguish the particularities of the kit of parts compared to other inventions.

The kit of parts is a type of combination inventions in which elements are brought together that, whether known or not individually from independent preparations, when combined or working in an interrelated manner can become or become a new technical solution to a technical problem. (See Section 11.10.4 of Chapter III, on cases of non-obvious combination)

The kit of parts is made up of separate elements or elements that come from individual, physically separate preparations, where such elements form a functional unit (true combination) directed to a final purpose or technical effect. Said functional unit presents a synergy or interaction between the elements that is necessary for the final purpose or technical effect.

The examiner will take into account that the mere association of elements or their simple aggregation does not necessarily make it a functional unit. For example, a kit of dismantling tools of different sizes is not considered a kit of parts susceptible to patentability examination since when using them there is no necessary work interaction between them, regardless of the fact that the user may need to use several disassemblers to carry out an objective such as assembling a piece of furniture.

The elements of the kit of parts are used together, simultaneously, in sequence or intervals, to achieve the final purpose or technical effect. For example, a test kit containing different reagents to be used in a certain sequence to test a sample.

In a kit of parts of pharmaceutical elements, the indication in the description of the purpose of their combined therapeutic function can establish the functional unity of the elements of the product, when it is described that the mixture or physical contact between its elements represents a genuine restriction to

the purpose. final or technical effect. (see Section 7.8.1 of Chapter III, on subject matter excluded from patentability in Kit of Parts and Section 7.2 of the same chapter on subject matter that will not be considered an invention).

Likewise, in the field of chemistry, you can find kit of parts for the realization and obtaining of different effects, including pesticide effects, fertilizers, cosmetics, among others. Such is the case of a nail polish kit that includes two or three units with different formulations, where one acts as a base, another as a glaze, and another as a gloss, and together they dry in minutes.

On the other hand, in the technical field of engineering, it is specified that when a kit is claimed, characterized as a set of elements related to each other and aimed at solving a specific technical problem, said "kit" may be understood as a system, a device or a piece of equipment, considering that a system is defined as an ordered set of equipment/appliances/devices related to each other that produce a technical effect; a device, as an organized set of parts that fulfills a specific function; and equipment, such as a collection of utensils, instruments and special devices to fulfill a specific purpose, so, kit-of-parts type inventions, in the field of engineering, may find their equivalent with the aforementioned products.

Examples of kit-of-parts:

a) a lock and its key
b) a match and a friction surface
c) a toy construction set
d) the components of an adhesive that carry out their function only until said components come into contact with each other

In accordance with the above, kit of parts can be patented, as long as they meet the requirements demanded by Decision 486.

7.8.1 Subject matter excluded from patentability in kit-of-parts

In the case of kit-of-parts, when studying the invention, the examiner must pay special attention to determine whether the invention is described based on non-patentable subject matter.

The pharmaceutical kit-of-parts may not be defined or characterized solely in terms of the form, clinical use, metabolism of the combined drugs, or the pharmacokinetic or pharmacodynamic parameters of the combined compounds. In this case, the examiner may raise an objection due to lack of clarity of the claimed combination.

The claimed pharmaceutical kit-of-parts may not include instructions for use or preparation or the method of administration or intake of each of the preparations. If this is the case, the examiner must advance the study due to lack of clarity by requesting that the reference to the therapeutic method and the administration of the preparations be removed from the claims.

Having considered that the application does not deal with a treatment method or subject matter excepted from patentability, the examiner must carry out the substantive study related to compliance with the three requirements: novelty, inventive level and industrial application, clarifying that, in relation to the combination or mixture of known elements, a conclusion cannot be reached a priori, since lack of novelty, inventive level and industrial application cannot be instantly determined.

The following is an example of kit-of-parts eligible for patentability study, in the pharmaceutical and biotechnology field:

Structure of claims accepted as kit-of-parts				
To what a composition **A** containing	a compound, a protein, a peptide, an antibody, cells modified, or a microorganism	and	To what a composition **B** containing	a compound, a protein, a peptide, an antibody, modified cells, a microorganism, or a set of excipients that allow the reconstitution or condition the composition of A (to be administered)

7.8.2 Examples of kit-of-parts

Examples related to kit-of-parts are found in Section 2.5 of Annex IV.

If the kit-of-parts is characterized in terms of the method of ingestion or administration, its clinical use, the metabolism of the combined drugs, the pharmacokinetic parameters of the compounds, its method of application, the preparation instructions, its method of use or the purpose of its application (to control acne, to control dandruff, etc.); In such cases an objection will be raised due to lack of clarity.

7.8.3 Support of claims for kit-of-parts

As for any other kit-of-parts, the examiner must identify that the subject matter contained in the claims of a pharmaceutical kit-of-parts is supported by the description. Here are some important considerations for evaluating sustenance:

(a) If the claim refers to kit-of-parts, but the description discloses a treatment method, a diagnostic method performed on the human or animal body or the combined administration of compounds concomitantly, simultaneously or sequentially and not the compounds from the kit; In this case, it will be considered that the application deals with non-patentable subject matter (Article 20, literal d) of Decision 486).

(b) Whether the original description and claim dealt with a method of treatment, a method of diagnosis performed on the human or animal body, or the combined administration of compounds concomitantly, simultaneously or sequentially; and the claim was objected due to an exception to patentability (Article 20, literal d) of Decision 486); after which the applicant modified a kit type claim, such modification will not be accepted because it will be considered an extension of subject matter.

(c) If the preamble of the claim is a kit-of-parts, but the characteristic part refers only to the manner of presenting information, such claim will not be considered eligible for study in accordance with the practice of each office.

(d) When the kit-of-parts includes in its characteristic part the elements that make it up and its instructions for use, the claim will be objected in accordance with the practice of each office, suggesting that the instructions for use be withdrawn.

8. SEARCH AND REQUEST FOR INFORMATION

8.1 Definitions

8.1.1 Search definition

The patent search is the action carried out by the substantive examiner, using pre-established strategies in internal or external collections of documents or databases available at their disposal, whose contents are systematically accessible, in order to find documents that are related to the object. that you want to protect. Primarily, the documents consist of patent documents from various countries, supplemented by a series of journal articles and other non-patent literature. Among the collections you can find patent documentary collections, patent office databases on the Internet or collections on external storage media, specialized journals, scientific and bibliographic publications in general.

The purpose of the search is to establish the closest "state of the art" in the particular field of the patent application under examination, taking into account the filing or priority date validly invoked, in order to determine, based on this, whether the invention meets the requirements of novelty and inventive step.
The invention complies with the requirements of novelty and inventive step. However, it should be borne in mind that, in the search for prior art, it cannot always be 100% complete, due to factors such as the inevitable imperfections of any information retrieval system. The search is carried out in such a way as to minimize the possibility of not discovering prior art of great relevance to the invention under examination.

8.1.2 Definition of the state of the art

"**Article 16.** - An invention shall be considered new when it is not included in the state of the art.

The state of the art comprises everything that has been made available to the public by written or oral description, by use or marketing or by any other means prior to the filing date of the patent application or, where appropriate, the recognized priority date.
Solely for the purpose of determining novelty, the contents of the

patent application pending before the competent national office and having a filing or priority date earlier than the priority date of the patent application under examination shall likewise be considered part of the state of the art provided that the said contents are included in the earlier-dated application where it is published, or where the period provided for in Article 40 has elapsed."

In general terms, the state of the art includes all information that, as of the filing or priority date (relevant date), has been accessible to the public by any means. Disclosure implies the possibility for the public to be informed, by any means and in any place, of the content of a disclosure even if the public has not actually become aware of said content.

By public means all those persons or group of persons who are not obliged to maintain the confidentiality of the information in the field of the invention that is being examined.

It should be noted that there is no restriction as to the geographical location in which the relevant information has been made available to the public, nor as to the language in which such accessibility has taken place or the manner in which it has been made available; Likewise, the documents containing this information are not subject to any age limit. Documents issued electronically are considered published, provided they are retrievable.

8.1.3 International Patent Classification (IPC)

The International Patent Classification (IPC), established by the Strasbourg Agreement of 1971, constitutes a hierarchical system of symbols that do not depend on any language. It is useful for classifying patents and utility models according to the different sectors of technology to which they belong. A new version of the IPC comes into force on January 1 of each year.

The IPC identifies all the characteristics relevant to the technical subject matter of the claimed invention (or of the objects of each of the claimed inventions, if there is more than one) in the most precise and complete manner that the IPC outline allows.

The IPC divides the fields of technology into eight sections (A to H) with some 75,000 subdivisions, each represented by a language-independent symbol composed of Latin characters and Arabic numerals. Furthermore, the IPC consists of several hierarchical levels. The level of the subgroup is indicated by a series of points: a higher number of points represents a lower level of the subgroup. The IPC can be used to search nearly 110 million patent documents worldwide.

8.1.3.1 IPC Green Inventory

There is an inventory of IPC classifications that are related to essential green technologies identified by the Secretariat of the United Nations Framework Convention on Climate Change (UNFCCC). This IPC Green Inventory was created by WIPO Member States to leverage the IPC classification scheme to facilitate the retrieval of patent information on green technologies. Through the WIPO search portal, the IPC Green Inventory allows direct access to patent documents, as well as statistics, graphs and diagrams that describe the state of the art of green technologies around the world, including technologies such as alternative energy production, energy conservation, transportation, waste management, as well as agriculture and forestry.

The IPC Green Inventory is currently available in English and French and can be accessed online.

8.2 Reporting requirements

"**Article 46.-** The competent national office may solicit reports from experts or from scientific technological bodies considered suitable, so as to have their opinion on the patentability of the invention. It may likewise, if it sees fit, solicit reports from other industrial property offices.

Where necessary for the purposes of the patentability examination the applicant shall, at the request of the competent national office, submit, within a period not exceeding three months, one or more of the following documents relating to one or more filed foreign applications relating wholly or partly to the same invention as that being examined:
(a) a copy of the foreign application;
(b) a copy of the findings of novelty or patentability

examinations carried out in relation to that foreign application;

(c) a copy of the patent or other protection title that has been granted on the basis of that foreign application;

(d) a copy of any judgment or decision by which the foreign application has been rejected or denied; or

(e) a copy of any judgment or decision by which the patent or other protection title granted on the foreign application has been cancelled or invalidated.

The competent national office may recognize the results of examinations referred to under subparagraph (b) above as being sufficient to prove compliance with the conditions governing patentability of the invention. Where the applicant fails to submit the documents requested within the period specified in this Article, the competent national office shall refuse the patent."

"**Article 47.-** At the request of the applicant, the competent national office may suspend the processing of the patent application where any document that should be filed under subparagraphs (b) and (c) of Article 46 has yet to be received or is pending for a foreign authority."

Article 46 also establishes that the competent national office may recognize the results of the examinations referred to in paragraph b) as sufficient to prove compliance with the patentability conditions of the invention; with which it can be understood:

- in the event that the result of an examination is recognized in accordance with literal b), it is understood as an essential condition that the claims on which this analysis was carried out are identical to the claims of the application that is being examined and that These are not covered by the exclusions and exceptions of Decision 486;
- that the office has the power to issue a technical report establishing an opinion different from that of the examination referred to in point b); or
- that the presentation of the documents mentioned in points c), d) and e) is not sufficient to prove or not compliance with the patentability requirements and to grant or deny the patent directly and immediately without the need to issue a report

technical about it.

8.3 Document recovery

It is the action that the examiner must take to have at his disposal the necessary documents to carry out the substantive examination.

The documents selected as the closest background information for the application being examined, depending on where they have been located (Internet databases or external storage media), may be recovered, to later be printed or saved in electronic format, according to what is best for the examiner.

When the complete document has been identified on the Internet or on external storage media, it must be verified whether it is in an accessible language. For example, if the document is in a language understandable to the examiner, an attempt should be made to locate it in patent families in order to be able to obtain it in a more commonly used language. Otherwise, if it is certain that said document is not available in a language understandable to the examiner, the need to translate it would have to be evaluated using the means available to each of the offices.

It must also be verified if the complete identified document is available in Spanish.

To recover the information contained in the different patent collections and found online, the examiner may resort to the following options:

1. **Patent Number:** this is used when you know the number of the patents and you want to delve deeper into the technical information contained therein.

2. **By the title:**
   - using a keyword; and
   - using two or more keywords.

   These words can be entered in Spanish, English, German, French or any other language, depending on the database used.

3. **Name of the author:** it can be the name of the inventor or applicant, it can be combined with keywords from the title.
4. **Classification:**
   - International Patent Classification (IPC); I
   - Cooperative Patent Classification (CCP);

The ranking can be combined with title keywords.

Depending on the database used, a list of requests that in one way or another deal with the searched topic is obtained. The list may include, depending on the database used:

- application number;
- publication date;
- title of the invention;
- summary;
- bibliographic data; and
- drawings.

Within this list, the most relevant documents are selected, keeping in mind the date of publication, and the full text is consulted.

Depending on the databases to which the examiner has access, they may also perform full-text searches, searches for chemical compounds, sequences, among others.

8.4 Document selection

The selection of the relevant documents to be considered for the development of the substantive examination is carried out from the different databases offered for this purpose. It is recommended that they be databases of the different patent offices in the world. Private services that provide technical information will also be taken into account.

8.5 Category of documents

The documents cited in the search report must be classified according to their relevance and importance in the substantive examination. A category is attributed to the cited documents in the form of an alphabetical character. A category must always be indicated for each cited document. If necessary, combinations of different categories are possible. Opinions on patentability are

also implicitly expressed in the search report by assigning document categories.

8.5.1 Particularly relevant documents

When a document cited in the search report is particularly relevant, it will be indicated by the letter's "X" or "Y".

Category "X" will be applicable to any document that, by itself, opposes a claimed invention being considered new, or to any document that opposes a claimed invention being considered to involve an inventive step when studied at a later date. the light of common general knowledge.

Category "Y" will be applicable to any document that prevents a claimed invention from being considered to involve an inventive step when it is associated with one or more other documents of the same category and that association is evident to the person skilled in the art.

8.5.2 Documents of the state of the art that do not impair novelty or inventive level

When a document cited in the search report represents the state of the art without prejudice to the novelty or inventive level of the claimed invention, it will be indicated by the letter "A".

8.5.3 Documents referring to an unwritten disclosure

If a document cited in the search report refers to an unwritten disclosure, the letter "O" is noted. As an example of this type of disclosure, conference proceedings can be cited. The "O" category document will always be accompanied by another letter that indicates the relevance of the document in accordance with Sections 8.5.1 and 8.5.2, for example, "O, X", "O, Y" or "O, A".

8.5.4 Intermediate documents

Documents published on dates between the filing date of the examined application and the claimed priority date, or the earliest priority if there is more than one, will be designated with the letter "P". The letter "P" will also be attributed to a document published on the same day as the earliest priority date of the examined patent application. The "P" category document will always be accompanied by another letter indicating the relevance of the document in accordance with Sections 8.5.1 and

8.5.2, for example, “P, X”, “P, Y” or “P, A”.

A “P” document has a publication date that falls between the priority date and the filing date of the application. If a document is found that corresponds to this category, the foreign application must be verified to check if the priority is valid, since if it is not, the document found will be relevant to the determination of novelty or inventive level.

8.5.5 Documents relating to the theory that constitutes the basis of the invention

When the publication date of any of the documents cited in the search report is later than the filing or priority date of the application and does not conflict with said application, but may be useful for a better understanding of the principle or theory on which the invention is based, or to demonstrate that the reasoning or facts on which said invention is based are incorrect, will be indicated by the letter “T”.

8.5.6 Potentially conflicting patent documents

Any patent document with a filing or priority date prior to the filing date of the searched application, but published on or after the filing date and whose content forms part of the prior art relevant to the search. determination of novelty, it will be indicated with the letter “E”. An exception is made for patent documents based on the priority in question. The code “E” may be accompanied by one of the categories “X”, “Y” or “A”, which indicates the relevance of the document in accordance with Sections 8.5.1 and 8.5.2.

A document corresponds to an “E” patent document when it has a date prior to the filing of the application being examined, but was published later. These documents are only valid to object to the novelty of the application being examined.

8.5.7 Documents cited in the application

If the search report cites documents already mentioned in the description of the application for which the search is being carried out, those documents must be identified with the letter “D”. Document category “D” must always be accompanied by some symbol indicating the relevance of the document in accordance

with Sections 8.5.1 and 8.5.2, for example "D, X", "D, Y" or "D, A".

8.5.8 Documents cited for other reasons

If a document is cited in the search report for reasons other than those mentioned in the preceding paragraphs (in particular as evidence), for example:

a. a document that may raise doubts about a priority claim under the Paris Convention; or

b. a document cited to determine the publication date of another citation; This document will be marked with the letter "L", with a mention that briefly explains the reasons for the appointment. With respect to documents of this type, it is not necessary to specify their relevance in relation to any given claim. However, when the evidence they provide concerns only certain claims (for example, document "L" cited in the search report may invalidate the priority with respect to certain claims, but not others), the citation of the document must refer to those claims.

8.5.9 Non-harmful disclosures and grace year

It refers to cases in which the invention has been disclosed during a year prior to the date of filing, or of claimed priority, so such information is not considered to be part of the state of the art in accordance with Article 17 of the Decision. 486.

"Article 17.- For the purposes of determining patentability, no account shall be taken of any disclosure that occurs during the year prior to the filing date of the application in the member country, or during the year before the priority date if priority has been claimed, provided that such disclosure is attributable to:

(a) the inventor or his successor in title;

(b) the competent national office which, in violation of the provisions applicable, publishes the contents of the patent application filed by the inventor or his successor in title; or

(c) a third party who has obtained the information directly or indirectly from the inventor of his successor in title."

In accordance with this article, any disclosure made, during the year prior to the filing or the priority date, by the inventor, his assignee or a third party who has obtained the information from the inventor or the assignee, including articles, books, marketing, exhibitions, etc., as well as accidental publications made by patent offices in violation of current regulations, may not be cited as state of the art.

Within this context, all publications of patents of the inventor or his successor in title made by a patent office in accordance with its regulations during the year prior to publication are not considered accidental publications and therefore, they will be part of the state of the art. submission or priority date.

In some cases, documents evidencing such prior disclosure may be cited in the search report using the appropriate category listed, if available.

8.6 Search report for other offices

Search reports from other offices may be used, such as:

- reports from the other offices of the Andean Community;
- search report from other foreign patent offices;
- supplementary search report (for applications submitted via PCT); and
- international search report issued by International Search Authorities.

Said search must be complemented with information from national patent databases, taking into account that their information is not always contained in the indicated databases. On the other hand, many of the applications that are abandoned without publication by the same applicant in their country of origin or other countries are later presented in the Andean area. In the case of applications that were not abandoned, they can constitute a precedent for applications submitted in our countries later.

8.7 Non-Patent Literature (NPL)

8.7.1 Search for the NPL

The examiner will first carry out a search of the patent literature. In certain technical fields, a search must be carried

out in collections of literature other than patent literature, that is, in non-patent literature NPL. However, regardless of the subject of the search, if a minimal, or even zero, number of relevant prior patents have been found, the examiner should consider expanding the resources searched to include databases containing the NPL.

8.7.2 Access to the NPL

In some cases, it is possible to obtain NPL documentation from sources such as the Internet, in some cases it will only be possible to obtain the summary. The high cost of subscriptions to journals implies the use of alternatives, such as the exchange of information with research centers that have collections of this type or the use of the WIPO document search and document sending service, among others. With the support of the Internet, there is access to databases of NPL abstracts. For example, citing a summary, the applicant can be asked for the complete document. When the summary is relevant, a translation of the document will also be requested, in case the document is in a language not understandable by the examiner.

8.7.3 NPL databases

Scientists and university researchers are generally familiar with two of the largest commercial databases of scientific literature, Clarivate Analytics' Web of Science/Web of Knowledge or Elsevier's Scopus. Open access databases such as Medline, PubMed and Crossref (containing metadata for more than 96 million publications) are increasingly popular and are linked to initiatives such as core.ac.uk that make public the full texts of more than 113 million publications. Databases such as Google Scholar are a popular open access source of information on NPL documents and access to copies of texts, while social networking sites for researchers such as Research Gate provide a means for academics to share their research and Create shared projects. An important feature of recent developments in scientific publishing is a shift in emphasis towards open access publishing by researchers and funding agencies. This is reflected in services such as core.ac.uk mentioned above and in services such as Unpaywall, which provides a browser plugin to identify open access versions of articles. Currently, Unpaywall contains links to more than 19 million scientific publications. An important

aspect of this shift in emphasis toward open access is integration between services. Therefore, Unpaywall relies on and resolves article IDs to Crossref content, while the commercial Web of Science database provides links to Unpaywall in its results to enable free retrieval of articles.

8.7.4 NPL bibliographic fields

NPL databases commonly have a variety of different fields. These can vary widely, but will commonly include most of the following:

- Author's name
- Author affiliation
- Qualification
- Summary
- Author keywords
- Document identifier (DOI, ISSN, ISBN)
- Fund recognition
- References cited
- Appointment count
- Researcher identifier (according to each database)

8.8 Search report

The search report is the document in which the result of the search for technical information is reflected and is used for the substantive examination of a patent application. The purpose of the search report is to serve as support for the examiner to conclude with a statement in the substantive examination on the protection of what is requested.

Said report contains the bibliographic identification data of the documents that, belonging to the state of the art, are closely related to the object that is requested to be protected.

The search report is reflected in a format that must contain the following data:

- identification of the patent application;
- date of filing of the patent application;
- priority date for filing the invention in another country, if any;
- international classification of patents of the subject matter sought to be protected;
- strategy that has been used in locating the documents found;

- minimum identification data for documents found, WIPO Standard ST.14 provides examples of how to identify documents cited in the search report;
- the claims that are affected by the content of the technical documents; and
- description of the categories of each document found according to point 8.5

8.9 Search process

To carry out a search and whenever the purpose of this is to identify the state of the art, the examiner is proposed to follow the following steps:

a. determine exactly the object of the application, for which the claims presented in light of the description and drawings will be taken into account. If the examiner is faced with an application that does not disclose the invention clearly and completely, it must be stated that it is not possible to carry out the search;
b. review the independent claims to verify whether there are dependent claims that exceed the scope of the independent claim to which they are subordinate or whether the description and drawings disclose means of executing the invention that are not included in the claims. In both cases, the search must also reach these objects, in such a way as to cover all aspects and embodiments of the invention;
c. consider the technical characteristics contained in both the independent and dependent claims;
d. indicate in the "Search Report" if there were any restrictions in the search for reasons of exclusion of patentability and/or lack of unity of invention, a priori;
e. determine the classification of the application, using the latest edition of the IPC classification, paying special attention to assigning a correct classification. It is suggested to also use the CCP classification, as deemed appropriate by the examiner;
f. plan various search strategies (equations) such as Boolean operators by combining keywords in different search fields (as allowed by each database), proximity operators and keyword truncation. It is advisable to use the title, claims and summary as the main search fields. It is important to mention that, when using the International Patent Classification IPC

as part of the search strategy, the probability of finding relevant documents is greater;

g. perform the search by patent family, if applicable;
h. carry out a background search up to the date of submission of the application, or its recognized priority;
i. The minimum information that should be taken into account when carrying out a search must be that which appears in the National Patent Databases and those contained in this manual;
j. In the case of applications claiming priority, if the search yields documents whose publication or disclosure date falls between the priority date and the filing date of the application being searched, the priority check will be carried out at the patentability examination stage, when the examiner will verify, using the priority document, whether the priority is recognized as valid;
k. Constantly evaluate and iterate the search results and, if necessary, to reformulate and refine the strategy used. The examiner should direct his attention primarily toward the concept of novelty, but at the same time should pay attention to any prior art that may be important in terms of inventive level; and
l. Select from all the documents you have recovered, those that you will cite in the Search Report, assigning them the appropriate category. These documents should be those closest to the subject of the application and those that best illustrate the state of the art. If the examiner does not find documents of special relevance in terms of novelty and inventive level, he or she must cite any document related to the technical field of the invention, if it exists.

8.9.1 Search equations

A search strategy or equation is the combination of different criteria using certain tools, such as the truncation of terms and logical operators, with the aim that the examiner can recover documents related to the invention that is desired to be protected, which describe the technical aspects closest to it.

The basic components available to the examiner to propose the search strategy are the classification symbols and keywords. However, there is no single way to do it, but it will depend on the experience and knowledge of the examiner.

However, a starting point is the study of the documents that the applicant himself mentions in the part corresponding to the description of the invention and which can be divided into:

- Those documents that are cited as starting points for the invention. These must be reviewed, as they contain relevant information for their understanding.
- Those documents that contain alternative solutions to the technical problem found and that could constitute the closest state of the art.
- Those documents that reflect the technological bases of the sector in which the invention is located or contain solutions that are far removed from that proposed by it.

In relation to keywords, special care must be taken not to use only the exact words, as they may lead to null results. In addition, you must use synonyms, equivalent expressions, truncations (which will allow the greatest number of terms derived from the keyword to be covered) and even antonyms. Most databases for searching patent documents allow the use of logical operators, which must be used to refine the results obtained.

The search must focus on the technical field to which the invention belongs, according to what the applicant indicates in the description; However, the expansion of the investigation to analogous technological sectors should be restricted to:

- Sectors in which a person skilled in the art could use the same or a similar element to those to which a generic concept of the claimed invention belongs;
- Sectors that are related to the utility function of the object of the claims; or,
- Techniques belonging to the sector in which the inventor's efforts are focused and that present a sufficient relationship with the particular problem of the invention.

8.9.2 Search without results

If the examiner does not have more relevant documents to assess the novelty and inventive level, he will consider citing the most relevant documents related to the "technological context" of the invention that he has been able to identify during the search. Normally, no particular effort should be made in this regard; However, in specific cases, the examiner may act as he or she

deems appropriate. In exceptional cases, a search may be terminated without any relevant documents being found.

8.9.3 Stopping the search

For reasons of economy, it is essential that the examiner exercise judgment in deciding to end the search when the chances of discovering other relevant elements in relation to the effort required are minimal. The search may also be stopped when the documents have made it possible to clearly establish the lack of novelty of all the elements that the claims imply or that can reasonably be expected to be involved, regardless of the characteristics whose application would not require any inventive step and for which immediate and indisputable demonstration can be made that they are so well known in the sector examined that it does not seem necessary to seek documentary evidence. Consequently, the examiner should not discontinue the search if lack of novelty has been established only for a limited number of claimed embodiments, even if this would lead to the formulation of an objection in the written opinion for lack of novelty.

Where the document is an Internet disclosure and there is uncertainty about its publication date (in the sense that it is not known with certainty whether it was published before the relevant date), the examiner should continue his search as if the Internet disclosure had not been consulted.

8.10 Patent databases

Patent databases are divided into two large categories, private databases that have some type of fee or payment and public databases that are generally free.

Patent databases on the Internet are a service that changes over time according to market interests and information needs. However, WIPO has created the WIPO INSPIRE portal which is a collection of reports on patent databases and their characteristics, where you can obtain updated, accurate and unbiased information to determine which patent database to use. We recommend that the examiner periodically consult this portal to find out about the databases that WIPO adds to this list. A list of patent databases is found in Section 1.2 of Annex II.

8.11 Inter-office information request format

"**Article 46.-** The competent national office may solicit reports from experts or from scientific technological bodies considered suitable, so as to have their opinion on the patentability of the invention. It may likewise, if it sees fit, solicit reports from other industrial property offices."

In accordance with the provisions of Article 46 of Decision 486, the competent national offices may exchange information to gather all the necessary elements to make their patentability opinion.

9. UNITY OF INVENTION

Prior to the patentability examination, it is necessary to verify whether the application has unity of invention.

9.1 Definition of unity of invention

"**Article 25 -** The patent application may only relate to one invention or to a group of inventions so related as to constitute a single inventive concept."

"Single inventive concept" should be understood as the set of new and inventive technical characteristics (or elements) that are common to all inventions.

The unity of invention requirement must be evaluated with respect to independent claims, but not dependent claims. When it is found that the independent claims have unity of invention among themselves, it is not possible to object to the lack of unity of invention for the claims that depend on them. On the other hand, in some cases within the same claim there are different inventive concepts, so the applicant must also be requested if this occurs. In a patent application you can claim:

a. a single invention; or
b. a group of inventions related to each other by a single inventive concept.

When it comes to case b), it must be considered that the unique inventive concept that relates the inventions must be technical, meet in itself the requirements of novelty and inventive level and be common to all the claims.

Example of unity of invention:

Claims:

1. A method for applying a paint containing a substance X that inhibits an oxidation process to an article, the said method comprising the following steps:
atomizing the paint using compressed air; electrostatically charging the atomized paint using an electrode system A; and applying the paint to the article.
2. Paints containing substance X
3. A paint applying apparatus including an electrode system A.

State of the art:

The paint containing substance X is novel and original, and electrode system A is also novel and original.
However, three general steps of the method of claim 1 are known.
State of the art:

Comments:

The special technical feature of claim 1 is as follows:
i) a paint containing substance X and ii) an electrode system A.
Since a special technical character i) is found in claim 2, there is a technical relationship between claim 1 and claim 2.
Since a special technical feature ii) is found in claim 3, there is a technical relationship between claim 1 and claim 3.
Since the special technical character i) of claim 2 is not the same as or related to the special technical character ii) of claim 3, the statements of claims 2 and 3 lack unity of invention.

The unity requirement must be met for the following reasons:(a) economic, to prevent the applicant from obtaining protection for several inventions by paying fees for a single patent and (b) technological, for convenience for the classification, search and examination of the invention. application.
The lack of unity of invention is manifested “a priori” or “a posteriori”:

9.2 Lack of a priori unity of invention

The lack of unity of invention can be identified by simply reading the application, particularly the claims, before identifying the state of the art. In this case, the lack of unity of invention has been determined “a priori”.

Example 1 of lack of a priori unity of invention:
When claimed:
a) product A;
b) production process of A, B, C, D; and
c) device X (which is not used to obtain product A nor is it used in process 2)
There is no single inventive concept common to all inventions.

Example 2 of lack of a priori unity of invention:
Consider the claims:
a) A telephone
b) A plug
c) A dial
d) A rotating dial
e) A button dial
It is clear from the beginning that there is no single inventive concept common to all inventions.

Example 3 of a priori invention unity:
Claim 1: A manufacturing process for chemical substance
Claim 2: Chemical substance
Claim 3: The (method of) use of substance X as an insecticide
There is a priori unity between claims 1, 2 and 3 because the particular technical element common to all claims is substance common to all claims. Therefore, there may be no unity.

Example 4 of a priori invention unit:
Claim 1: Chair equipped with a lifting mechanism.
Claim 2: Chair equipped with a mechanical thread lifting mechanism.
Claim 3: Chair equipped with a hydraulic lifting mechanism.
There is a priori unity between claims 1, 2 and 3 because the particular technical element common to all claims is a chair equipped with a lifting mechanism. However, if a chair equipped with a lifting mechanism were known in the art, the claims would not have any particular common technical element and there would be no unity of invention.

Example 5 of lack of a priori unity of invention:
Claim 1: Turbine rotor blade shaped to have a semicircular cross section.
Claim 2: Turbine rotor blade according to claim 1 containing alloy

Z.
Claim 3: Alloy Z.
Independent claim 1 relates to a turbine blade. The characteristic "blade shaped to present a semicircular cross section" is considered to be the particular technical element of this claim.
Independent claim 3 refers to "alloy Z", which is considered the particular technical element of this claim.
Consequently, there is no a priori unity between independent claims 1 and 3, since there is no particular technical element that is common to both.

Example 6 of lack of a priori unity of invention:
Claim 1: An antibody that specifically binds TAU and recognizes an epitope of SEQ ID NO: 1 (DRKDQGGYTMHQD) and comprises: A light chain consisting of the amino acid sequence of SEQ ID NO: 2; and a heavy chain consisting of the amino acid sequence of SEQ ID NO: 5.
Claim 2: An antibody that specifically binds TAU and recognizes an epitope of SEQ ID NO: 3 (ESLFCQPMVTTRS) and comprises: A light chain consisting of the amino acid sequence of SEQ ID NO: 7; and a heavy chain consisting of the amino acid sequence of SEQ ID NO: 9.
The description mentions the production of two antibodies with the same activity, that is, they specifically bind to the TAU antigen. However, each of the antibodies described in claims 1 and 2 recognizes different epitopes, which are characterized by the amino acid sequences SEQ ID NO: 1 and SEQ ID NO: 3 respectively.
In this case, two inventive groups are claimed since the claims do not share a common inventive concept since they do not have the same functional and structural technical characteristics.
Therefore, the request is objected a priori.

9.3 Lack of unity of invention a posteriori
When the lack of unity of invention is evident after having carried out the search for priors and having identified the relevant documents, the lack of unity of invention has been identified "a posteriori".

Lack of unity of invention a posteriori is determined by considering the claims only after evaluating the relevant prior art documents. It is the most frequent, since it is determined that what is being considered as an inventive concept common sole does not meet the requirements of novelty and/or

inventive level. In this case, the special technical characteristics of each "alternative" can no longer be united by that single concept.

Example 1 of lack of unity of invention a posteriori:

a) product A;

b) process I, for the production of A; and

c) process II, for the production of A.

Analysis: When backtracking proves that A is not new, then Process I and Process II will be two independent inventions.

Example 2 of lack of unity of invention a posteriori:

Consider the following indications:

a) A telephone

b) A telephone with a plug

c) A telephone with a disc

d) A telephone with a rotating dial

e) A telephone with a dial button dial

Analysis: Any of these claims alone represents an invention (the patentability criteria of said claims are not examined now).

A single patent application containing any one and only one of these claims will be considered to present unity of invention.

If a patent application contains all five independent claims, they are united by a single general inventive concept: the telephone. If the phone meets the patentability criteria, then the five independent claims.

They are part of a group of inventions linked together and therefore present a unity of invention. But if the phone does not meet the patentability criteria, claim a) will not be accepted and the following claims will no longer be united by a general inventive concept. Consequently, the case is considered as lacking of unity of invention a posteriori, because it has been necessary or necessary to examine the claims in order to know if there was a single inventive concept.

Example 3 of lack of unity of invention a posteriori:

Claim 1: Antibody that binds to GPRC5D comprising:

a. One VH-CDR1 SEQ ID NO: 1, one VH-CDR2 SEQ ID NO: 5, one VH-CDR3 SEQ ID NO: 9, one VL-CDR1 SEQ ID NO: 13, one VL-CDR2 SEQ ID NO: 16 and a VL-CDR3 SEQ ID NO: 19;

b. one VH-CDR1 SEQ ID NO: 2, one VH-CDR2 SEQ ID NO: 6, one VH-

CDR3 SEQ ID NO: 10, one VL-CDR1 SEQ ID NO: 13, one VL-CDR2 SEQ ID NO: 16 and a VL-CDR3 SEQ ID NO: 19; or

c. one VH-CDR1 SEQ ID NO: 3, one VH-CDR2 SEQ ID NO: 7, one VH-CDR3 SEQ ID NO: 11, one VL-CDR1 SEQ ID NO: 14, one VL-CDR2 SEQ ID NO: 17 and a VL-CDR3 SEQ ID NO: 20.

In this case, the common concept is an antibody that binds to the GPRC5D antigen.

When the examiner performs the search in the state of the art, it is established that anti-GPRC5D antibodies already existed, consequently, it is concluded that the common inventive concept for antibodies a, b and c disappears. Additionally, the description shows that each of the antibodies a, b and c of claim 1 have structures different for their six antigen-binding CDRs. Consequently, the application lacks a posteriori unity of invention.

Example 4 - Different inventions in different independent claims:

1. An antibody that binds to human DLL4, comprising the following hypervariable regions: CDR-H1 consisting of SEQ ID NO: 1 (SSSYYWG); CDR-H2 consisting of SEQ ID NO: 2 (DIYYTGSTYYNPSLKS); CDR-H3 consisting of SEQ ID NO: 3 (QALAMGGGSDK) or SEQ ID NO: 4 (QALALGGGSDK); CDR-L1 consisting of SEQ ID NO: 5 (SGQRLGDKYAS); CDR-L2 consisting of SEQ ID NO: 6 (EDSKRPS); and CDR-L3 consisting of SEQ ID NO: 7 (QAWDRDTGV).

2. An antibody that binds to human DLL4, comprising the following hypervariable regions: CDR-H1 consisting of SEQ ID NO: 8 (NHWMS) or SEQ ID NO: 9 (SHWMS); CDR-H2 consisting of SEQ ID NO: 10 (DISSDGRYKYYADSVKG) or SEQ ID NO: 11 (MISYDGTIKYYADSVKG); CDR-H3 consisting of SEQ ID NO: 12 (AGGGNVGFDI); CDR-L1 consisting of SEQ ID NO: 13 (SADKLGTKYVS); CDR-L2 consisting of SEQ ID NO: 14 (QDAKRPS); and CDR-L3 consisting of SEQ ID NO: 15 (QSWDRSDVV).

Analysis: For a better understanding of the example, the amino acid sequences are described along with their corresponding identifiers (SEQ ID NO: XX). Thus, it can be seen that anti-DLL4 antibodies differ from each other in their structural characteristics. In any case, the common technical element that links both antibodies is an antibody that binds to human DLL4, so the two inventions are linked only by their functional characteristic.

In the event that the state of the art does not disclose any

anti-human DLL4 antibody, then the common technical element can be considered the single common inventive concept that relates the two inventions, and therefore, they maintain unity of invention, despite the structural differences.
If, on the other hand, any document of the state of the art discloses at least one anti-human DLL4 antibody, even if it is structurally very different from any of those claimed, then this antibody anticipates the common technical element, therefore which said element cannot be considered as the common inventive concept that relates the two inventions. In that sense, said document of the state of the art destroys the unity of invention between the two inventions (lack of unity of invention a posteriori).
In the present case, a background has been found that reveals an anti-DLL4 antibody whose heavy chain variable region comprises a CDR-H1 identical to SEQ ID NO: 1 of the invention. Therefore, the two inventions do not have a unity of invention (a posteriori) between them.

Example 5 - Different inventions in the same independent claim:
1. An insecticidal chimeric protein comprising an amino acid sequence as set forth in any of SEQ ID NOS: 1 to 4.
ANALYSIS: In the present case, the peptide sequences are not described along with their identified ones because they are extensive (more than 1000 amino acids in length). However, the description discloses information about the construction of said chimeric proteins.
insecticides, as follows:

SEQ ID NO	Dom1	Dom2	Dom3	Protoxin
1	Cry1Ah	Cry1Ac	Cry1Ca	Cry1Ac
2	Cry1Be2	Cry1Be2	Cry1Ka	Cry1Ka
3	Cry1Be2	Cry1Be2	Cry1Ca	Cry1Ab3
4	Cry1Be2	Cry1Be2	Cry1Ca	Cry1Ab3

A priori, the common technical element that links SEQ ID NOS: 3 and 4 is an insecticidal chimeric protein comprising Dom1 and Dom2 of Cry1Be, Dom3 of Cry1Ca and protoxin of Cry1Ab3; therefore they maintain unity of invention.
SEQ ID NOS: 3 and 4 have the Dom3 of Cry1Ca in common with SEQ ID NO: 1, so the common technical element that links them is an insecticidal chimeric protein that comprises the Dom3 of Cry1Ca.

However, a background has been found revealing hybrid protein endotoxins containing Dom1 and Dom2 domains of various Cry1 toxins combined with Dom3 of Cry1Ca. Thus, to the extent that said technical element is anticipated by the state of the art, there is no single common inventive concept that relates SEQ ID NO: 1 with SEQ ID NOS: 3 and 4.
SEQ ID NOS: 3 and 4 have Dom1 and Dom2 of Cry1Be2 in common with SEQ ID NO: 2, so the common technical element that links them is an insecticidal chimeric protein that comprises Dom1 and Dom2 of Cry1Be2. However, another background has been found that reveals hybrid protein endotoxins containing the Dom1 and Dom2 domains of Cry1Be2 combined with Dom3 and protoxin of certain Cry toxins. Thus, to the extent that said technical element is anticipated by the state of the art, there is no single common inventive concept that relates SEQ ID NO: 2 with SEQ ID NOS: 3 and 4.
Therefore, the following inventive groups have been found:
Group 1: SEQ ID NO: 1
Group 2: SEQ ID NO: 2
Group 3: SEQ ID NOS: 3 and 4

9.4 Indications of lack of unity of invention

The following cases are indicative of lack of unity:

- Several independent claims of the same category that differ in their technical characteristics
- An independent claim with many alternatives
- Need to search in various technical fields
- Indication of several problems that do not seem to be related
- A prior art document destroys the novelty of just an independent claim.

9.5 Method for examining the unit of invention

The method for determining the unity of invention is explained in greater detail through four particular situations.

9.5.1 Combinations of different categories of claims

It will be kept in mind that in the following cases there is unity of invention and therefore it is allowed to include within the same application the following combinations of claims, of different categories:

Case 1. Product and process:

1. Independent claim for a product and
2. Independent claim for a process specially adapted to manufacture said product

Case 2. Process and apparatus:

1. Independent claim for a process and
2. Independent claim for an apparatus or means specifically designed to carry out said process

Case 3. Product, procedure and apparatus Independent claim for a product:

1. Independent claim for a process specially adapted to manufacture said product, and
2. Independent claim for a device or means specifically designed to carry out said process.

To formulate an objection based on a unit of invention, it must first be verified whether there is a single inventive concept. The common inventive concept is: i) the common structure and ii) the common property.

The study of the requirement involves a study of the unit of invention "a posteriori", that is, considering the closest state of the art so that the examiner can determine if there are documents that anticipate the technical characteristics that define the only common inventive concept. and in that case, conclude that there is no single common new and inventive concept for the claimed group of inventions.
If it is considered, at first glance, that the application under study may not have a unity of invention, the examiner must follow the following steps:

Step 1 – Identify the first mentioned invention and identify its essential technical characteristics.
The first mentioned invention may be claim 1, the first alternative if the object of claim 1 is expressed by alternatives, or the first example of the description.

Step 2 – Do the search for the invention mentioned first.

Step 3 – Identify all other possible inventions and their essential technical characteristics.

Step 4 – Examine the novelty and inventive level of the first inventive group claimed in the claiming chapter of the application under study. To do this, the problem/solution method will be applied for each possible inventive group.

Step 5 – Compare the target technical problem and essential technical characteristics of each possible inventive group.

Example - claims of different categories:
Claim 1: A manufacturing process comprising stages A and B.
Claim 2: Apparatus specifically designed to carry out stage A.
Claim 3: Apparatus specifically designed to carry out stage B.
Analysis:
- *There is unity of invention between claims 1 and 2 and 1 and 3.*
- *There is no unity of invention between claims 2 and 3, since they have no particular technical element in common.*
- *Since there is unity of invention between claims 1 and 2; claim 3 would be objected for not having unity of invention with the first inventive group (whose common element is step A).*

Example - Claims of different categories:
Claim 1: A process for painting an article in which the paint contains a new substance X inhibitor of oxide formation and that consists of the following steps:
spraying of the paint by compressed air, electrostatic load of the powdered paint using a new Electrode A device and addressing paint towards the article.
Claim 2: Paint containing substance X.
Claim 3: Apparatus comprising electrode device A.
Analysis:
- *There is unity of invention between claims 1 and 2, as the particular common technical element is the paint containing substance X common particular technical element is the paint containing substance X.*
- *There is unity of invention between claims 1 and 3, since the particular technical element is the electrode device A.*
- *There is no unity of invention between claims 2 and 3, since they have no particular technical element in common.*

Example - Claims of different categories:

Claim 1: A process for painting an article wherein the paint contains a new substance X inhibiting the formation of rust and comprising the following steps: spraying of the paint using compressed air, electrostatic charging of the sprayed paint using a new A-electrode device and directing the paint onto the article.

Claim 2: Paint containing substance X.

Claim 3: Apparatus comprising electrode device A.

Analysis:

- *There is unity of invention between claims 1 and 2, as the particular common technical element is the paint containing substance X common particular technical element is the paint containing substance X.*
- *There is unity of invention between claims 1 and 3, as the particular technical element is the electrode device A element is the electrode device A.*
- *There is no unity of invention between claims 2 and 3, since they have no common particular technical element. particular technical element in common.*

Example - Claims of different categories:

Claim 1: A fuel burner provided with tangential fuel inlets towards a mixing chamber.

Claim 2: A procedure for manufacturing a fuel burner comprising the step of forming tangential inlets of the fuel towards a mixing chamber.

Claim 3: A procedure for manufacturing a fuel burner comprising a melt stage A.

Claim 4: An apparatus for carrying out a procedure for manufacturing a fuel burner, comprising feature X enabling the formation of tangential inlets of the fuel.

Claim 5: An apparatus for carrying out a procedure for manufacturing a fuel burner, comprising a protective cover B.

Claim 6: A carbon black manufacturing procedure comprising the step of tangentially introducing fuel into a mixing chamber of a fuel burner.

Analysis:

- *There is unity of invention between claims 1, 2, 4 and 6, since the particular technical element common to all of them is the tangential fuel inlets.*

- *There is no unity of invention between claims 3 and 5, nor of them with respect to claims 1, 2, 4 and 6 since there is no particular technical element common to all of them.*

Example - Claims of different categories:
Claim 1: A ferritic stainless-steel strip of high corrosion resistance and high strength, consisting mainly of, by weight percent: Ni=2.0-5.0; Cr=15-19; Mo=1-2; Fe=the rest. Thickness ranges between 0.5 and 2.0 mm and the yield strength is 0.2% above 50 kg/mm2.
Claim 2: A method of producing a ferritic stainless-steel strip of high corrosion resistance and high strength, consisting mainly of, by weight percentage: Ni=2.0-5.0; Cr=15-19; Mo=1-2; Fe=the rest, comprising the following steps: a) hot rolling to a thickness of 2.0 to 5.0 mm; b) annealing of the hot rolled strip at 800-1,000 °C under essentially non-oxidizing conditions; c) cold rolling of the strip to a thickness of 0.5 to 2.0 mm; and d) final annealing at 1120 and 1,200 °C of the cold rolled strip for 2-5 minutes.

Analysis: There is unity of invention between claims 1 and 2. The particular common technical element corresponds to the yield strength of 0.2% above 50 kg/mm2. The process steps of claim 2 produce per se a ferritic stainless-steel strip with a yield strength of 0.2% above 50 kg/mm2.
Although this feature is not apparent from the text of claim 2, it is disclosed in the description. Therefore, said process steps constitute the particular technical element corresponding to the limitation of the product claim referring to the same ferritic stainless steel endowed with the above-mentioned strength characteristics.

9.5.2 Process and products
- Synthesis processes of a known product:
There is no unity of invention between the synthesis processes of a known product, if the synthesis routes do not have technical elements in common, even if such processes are new and inventive. Each procedure is a different inventive group, because the product is not the particular technical element common to all processes.

- Synthesis processes for a new and inventive product:
There is unity of invention between the synthesis processes of a new and inventive product, although the synthesis routes do not have technical elements in common, because the product is the inventive concept common to all processes.

- Compositions of compounds (1):
The composition contains: a first type of compounds that have a first function that is similar and a first common structure that, as disclosed, is essential for that first function and a second type of compounds that have a second function that is similar and a second common structure that is disclosed to be essential for that second function. Therefore, it will be considered that there is unity in compositions of this type.

Example - Composition of compounds with invention unit:
The claimed composition contains an X compound, new or known in the state of the technique and a compound selected from the consistent group of A, B and C.
Analysis: *The state of the technique makes known that A, B and C have a similar function and have a common structure that, as it is disclosed, is essential for the function.*

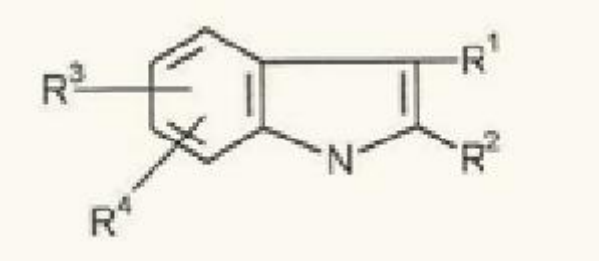
- Compound compositions (2):
The composition contains: a first type of compounds that have a first function that is similar and a first common structure that, as disseminated is essential for that first function; and a second, third, fourth ... type of compounds that have a second Similar function, but a second, third, fourth ... structures that are different. There will be a unit in compositions of this type.

Example – Compositions of Compounds without unit of invention:
The composition contains compound X and a compound chosen from the group consisting of A, B and C.
It is reported that A, B and C have similar function, but are structurally different molecules.
Analysis:
So there are three inventive groups:
- Group I: composition containing compounds X and A
- Group II: composition that contains compounds X and B.
- Group III: composition that contains compounds X and C.

9.5.3 "Markush" Practice

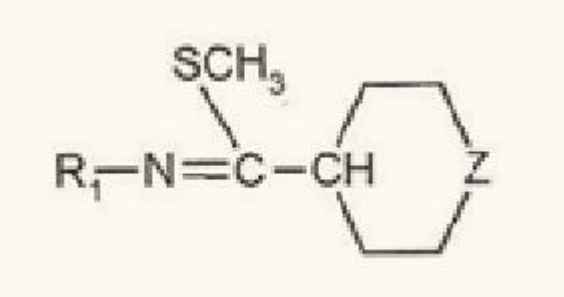
If the possible inventive groups solve the same objective technical problem and have essential technical characteristics in common, these are the only inventive concept common to all the inventive groups and in such case it will be concluded that there is unity of invention among the inventions examined.
If the possible inventions do not have essential technical characteristics in common, that is, there is no new and inventive technical characteristic (or element) that is common, it will be concluded that there is no unity of invention.

Example - Practice "Markush" / Common Structure:
Claim 1: compound of the formula:



where R1 is selected from the group composed of phenyl, pyridyl, thiazolyl, triazolyl, alkyl, alkoxyl and methyl; R2, R3 and R4 are methyl, benzyl or phenyl.
Note: According to memory, compounds have activity from the pharmaceutical point of view, to increase blood capacity to absorb oxygen.
Analysis:
The significant structural element collected by all variants is the indoyl and is the one that gives the activity or property to the compound. Since all variants have the same activity or property, there is a unit of invention.

Example - Practice "Markush" / Common Structure:
Claim 1: compound of the formula:



where R1 is selected from the group composed of phenyl, pyridyl, thiazolyl, triazolyl, alkyl, alkoxy and methyl; Z is selected from the group composed of O, S, Imino (NH) and Methylene (-CH2-) .
Note: It is indicated that the compounds have activity in the relief of pain in the lower back.

Analysis:
The Iminothioether group –N = CSCH3 attached to a 6-atom ring is the significant structural element collected by all variants. As the same activity is alleged for all claimed compounds, there is a unit of invention.

Example – "Markush" Practice / lack of common structure:
Claim 1: A herbicidal composition composed essentially of an effective amount of the mixture of A 2,4-D (2,4-dichlorophenoxyacetic acid) and B, a second herbicide which is selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, dipenamide (an amide), ioxynyl (nitrile), dinoseb (phenol), triflualine (dinitroaniline), EPTC (thiocarbamate) and simazine (triazine), with an inert carrier or diluent.
Analysis:
There is no unity of invention, since the different components included in B must be members of a recognized class of compounds. In this case, the members of B are not recognized as a class of compounds, but rather represent a plurality of classes that can be identified as follows:
a) inorganic salts (copper sulfate; sodium chlorate; ammonium sulfamate);
b) organic salts and carboxyl acids (sodium trichloroacetate; dichloropropionic acid; 3-amino-2,5-dichlorobenzoic acid);
c) amides (diphenamide);
d) nitriles (ioxynyl);
e) phenols (dinoseb);
f) amines (trifluralin)
g) heterocyclic (simazine).

9.5.4 Intermediate products and final products
The examiner will keep in mind that there is unity of invention between intermediate products and final products, when:

- The intermediate product and the final product have the same essential structural elements (the same basic chemical structure),
- The intermediate introduces an essential structural element in the final product,
- The final product is obtained directly from the intermediate, or
- They are separated by few intermediates that share the same essential structural element.

Considering the novelty of intermediate products and final products. Whenever they have the same essential structural element or the intermediate one incorporates an essential element in the final product, the examiner will keep in mind that there is unity between:
- A new intermediate and a new final product, or
- A known intermediate and a new final product, or
- Different intermediates used for different processes to obtain the final product.
- An intermediate and a final product of a process that leads from one to another, through a known intermediate.

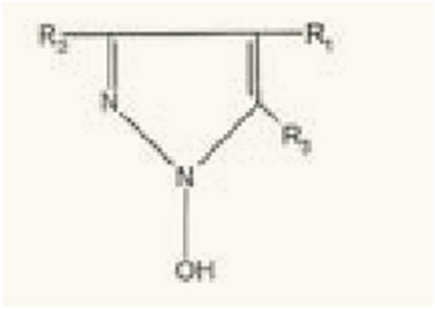
Intermediate products and Final products:
- The intermediate and the final product are separated by a known intermediate

There is no unity between the intermediate and the final product, separated by a known intermediate.
- Different intermediates for different structural areas of the final product

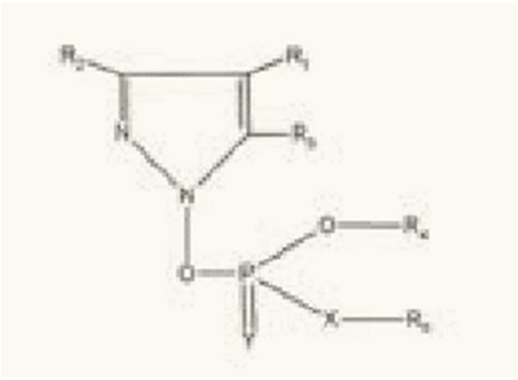
It will be considered that there is no unity between different intermediates for different structural zones of the final product.

Example – Intermediate and final products – on unit of invention:

Claim 1: Formula compound (intermediate compound)

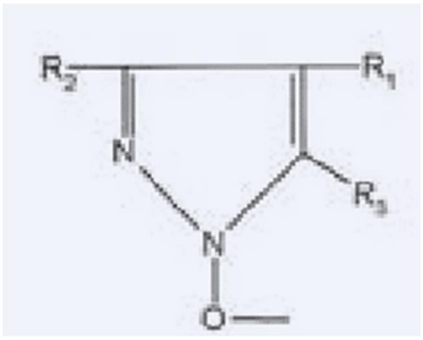


Claim 2: Formula compound (final compound)



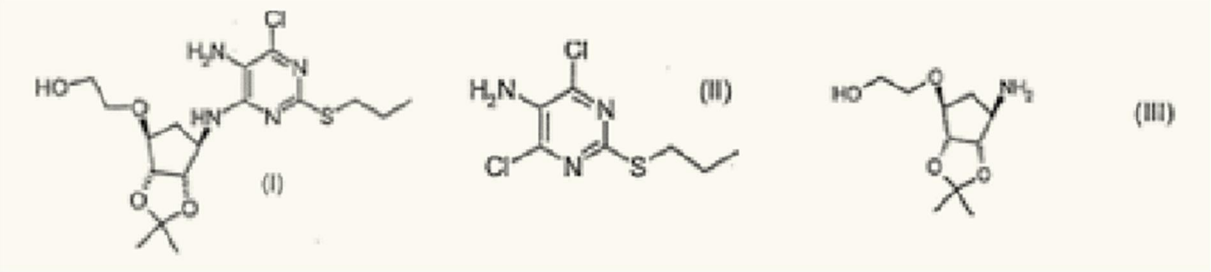
Analysis:

There is unity of invention between claims 1 and 2, since the chemical structures of the intermediate and final products are closely related to each other from a technical point of view. The essential structural element that is incorporated into the final product is:



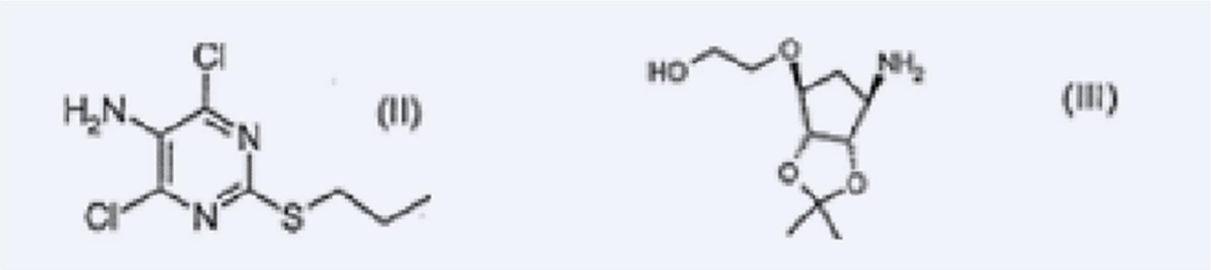
Example – Intermediate and final products – invention unit registration:

The claim chapter includes Compound (I) and its preparation intermediates (II) and (III):



Analysis:

Since the compound (I), which is the final product, is known (in WO9941254), it is considered that there is no unity between the two intermediates II and III, which make up different structural zones of the final product.



If it is recognized that there is unity of invention by applying the previous interpretations, the fact that intermediates, in addition to their use to obtain final products, have other effects or other activities, will not affect the decision on the unit of invention.

9.5.5 Polymorphs

With reference to the unity of invention of a group of claimed polymorphs, it will be kept in mind that, if the new and inventive distinctive characteristics of the polymorphs are common to all the claimed polymorphs, in such case it will be considered that there is a unity of invention.

Example - Polymorphs without unit of invention:

If claimed:

1. Polymorph B of compound
2. Polymorph C of compound
3. Polymorph D of compound
4. The Monohydrate of compound X, and

5. The Ethanolic Solvate of Compound
Since the closest prior art discloses 'Polymorph A of Compound the claimed Polymorphs B, C or D. Therefore, there is no unity of invention between them.

The characteristic that 'Compound X monohydrate' and 'Compound X ethanolic solvate' have in common is the fact that they are solvates. But the first is a hydrate solvate and the second is an ethanolic solvate and being a solvate is not a new or inventive characteristic.

So there is no unity of invention between them.
From which it is concluded that there is no Unit of Invention and the application contains five different inventions, namely:
- Polymorph B of compound
- Polymorph C of compound
- Polymorph D of compound X
- The monohydrate of compound X and
- The Ethanolic Solvate of Compound

9.6 Splitting the application
"**Article 36. -** The applicant may, at any stage in the processing, divide his application into two or more divisional applications, but none of them may involve any broadening of the protection accorded to the disclosure contained in the original application. The competent national office may, at any stage in the proceedings, require the applicant to divide the application if it does not fulfill the condition of unity of invention.
Every divisional application shall have the same filing date and, where applicable, the same priority date, as the original application.
Where multiple or partial priorities have been claimed, the applicant or the competent national office shall specify the priority date or dates corresponding to the subject matter that should be covered by each of the divisional applications.
For the purposes of the division of an application, the applicant shall file such documents as may be necessary to make the corresponding divisional applications complete."

When analyzing patentability, the examiner, if he considers that there is no unity of invention, will ask the applicant to submit

“divisional applications” or “fractional applications” whenever they are derived from a main application and benefit from its filing date, or that identifies the part of the invention with which you prefer to continue the process (Article 36).
If the applicant does not comply with the office's requirement, the application must be rejected due to lack of unity (Articles 25 and 45).
Additionally, it is worth mentioning that the first paragraph of Article 36 establishes the possibility for the applicant to divide the patent application voluntarily, that is, without a requirement being necessary due to lack of unity of invention. In this regard, the examiner must verify the viability of the application or fractional applications presented, and will proceed to the corresponding substantive examination in each case, in accordance with the internal provisions of each office.

10. NEW

10.1 Requirements of Article 16 of Decision 486

“**Article 16.-** An invention shall be considered new when it is not included in the state of the art.
The state of the art comprises everything that has been made available to the public by written or oral description, by use or marketing or by any other means prior to the filing date of the patent application or, where appropriate, the recognized priority date.
Solely for the purpose of determining novelty, the contents of the patent application pending before the competent national office and having a filing or priority date earlier than the priority date of the patent application under examination shall likewise be considered part of the state of the art provided that the said contents are included in the earlier-dated application where it is published, or where the period provided for in Article 40 has elapsed.”

According to Article 14, the fact that an invention is not new is sufficient to reject the application.
An invention as claimed is considered new if it is not part of the state of the art. The examiner must demonstrate that the invention is not new. In this sense, when an inventor files a patent application for an invention and there is no data to prove

that it is not new, the claimed invention will be considered new.

For the analysis of novelty, different documents of the state of the art cannot be combined. However, if a document explicitly refers to another document to provide more detail about some feature, the content of the second document relating to that feature may be considered to be incorporated into the first.

A prior art document may contain information implicitly, that is, anything that a person skilled in the art can derive directly and unambiguously from the document. For example, if a document talks about a bicycle, it implicitly refers to the bicycle's wheels, even if it does not mention them.

Some definitions from European regulations are:
- Novelty: everything that is not part of the state of the art.
- Lack of novelty: the novelty of the claimed subject matter is affected if it is derived from one that is directly part of the state of the art, whether explicitly or implicitly by a technician in the subject.

The examiner may support a lack of novelty in disclosures made in documents, conferences, fairs, drawings, etc., or based on his own knowledge as long as it is duly supported. The challenge of the novelty must be made based on the same disclosure, taking into account that different reference sources cannot be combined.

If one element is equivalent to another, the objection could not be due to lack of novelty but rather due to lack of inventive level. Thus, a copper wire and a silver wire are equivalent because they have the same function, but they are not the same.

If the same element is assigned different names but its technical characteristics are the same, the novelty is affected. This would be the case of “blanket” or “towel” that do not have different technical characteristics.

A particular element of the state of the art nullifies the novelty of a general expression that is claimed. For example, the disclosure of 'copper' in the state of the art nullifies the novelty of an invention of the general concept 'metal'. But the

disclosure of a general expression of the state of the art does not nullify the novelty of a particular element that is claimed.

In the case of ranges, the novelty is destroyed if in the state of the art there are examples contained in said range. Thus, for example, if the application claims a process between 120 and 150 degrees and the state of the art describes the same process at 130 degrees, there would be nothing new.

Novelty test:
Is the publication of the document prior to the presentation date or priority? Yes/No Does it contain all the if the answer is affirmative in both cases, then the invention is not new.

10.2 Priority
The subject of the application must be consistent with the subject of the previous application. There does not need to be an exact correspondence but the right of priority cannot be based on a general reference. A patent application where two elements A and B are described and claimed can claim priority from an application containing element A and another containing element B even though they have been filed in different countries. This is not the case when the application describes and claims the combination of elements A and B and in none of the previous applications said combination is mentioned, in this case priority could not be claimed based on said applications.

A priority or patent application cannot be rejected on the ground that an application claiming one or more priorities contains one or more elements that are not included in the application or applications whose priority is claimed (Article 4 of the Paris Convention). This same order states that, in initial applications, it is not necessary that the subject matter for which priority is claimed be within the claims; it is enough for the set of application documents to reveal the existence of said subject matter.

It is up to the examiner to evaluate the validity of the priority for the purposes of determining the state of the art. When there are anticipations that destroy the novelty between the priority date and the filing date of the application whose priority is

claimed, the content of the priority document must also be analyzed with respect to that of the submitted application. The provisions of the second paragraph of Article 9 of Decision 486 will apply in the case of applications based on a previous one submitted to the same office.

10.3 New information regarding another previous national application pending before the processing office

This is the case contemplated in the third paragraph of Article 16 of Decision 486, which applies only to the study of novelty and has the purpose of preventing the same object from being patented twice. The inventor who was the first to submit the application is entitled to protection, while the applicant who submits the subsequent application, although he was not aware of the existence of the first, since it had not been published at the time of submitting his application, you have to limit the scope of your claims to eliminate the matter disclosed in the application that is already pending.

Considering the above, a request that meets the following conditions will be part of the state of the art:

1. That it is being processed at the national office,
2. That its filing or priority date is prior to the filing or priority date of the application being examined,
3. That it contains the same material that is claimed in the application under examination, and
4. That it has been published at some point during the process.

10.4 Double patenting

It is an accepted principle in various patent systems that two patents cannot be granted to the same applicant for the same invention. In these systems an applicant is considered to have no legitimate interest in the proceedings leading to the grant of a second patent for the same subject matter if the applicant already holds a granted patent for that subject matter.

10.5 Analysis of the novelty

To determine the novelty of the invention, it must be checked whether there is prior art in the state of the art that contains all the essential technical characteristics of the invention. The examination of novelty is carried out by comparing element by

element of the invention as defined by the claims with those of the state of the art.

We must not forget that the wording of the claims is what determines the scope of the protection conferred by the patent, in accordance with Article 51 of Decision 486. Therefore, when analyzing the novelty, the claims must be interpreted taking the meaning broader of the definitions used (see Section 4.6 of Chapter III).

The independent claims of the application must be compared with the content of each prior art background, one by one, in order to determine whether a background alone describes the technical characteristics contained in said claims.

If all the technical characteristics of the independent claim are described in the same antecedent and are also closely related, the object of said claim lacks novelty. If a characteristic, even if banal, is not contained in the antecedent, the claim is new.

It is important to note here that novelty and inventive level are different criteria and must be analyzed separately.

A background of the state of the art cannot be interpreted. Only what is clearly described or what is directly derivable from the disclosure of said background can be used against the novelty of a claimed object.

Obvious or equivalent modifications of the object described in the state of the art cannot be cited against the novelty of the claimed object unless they are themselves described in the background.

The same procedure is followed with the other independent claims, where applicable, and with the dependent claims, in order to determine the existence or not of novel matter with respect to each of the prior art. (see examples 1 – 5, 7 and 9 of Section 3 of Annex IV).

Example of invention with novelty:
A sliding door system for a cabinet containing a television,

radio or similar electronic device, characterized in that the doors are made of a series of adjacent vertical slats, each of the slats being flexibly attached to the adjacent slat and that its lower and upper extremities are directed by horizontal linear guides that extend above and below, along the front and side parts of the cabinet, allowing the doors lateral movement to open and close the front part of the cabinet. cupboard.
In claim two the guides are defined as slots and in claim three it is specified that the slats are made of the same material as the cabinet.

In the state of the art, a document was found that describes an airplane hangar with sliding doors that move by means of small wheels on which slats are supported, the upper extremities of which are only directed by guides.
This document cannot be considered as an anticipation for the purposes of the novelty, because it does not describe the interior guides (wheels instead of a guide). All other technical characteristics were explicitly or implicitly (drawings) described.

In case of absence of novelty, the technical report must cite the background that contains all the elements of the claim, indicating the passages where each of them is found. (see examples 8 and 10 of Section 3 of Annex IV).

Example of invention with a lack of novelty:
A precision electrical resistor, which comprises a bar of ceramic material that has a spiral metal track on the surface, characterized by the resistivity of the metal being 2.8 Ω.cm.
The state of the art cited in the search report consists of a commercial catalog that presents several resistors in the form of an aluminum spiral deposited on the surface of an alumina bar. In a reference manual you can find that aluminum has a resistivity of 2.8 Ω.cm.
All technical characteristics being explicitly or implicitly present in the cited document, that is: ceramic metal bar (alumina), metal spiral (aluminum) deposited on the surface, resistivity of aluminum = 2.8 Ω.cm (inherent characteristic). In this case there is a lack of novelty.

It should be noted that, when examining novelty, it is not permitted to combine separate elements of the prior art with each other. However, if an "initial" document makes explicit reference to another document that provides more detailed information on certain characteristics, the content of the latter may be considered incorporated into the initial document to the extent indicated in said initial document.

Likewise, the use of a dictionary or similar reference document is permitted to interpret a special term used in the initial document at the date of its publication. It is also possible to refer to other documents that demonstrate that the disclosure contained in the initial document was sufficient. For example, a chemical compound intended to be prepared and separated or, in the case of a product of nature, to be separated.

Other documents may also be invoked to demonstrate that a feature that was not disclosed in the initial document was an implicit feature of that document at the date of its publication. For example, documents proving that rubber is an "elastic material".

When said information is contained in different parts of the same document, information may be combined, provided that said information is related in some way within the document.

It is not permitted to object to novelty on the basis of common general knowledge in the art that may be known to the examiner. This knowledge must be justified by documentation.

10.5.1 New regarding general expressions and specific examples

When a claim defines an invention according to generic terms, the disclosure of a particular example that falls within the parameters of the generic claim, for the purposes of assessing novelty, constitutes prior to that claim. That is to say that a particular element of the state of the art nullifies the novelty of a general expression that is claimed. (see example 1 of Section 3 of Annex IV).

Example 1 of a particular element affects the novelty of a general expression:

Application: metal shaft

State of the art: copper shaft
Conclusion: lacks novelty

Example 2 of a particular element affects the novelty of a general expression:
Application: lubricant (pharmaceutical tablet formulation)
State of the art: stearic acid
Conclusion: lacks novelty

However, an element of generic prior art generally does not precede a claim dealing with a specific element of that generic category. That is to say, the disclosure of a general expression of the state of the art does not nullify the novelty of a particular element that is claimed. (see example 3 of Section 3 of Annex IV).

Example of a general expression that does not affect the novelty of a particular element:
Application: fluorine
State of the art: halogens
Conclusion: lacks novelty

Example of novelty for members specifically described
Expressions of the type "CnH2n+2" where n = 1 to 8 destroy the novelty of the final members of the family, that is, for n = 1 (C1H4) and for n = 8 (C8H18) but not that of the intermediate members (e.g., C5H12), unless these intermediate members are explicitly and specifically described in the document under consideration.

10.5.2 Value ranges or intervals
Disclosure of a continuous range or interval is interpreted in a manner analogous to how generic disclosures have been interpreted. For example, a distinction is made between the disclosure of a range of temperatures and the disclosure of a particular temperature within a range.

As mentioned above, a general expression of the prior art does not nullify the novelty of a specific element of the application examined. But a specific element of the prior art does nullify the novelty of a general claim that includes it.

Thus, if the claimed invention differs from the state of the art only by a numerical range or interval, for example, temperature, pressure, percentage of components in a composition and the other essential technical characteristics are identical to those found in the document of the state of the art, to examine the novelty the following must be taken into account:

(1) When the range of the application is broader than that disclosed in the prior art, the prior art document nullifies the novelty of the claimed invention.
Example: The application claims a composition that comprises 10 to 35% Zinc, 2 to 8% aluminum and the rest is copper. If the state of the art discloses a composition with 15 to 30% zinc and 3 to 7% aluminum and the rest is copper, the claimed invention loses novelty.
(2) When the application claims a range and the prior art teaches a specific element that is included in that range, the prior art document nullifies the novelty of the claimed invention.
Example: The application claims a temperature of 20 to 40 °C. And the state of the art discloses a temperature of 35°, the claimed invention loses novelty.

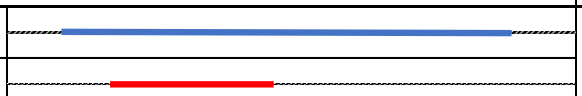
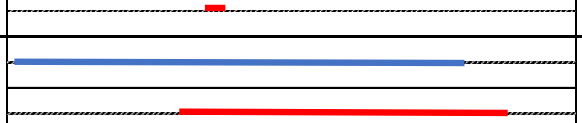
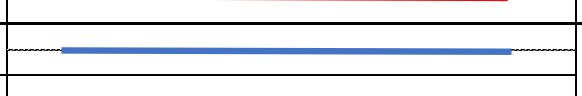
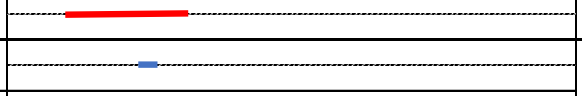
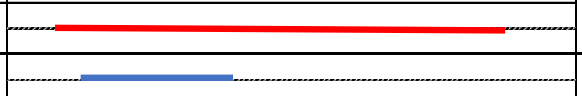
(3) If the application claims a range and the prior art teaches a range that partially overlaps that range, the prior art document voids the novelty of the claimed invention.
Example: If the application claims a content of component X of 20 to 50%. And the state of the art discloses a content of component X of 30 to 60%, the claimed invention loses novelty.

(4) If the application claims a range and the prior art teaches a range that has an end in common with the range claimed in the examined application, the novelty of the examined application is nullified.
Example: the application claims a process for making ceramics where the calcination time is 2 to 10 hours. If the state of the art discloses a process where the calcination time is 2 to 12 hours, the claimed invention is not new.

(5) If the examined application claims a specific element and the prior art teaches a range that includes that specific element, the application is considered new.

Example: If the application claims a process where the power is 50 KW and the state of the art discloses a process where the power is 25 to 80 KW, the application is considered new.

(6) If the examined application claims a range and the prior art shows a broader range that includes it, the application is considered new (see example 2 of Section 3 of Annex IV).
Example: If the application claims a process where the drying temperature is 30 to 45 °C and the state of the art discloses a process where the drying temperature is 20 to 90 °C and does not contain examples with specific drying temperatures between 30 and 45 °C, the application is considered new because it is a selection from the known range.

CASE				CONCLUSION
1	Application	Extensive Range		Lack of Novelty
	Prior Art	Narrow Range		
2	Application	Range		Lack of Novelty
	Prior Art	Data		
3	Application	Range Overlap		Lack of Novelty
	Prior Art			
4	Application	External		Lack of Novelty
	Prior Art	Extreme		
5	Application	Data		Cancel the lack of Novelty
	Prior Art	Range		
6	Application	Narrow Range		Cancel the lack of Novelty (it's selection)
	Prior Art	Extensive Range		

10.5.3 Restriction of scope through the use of negative limitations or disclaimers

"Disclaimer" means the express exclusion of subject matter from the scope of a claim, through a negative definition, for example, in order to comply with the novelty requirement. It should only be used when there is no more convenient way to define the object of the claim with positive characteristics, as mentioned in Section 4.6.11 of Chapter II.

When faced with an objection due to lack of novelty, the applicant can restrict the claim by introducing a disclaimer. For

this it is not necessary that the disclaimer be supported in the application as initially presented. If a disclaimer is correctly formulated, it does not constitute an extension within the meaning of Article 34 of Decision 486. (see example 4 of Section 3 of Annex IV). It is important to consider that the inclusion of a disclaimer to overcome an objection due to novelty only applies when the excluded matter is disclosed in a document that does not belong to the technical field of the application.

10.5.4 Explicit and implied disclosure

As mentioned above, lack of novelty may arise when the technical content of a prior art document discloses the explicitly claimed subject matter. This type of disclosure is recognized as explicit disclosure.

However, the disclosure may be implied, since, in carrying out the teaching of the prior art, the skilled person would inevitably arrive at a result that falls within the terms of the claim. In this case an objection of lack of novelty should only be raised when there is no reasonable doubt about the practical effect of the previous teaching.

Example of lack of novelty due to implicit characteristics:

Claim:

A sterile, apyrogenic parenteral composition comprising taxol and cremophor.

Background D1：

An injectable composition comprising taxol and cremophor (not mentioning sterility and apirogenicity) .

The invention lacks novelty since it is an implicit description, since an injectable must be sterile and non-pyrogenic by definition.

10.5.4.1 Implicit disclosure and parameters

Situations of this type can also occur when the claims define the invention or one of its characteristics by parameters. It may happen that no parameters are mentioned in the above technique. Therefore, if the claimed product is the same as the known product in all other respects (which is to be expected if, for example, the initial products and manufacturing processes are identical), a lack of novelty objection will be raised.

The burden of proof of an alleged distinctive characteristic rest with the applicant and the benefit of the doubt cannot be given if the applicant does not provide evidence to support its arguments. However, the applicant can show by appropriate comparison tests that there are differences with respect to the parameters, it will be questioned whether the application reveals all the characteristics essential for the manufacture of products having the parameters specified in the claims.

10.5.5 Selection inventions

Selection inventions are applications that claim a single element or a small group of elements, which belongs to a large group of elements already known. These inventions refer to matter that constitutes a selection on something already known in the state of the art. (see example 57 of Section 3 of Annex IV).

Example – selection inventions:

A chemical procedure that can be carried out at a temperature range between 10° and 100 °C, giving examples that take place at 20°, 40°, 60° and 80 °C and that we are examining an invention that claims the same procedure indicating that in the range between 68° and 72 °C the procedure is much more efficient since it considerably increases the yield of the product obtained.
In this case, although the range between 68° and 72 °C falls within the already described range of 10° to 100 °C and the intermediate temperatures of 20°, 40°, 60° and 80 °C, taking into account that the previous document did not mention that there was any part of the range described in which the procedure would behave differently, it is considered that said information was not available to the public and, therefore, is new.

It will be considered that the procedure described in the state of the art can be carried out normally, at the temperatures indicated as limits, that is, 10 and 100 °C and at the intermediate temperatures described in the tests, that is, 20, 40, 60 and 80°C. The document does not describe that, at other temperatures, within or outside the range originally described, the procedure can be performed differently. This information has not been made available to the public before the date of submission of the other application.
Taking into account the generic description criterion for judging

novelty, a claim limited to the range between 68 and 72°C will be considered new because: that particular, limited range has not been specifically described in the prior art document;
The document of prior art has not specified well in its examples, in the description, claims or drawings, the concrete temperature value falling within the range of 68 to 72 °C and a third criterion to be considered when dealing with contiguous values is the following:
the range from 68 to 72 °C is small compared to the range described in the document of prior art and, moreover, is not close to one of the particular values described in the reference document.
We must not forget that the existence of an unexpected effect has nothing to do with novelty. Even if the effect had been as expected, the claimed interval would also be new, but in this case, the claim would not imply an inventive step. When dealing with contiguous intervals, care must be taken when examining novelty.

A description that a particular procedure is performed at 55°C may be interpreted by the person skilled in the art, aware of the tolerances and inaccuracies that result from measuring or controlling in said particular procedure, as meaning that the temperature is, in practice 55 °C, more or less. This confirms once again that the information contained in a document must be read as an operator in that field would read it and not as an exact mathematical document that does not normally exist in everyday life.

10.5.5.1 Selection from two or more lists
If a prior art document discloses two lists of elements, an invention that consists of the selection of elements from both lists will be considered new.

Example – Invention of selection from two or more lists:
If compositions containing:
Component 1: paracetamol, aspirin, ibuprofen, morphine, codeine or antibiotics, and Component 2: Vitamin A, vitamin B, vitamin C, vitamin D1, vitamin D2, caffeine or taurine.
So, the invention of a composition containing aspirin and vitamin C is new.

10.5.5.2 Subrange selection

The selection of a subrange, which had not been explicitly mentioned in the known extensive group or range, is considered new, if the following three conditions are met:

- The selected subrange is narrower than the known range;
- The selected subrange is sufficiently far from the disclosed range, defined by the examples and by the extremes;
- The selected subrange is new and has a different technical effect.

Example – Subrange selection invention:

Claim 1: Titanium Alloy containing 0.6 to 0.7% nickel and 0.2 to 0.4% molybdenum.

State of the Art: *describes a titanium alloy that contains 0.65% nickel and 0.3% molybdenum, since the nickel and molybdenum contents of the state of the art are particular, they nullify the novelty of the general contents that they claim.*

Example - Invention of subrange selection:

Range claimed in the application X = 400 to 4000.

Range described in the prior art: X = 600 to 1200

Acceptable: X *= 400 to 4000 where X is less than 600 or X is greater than 1200.*

Not acceptable: X = 400 to 600 or 1200 to 4000 since the values 600 and 1200 are included in the prior art.

Example - Invention of subrange selection:

Range claimed in the application: X = 6 to 10,000.

Range described in the prior art: Y = 240 to 1500

Acceptable: *greater than 1500 and up to 10,000*

Not acceptable: It is from 1500 to 10,000 since the value 1500 is included in the prior art.

10.5.5.3 Range overlap

If the application claims a range and the prior art teaches a range that partially overlaps that range, the prior art document voids the novelty of the claimed invention. In this case, the applicant is notified of the lack of novelty.

However, if the applicant in its response argues that a part of the claimed range that overlaps with the previously disclosed range provides a new technical effect and the previous document

does not mention a specific example within the overlapping interval, the range is considered new. If not, the examiner should consider whether the subject matter expert would consider working in that range of overlap. In that case, the novelty would be objected to.

10.5.6 Novelty in specific areas of technology

10.5.6.1 Chemistry and pharmaceuticals

A chemical compound is considered known if it is mentioned in a background and the information contained therein, complemented by general knowledge at the date of this, allows a person versed in the matter to prepare and separate it or, in the case of a natural product, only separate it. It must be mentioned by its name, its formula, its parameters or its manufacturing process.

Example – Novelty of inventions defined by a family of chemical compounds:

The application claims products of the general formula:

N ----x

where N is an organic nucleus and X is an alkyl group.

The description mentions three compounds explicitly and the group of compounds where X = C1 to C3 implicitly:

X = methyl (C1)

X = propyl (C3)

X = isopropyl (C3)

The state of the art describes that X = decile (C10). Therefore, the general formula claimed is not new.

The invention may be limited to meet the objection of novelty only without limitations implicitly or explicitly derivable from the content of the original application.

In this case, the following limitations are considered acceptable:

C1

C3

C1 and C3

C1 to C3

The general formula where X = alkyl group except C10 (disclaimer)

In the case of a precedent that mentions the manufacturing process, for there to be a lack of novelty, said antecedent must indicate the starting products and a process that, with those

starting products, necessarily leads to the claimed product (see example 4 of Section 3 of the Annex IV).

Example – Novelty in chemical compounds:
The compound is defined in the state of the art by:
a) your name;
b) its chemical formula;
c) its physiochemical parameters; either
d) as the product resulting from a process.
If the name or chemical formula is sufficient to characterize the compound, the state of the art corresponding to cases a) and b) will destroy the novelty of the claimed compound.
In case c), if the state of the art describes a compound by physicochemical parameters different from those of the invention, then that state of the art will not destroy the novelty of the claimed compound.
In case d), if the prior art describes the starting materials of the process in such a way that their use inevitably results in the claimed compound using them in the described process, then the prior art destroys the novelty of the compound.

Analogous to the principles of general expressions and specific examples, a general formula does not destroy the novelty of a compound or a subgroup of compounds included in it. However, specific compounds in a document destroy the novelty of a general formula (see example 3 of Section 3 of Annex IV).

If a formula has specific substituents listed, selecting one of the possibilities when there is only one list of alternatives for a substituent is considered novel. That is, a general formula with a variation in a single substituent is considered and in which all the alternatives for this substituent are listed is equivalent to the listing of all the specific compounds. However, if a selection must be made from two or more lists of substituents to reach the object of the claim, then it is considered that there is novelty.

Example – Novelty with implicit description of individual compounds from a general formula:
The state of the art defines a series of compounds by a general formula that has several variable substituents.

The applicant claims a specific compound that is one of the possible combinations of the general formula.
Under what circumstances is this compound considered new?
In the state of the art, the general formula (I) is described with many different substituent options to choose from. Choosing a single alternative from a single list of alternatives for a substituent does not confer selection novelty. The selection will be new if it is made from at least two lists of at least two different substituent lines.

In the case of natural products, it should be noted that their activity alone (without a chemical formula or physical-chemical characteristics) is not sufficient to unambiguously define the product. If a product is known in purified form, for example by its activity and parameters, a claim targeting the formula of the compound would not be new.

10.5.6.1.1 Markush type formulas

When both the claim and the prior art document are defined by overlapping Markush formulas, that is, there is a subgroup of compounds common to both, but the prior art does not describe any specific compound in this subgroup, it is appropriate allege lack of novelty by arguing that the claimed compounds are partly in the state of the art.

10.5.6.2 Biotechnology

10.5.6.2.1 Nucleotide or amino acid sequence

When a synthetic nucleotide or amino acid sequence is claimed and there is a natural product identical or equivalent in structure, sequence and morphology, said natural product destroys the novelty of the synthetic product.

10.5.6.2.2 Proteins

If a known protein is claimed, whether recombinant or not, that is, it has the same amino acid sequences as the prior art protein, it will be concluded that the claimed protein is not new. However, when appropriate, the procedure by which the protein is obtained must be examined to define if it has any characteristic that makes it different from the procedure already disclosed in the state of the art, in which case the procedure

would be new even if the protein produced is not new.

However, if the recombinant protein has different amino acid sequences from the prior art protein, it will be considered new. In the same way, the nucleic acid that codes for the new protein is also new.

10.5.6.2.3 Antibodies

When an application claims an antibody X that binds to an antigen A and has a different structure than an antibody Y found in the prior art. structure different from that of an antibody Y that is in the prior art and also binds antigen A, the antibody X will be considered to be new. and also binds antigen A, the antibody X will be considered to be new.

10.5.6.2.4 Microorganisms

A microorganism that has been cited in the state of the art but is not marketed or deposited with a depositary authority is understood to be accessible and therefore destroys novelty since it is generally possible to request samples from the authors. of publication, unless the applicant proves otherwise.

Some examples of the analysis of novelty in these fields are found in example 6 of Section 3 of Annex IV.

10.5.6.3 Mechanical and electrical

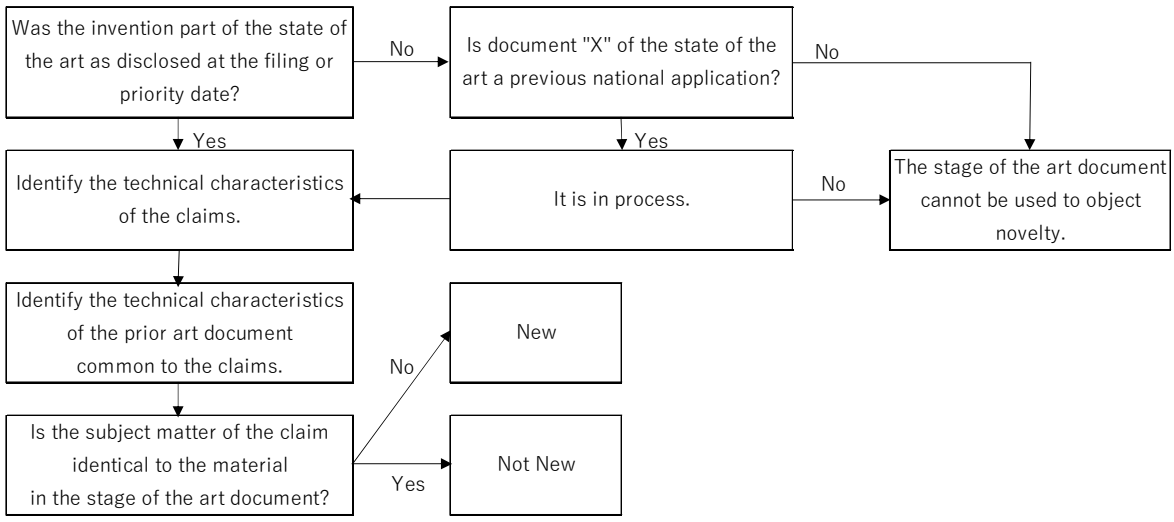
In the context of patents, mechanical and electrical inventions are more related to the structural and functional aspect of a system. In these cases, the description must include the physical structure, steps and/or means by which the results of a mechanical/electrical process are achieved. It is important to focus the invention with the specific variables used to obtain the intended result, or to specifically claim the devices used to achieve the intended result.

Some examples of the analysis of novelty in these areas are found in examples 7 - 10 of Section 3 of Annex IV.

Likewise, illustrative drawings accompanying the description are essential for most patent applications, but especially for mechanical and electrical inventions. As mentioned in Sections

3.2.2 and 5.2 of Chapter III of this manual, drawings may include implicit technical characteristics as long as they do not expand on the subject matter originally described (see example 2 of Section 1 of Annex IV).

10.6 Novelty evaluation diagram



10.7 Suggested wording of technical report (new)

Model 1

Article 16 of Decision 486

The present application does not meet the requirement of Article 16 of Decision 486 because the subject matter of the claim(s) is not new.

"Document D1 describes a (device, compound, process) consisting of an element A (see page ____, lines ____), an element B (see pages ____, lines ____ and figure ____) and an element C (see page ____ , formula ____). Therefore, D1 contains all the characteristics of claim 1 which does not meet the novelty requirement of Article 16."

Model 2

Article 16 paragraph 3 of Decision 486

The present application does not meet the requirement of Article 16, paragraph 3, of Decision 486 because the subject matter of

the claim(s) is not new.

Document D1 has a priority date ____ and a filing date ____ and a publication date ____ and is pending before this national office. Therefore, the content of this document is considered to be within the prior art as defined in Article 16, paragraph 3.

"Document D1 describes a (device, compound, process) consisting of an element A (see page ____, lines ____), an element B (see pages ____, lines ____ and figure ____) and an element C (see page ____ , formula ____). Therefore, D1 contains all the characteristics of claim 1 that does not meet the novelty requirements of Article 16."

11. INVENTIVE LEVEL

11.1 Requirements of Article 18 of Decision 486

"**Article 18.-** An invention shall be regarded as involving an inventive step if, for a person in the trade with average skills in the technical field concerned, the said invention is neither obvious nor obviously derived from the state of the art."

The inventive level is considered as a creative process whose results are not evident from the state of the art for a technician with average knowledge of the subject, on the date of submission of the application or the recognized priority.
The term "evident" means that something does not go beyond the normal progress of technology, but is simply or logically deduced from the state of the art, that is, it does not involve the exercise of any skill or capacity beyond that expected of an expert in the field.

11.2 Professional person normally versed in the subject

The person in the trade normally versed in the matter is a hypothetical figure. Their knowledge and skills will serve as a basis for assessing whether the claimed solution involves an inventive step. This person is one normally versed in the technological field to which the invention relates, with a higher level of knowledge than the general public, without exceeding what can be expected from a duly qualified person. The person of the trade must have the following characteristics and

capabilities:

- Have sufficient knowledge in the respective technical field.
- Know and understand the common general knowledge of said technical field on the date the invention is presented.
- That you have access to the content of the state of the art.
- Have had at your disposal the means and capabilities for routine experimentation.
- Be constantly involved in the development of the technical field to which it belongs and be oriented towards the search for background information in related technical fields, general technical areas and intellectual property aspects.

If the problem derived from the closest state of the art that the invention must solve prompts the person of the trade or expert in the field to seek its solution in another technical field, the specialist in that field will be the person qualified to solve the problem. Consequently, the knowledge and skills of that specialist will serve as a basis for assessing whether the solution involves an inventive step. In certain circumstances, it may be more appropriate to consider the subject matter expert as a group of people, for example, a research or production team, rather than a single person. This may be the case, for example, for certain cutting-edge technologies such as computers or telephone networks and for highly specialized processes such as those in the commercial production of integrated circuits or complex chemicals.

11.3 Analysis of the inventive level

The question for the examiner is whether or not the claimed invention is obvious to a person skilled in the art. The patent examiner must place himself in the position of the person skilled in the matter to define whether the object of the application is obvious, for that person skilled in the art, or is evidently derived from the state of the art. The examiner should not rely on personal assessments; Any objection regarding the lack of an inventive step of an invention must be proven from the state of the art.

The existence or lack of any technical advantage is not an absolute criterion for recognizing or not an inventive step. The examiner should not determine what “amount” of inventive step

exists. The inventive level exists or not, there are no intermediate answers.

To judge whether the invention defined by the claims is really evidently derived from the state of the art, it must be determined whether it lacks an inventive step when considering the differences between it and the closest state of the art. The examiner has the burden of proving that the invention lacks an inventive step and not only limit itself to establishing the differences between the application and said state of the art.

When the lack of novelty of the invention has been established, it is not necessary to evaluate the inventive level, since there are no differences between the invention and the state of the art. Therefore, it is important to examine the inventive level after novelty, because the novelty requirement is easy to meet, given that banal modifications make an invention new. But the modifications must be such that they do not result obviously from the prior art, that is, they have not been made "easily" by the person versed in the matter. If the invention has an inventive level, it means that it has one or more characteristics that imply a technical advance, compared to existing knowledge.

Normally the closest state of the art is in the same field as the invention or tries to solve the same or a similar problem. For example, in the chemical area the closest state of the art may be that which describes a product structurally similar to the product of the invention or a use or activity similar to that of the invention.

11.4 Method for evaluating the inventive level

The method to examine inventive level will be the problem-solution method.

11.4.1 "Problem-solution" method

To determine whether the object of the claim is obvious or is evidently derived from the state of the art, the "problem-solution" method is used, whenever possible. The method includes the following stages:

Step 1: Identify the state of the art closest to the claimed invention.

The closest state of the art is a document that must be from the same technical field as the invention, in addition, it mentions a function, purpose, problem to be solved or activity similar to that of the invention and is usually the one that has the most characteristics in common with the invention.

Step 2: Determine the difference between the invention and the closest prior art.
Compare the essential technical characteristics of the invention with those of the closest state of the art.

Step 3: Define the technical effect caused and attributable to the differential element.
The analysis must focus on the difference(s) and the technical effect caused by and directly attributable to each of them must be extracted.

Step 4: Deduce the target technical problem.
The problem must be defined without including elements of the solution, because then the solution would be obvious. The technical problem will not always be the one indicated in the application and sometimes has to be reconsidered based on the results of the background search. The closest state of the art may be different from that known to the applicant and from which he started.
Therefore, the technical problem must be reconsidered based on the originally reported technical effect and in light of the closest state of the art.

The objective technical problem is posed in terms of: "how to modify or adapt the closest state of the art to obtain the technical effect that the invention provides? The definition of the objective technical problem is based on specific objective facts of the state of the art and on the results achieved by the invention.

The expression "objective technical problem" should be interpreted broadly; It does not necessarily imply that the solution constitutes a technical improvement in relation to the state of the art; since the problem may simply consist of finding a replacement solution to a known device or procedure that

produces identical or similar effects.

Step 5: Evaluate whether the claimed invention, based on the closest state of the art and the objective technical problem, would have been obvious to the person moderately versed in the subject.

This stage consists of answering the question of whether in the state of the art, as a whole, there is a second document that contains teaching that would indicate (not only could indicate, but would indicate) to the person skilled in the art, faced with the technical problem, how to modify or adapt the closest state of the art to solve the problem, in the manner claimed, without making an inventive effort.

If the answer is affirmative, the Invention is considered obvious and therefore it is concluded that it does not have an inventive level.

If the answer is negative, the invention is not obvious and is considered to have an inventive step.

Technical information must always be considered in its context, it should not be extracted or interpreted outside of this. That is, the technical characteristic being analyzed must be sought in the same technical field or one that the person versed in the craft would consider anyway.

It must be taken into account that the search for priors is carried out, taking the same invention as a starting point. Therefore, the examiner must make the intellectual effort to place himself in the situation that the technician with average knowledge of the subject has had to face at a time when the invention was not known, that is, before the invention.

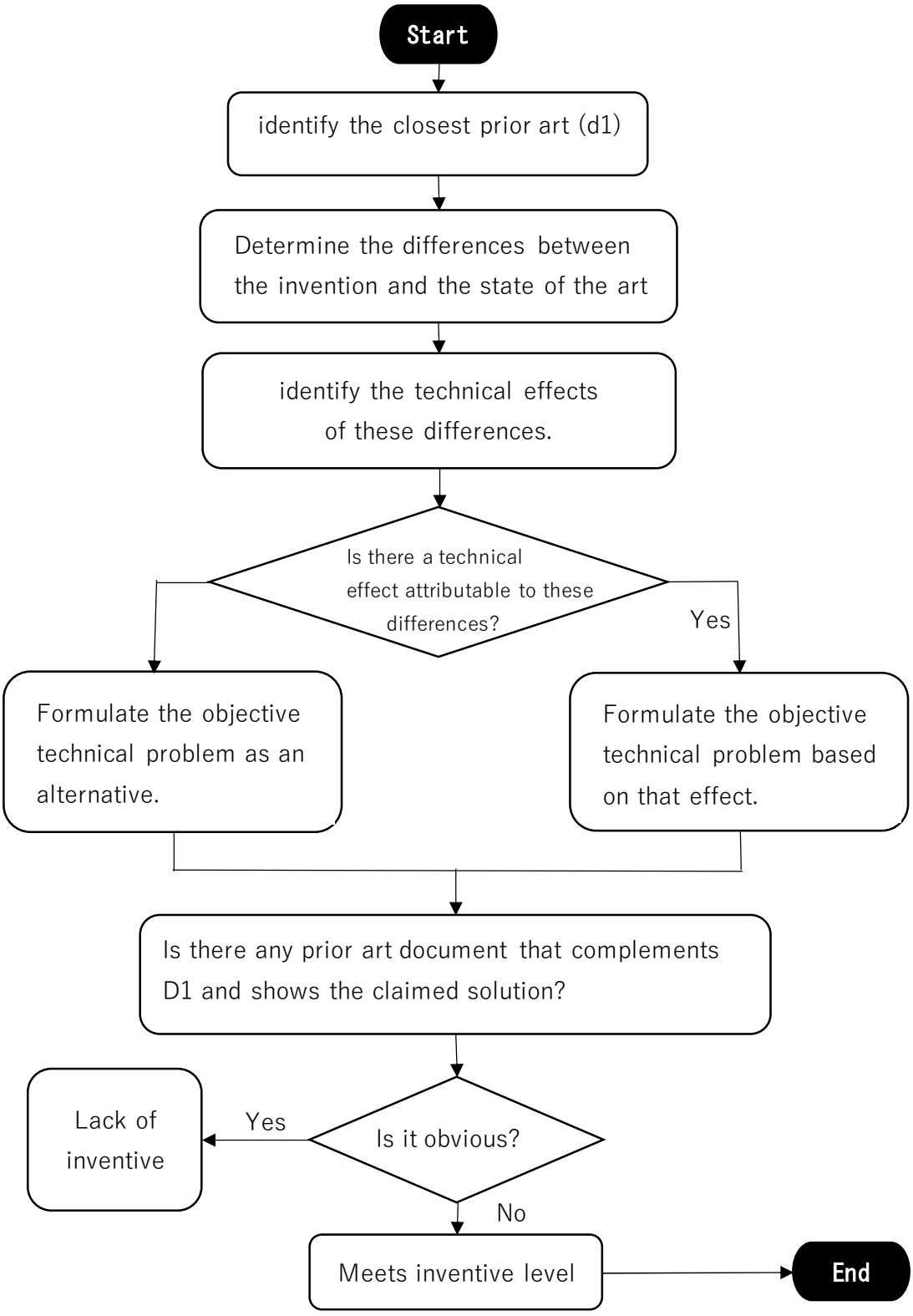
The claimed invention has to be considered as a whole. If it consists of a combination of elements, it is not valid to argue that each one separately is obvious, since the invention can be in the relationship (technical nature) between them. The exception to this rule is the case of juxtaposition in which the elements are combined without there being a technical

relationship between the different characteristics.

A novel composition of AB where A and B are known independently will be inventive if there is an unexpected effect. If the effect is reduced to the sum of the effects of A and B, there will be no inventive step.

Example – Problem-solution method, technical problem.
Gloves are claimed to have small flexible metal plates at the ends of the fingers. The purpose would be to enter data into a computer by touching the screen.
The closest state of the art (D1) describes the same gloves with rigid plates.
Another document cited in the search report describes similar gloves that are not identical, otherwise there would be nothing new with flexible metal plates, but to be used by surgeons when suturing vessels during surgical interventions. Since it is not assumed that the person of trade in the field of computers would have considered the document D2 which refers to a totally different technical problem and very far from the problem of the application the two documents D1 and D2 cannot be combined to arrive to the content of the invention. The claims therefore imply an inventive step.
In order for the existence of an inventive step to be denied, it is necessary not only that the combination of the teachings can be done, but also that there is such a suggestion or reason that leads the technician with average knowledge to combine the teachings of the documents. A suggestion may be explicit or implicit and may be in a single document or in the prior art as a whole.

11.4.2 Diagram of the "problem-solution" method



11.5 Inventive step of dependent claims

If an independent claim is new and inventive, so are its dependent claims. Likewise, if a product is new and inventive so will the process claims that necessarily lead to that product and the product claims.

11.6 Indications of the existence of an inventive step

In the practice of the substantive examination, a series of indications can be used to identify the existence of an inventive step, such as:

- Unsolved technical problem before invention
- If the claimed invention solves a technical problem that has been attempted to be solved for a long time, but was not achieved successfully, the invention has an inventive level because it represents a technological advance.
- Overcoming a technical prejudice (because the experts are very far from the solution): technical prejudice is the fact that specialists, in the corresponding technical field, think that there is only one way to solve the technical problem. If the invention is made to eliminate said prejudice, adopting technical means not previously used, it is an indication in favor of the existence of an inventive level.
- Simplicity: replacement of complicated machines or processes with simpler versions.
- Surprising technical effect.
- Overcoming difficulties not resolved by routine techniques.
- Need for more than two documents to examine inventive level.
- In a process: elimination of a stage considered necessary, without producing a harmful effect.
- Transfer of the way of doing things from a field of technology not related to the Invention.

11.7 Indications of lack of inventive step

They are indications of a lack of inventive level:

- Add known stages in known processes or placement of devices, functioning without alteration and without unexpected effects (juxtaposition).
- Simple and direct extrapolation of known facts.
- Change in size, shape or proportion, obtained through testing, but without unexpected effect.
- Exchange of material for another known analogue.

- Use of known technical equivalents and selection from a number of known possibilities without any unexpected effects, since the result obtained could be foreseen by the person normally versed in the matter.
- Known equivalents.
- The simple selection of equally probable alternatives.
- Simple replacement of one technical characteristic by another, which is obvious to the person normally versed in the matter. For example: replacing the material of an aluminum structure with another material that does not provide a significant advantage.
- Simple substitution of a compound, to form a new synergistic combination of two specific compounds, instead of a previously known synergistic combination of two categories of compounds.

This list is not exhaustive and should serve only as a guide, taking into account the circumstances of each case. If there are reasonable doubts about the presence of an inventive step in the invention in question, the corresponding objection must be formulated.

11.8 Document combination

Contrary to when analyzing novelty, when studying the inventive level, it is permitted to combine two or more documents or different embodiments or parts of the same document, but only if said combination would be obvious to the person versed in the corresponding technical subject.

In principle, it is considered that the combination of more than two documents (or the combination of different embodiment examples in a second document different from the one that constitutes our closest state of the art) is not obvious to a person versed in the corresponding technical subject matter, unless such a combination has been defined somewhere as possible. Therefore, as a general rule, no more than two or three documents will be used to attack the inventive level of the subject matter of a claim. An exception to this rule is that situation, as defined above, in which it is a juxtaposition of characteristics, each one producing its own effect and without any effect in the combination of these. In this case, it is allowed to combine the teachings of more than two documents, each of the documents being

relevant to each of the juxtaposed characteristics (or group of characteristics).

On the other hand, combining two or more parts of the same document would have been obvious if there had been a reasonable possibility that the person skilled in the art could have associated those parts with each other. It would also have been obvious for the person skilled in the art to combine an accredited manual or a classical dictionary with other documents of the state of the art; This is only a particular case of the general principle according to which it is evident to combine the instructions contained in one or more documents with the general knowledge current in the technical field considered. As a general rule, it would also have been obvious to the person skilled in the art to combine the contents of two documents of which one refers to the other in a clear and unambiguous manner.

In certain cases, the content of a single element of the prior art may determine the lack of an inventive step. For example, when a technical characteristic known in one technical field is applied to another field and that application would have been obvious to a person skilled in the art, or when the difference that exists between the content of the document and the claimed subject matter was sufficiently known so that documentary evidence is unnecessary. Also, the examiner can determine the lack of inventive step with a single document when the claimed subject matter deals with the use of a product described in the state of the art, that use would have been evident taking into account the known properties of the product or when the invention claimed differs from the existing technique simply due to the use of equivalents that are sufficiently known to make documentary evidence unnecessary.

It should be noted that the reasons that lead the applicant to an invention do not necessarily have to be the same as those that would have led, in the analysis carried out by the examiner, the expert in the field to make the modifications of the state of the art to obtain a result that affects the inventive level of the claimed object. Indeed, the inventor and the hypothetical expert in the field have not necessarily considered the same documentation.

On the other hand, it is necessary that there be a basis in the state of the art that suggests the combination, but said combination may not be suggested in order to obtain the same benefit or result as that identified by the applicant. Indeed, the state of the art may suggest the claimed invention, but for a different purpose or to solve another problem.

11.9 Supplementary information and comparative examples

When faced with an objection due to lack of inventive level, the applicant can provide evidence to support that level in the form of arguments or documents, for example, to demonstrate that there was a technical prejudice that led the person versed in the matter in the opposite direction to the invention, or, through especially comparative tests to demonstrate the presence of a technical effect or advantage of the invention, with respect to the closest state of the art.

However, the tests and data reported should not be included in the description and therefore, they will not be considered an extension of the subject. Furthermore, the results of these tests, through which the applicant intends to demonstrate the inventive level, must be related to the technical effect that had initially been mentioned in the description and not to a different one.

Example:

The state of the art describes the preparation of a compound under extreme conditions, the applicant may provide the result of a test that demonstrates that the process claimed can be prepared under less extreme conditions. So such a result is proof that a technical prejudice has been overcome and the claimed procedure is inventive.

Comparative tests may be required only if absolutely necessary.

Example:

In inventions in the pharmaceutical area, comparative trials could be requested if the claimed product and the state of the art are structurally very close and describe the same type of effect (for example, that both are analgesics) or a similar one (for example, that one is analgesic and the other is anesthetic).

11.10 Cases to illustrate aspects of the assessment of the inventive step

Below are several cases of inventive level assessment. However, the application of these depends on their viability under the local legislation of the CAN Member Countries.

11.10.1 Cases of claimed inventions that represent the application of known measures in an obvious manner and, therefore, without an inventive step

The content of a previous document is incomplete with respect to the claimed invention as a whole and at least one of the possible means to fill that gap could occur naturally or easily to the person skilled in the art, resulting in the claimed invention.

Example: The claimed invention refers to a building structure made of aluminum. A previous document exposes the same structure and states that it is made of light material, but without mentioning the use of aluminum. Aluminum is a light material whose use in construction is well known in the art.
The claimed invention differs from the state of the art simply in the use of well-known equivalents (mechanical, electrical or chemical) that have the same purpose, this equivalence being recognized in the state of the art.

Example: The claimed invention relates to a pump-motor combination which differs from a known pump- motor combination by the sole fact that the motor is hydraulic rather than an electric motor.
However, it may be that, although the applicant has acknowledged in the application that one element is equivalent to another element that had hitherto been used for a different purpose, this does not necessarily mean that it was obvious to use that element instead of the other.
The claimed invention simply consists of a new use of an already known material that employs the known properties of said material.

Example: A washing composition containing, as a detergent, a known compound, which has the known property of reducing the surface tension of water, when this property is known to be essential for detergents.

The claimed invention consists of the substitution, in a known device, of a newly developed material, the properties of which make it clearly suitable for that use (analogous substitution).

Example: An electrical cable comprises a polyethylene sheath glued to a metal shield by means of an adhesive. The claimed invention lies in the use of a specific, recently developed adhesive, which is known to be suitable for bonding between polymer and metal.
The claimed invention consists solely of the use of a known technique in a very similar situation (analogous use).

Example: The claimed invention consists of applying a pulse control technique to the electric motor that drives the auxiliary mechanisms of an industrial truck, for example, a forklift, the use of this technique for controlling the electric propulsion motor being already known of the wheelbarrow.

11.10.2 Cases of claimed inventions that represent the application of known measures in a non-obvious way and that, therefore, have an inventive level

A known procedure or means of work, when used for a different purpose that achieves a new and surprising effect.

Example: It is known that high frequency electric current can be used for inductive butt welding. It would therefore be evident that said high frequency energy could also be used in conductive butt welding with a similar effect; However, in this case an inventive step would exist if the high frequency energy were used for the continuous conductive butt welding of a rolled strip, but without removing the adhesions (such removal of adhesions being normally necessary in order to prevent them from forming arcs between the weld contact and the strip of material). The unexpected effect is that it is found that it is not necessary to remove these adhesions because, at high frequencies, the current is supplied in a basically capacitive manner, through the adhesions, which form a dielectric.

A new use of a known device or material represents the solution of technical difficulties that cannot be resolved by routine techniques, provided that the means used to overcome the

technical difficulties are defined in the claim.

Example: The claimed invention refers to a device to support and control the rise and fall of gas containers, allowing the external guide frame previously used to be dispensed with. A similar device was known for supporting floating docks or pontoons, but to apply the device to a gas container, practical difficulties had to be overcome that were not found in known applications.

11.10.3 Cases of obvious combination of characteristics that do not imply an inventive step

The claimed invention consists simply of the juxtaposition or association of known devices or processes that function normally and that produce obvious operational interrelationships.

Example: A sausage production machine consists of a known meat grinding machine and a known stuffing machine arranged one after the other.

11.10.4 Cases of non-obvious combination of characteristics that imply an inventive step

In a combination invention, the combined features support each other in their effects, to the point that a new technical result is obtained. In this case, the fact that each individual characteristic is fully or partially known by itself is irrelevant.

Example: A mixture of active ingredients consists of a combination of a compound to eliminate pain (analgesic) and a tranquilizing compound (sedative). It has been found that adding the tranquilizer, which by itself did not appear to have any analgesic effect, intensified the analgesic effect of the compound to eliminate pain in a way that could not have been predicted by the known properties of the active substances.

11.10.5 Cases of obvious selection or choice among a series of known possibilities that do not imply an inventive step

The claimed invention consists solely of choosing between a series of equally probable alternatives.

Example: The claimed invention relates to a known chemical process in which the electrical supply of heat to the reaction mixture is known. There are a series of alternative systems already known to supply heat and the claimed invention consists merely of the choice of an alternative.

The claimed invention consists of choosing specific dimensions, concentrations, temperature ranges or other parameters from a limited range of possibilities and it is evident that these useful parameters or ranges were covered by the state of the art and could be arrived at by routine trial and error. or by the application of normal design processes. When the general conditions of a claim are described in the state of the art, the discovery of the optimal or useful ranges by routine trials does not imply an inventive step.

Example: The claimed invention relates to a process for developing a known reaction and is characterized by a specified flow rate of an inert gas. The established flow rates are simply those that any expert in the field should necessarily obtain.

The claimed invention can be arrived at merely by a simple extrapolation, directly, from the state of the art.

Example: The claimed invention is characterized by the use of a specified minimum content of a substance of the already known technique, which relates thermal stability to the content of substance X.

The claimed invention consists simply of choosing a small number of chemical compounds (i.e., a subgenus or species) from a large field of chemical compounds (genus).

Example: The state of the art includes the disclosure of a chemical compound characterized by a generic formula that includes a substituent group designated as “R”. This substituent "R" is defined to encompass full ranges of broadly defined radical groups, such as all alkyl or aryl radicals, substituted or unsubstituted by halogen and/or hydroxy. Only a very small number of specific embodiments within the broadly defined radical groups are set forth in the state of the art. The claimed

invention consists of the selection of a specific radical or small group of radicals from which it is known that they are contained in the radical groups broadly defined in the state of the art as substituent "R". To the extent that the state of the art induces the selection of any well-known member of those generally defined groups of radicals, the person skilled in the art would be motivated to proceed with the modifications necessary to achieve the compound(s). claimed(s).

Furthermore, for the resulting compounds:
- they are not described or demonstrated to have any advantageous property that the prior art examples did not possess; or
- are described as having advantageous properties, compared to the compounds specifically cited in the prior art, but these properties are of the type that anyone skilled in the art would expect such compounds to possess, so it would most likely be felt driven to make this selection.

11.10.6 Cases of non-obvious selection or choice among a series of known possibilities that imply an inventive level

The claimed invention involves the special selection in a process of particular operating conditions (for example, temperature and pressure) within a known scale, said selection producing unexpected effects on the operation of the process or on the properties of the resulting product.

Example: In a process in which substance A and substance B are transformed at elevated temperature into substance C, it was known in the state of the art that, as the temperature increases on the scale between 50° and 130°C, there is generally an increasing yield of substance C. It has now been found that, in the previously unexplored temperature range of 63° to 65°C, the yield of substance C was noticeably higher than that previously reported.

The claimed invention consists of choosing specific chemical compounds (subgenus or species) from a wide field of compounds (genus), the chosen compounds presenting a technical advantage or unexpected effect.

Example: In the example of a substituted chemical compound cited in Section iv) of paragraph e) above, the claimed invention also resides in the selection of the substituent radical "R" from the total field of possibilities defined in the state of the art. In this case, however, the invention not only encompasses the selection of specific compounds from the possible generic field of compounds and results in compounds that are described and shown to possess advantageous properties, but there is no indication that would prompt a skilled person in the art to this particular selection, instead of any other, in order to achieve the advantageous properties described.

11.10.7 Cases of elimination of a technical prejudice

As a general rule, an inventive step exists if the state of the art takes a person skilled in the art far from the procedure proposed by the claimed invention. This applies, in particular, when it would not even occur to the person skilled in the art to conduct experiments to determine whether they are alternatives to the known means of eliminating a real or imagined technical obstacle.

Example: Once sterilized, beverages containing carbon dioxide are bottled in sterilized bottles while hot. The general opinion is that, immediately after the bottle is removed from the filling device, the bottled beverage should be automatically protected from outside air, in order to prevent the jetting of the bottled beverage. A procedure that included the same steps, but in which it would not be necessary to take precautions to protect the beverage from outside air (because, in fact, none are needed) could therefore represent an inventive step.

11.11 Inventive level in specific areas of technology

11.11.1 Chemistry

11.11.1.1 Inventive step for a chemical compound

It is rare for a compound to have an unexpected structure. When the structure of the new compound could not have been deduced by the average person skilled in the art, the examiner will not need to examine whether or not this compound has a surprising use or effect since the mere chemical structure of the new compound

already confers the inventive level.

On the other hand, it is more common for a chemical compound to present an unexpected effect, especially if the compound is similar to others in the state of the art. The unexpected effect may be completely different from those described for similar known compounds, or it may be the same, but with an improvement in the results.

There are two types of surprising effect:
completely different from the known uses or effects of compounds described in the state of the art; and
a substantial improvement of an effect of the same nature exhibited by a compound known from the closest state of the art.

Use or effect not previously described: a use or effect will be considered surprising when for the compounds described in the state of the art no use or effect has been described and this cannot be derived from general knowledge. (see examples 2 – 4 of Section 4 of Annex IV)

11.11.1.2 Markush Formula
It is necessary that all possible compounds of the Markush formula present an inventive step based on the same technical effect.

For example, the selection of a subgroup of compounds in a Markush formula that meet the novelty requirement has an inventive step if all the compounds in the subgroup present an effect or technical property not described in the prior art and that is also unexpected.
Therefore, if the examiner can demonstrate that this effect does not occur in a part of the claim (for example, due to the type of substituent that makes the compound insoluble or toxic, because the compound is unstable, etc.), then no There would be an inventive step in the entire set of compounds of the Markush formula and the applicant would have to restrict those compounds that do present activity. (see example 11 of Section 4 of Annex IV)

On the other hand, when the kit of parts claim includes a general

Markush type structure, an objection for lack of inventive step may be formulated, if according to the information in the description there are not sufficient reasons to infer that all the combinations included in the claim they will achieve the new and unexpected technical effect.

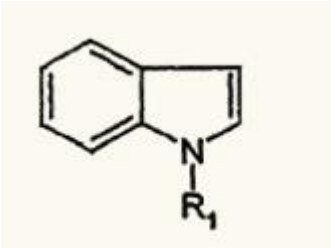
11.11.1.3 Selection inventions

The examination of a selection patent application is carried out in the conventional order. That is, novelty is examined first and then inventive level.

In the examination of this type of applications, it is important to consider that the selection of a subgroup of products, which is new, has an inventive level only if all the products of the subgroup present an effect or technical activity not described in the state of the art and furthermore, it is unexpected.

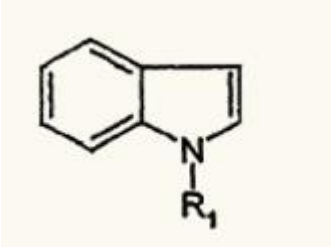
Example of selection inventions:

If the specific group of compounds claimed,



in which R 1 is C 3-5 alkyl:

A state-of-the-art document describes a large group of compounds with the general formula:



in which R1 is C1-20 alkyl.

If the specific group of compounds claimed, in which R1 is C3-5 alkyl:

- is not explicitly described in any background of the state of the art by its chemical name, nor by its chemical formula,
- is far from the examples of the state of the art (compounds in which R1 is C16-17 alkyl) and the ends (C1-20 alkyl), and

- exhibits an unexpected technical effect, not described in the state of the art.

In this case, the claimed reduced group is new (selection) and has an inventive step if the technical effect is surprising compared to the indications of the state of the art.

A selection is considered inventive only when the selected elements have a surprising technical effect, and is denied when there is no such advantage, but rather it is an activity common to the elements of the extended group.

In the following cases the selection is considered obvious and, consequently, not inventive:
- When the invention simply consists of choosing between a number of equally probable alternatives.
- When the invention lies in the choice of particular dimensions, temperature ranges or other parameters from a limited range of possibilities and it is clear that these parameters could have been arrived at by routine trial and error or by the application of testing processes common design, so that the results obtained are absolutely predictable.
- When the invention can be arrived at through a simple extrapolation directly from prior art.
- When the invention simply consists of selecting certain chemical compounds or compositions (including combinations) from a wide field. And the claimed compounds do not have advantageous properties compared to those of the State of the Art or those properties were to be expected by the person skilled in the art. Contrary to the previous cases, the selection is considered non-obvious and therefore inventive, when:
- The invention involves a special selection in a process of particular operating conditions (e.g., temperature and pressure) within a known range, but such selection produces unexpected effects on the operation of the process or on the properties of the resulting product.

11.11.1.4 Inventive level in claims of "intermediate compounds"

"Intermediate compounds" are those for which a direct activity cannot be used to establish the inventive level. They are used to

prepare products from them, which will be inventive, or they are intermediate products obtained in intermediate stages of an inventive process.

The criteria that are applied to examine the inventive level of an intermediate product is that it can be derived from the contribution of this intermediate to the inventive process.

In the event that the intermediate product serves to produce the inventive final product, the intermediate must be responsible for providing the final product with the structural part that gives it the surprising properties and that therefore confers an inventive level to the final product. Therefore, the examination of the degree of structural contribution due to the intermediate product will be key to deciding whether this contribution confers at least one of these characteristics that will distinguish the final product from those described in the state of the art.

Example – Inventive step of chemical compounds:
A sulfonylurea is claimed as an antidiabetic (H2N-C6H4-SO2-NHCONHF). In the state of the art, it is known that the sulfonamide of formula H2N-C6H4-SO2NHR1 has antibiotic properties.

In this case, although the sulfonamide and the sulfonylurea have very similar chemical structures, the claimed physiological activity of the sulfonylurea compound (antidiabetic) is very different and cannot be extrapolated from the known activity (antibiotic). The sulfonylurea of the application would therefore be inventive.

If in the description of the prior art there was an indication that the sulfonamide or structurally related compounds also present antidiabetic or similar effects, then it would be necessary to analyze whether the indication is sufficient for the claimed invention to be obvious to the person skilled in the art. If the answer were affirmative, the sulfonylurea claimed would not have an inventive step.

If the indication of the prior art description were not so clear, the applicant could be invited to provide additional comparative

tests to demonstrate the inventive scope of the invention.

11.11.1.5 Polymorph

As mentioned in Section 7.6.1 of this Chapter, countries are responsible for technically and scientifically determining the patentability requirements for polymorph. Therefore, it is suggested that, to evaluate the inventive level of polymorph, the Examiner applies the problem-solution method as follows:

Applying the problem – solution method

Step 1: Identify the closest prior art.

The closest state of the art will be that document that:

- Disclose other polymorphic forms of the same compound (that is, that have the same chemical structure of the polymorph); or
- Disclose the same compound, although it does not define a particular polymorph or disclose its amorphous form; or
- Disclose the greatest number of structural characteristics of the compound (organic or inorganic molecules that form addition salts, or solvent molecules that form solvates) present in the claimed polymorph.

In general, the closest state of the art will be that document that discloses a compound (crystalline or amorphous) with the greatest number of technical characteristics in common with the claimed polymorph and whose technical purpose is the same or similar to that of said polymorph.

Step 2: Determine the difference between the invention and the closest prior art.

Determine the differences between the structures and the technical effects that result from the differences between the claimed polymorph and the forms revealed in the closest state of the art.

The distinctive technical feature lies in the crystalline nature of the claimed polymorph (physical property).

Step 3: Define the technical effect caused and attributable to the differential element.

The identification of the technical effects resulting from the differences between the compared forms must be carried out from

what is revealed in the description or, at least, be derivable from it. In that sense, the result of the comparison may be related to a different property. If the background information studied does not in itself reveal the technical effects that are the subject of the comparison, the examiner will verify whether the description discloses these effects.

If these differences are not disclosed, it will be established that the inventive step cannot be recognized.

Step 4: Determine the target technical problem to solve.
The technical problem to be solved must be posed based on the closest state of the art and considering the technical effect produced by the technical characteristic that differentiates the claimed polymorph from the closest state of the art.
Most of the problems to be solved by polymorphs are related to properties such as hygroscopicity, solubility, dissolution rate, bioavailability, stability, fluidity of solid particles or compressibility, among others.

If the technical problem to be solved is to provide an alternative solid form of a known compound, it is suggested that the new polymorph be considered obvious since in the pharmaceutical field it is routine to obtain polymorphs of already known compounds.

Step 5: Determine whether the proposed solution is inventive or not obvious or evident.
This task is part of the usual practice of the examiner who, in general terms, must evaluate whether the claimed polymorph would be obvious, starting from the closest state of the art and the objective technical problem, considering the state of the art as a whole in order to to determine if there is any document containing indications that would motivate modifying the closest state of the art to resolve the technical problem by providing the claimed polymorph. In any case, general knowledge related to the phenomenon of polymorph must also be considered, for the purposes of determining whether or not the proposed solution is obvious (see Section 10.6 of Chapter III).

If the claimed Polymorph has an unexpected effect on the form of

the closest prior art, it will be recognized as inventive.

Similarly, it must be evaluated whether the process of obtaining the polymorph involved an inventive step. So, if the technical effect of the polymorph is unexpected, the process will be considered inventive.

Suggestion of indications of lack of inventive level:

- Justify advantages suitable for commercial use of the polymorph of a compound based solely on improved purity levels, or a higher melting point.
- Justify improved bioavailability based solely on improved solubility data. The improved bioavailability does not depend only on solubility, which is why it should also be justified by pharmacokinetic parameters (AUC, tmax, Cmax or t1/2, among others) and optionally, also by the dissolution profile.
- Justify improved stability based solely on improved hygroscopicity data or at a higher melting point. The improved stability must be further justified by storage stability data under different temperature and relative humidity conditions.
- Obtaining a polymorph by spontaneous interconversion from another crystalline form. The conditions for spontaneous interconversion are not a product of the inventive level, but rather occur naturally.
- Obtaining a single crystalline form using several crystallization processes that use various solvent systems. It is not inventive due to the high probability of obtaining the claimed form.
- Justify improvement in the solubility of a crystalline form obtained by crushing or grinding another crystalline form of the same compound.
- If the structure of the claimed polymorph is predictable through computational models.
- When the state of the art has motivated the search for polymorphs with particular properties that are common to crystalline forms (such as ease of filtration or drying properties).

11.11.2 Biotechnology

11.11.2.1 Microorganisms

Example – Inventive step of modified microorganisms:
A modified microorganism was claimed. The claim reads as follows: "Streptomyces P. NRRL 123456."
The application describes that this modified microorganism is capable of producing substance X.
The inventive step cannot automatically be granted to the modified microorganism per se without considering the state of the art related to substance in the application.
If compound X exhibits surprising effects or advantages over similar compounds in the state of the art, or compound X is structurally very different from any of the known compounds that exhibit the same technical effect, such that these properties could not have been predicted, in this case the modified microorganism would be considered to have an inventive step.

Some examples of the inventive step analysis in these fields are found in examples 8 to 11 of Section 4 of Annex IV.

11.11.3 Mechanical and electrical

Below is an example of the application of an inventive level in the mechanical area:

Example:
The invention relates to a dining table. In the specification, the applicant describes a problem inherent to all four-legged tables, namely that the table rocks on uneven surfaces. The problem is described like this:
"The purpose of the invention is to provide a three-legged dining table that can be placed on an uneven surface without rocking."

The independent claim is formulated as follows: "Dining table whose top table (part) is supported by only three legs and its center of gravity is located between said three legs."

Two documents have been cited in the search result:
D1: normal four-legged dining table. It doesn't mention the sway issue.
D2: three-foot stool used by milkers in the field or in the

stable.

It also does not mention the problem of rocking, as long as it provides an ergonomic seat.

It can be assumed that the person of trade in the field of furniture would take both documents into consideration. Furthermore, after having made the D1 table, you would notice that it sways when used in the garden. The person in the trade already knows of course that in a stable or in the field there are always uneven surfaces.

Analysis of differences with respect to the state of the art

Features	D1	D2
- Dining table	Yes	NO
- Upper table	Yes	NO
- Only three legs	NO	Yes
- Center of gravity between the legs	Yes	Yes
- Stable on rough surfaces	NO	Yes

The closest state-of-the-art is the D1 dining table, because it serves the same purposes as the application.
The application differs from D1 only by: three legs instead of four.
The technical effect achieved by this difference is that the dining table can be placed on uneven surfaces without rocking.
The objective technical problem solved by the request could therefore be formulated as: “How to prevent the rocking of a dining table on uneven surfaces” (note that this formulation does not contain elements of the solution).
It is known that document D2 describes a way to solve the technical problem: as already said above, in a stable or in the field there are always uneven surfaces; Furthermore, the two solutions proposed by the request and D2 are the same.

Therefore, the request as claimed will be considered obvious, because the person in the trade who has to solve the problem and knows the state of the art would make the combination of the proposed solution for the stool with the D1 table (state of the art closest technique), thus arriving at the content of claim 1.

Some examples of the inventive level analysis in these areas are found in examples 1, 5 and 6 of Section 4 of Annex IV.

11.11.4 Inventions implemented by computer (inventive level)

The analysis of novelty for CIIs is subject to the steps to examine this type of inventions, which are listed in Section 7.7.2.2.

In this way, particularly for CIIs, the inventive level analysis is carried out using the problem-solution method, where if the differences with the closest previous technique do not contribute to the technical character, the inventive level is objected, but if the differences include features that contribute to the technical character, the following applies:

- The objective technical problem is formulated on the basis of the technical effects achieved by these features. Furthermore, if the differences include features that do not contribute to technical character, these features, or any non-technical effects achieved by the invention, may be used in the formulation of the objective technical problem as part of what is given to the expert, in particular as a restriction that must be met.
- If the claimed technical solution to the objective technical problem is obvious to the person skilled in the art, inventive level is objected.

11.11.5 Nanotechnology (inventive level)

In addition to demonstrating novelty, a nanotechnology patent application must pass the inventive step test. Generally, an invention will be considered obvious if it miniaturizes known elements, fulfills the same function and does not provide more than what would be expected from the reduction in size. A technology is considered non-obvious when it produces new and unexpected results or fulfills previously unrecognized functions that solve a technical problem related to the prior art. As practically all nanoscale technologies have these characteristics, only those results that are not likely to arise from extrapolations carried out by an expert working with smaller structures are considered patentable (see example 7 of Section 4 of Annex IV).

11.12 Suggested wording of technical report (inventive level)

The present application does not comply with the requirement of Article 18 of Decision 486 because the content of the claims does not imply an inventive step.

Document D1, which is considered the closest state of the art, describes (see page ____ lines ____ a (device, system, composition, etc.) that differs from the content of the claim(s) ____only in what ____

It can therefore be considered that the objective technical problem that is attempted to be solved in this application would be ____.

In the state of the art, there is a document D2 that complements document D1. Therefore, the solution proposed in the claims does not imply an inventive step for the following reasons:

Alternative 1

The feature(s) described in document D2 provides the same benefit as the application. It would therefore be obvious for the person skilled in the art to consider the possibility of including that characteristic(s) in the (device, system, composition, etc.) described in document D1 to solve the problem posed.

Alternative 2

Characteristic(s) Its inclusion in the (device, system, composition, etc.) described in document D1 would therefore be an obvious possibility for the person in the trade who would like to solve the problem posed.

Alternative 3

From the document, feature(s) X, Y, Z is/are simply one of several possibilities from which the person skilled in the art would choose under the circumstances, without using any inventive effort.

Alternative 4

It is, however, widely known to the person skilled in the art that characteristic X is equivalent to characteristic Y of document D2 and that the two characteristics can be interchanged

when circumstances require it.

Alternative 5
However, this feature(s) has already been used for the same purpose in a similar (device, system, composition, etc.) (see document D2 pages ____, lines ____). It would be obvious for the average technician in the field when he/she wanted to reach the same result to use this characteristic(s) with effects corresponding to a(n) (device, system, composition, etc.) according to document D1 and therefore both obtain a (device, system, composition, etc.) according to claim ____. Therefore, the content of the ____ claim does not seem to imply that it has an inventive step (Article 18).

12. INDUSTRIAL APPLICATION

The industrial application requirement finds its basis in Article 19 of Decision 486.

The means proposed by the inventor must be capable of providing, with greater or lesser perfection, the intended industrial result. The examiner will verify the requirement that the invention be susceptible to industrial application, taking as a basis for its determination the date of filing of the patent application.

When evaluating the industrial application of the invention, it will be sufficient for the examiner to observe whether or not it is susceptible to industrial application, so it will not be required that the invention whose patent is requested be applied industrially.

Example 1 of industrial application:
A chemical product of which the formula is known but the way of manufacturing it is not known at the date of filing the patent application cannot be considered susceptible to industrial application.

Example 2 of industrial application:
In the case of claims relating to contraceptive methods, some alternative claims may be of the following type:

1. A compound
2. Contraceptive method that includes administering compound
3. A contraceptive composition comprising compound
4. A contraceptive patch comprising compound

Contraceptive methods are not considered therapeutic treatment methods since pregnancy is not a disease. However, contraceptive methods in humans are not considered industrially applicable because they refer to the person's intimate sphere. Therefore, claim 2 (above) would not therefore be patentable.
Type claims 1, 3 and 4 would be patentable if compound X is new and has an inventive step.

An exception would be a claim that refers only to a contraceptive method for animals for agricultural purposes, this is considered industrially applicable. (More on contraception methods see Section 7.3.4.4 of Chapter III)

12.1 Suggested wording of technical report (industrial application)

Model 1.
The claim(s) refers to (a method for treating, for example, scabies, which turns out to be a method of therapeutic treatment of the human or animal body, software, mathematical formulas, etc.) not capable of application industrial.
This content is expressly excluded from patentability under the Articles
The above claim(s) should be properly rephrased (e.g. in terms of a device, etc.) or withdrawn.
Even if the claim(s) were correctly restated, the objections listed below regarding the patentability of the entire claims would apply.

Model 2.
The claim(s)…refers to
X*…, which is contrary to the principles of physics and therefore not susceptible to industrial application (Art…).
The above claim(s) should be properly rephrased (e.g. in terms of a device, etc.) upon withdrawal.

Even if the claim(s) were correctly restated, the objections listed below regarding the patentability of the entire claims would apply.

*In this case, X could be, for example, a method to carry out the "mobile continuum", or something similar.

13. MODIFICATIONS

"**Article 34.-** The applicant for a patent may request that his application be amended at any time during the processing thereof. The amendment may not involve any broadening of the protection that would have been accorded to the disclosure contained in the initial application. The correction of any clerical error may be requested in the same way. "

The applicant may make modifications or complement their application as long as they do not imply an extension of protection in accordance with the matter initially contained. If the modifications do not comply with this condition, they will not be accepted.

13.1 Acceptable modifications

Modifications will be accepted (in the description, claims or drawings), as long as they comply with the requirements stipulated in Article 34 of Decision 486 and do not expand the object of the protection initially stated.

If it is a new claim chapter, it must comply with the requirement of unity of invention (Article 25 of Decision 486), that is, include a single inventive concept. In some cases, these modifications involve performing a new search.

When a new claim chapter is received, it must be analyzed whether it is clear and precise enough and whether it is related to the description. In some cases, it may happen that within the description certain characteristics are indicated as essential for the invention and within the claim chapter there is no reference to said characteristic. This tells us that the claims are not clear.

In the case of a chemical compound, modifications where the meaning of the substituents or the meaning of the radicals are being varied will not be admitted. For example, if in the initial claims R1 corresponds to a C1-C6 alkyl and in the modifications R1 is defined as an alkyl. Although the initial claims also deal with an alkyl, the modifications are expanding the protection, in this case this modification cannot be accepted. To accept modifications, it is important to carefully analyze when the variation that has been made is in the terminology since this can lead to the protected matter being expanded from specific to very general terms. If there is adequate support when moving from specific to general terms, this will be admissible.

Example of acceptable modifications:
This is the case when the initial object is a transmission device and the modification corresponds to a signal processor, the latter being a very general term since it does not only include transmission devices but also reception, transformation, selection, etc.
Modifications may be accepted when at the beginning it is an exception to patentability such as a therapeutic method using a compound special care when analyzing patentability requirements.

13.2 Special requests
These are requests with special characteristics, such as the ones we analyze below:

13.2.1 Fractional or divisional applications (Article 36 of Decision 486)
Patent applications can be divided into two or more fractional applications, but these may not imply an extension of protection that corresponds to the disclosure of the initial application.

The division can be made at the request of the applicant at any time during the process, before the issuance of an administrative resolution in the first instance.

The office may require the applicant to divide its application if it does not meet the unity of invention requirement, as mentioned in Section 9.6 of Chapter III.

Each fractional application benefits from the filing date and, where applicable, the priority date of the initial application.

Each of the fractional applications must contain the documents required to be a patent application.

If multiple priority has been claimed, the applicant must indicate which corresponds to each of the fractional applications.

13.2.2 Modality conversion (Article 35 of Decision 486)

An application for a patent for an invention can be converted into a utility model patent or an industrial design as long as the nature of the invention allows it.
Procedures, processes, methods, substances or compositions nor the subject matter excluded from protection by the invention patent may not be the object of a utility model (Article 82 of Decision 486).

Modality changes can be made at the request of the applicant at any time during the process.

The converted application maintains the filing date of the initial application.

When the conversion is suggested by the office, the applicant may accept or reject said suggestion; If it is not accepted, the procedure will be followed in the original modality.

In this case, the office will check that the applicant has properly submitted the conversion, and that the corresponding fee has been paid in accordance with the rate in effect at the time of making the conversion.

13.2.3 Request Merger

The applicant may, at any time during the process, merge two or more applications as long as it does not imply an extension of protection. In order to merge two or more applications, it is necessary that the resulting merger meets the unity of invention requirement (Article 25 of Decision 486). The merged application benefits from the filing date and the priority date or dates that

correspond to the subject matter contained in the initial applications.

In this case, the office will check that the applicant has properly submitted the merger of applications, and that the corresponding fee has been paid in accordance with the rate in effect at the time of the merger.

13.2.4 Requests related to biological material

When an application involves a microorganism or a process involving a biological material that is not available to the public and cannot be described in a patent application in such a way as to allow a person skilled in the art to execute that invention, you must declare that you have deposited the material in a recognized institution. You must provide the name and address of the deposit institution, date of deposit and the deposit number assigned by such institution (see Section 3.1.2.6 of Chapter III referring to sufficiency and Section 7.5.1 referring to microorganisms).

13.2.5 Requests related to nucleotide or amino acid sequences

If the application refers to nucleotide or amino acid sequences, the description must contain a sequence listing, which must be presented separately from the description and bear the title "Sequence listing." Each disclosed sequence will be assigned an identification number described as SEQ ID NO. The number of sequences must be indicated in the sequence listing.

In the description and claims, sequences presented in the sequence listing will be indicated by their identification number, even if the sequence or other additional or modified representations of the sequences are included in the text or drawings accompanying the description.

The sequences will be represented by a nucleotide sequence, an amino acid sequence or a nucleotide sequence together with its corresponding amino acid sequence.

The amino acids in a protein or peptide sequence must be listed in the amino-carboxy direction from left to right and the amino and carboxy groups must not be represented in the sequence.

13.3 Result of the analysis of the modifications

If a modification is accepted, the following processes will be

made based on the modified description, claims or drawings. An accepted modification does not mean that the application cannot be objected again in accordance with Decision 486. If the modifications are not accepted, the reasons for this are communicated to the applicant and based on what background the following studies will be carried out, in accordance with the provisions of Article 45.

14. PATENTABILITY EXAMINATION PROCEDURE

14.1 Generalities

The background examiner will take the following steps:
study the description, claims and drawings (if any) or modifications to them initially sent by the applicant; and
If, after the study, the substantive examiner finds that the established requirements of sufficiency, clarity, conciseness, support, unity of invention, exceptions to patentability are not met, or the patentability requirements are not met, it will be communicated to the applicant, who may modify or complement your request within the corresponding legal period (Article 45).

The substantive examiner must indicate for each objection, the part of the application that is deficient, the legal requirement that it does not satisfy, and the reasons supporting the objection. For example, when determining the state of the art, some claims are affected in their novelty, inventive level or industrial application, while others have no unity of invention. The examiner must be clear in indicating which claims are affected by novelty, inventive level, industrial application and unit of invention, justifying each case.

These deficiencies are made known to the applicant through a communication, indicating the time they have to comply with this requirement (Article 45).

14.2 Strategy

A. Analysis of the claims

The examiner must begin the analysis of the application with the claims to determine whether they are completely identifying the invention, according to the following steps:
1. verify the clarity, conciseness and support of the claims;

2. identify the categories of claims;
3. identify independent claims;
4. identify dependent claims;
5. identify whether all matter contained within the claims can be considered an invention in accordance with Article 15;
6. identify within the claims the non-patentable inventions in accordance with Articles 20 and 21 of Decision 486;
7. determine the clarity, content and scope of the claims; and
8. determine the unit of invention.

B. Analysis of the description

The examiner must:

1. verify that the description contains the information in accordance with the provisions of Article 28 of Decision 486;
2. verify that the units are in the international system of units;
3. verify that the description of the drawings is directly related to the description;
4. verify that recognized technical terms are used in the corresponding technical field. If they are little recognized terms, they must be defined correctly;
5. identify the technical characteristics of the invention;
6. verify that the claimed subject matter is found in the description;
7. When it comes to applications from the biotechnology area that refer to nucleotide or amino acid sequences, verify that the application contains a list of these, which must be presented separately from the description and bear the title "List of sequences";
8. verify if there are indications that suggest that the invention is related to genetic resources or traditional knowledge and if it complies with the provisions of Article 26 of Decision 486; and
9. In the case of biological material, verify if a deposit certificate is necessary to support its description.

C. Analysis of the drawings (see Section 5 of Chapter III)

D. Presentation of oppositions by third parties

Analyze the arguments and evidence presented by the opponent and verify the validity of the impact on the novelty requirement in

terms of the technical part, taking into account that any evidence must be prior to the date of presentation of the application under study or the claimed priority. .

E. Determination of the state of the art

Once the analysis of the claims, description and drawings has been carried out and the subject matter of the invention has been understood, the examiner begins to determine the state of the art. If the subject matter of the invention has not been understood, the examiner must refer to the point relating to notification. (see Section 8.9 of Chapter III)

F. Evaluation of novelty

To determine whether an invention is novel or not, having already determined the state of the art, the following steps must be followed:

1. compare element by element between what is in the state of the art and the proposed solution which must be done first by comparing the independent claim with the entire content of each publication or other disclosure, taken in isolation.
2. compare whether the claimed invention is identical to what is disclosed in the state of the art. If the matter alone contains all the characteristics of the analyzed claim, it is considered to be nothing new.
3. Check if there are other independent claims under the same previous analysis and review the dependent claims to examine if there are new elements.
4. consider within the state of the art, the content of a patent application pending before the national office whose filing or priority date is prior to the filing or priority date of the application being studied, provided that said content is included in the request of a previous date when it is published or the period provided for in Article 40 of Decision 486 has elapsed.

G. Evaluation of the inventive level

The examiner must follow the steps below:

define the closest state of the art. Said determination will be made based on antecedents that solve the same problem and, failing that, on the antecedents that share the greatest number

of technical characteristics;
identify the different characteristics with respect to the closest state of the art;

evaluate whether the existence of the differential technical characteristic to solve the problem is evident or not to an expert in the field; and

evaluate if there is an indication in another document that suggests to the average technician in the field the possibility of combining the teaching of the closest document with the second, to arrive at the proposed solution.

H. Evaluation of industrial application (see Section 12 of Chapter III)

15. Preparation of the Examination Report

Once the substantive examination of the application has been carried out, the examiner will prepare the technical report(s) (Article 48 of Decision 486).

15.1 Technical reports

If the examiner finds that the application is not patentable or does not comply with the requirements established in the Decision after analyzing the description, claims or drawings, if any, he will notify the applicant so that he can correct or present his arguments if applicable.

The report must contain:

1. name of the applicant or representative;
2. application number and, if applicable, procedure number, event, action, official letter and file number:
3. motivation of the technical-legal concept, which must contain at least the following aspects:
   - indication of the parts of the file on which the examination was based, indicating the pages in which they are found;
   - object of the invention;
   - exceptions to patentability;
   - claims of use;
   - clarity of the invention;

- evaluation of the invention
- indication of whether it is an invention (exclusions)
- unit of invention;
- determination of the state of the art;
- evaluation of compliance with patentability requirements (novelty, inventive level and industrial application); and

- indication of the legal basis, citing the reference source and regulatory basis.
- It should be clarified that, with regard to the number of technical reports issued during the substantive examination of an application, Decision 486 does not establish a minimum or maximum number. However, each office has an established practice of issuing two or three maximum reports before the final resolution.

15.2 Final resolution

In accordance with article 48 of Decision 486, after completing the stages indicated in Article 45 of Decision 486, the final resolution that grants in whole or in part or denies the patent is prepared, in accordance with the content and formalities of the Member Countries.

CHAPTER IV UTILITY MODELS

1. FUNDAMENTALS OF THE UTILITY MODEL FIGURE

The figure of protection of the utility model is mentioned for the first time in an international instrument in the Paris Convention for the Protection of Industrial Property of 1883. This figure was initially developed in Germany in 1891, where there was interest in establishing a mechanism of protection for those inventions of a mechanical nature and of a practical and more common level of technological development, for which it was desired to provide a protection title without initially going through the necessary procedure to obtain a patent for an invention. Under this system, the utility model was subject to substantive examination after its grant to determine whether it met the conditions of patentability, particularly those of novelty and inventive step. If the invention protected by a utility model did not meet these conditions, the title could be canceled or revoked. Until the substantive examination of the utility model was carried out (including verification of novelty and inventive step), the utility model did not allow infringement action against third parties. This exam was carried out upon express request.

Since the German initiative, the international implementation of this protection figure has been constant. Currently, there are a large number of countries that have the utility model or an alternative title to the invention patent in their industrial property regulations. Andean community legislation includes this figure for the first time in Decision 311 of 1991. This figure has been maintained since then in the common industrial property regime, in Decisions 313, 344 and currently in Decision 486.

The importance of the utility model being regulated by a community standard lies in the homogeneity it provides to coordinate the various protection mechanisms for minor inventions within the Andean Community, especially due to the economic interest behind the protection mechanisms for inventions, since the utility model allows access to exclusive protection, (but in a faster and less expensive way), for those who develop creations conditioned by various factors such as: infrastructure, short cycles of relevance of their products, etc., thus promoting

research and development.

2. DEFINITION OF THE UTILITY MODEL PATENT

In general terms and collecting the doctrinal, legal and jurisprudential concepts expressed in this matter, the utility model can be defined as a minor invention or industrial creation with less inventive demand.

Pursuant to Article 81 of Decision 486, the utility model patent is granted for an artifact, tool, instrument, mechanism or other object or some part thereof, which has a new shape, configuration or arrangement of elements, thanks to which it is possible that its operation, use or manufacture is better or different and that, in addition, provides some utility, advantage or technical effect that it did not have before.

To better understand the concept of utility model, the following characteristics can be noted:

- It is manifested through an external configuration, internal structure, incorporation or new arrangement of elements.
- This new configuration or incorporation of elements must improve the usefulness, provide a technical effect or practical advantage that it did not have before.
- The utility must occur in its use or manufacture, that is, both the average products for production and the final products will be protectable as utility models.

Some examples of utility models would be:

Examples of patents for utility models in the field of mechanics:

1. A clamp to which a small flashlight has been incorporated that provides a technical advantage over the original clamp without a light accessory.
2. A napkin dispenser that incorporates a flexible arm and an adhesive on the tip, providing a technical advantage that makes it easier to use.

Examples of patents for utility models in the field of electronics:

Intelligent screen for communication with citizens through software embedded in this screen that incorporates a series of

side speakers with a number of additional LED screens, which provides the advantage of allowing the location of the electronic screen on any pole or wall and providing audio and visual alerts when dangerous or threatening situations requiring assistance occur.

In conclusion, the utility model constitutes a category of industrial property similar to the invention patent, whose inventive requirement, scientific value and technological advance is lower, because it is rather a technical improvement that translates into a practical improvement or advantage in its use or manufacture and/or a beneficial effect in terms of the object's ability to satisfy a human need.

3. MATTER NOT PROTECTABLE UNDER THE UTILITY MODEL

In a similar way to invention patents, for utility model patents there are also some legal exceptions and exclusions that prevent the protection of some subjects. In this regard, Article 82 of Decision 486 establishes that processes cannot be patented as utility models, nor can materials be patented excluded from protection as invention patents. In accordance with the above, the rules related to obtaining a product through patented processes cannot be applied to the utility model, since the processes are not susceptible to protection through the utility model patent.

Likewise, Article 82 of Decision 486 states that the following will not be considered utility models: sculptures, works of architecture, paintings, engravings, prints or any other object of a purely aesthetic nature.

Likewise, given the definition of utility model, it is considered that the following are not patentable through this category of industrial property: devices characterized essentially by their color or by the material in which they were made, systems that are made up of different devices that do not make up a single device or equipment, such as telecommunications systems, devices characterized solely by their programming or configuration of instructions readable by processing means.

4. DURATION OF PROTECTION

In accordance with the provisions of Article 81 of Decision 486, utility models will be protected by patents. However, the established term is not the same as for invention patents of 20 years, but for the utility model it is 10 years from the date of application in the respective Member Country, in accordance with Article 84 of Decision 486. In the case of applications via PCT, the validity will be counted from the date of presentation of the international application.

5. REGIME APPLICABLE TO UTILITY MODEL PATENTS

The closeness between the figures of utility model and invention patent means that the regulations of the latter are applicable to the former in everything that is relevant to it. This is what Article 85 of Decision 486 provides:

"**Article 85.- The provisions of this Decision on patents for invention shall be applicable to utility model patents** where appropriate, with the exception of the provisions on processing times, which shall be reduced by half. Without prejudice to the foregoing, the period laid down in Article 40 shall be reduced to 12 months." [emphasis added]

In this way, the invention patent regime is generally applicable to utility model patents, except in what is incompatible with this figure, which will be up to interpretation.

6. UTILITY MODEL REQUIREMENTS

6.1 New utility models

Within the framework of the Andean Community, a utility model will be patentable when it is not within the "state of the art." The state of the art determines or not the novelty of an invention and is defined in the second Section of Article 16 of Decision 486.

"**Article 16.-** The state of the art comprises everything that has been made available to the public by written or oral description, by use or marketing or by any other means prior to the filing date of the patent application or, where appropriate, the recognized priority date."

In this regard, for the Andean legal system, the opinion of the Court is absolute or universal, that is, it includes the state of the art worldwide.

There is no difference between the novelty study carried out for an invention patent application and a utility model patent application. However, although both are aimed at solving a technical problem, the invention patent is based on an object that had not existed before; On the other hand, in utility model patents, novelty is an innovation to a known product that causes an advantage or benefit to be added to it that makes it more efficient or productive. In this way, the object of the invention is compared with the existing object and it is determined which instrument, mechanism, tool or object has been added to the original object, providing it with a new shape or configuration, improving its industrial application and furthermore, said improvement is not included within the state of the art.

It should be noted that any technical solution is necessarily based on the prior art. Both ordinary inventions and utility models start from something pre-existing, although the distance may be greater or lesser. When the distance is very great, we speak of “pioneering” inventions, which are statistically very rare. The vast majority of technical solutions (inventions and other figures) consist of incremental improvements on the state of the art. These improvements, although they differ slightly from the state of the prior art, must meet the inventive level requirement, that is, they must not be obvious or evident to the person versed in the technical matter. Otherwise, monopolies would be granted that would unduly affect competitors, the public and the country's economy.

Now, within the context of utility model patents, it is important to note that the word “configuration” refers to the configuration of physical elements that constitute the claimed device or object and cannot be interpreted as a new configuration of readable instructions. by processing means.

6.2 Other utility model requirements

There are other requirements during the substantive examination of a utility model patent. In this regard, each Member Country

has defined its practice based on its local legislation and interpretation of the standards.

For example, the requirement of susceptibility to industrial application is common to patents for inventions and utility models. For utility model patents it essentially means that the object has to be capable of mass reproduction and being used in practice. There are various reasons to justify the need for industrial application to obtain a utility model patent, despite not expressly appearing in the corresponding Title III of 486, leaving aside the very foundation of patent law as an instrument for driving technical-industrial progress as a more general reason. Article 19 of Decision 486, when defining what is meant by susceptibility of industrial application, refers to the possibility of being "produced or used in any type of industry, industry being understood as referring to any productive activity, including services." In both cases, the use or manufacture of the object of the invention is required. Even in utility model patents this is not a merely potential requirement, but there does not seem to be any other way to verify the protected advantage other than by using or developing the object on which the invention relates.

7. MODALITY CONVERSION

(Article 83 of Decision 486)

The intermediate location of the utility model figure between the invention patent and the industrial design imposes the need to facilitate their reciprocal conversion in order to solve errors in the requested form of protection. In accordance with Article 83 of Decision 486, the applicant for a utility model patent may request that his or her application be converted into an application for a patent for invention or for registration of an industrial design, provided that the subject matter of the initial application allows it.

For the purposes of the latter, the requirements established in Article 35 of Decision 486 must be met.

Now, the aforementioned Article 35, which establishes the conversion of patents, indicates that it may be requested, at any time during the process, and only once, that an application for

an invention patent be converted into an application for a utility model patent. In this sense, the conversion of the application will only proceed when the nature of the invention allows it, as discussed in Section 13.2.2 of Chapter III.

The conversion occurs at the request of the applicant, with the competent national office limiting itself to formulating the objection linked to the origin of the figure originally pursued. The conversion is not conditional on the origin of the new figure, since this verification takes place with its new substantive examination. An example of a request related to the conversion process can be reviewed in example 3 of Annex IV.

It is interesting to note that in this provision there is no reciprocity regarding industrial designs. Although the transition from utility model to patent and vice versa and from utility model to industrial design is feasible, industrial design cannot be transformed into a utility model. This is due to the fact that the description of industrial models is generally insufficient to maintain priority.

8. SCOPE OF UTILITY MODEL PATENTS

The scope of protection conferred by the utility model patent will be delimited by the approved claims. The utility model patent gives the owner the right to prevent third parties from manufacturing, offering, selling, using, importing or storing the patented product without his or her consent. Some examples of utility models can be reviewed in examples 1 to 5 of Annex IV.

CHAPTER V ACTS AFTER THE GRANT

1. OTHER MODIFICATIONS

(Article 70 of Decision 486)

Changes to bibliographic data such as: name of the applicant or owner, address of the applicant or owner, representative, legal representative, inventor, name of the invention, among other data, will be analyzed by the office so that it determines its relevance. and adequate support, so that the corresponding registration in the registry can proceed.

It should be noted that changes to bibliographic data can also be requested when the application is in process.

2. REGISTRATION OF EVENTS

Any act linked to the registration of the invention patent or utility model patent must be registered therein. Resolutions, sentences, assignments, transfers, change of name and address, among other changes to bibliographic data, must be registered.

Examples of post-grant acts:

Modification of claims
Elimination of claims
Modification of bibliographic data
License registration
Registration of assignments
Divisional requests

CHAPTER VI GLOSSARIES

1. TREATIES AND NORMS

(Omission)

2. OFFICES AND AUTHORITIES

(Omission)

3. DEFINITIONS

Abandonment: The declaration by the office as a result of the applicant's inaction and which causes the termination of the process.

Withdrawal: The exercise of the applicant's right to waive the continuation of the processing of his or her application (procedure) or claim.

Nearest state of the art: The background of the state of the art that most closely approximates, in its content, the invention examined.

Inventor: Natural person to whom the right to the patent corresponds.

Notification: Procedural-administrative act through which the office communicates to the applicant a certain procedural situation or requires some action.

Obvious or Evident: That which does not go beyond the normal progress of the state of the art and that can simply be deduced from it.

Priority: Right of the applicant to have the date of the first application on which it is based taken as the filing date of a patent application.

Applicant: Natural or juridical person that appears designated in the petition with a stake.

Person normally versed in the technical subject: Hypothetical person(s) with average knowledge in the subject and who have at their disposal all the technical information related to their field that was available to the public on the date the first application was submitted, but who do not have any inventive ability. A person skilled in the art is neither the inventor nor an expert in the art.

Owner: The natural or legal person that appears in the records of the office to whom the title of the patent corresponds.

4. ABBREVIATIONS

IPC - International Patent Classification adopted by the Strasbourg Agreement of 24 March 1971 and amended on 28 September 1979

CNO - Competent National Office for Intellectual Property of the Member Countries

CNA - Competent National Authority

GR.GG. - Genetic Resources

CC.TT. - Traditional Knowledge

NPL - Non-Patent Literature

CII - Computer-implemented inventions

5. GLOSSARY ON BIOTECHNOLOGY

Biological material - any material that contains genetic information and can reproduce itself or be reproduced in a biological system.

Biological resources - individuals, organisms or parts thereof, populations or any biotic component of actual or potential value or utility contained in the genetic resource or its derived products.

Derived product - molecule, combination or mixture of natural molecules, including crude extracts of living or dead organisms of biological origin, coming from the metabolism of living beings.

Genome - is the totality of genetic information (genes) that a particular organism has.

Germplasm - set of genes that is transmitted through reproduction to offspring through gametes or reproductive cells.

Natural biological processes - any biological process that occurs spontaneously in nature, that is, those in which there is no human activity or intervention (exclusively biological processes or essentially biological processes)

Microbiological processes - are processes that involve, are carried out or result in microbiological material

Therapeutic methods - are the set of practices and knowledge aimed at curing diseases or malfunctions of the body.

Surgical methods - those that involve intervention with instruments of any type on the human or animal body.

Diagnostic methods - those that try to discover and individualize a pathological situation, to propose the necessary curative procedure.

6. GLOSSARY RELATED TO CII

Computer-implemented invention (CII) – is one that involves the use of a computer, computer or computer network or other electronically programmable device, where the invention has one or more characteristics that are carried out in whole or in part by means of a computer program. computer, computer or computer.

Computer program – is a sequence of computational steps that can be effectively performed by a digital computer, where its steps are written in a systematic notation known as a programming language.

Software – is commonly used as a synonym for computer program.

Software – commonly used as a synonym for computer program.

Hardware – material components that make up a computer or computer system, necessary to make the equipment work.

Algorithm – can be defined as a systematic procedure to carry out a task in a finite number of steps

System – is the set of elements and their characteristics related to each other to solve a technical problem.

Computer-readable medium – is a medium capable of storing data in a computer-readable format.

Technical effect – is an effect that allows said transformation of the matter or energy that exists in nature, for its use by man and satisfy his specific needs.

Technical nature – all the particularities of the invention that contribute to solving a technical problem posed.

Technical contribution – when the characteristics contribute to the technical character.

Artificial intelligence (AI) is the ability of a machine to exhibit the same capabilities as humans, such as reasoning, learning, creativity, and the ability to plan.

Blockchain – is a technology that consists of a chain of blocks or data structure whose information is grouped into sets (blocks) that contain meta-information relative to another block of the previous chain in a timeline. In this way, thanks to cryptographic methods, the information contained in a block can only be deleted or edited by modifying all subsequent blocks.

Internet of Things (IoT) – refers to the Internet of Things that describes the network of physical objects (things) that incorporate sensors, software and other technologies in order to connect and exchange data with other devices and systems through Internet.